



Biotechnology in Europe

The tax, finance and regulatory framework and global policy comparison



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The European Association for Bioindustries

Contents

Foreword	3
Introduction	4
Executive summary	6
Regulatory overview	9
EU country profiles	37
Non EU country profiles	137
Outlook for biotechnology	191
Acknowledgements	224
Glossary of terms	228

Foreword



As I reach the end of my term as Commissioner for Research, Innovation and Science, I am greatly impressed by the scope and range of activities that the Commission has undertaken to further the development of innovation in science, particularly in the biotech sector.

It has been proven time and again that Europe is a world-class hub for new ideas and collaborative research. It is essential that, for the future, we have in place the right legislative and financial conditions to translate this research into beneficial products and services for our society. Small and medium-sized enterprises (SMEs) are at the center of making this happen. We have thousands of biotech SMEs in Europe, employing a highly skilled and motivated workforce that is dedicated to finding solutions to our most pressing global challenges. These companies are vital to the creation of innovative products and processes. However, the financial crisis has highlighted the ongoing limited flow of capital to these companies, capital that is key to ensuring the sector's sustainability. Losing the contribution of these enterprises would have significant repercussions – not only for the biotech industry, but also for the competitiveness of Europe more generally.

Clear steps have been taken at European level to address these needs. SMEs are already receiving a larger share of funding than ever before, thanks to new, simplified rules for collaboration and applications for funding under Horizon 2020. There are also dedicated funding instruments for SMEs, such as the EU program for the Competitiveness of Enterprises and Small and Medium-sized Enterprises (COSME).

The importance of the biotech industry to growth and competitiveness is clear: it is recognized as a Key Enabling Technology

(KET) under Horizon 2020. The new funding program also emphasizes the significant role played by industry-driven research, both by co-sponsoring of public-private partnerships and by participating in programs as evaluators and contributors.

Over the last few years, the EU has come a long way in developing a holistic approach to policy-making for the bioeconomy – an area of the European economy that employs approximately 22 million people and generates income of €2t. The Europe-wide Bioeconomy Strategy, Innovating for Sustainable Growth, and the EU Industrial Policy Communication, both adopted in October 2012, as well as the more recent launch of the Bioeconomy Observatory, have all helped in making coordinated policy action in Europe a reality.

It is on this basis that I welcome the second edition of the joint EuropaBio and EY report that analyzes current tax, finance and regulatory regimes for biotech SMEs in Member States and provides solutions for offering incentives to start-ups and investments in the future.

While much has been done in recent years to bridge the gap between innovation and the marketplace, more incentives are needed to encourage high-tech entrepreneurship in Europe. I hope that this report will provide a valuable contribution to the debate and encourage greater investment in science and technology in Europe.

A handwritten signature in black ink, reading 'Máire Geoghegan-Quinn'.

Máire Geoghegan-Quinn,
European Commissioner for
Research, Innovation and Science

Introduction

What is biotechnology?

The word biotechnology is a cross between the Greek words “bios” (everything to do with life) and “technikos” (involving human knowledge and skills). The OECD (the Organisation of Economic Co-operation and Development) defines biotechnology as “the application of scientific and engineering principles to the processing of materials by biological agents.” More simply, biotechnology is using living organisms to make useful products.

Production may be carried out by using intact organisms, such as yeasts and bacteria, or by using natural substances (e.g., enzymes) from organisms.

Biotechnology makes use of biological systems and processes to manufacture useful products and provide services.

Health care or red biotechnology refers to a medicinal or diagnostic product or a vaccine that consists of, or has been produced in, living organisms and may be manufactured via recombinant technology (recombinant DNA is a form of DNA that does not exist naturally. It is created by combining DNA sequences that would not normally occur together).

This technology has a tremendous impact on meeting the needs of patients and their families as it not only encompasses medicines and diagnostics that are manufactured using a biotechnological process, but also gene and cell therapies and tissue engineered products.

Today, the majority of innovative medicines, whether manufactured using biotechnology or via a chemical synthesis like a traditional small molecule medicine, as well as many diagnostic products, are made available by applying modern biotechnology in their development and/or manufacturing processes.

Agricultural or green biotechnology encompasses a range of modern plant breeding techniques. For centuries, farmers have tried to improve their crops by means of crossing, relying on the random rearrangement of existing genes between two closely related parent plants. Modern agricultural biotechnology improves crops in more targeted ways. The best known technique is genetic modification, but the term agricultural biotechnology (or green biotechnology) also covers such techniques as Marker Assisted Breeding, which increases the



effectiveness of conventional breeding. Whatever the particular technology used, the crops may be destined for use for food, biomaterials or energy production.

Genetic modification means that existing genes are modified or new genes included to give plant varieties desirable characteristics, such as resistance to certain pests or herbicides, or for vitamin fortification. Because only a few genes with known traits are transferred, GM methods are more targeted and faster than traditional breeding. They are used alongside conventional plant breeding.

Industrial or white biotechnology uses enzymes and micro-organisms to make bio-based products in sectors such as chemicals, food and feed, detergents, paper and pulp, textiles and bioenergy (such as biofuels or biogas). In doing so, it uses renewable raw materials and is one of the most promising, innovative approaches toward lowering greenhouse gas emissions.

The application of industrial biotechnology has been proven to make significant contributions toward mitigating the impacts of climate change in these and other sectors. In addition to environmental benefits, biotechnology can improve industry's performance and product value and, as the technology develops and matures, white biotechnology will yield more and more viable solutions for our environment. These innovative solutions bring added benefits for both our climate and our economy.



Executive summary

National governments have done much to encourage innovation, often through a web of tax incentives for research. Yet, by and large, much remains to be done to ensure that these ideas are translated into new businesses, new products, additional jobs and so, in time, to ensure a faster rate of economic growth in Europe.

Biotechnology in Europe: The Tax, Finance and Regulatory Framework and Global Policy Comparison is a joint report by EY and EuropaBio. In it, we examine what the continent has to offer investors, entrepreneurs and researchers alike. We look at everything from what to take into account when importing materials for clinical trials to the best way to exploit intellectual property within Europe's various jurisdictions. We also profile key global locations on the increasingly important topic of R&D incentives.

At a time when big biotech companies are looking for inspiration, governments need to encourage small and medium-sized enterprises (SMEs) to take steps which may help them one day to become large firms in their own right. There is more to creating a successful industry, says the report, than putting in place the right standard of regulation. What is needed is a climate of

innovation and entrepreneurship, coupled with the bricks and mortar with which to build industries around it, not to mention the correct implementation of regulation.

Initiatives such as Horizon 2020, a program for research and innovation funding, implemented by the European Commission, with a budget of nearly €80b, and the Bioeconomy Strategy and Action Plan for Europe will both contribute toward bridging the gap between good people with good ideas and the investment and opportunity to make them a reality.

However, the recently published 2014 EU Innovation scoreboard underlies that Europe risks becoming the world's research hub while innovative products and processes and the jobs and growth that go with their development, will be found elsewhere.

In an analysis of individual countries across Europe, we set out which agencies to contact for information when considering where to establish centers of research or manufacturing. We examine the tax concessions on offer in each country and the financial burdens for SMEs and which benefits are likely to flow from a decision to establish a research facility or a startup in a particular location.

Because jurisdictions influence how, when and why investors in biotechnology decide to enter or exit a business, we weigh up the advantages and disadvantages of individual countries. In addition, we examine the priorities facing small and medium-sized enterprises, those which create most of the new jobs in Europe.

Our global comparison highlights the increasingly important topic of R&D incentives. This growing importance was recognized in a recent OECD report which stated that: "R&D incentives have proliferated and become more important with 34 member countries providing tax incentives to support business R&D." For the purpose of this report, we focus on those countries with a thriving Biotechnology sector and provide a detailed description of available benefits, the incentive application process, eligibility and IP jurisdictional requirements. Where available, patent and innovation boxes are also described.

Too often, say those in biotechnology and allied industries, regulators dictate the rules governing the process toward new products or processes while losing sight of the end result. Europe may have a well-deserved reputation for innovation and the skills required to research and develop new

ideas. Yet the journey from innovation to manufactured products is often laboured, long and at times entirely unpredictable.

Regulators can make it hard for businesses to assess a likely rate of return from a new product. New firms can also find it difficult to maintain the momentum needed to bring a product to market and so to begin to generate returns if the road to product approval is not predictable. And only if they see a possible return, of course, will investors risk their capital in the first place.

There is currently a three-speed Europe for the biotechnology industry, with each of the three applications – health care, industrial and agricultural – all operating under different and more or less predictable and workable regulatory and approval processes.

In today's markets, entrepreneurs may be better advised to devote their time and energies to creating a suite of products, not just a single one. In this way, says the report, firms may increase their chances of securing backing from an investor while improving the prospects of creating a product which reaches the market. History would suggest, too, that the earlier such a decision is made, the better it may be for the company as well as the investor.



Regulatory overview



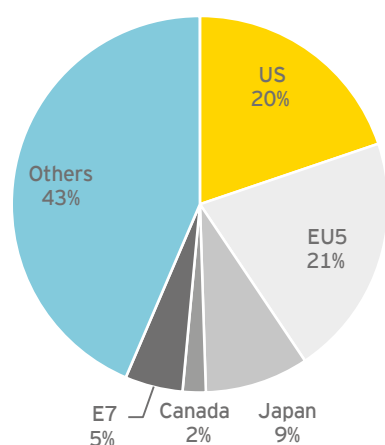
Outline of regulatory framework for health care biotechnology products in the European Union

The health care biotechnology industry explained

The European health care biotechnology industry is currently facing unprecedented challenges and companies are refocusing on ways to increase productivity of their R&D and on streamlining costs in the value chain. The result is an industry in which specialty and niche health care biotech products (as opposed to large-volume blockbusters) are prized for their potential for sustainable health care solutions.

The global biologics market has expanded at a CAGR of 9.8% from 2007 to 2012, to €169b in 2012. This represents 18% of total worldwide medicine sales in 2012. Of total biologics sales, 0.4% is contributed by biosimilars in 2012.

Biologics sales by geography in 2011 is depicted by the following pie chart, where, total global biologics market size was approximately €161b.



Global health care biotech sales are to rise at a CAGR of 5.5% from 2012 to 2017. This gain will largely be driven by robust growth in emerging markets and increasing adoption of monoclonal antibodies (MABs) and human insulin for the treatment of patients. In addition, governments in some markets (including the US and Europe) have introduced biosimilar pathways as a measure to further competition in this area.

Health care biotech companies face many challenges and uncertainties, including heightened competition from makers of generic drugs, unprecedented pressure from payers, constraints on public sector budgets because of ongoing austerity measures and declining R&D productivity.¹ Therefore, the pressure to reorganize R&D, provide affordable prices and marketing overhauls is intense. Even so-called "Big Pharma" (a term used to indicate pharmaceutical companies with large capitalizations) are struggling to grow, with generic firms outperforming them, according to IMS Health.² However, improvements in early-stage product pipeline development, particularly in the fields of cancer and diabetes, are delivering on long-term promises for the industry.

Health care biotech enables citizens to live healthier, and for longer, by providing more medical choices and solutions

- ▶ **350 million** patients around the world are already benefiting from direct use of biotech medicine to treat and prevent every day and chronic illnesses including heart attacks, stroke, multiple sclerosis, breast cancer, cystic fibrosis, leukaemia, diabetes, hepatitis and other rare or infectious diseases.

¹ "Industry Survey Healthcare: Pharmaceuticals," 2 June 2011, Standard & Poor's, 2011.

² Ibid.





- ▶ Health care biotech enables the development of therapies for rare diseases that are often debilitating and life threatening and that affect **20 million to 30 million** Europeans and their families.
- ▶ Some examples of treatments that health care biotech is already creating: insulin for patients, Factor VIII coagulant for haemophiliacs, antibodies for immunotherapy of cancer, orphan medicinal products for rare diseases, vaccines, advanced therapies that repair organs, skin, bones and cartilage damage.
- ▶ Health care biotech is estimated to account for more than **20%** of all marketed medicines.
- ▶ By **2015**, it is estimated that **50%** of all medicines will come from biotech.
- ▶ Health care biotech increases the effectiveness and safety of treatments as well as reducing the use of ineffective treatments and adverse reactions through its approach on personalized medicine that works to diagnose what one patient's problems are precisely and then work to better adapt the health care solutions to suit their specific needs.
- ▶ Health care biotech comprises more than **1700 companies** and a market worth more than **€17b** in Europe alone.
- ▶ Health care biotech creates jobs. Between **2000 and 2008**, employment in all departments of companies working on the development of orphan drugs for rare disease patients in the EU more than doubled, showing an increase of **158%** according to the Office of Health Economics, UK.

Legislative overview

Clinical trials

The uneven and inconsistent implementation of Directive 2001/20/EC on Clinical Trials in the EU resulted in cumbersome, lengthy and costly processes for clinical trial sponsors. On this basis, in July 2012, the European Commission proposed a revision of the legislation in order to strengthen the EU's competitiveness in clinical research.

The new rules – currently in the final stage of the legislative process and will take the form of a Regulation – will be directly applicable in all EU Member States. It is expected that the Regulation will contribute to greater harmonization and efficiency in the regulatory framework for clinical trials, while maintaining high standards of patient safety and robustness of clinical data.

Marketing authorization

A pharmaceutical product can only be placed on the market in the European Union (and the European Economic Area more broadly) when: an authorization has been granted by the European Commission via the centralized procedure (Community authorization) for all the EU markets; or when a marketing authorization has been granted by the competent authority of a Member State for its own territory (national authorization, which can be the subject of mutual recognition between Member States); or when an authorization has been granted through a decentralized procedure.³ The marketing authorization holder must be established within the EU or the EEA.

³Notice to applicants. Volume 2A; Procedures for marketing authorization; Chapter 1: Marketing Authorization; November 2005.



This chapter focuses on the centralized procedure, since it is the mandatory regulatory pathway for the marketing authorization of any medicinal products developed by means of biotechnological processes such as recombinant DNA technology or any monoclonal antibody methods.⁴

The centralized procedure was established in 2005 following the revision of EU pharmaceutical legislation in 2004. This procedure includes an application by the developer of a new pharmaceutical product to the European Medicines Agency (EMA) which is responsible for the scientific evaluation of the safety, efficacy and quality of the new product – today regulators tend to conduct this evaluation by looking at the benefit/risk ratio of the product. The scientific assessment is conducted by the EMA Committee for Medicinal Products for Human Use (CHMP). Based on an application dossier, including all relevant clinical data about the product, the CHMP adopts an opinion which is communicated to the European Commission. In consultation with the Member States and the European Parliament, the European Commission is responsible for granting a marketing authorization, provided that the CHMP adopted a positive opinion in the first instance.

The active time for scientific evaluation of the marketing authorization application by the European authorities is below 210 days. As an example, in 2010 the CHMP took an average of 167 days for the assessment of an application,

and the final decision on the marketing authorization took an average of 59 days. Clock-stop time (i.e., the time given to a company to respond to questions from the CHMP) averaged 114 days.⁵

After a marketing authorization is granted via the centralized procedure, the CHMP publishes a European public assessment report (EPAR), setting out the scientific grounds for the CHMP's opinion in favor of granting the authorization, plus a summary of product characteristics (SPC), labeling and package leaflet (patient/user information leaflet) for the medicine, and details of the procedural steps taken during the assessment process.

Specialized EMA Committees, such as the Committee for Orphan Medicinal Products (COMP) or the Committee for Advanced Therapies (CAT), are responsible for preparing a draft opinion on each specific product's application falling under their expertise, before the CHMP adopts a final opinion on the granting of the marketing authorization.

To help applicants better understand the efficacy, quality and safety requirements and prepare their marketing authorization applications, the CHMP and specialized Committees develop scientific guidelines in consultation with national regulatory authorities. These guidelines can be general or product specific, and provide a basis for practical harmonization of how Member States and the EMA interpret and apply the detailed requirements provided by the Community legislative relevant to pharmaceuticals.⁶

⁴Regulation (EC) No 726/2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

⁵EMA 2010 Annual report – Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Annual_report/2011/06/WC500108073.pdf

⁶The rules governing medicinal products in the European Union. EUDRALEX. Available at: http://ec.europa.eu/health/documents/eudralex/index_en.htm.



Orphan medicinal products

Orphan medicinal products (OMPs) are an important category of health care biotechnology. They are intended for the diagnosis, prevention or treatment of life-threatening or seriously debilitating conditions that are rare.⁷ In order to stimulate the research and development of orphan drugs and improve our understanding of rare diseases, in 2000, EU institutions adopted the EU Regulation on OMPs.⁸ This regulation established a centralized procedure for the designation of OMPs and put in place incentives for the research, marketing and development of these, such as fee waivers, a 10-year market exclusivity period post authorization and scientific assistance for marketing authorizations. This legislation has significantly stimulated research and development of orphan drugs and enabled more than 82 new treatments to be authorized across the EU. This regulation, and the treatments developed thanks to the efficient regulatory system it lays down, have made and continue to make a significant difference for rare disease patients, bringing hope to some 30 million Europeans and their families affected by one of the 5,000 to 8,000 rare and very rare diseases identified so far.

Advanced therapy medicinal products

Advanced therapy medicinal products (ATMPs) represent a category of human medicines characterized by a very complex development phase. They include

gene therapy, cell therapy and tissue engineered products.

In order to address these new therapies, EU institutions agreed on a regulation on advanced therapies (Regulation (EC) 1394/2007).⁹ The regulation introduced a centralized marketing authorization procedure for ATMPs, technical requirements and some incentives for small and medium-sized enterprises. It also introduced an expert Committee (Committee for Advanced Therapies) within the European Medicines Agency to assess advanced therapy products and follow scientific developments in the field. Unfortunately, to date the Regulation has not resulted in a noticeable uptake of ATMPs at European level (there are many ATMPs being marketed nationally mainly via hospitals) and the industry is cooperating with policymakers in order to identify appropriate solutions to the perceived hurdles.¹⁰

EMA SME office

In 2005, an EMA SME office was created to support small and medium-sized companies in navigating the regulatory maze of marketing authorization applications and guidelines. Provided that the company complies with the EU criteria to be granted the SME-guidelines,¹¹ the EMA SME office provides support in terms of administrative and procedural assistance, fee reductions for scientific advice and inspections, fee exemptions for certain administrative services, and assistance with translations of the product information documents.

⁷The European Commission defines as rare diseases those that affect not more than 5 per 10,000 persons in the European Union.

⁸Regulation (EC) No 141/2000.

⁹Regulation on advanced therapies (Regulation (EC) 1394/2007).

¹⁰A revision of the existing legislation could be decided by the European Commission in 2014.

¹¹User guide for micro, small and medium-sized enterprises (SMEs) on the administrative and procedural aspects of the provisions, laid down in regulation (EC) No 726/2004, that are of particular relevance to SMEs. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004134.pdf.

Pharmacovigilance

After marketing authorization is granted, the holder is subject to the pharmacovigilance requirements as provided in the new legislation on pharmacovigilance.^{12,13} The new post-authorization requirements became applicable in 2012 and aim to improve the pharmacovigilance system in the EU, introducing special provisions for medicines that need additional monitoring. In March 2013, the Commission adopted an implementing measure, introducing a black symbol to identify medicinal products that are subject to additional monitoring. The pharmacovigilance legislation also aims to improve information provided to the public. A new EMA Committee – the Pharmacovigilance Risk Assessment Committee (PRAC) – was created to provide recommendations to the CHMP on

questions relating to pharmacovigilance activities and on risk management systems. While acknowledging that patient safety is paramount, the impact of the new pharmacovigilance legislation on companies, especially SMEs with products on the market, will need to be closely monitored to ensure that these companies are not subject to unnecessary administrative and financial burden.

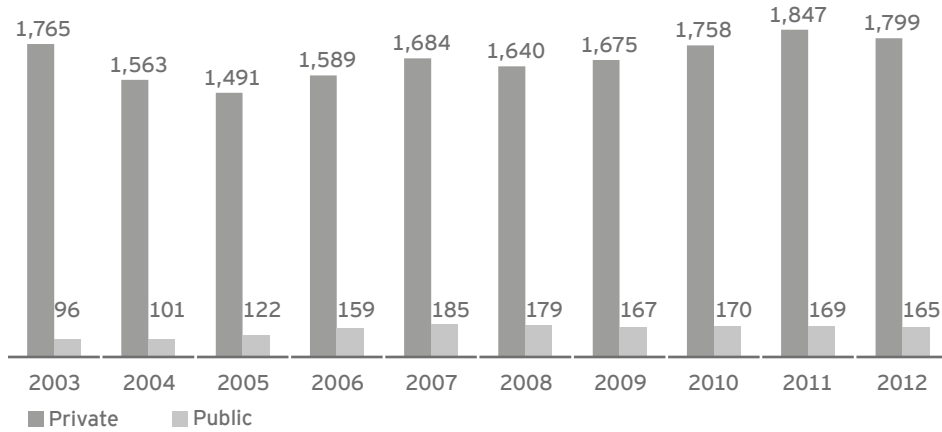
Snapshot – second most established region, with stable commercial leaders

European industry is almost stable with respect to the number of biotech companies over the past decade. It is dominated by small to mid-sized private players, constituting nearly 90% of the biotech industry.

¹²Regulation (EU) No 1235/2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products.

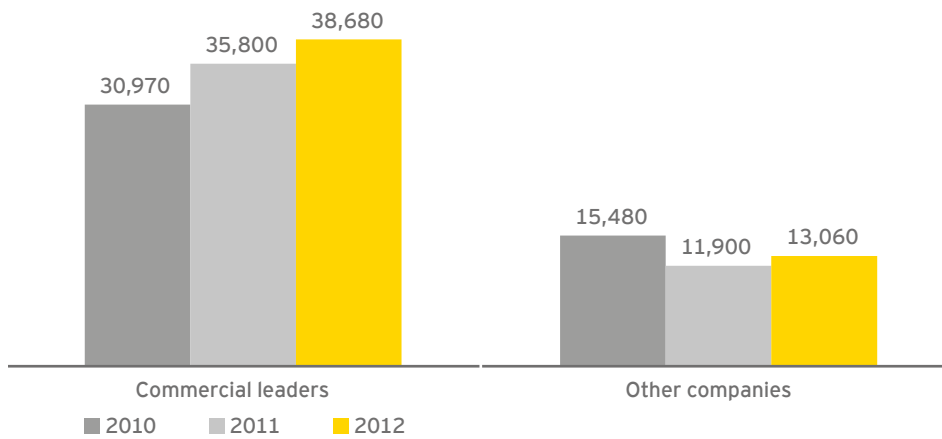
¹³Directive 2010/84/EU amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use.

Figure 1: Number of health care biotech companies in Europe



Source: EY and company financial statement data (taken from *Beyond Borders* report 2005-2013)

Figure 2: Number of employees in Europe



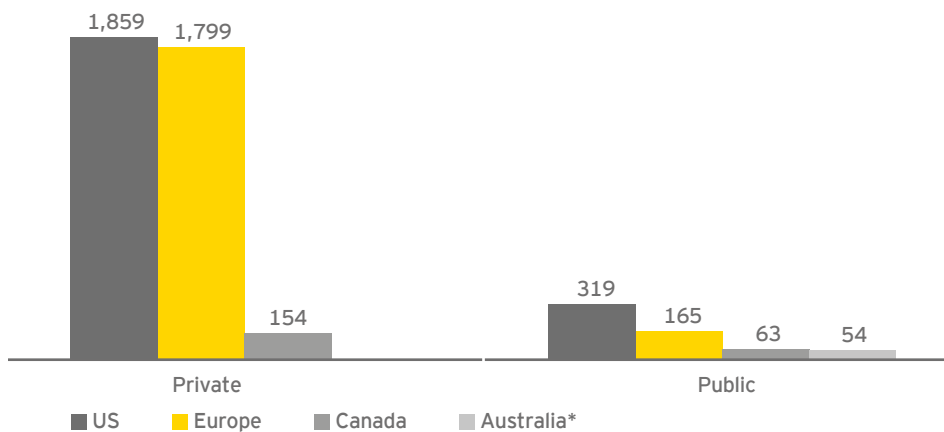
Note: Data covers public companies only; commercial leaders are the companies with revenues in excess of US\$500m; other companies include all companies except commercial leaders

Source: EY and company financial statement data (taken from *Beyond Borders* report 2012-2013)

Among the four established biotech centers (US, Europe, Canada and Australia), the US and Europe are the largest in terms of number of health care biotech companies. All these markets are dominated by the private sector, except Australia. In the US, the list of commercial leaders has changed considerably over the last five years as the acquired companies have been replenished by the emergence of newer, fast-growing companies. In Europe, on the other hand, the list of commercial

leaders has remained static, with just eight members – Actelion Pharmaceuticals, Elan Corp., Eurofins Scientific, Ipsen, Meda Pharmaceuticals, Novozymes, Qiagen and Shire. In 2012, a ninth firm was added to the list as a result of the relocation of a US-based enterprise – Jazz Pharmaceuticals, which moved its headquarters to Ireland in merger with Azur Pharma. In 2013, Elan Corp. was acquired by Perrigo and now operates under the name of Perrigo Company.

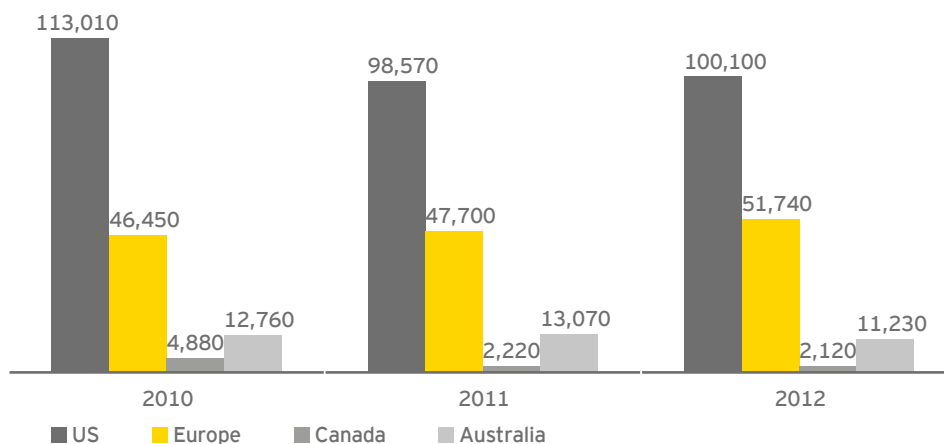
Figure 3: Geographic comparison – number of health care biotech companies in 2012



Source: EY and company financial statement data (taken from *Beyond Borders* report 2013)

*Only public companies are present

Figure 4: Geographic comparison – number of employees



Note: Data covers public companies only

Source: EY and company financial statement data (taken from *Beyond Borders* report 2013)

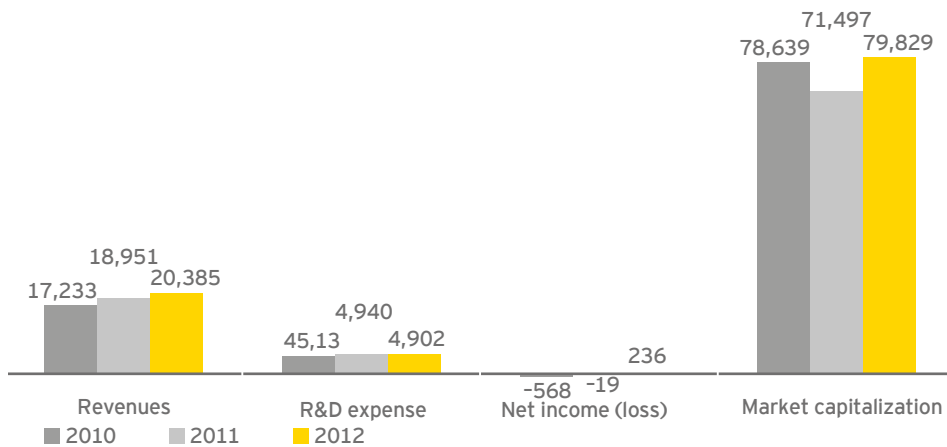
Financial performance – non-commercial leaders drive revenue growth and R&D cuts

The revenues of European publicly traded health care biotech companies have been growing steadily over the past three years. However, the same cannot be said about R&D expense, which declined by 1% in 2012. This clearly reflects that many European firms, particularly non-commercial leaders, are still in cost-cutting mode almost five years after

the global financial crisis of 2008. This signals challenges in raising capital from the market. In terms of profitability, the European industry returned into the black primarily due to the companies' efforts at cost-containment. Profitability was also boosted by the superior top-line growth posted by the non-commercial leaders (16% y-o-y) as compared to the commercial leaders (6% y-o-y) in 2012.

The addition of Jazz Pharma led to an improvement in the top-line of the commercial-leaders.

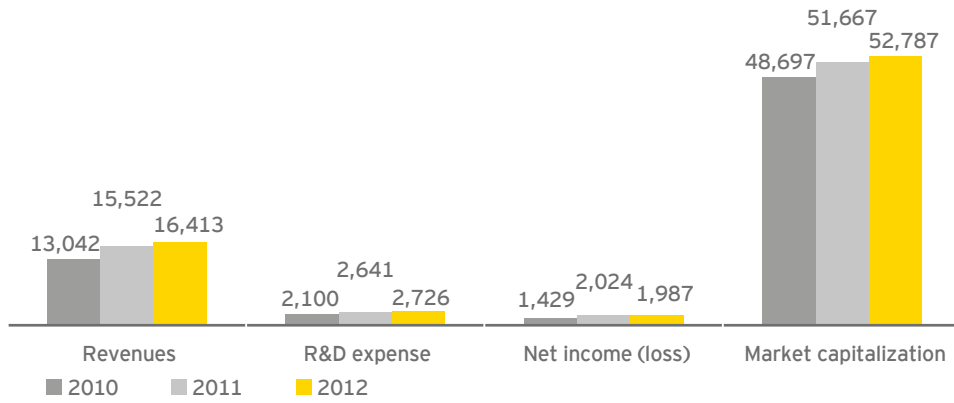
Figure 5: European health care biotech industry – all companies (in \$m)



Note: Data covers public companies only

Source: EY and company financial statement data (taken from *Beyond Borders* report 2012-2013)

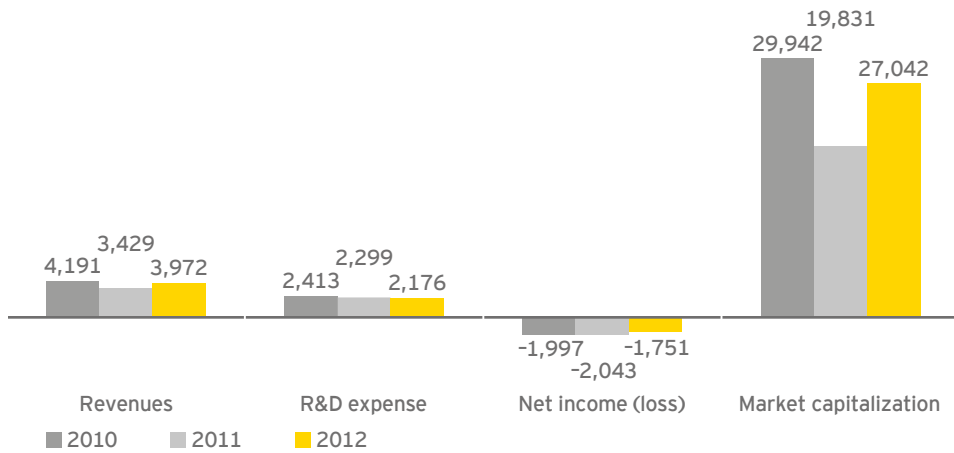
Figure 6: European health care biotech industry – commercial leaders (in \$m)



Note: Data covers public companies only; commercial leaders are the companies with revenues in excess of €500m

Source: EY and company financial statement data (taken from *Beyond Borders* report 2012-2013)

Figure 7: European health care biotech industry – other companies (in \$m)



Note: Data covers public companies only; other companies include all companies except commercial leaders

Source: EY and company financial statement data (taken from *Beyond Borders* report 2012-2013)

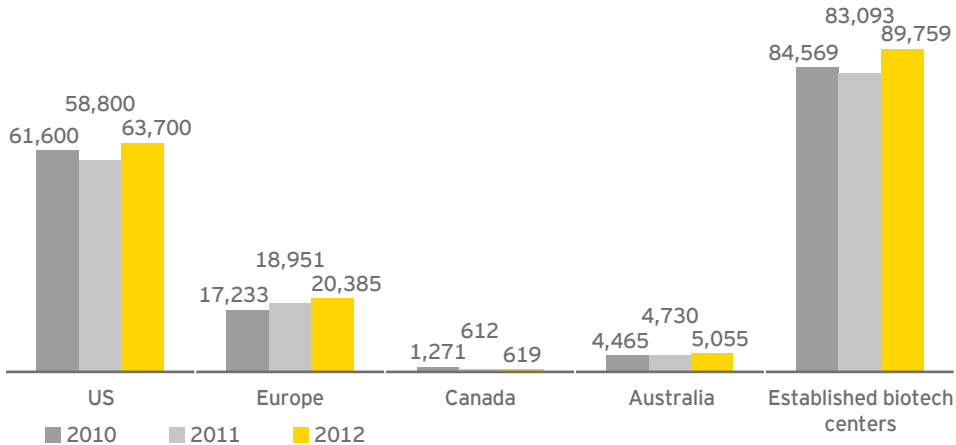
Revenue growth down in all major regions

Looking at the geographic comparison, revenues for the four established biotech centers grew by 8% y-o-y in 2012 as against 10% (normalized for large acquisitions) in 2011. This decline is attributed to the slower growing regions of the US and Europe. In the US, publicly traded firms exhibited y-o-y growth of 8% as compared to 12% (after adjusting for acquisitions) in 2011, primarily reflecting increased competition among the fast growing companies. Revenues for US commercial leaders showed y-o-y growth of 12% in 2012 while for non-commercial leaders, revenues declined by 10% y-o-y. In Canada, revenues for 2012 were flat relative to 2011. For Australia, revenue growth was slightly better in 2012 (7% y-o-y) as compared to 2011 (6% y-o-y).

Only US sees R&D spend growth

R&D expenditures among the publicly traded companies in the four established markets grew only 5% as compared to 9% (y-o-y) in 2011. Cutbacks on the part of smaller, pre-commercial entities have affected the pace of R&D spending in the industry. However, commercial leaders continued to invest strongly in R&D activities. This pattern is very prominent in the US, where the commercial leaders exhibited growth in R&D spend of 18% y-o-y in 2012 while the small and medium-sized biotech firms remained under pressure, with 5% decline in their R&D spend. In Canada, R&D expenses have continued a downward trajectory with 12% decline in 2012 as a result of acquisitions of leading Canada-based companies by foreign entities. In Australia, all public companies, except CSL, experienced decline of 8% in their R&D expenditure.

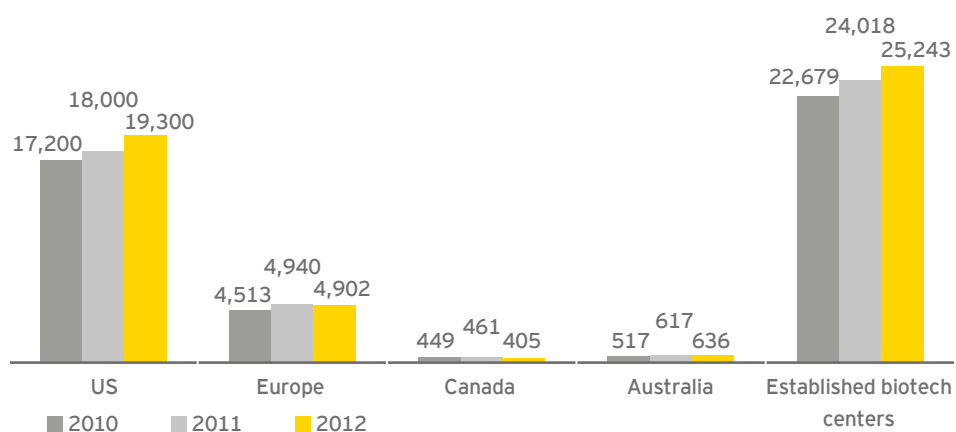
Figure 8: Geographic comparison – revenue analysis (in \$m)



Note: Data covers public companies only

Source: EY and company financial statement data (taken from *Beyond Borders* report 2012-2013)

Figure 9: Geographic comparison – R&D expenditure analysis (in \$m)



Note: Data covers public companies only

Source: EY and company financial statement data (taken from *Beyond Borders* report 2012-2013)

Table 1: Revenues (in \$m)

	2010	2011	2011 growth rate	2012	2012 growth rate
US*	61,100	58,800	12%	63,700	8%
Europe	17,233	18,951	10%	20,385	8%
Canada	1,271	612	-21%	619	1%
Australia	4,465	4,730	6%	5,055	7%
Established biotech centers*	84,069	83,093	10%	89,759	8%

*adjusted due to large acquisitions

Table 2: R&D expenses (in \$m)

	2010	2011	2011 growth rate	2012	2012 growth rate
US*	17,200	18,000	9%	19,300	7%
Europe	4,513	4,940	9%	4,902	-1%
Canada	449	461	3%	405	-12%
Australia	517	617	13%	636	3%
Established biotech centers*	22,679	24,018	9%	25,243	5%

*adjusted due to large acquisitions

Agriculture overview

The agriculture biotechnology industry explained

A record 18m farmers grew genetically modified (GM crops) in 2013, up from 17.3m farmers in 2012, according to the latest figures from the International Service for the Acquisition of Agri-biotech Applications (ISAAA). Of these, more than 90% were small scale, resource-poor farmers from developing countries. Worldwide, 175m hectares of GM crops were planted in a total of 27 countries; that's a 100-fold increase since their introduction in 1996. Despite a 15% increase in surfaces cultivated in 2013 compared to 2012, the EU is notably absent from the list of top 10 countries planting GM crops in 2012. A lack of choice for farmers (only one crop is approved at present) coupled with politicised and nonscience-based decision-making and a legislative framework that is not being correctly adhered to by some member states, result in the EU lagging behind other nations in this area.

For the time being, the only GM crop approved for cultivation in Europe and which is being grown is an insect resistant Bt maize, MON810. It was first approved in Europe in 1998 and since then, several EU countries have put in place scientifically unfounded and legally questionable bans on GM cultivation. Many of these bans have now been overturned by the European Court of Justice and current discussions are focusing on how to give member states more say regarding the right of their farmers to cultivate GMOs on their national territory.

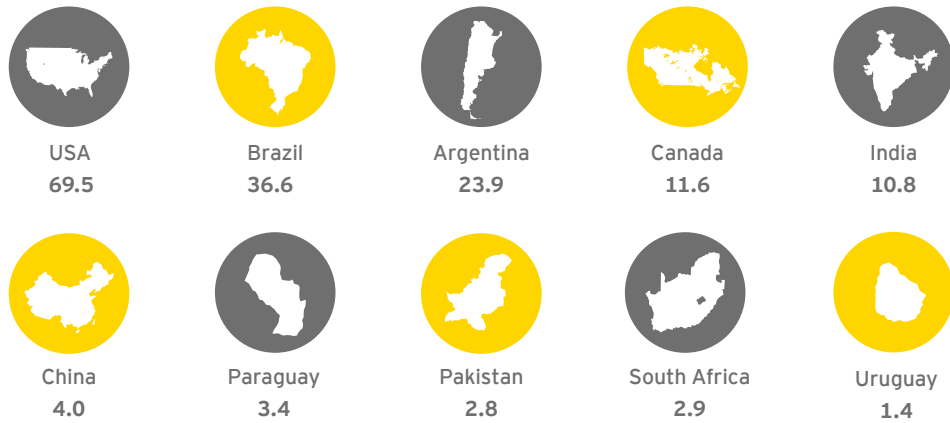
In the EU, the 15% increase in GM cultivation in 2013 shows that Spain leads the five EU countries planting GM crops with a record 136,962 hectares of biotech maize cultivated in 2013, up 18% compared with 2012. The other countries that continue to cultivate GMOs in Europe are Romania, Portugal, the Czech Republic and Slovakia.

50 GM products have now been approved for import and processing for food and feedstock in Europe. More than half of these crops are types of GM maize with the rest being soybeans, rapeseeds, sugar beet and cotton.

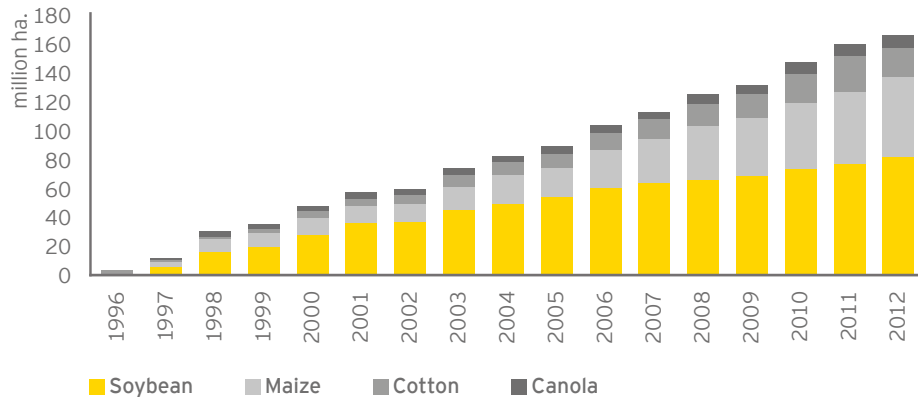
Global food insecurity has been recognized as one of the world's most crucial challenges with an estimated 1 billion people chronically hungry and up to an additional 2 billion lacking food security intermittently due to varying degrees of poverty. Like many other agricultural technologies, agricultural biotechnology is geared to responding to such challenges by protecting and enhancing yields while minimizing pressure on the environment growing the same amount of food or more with less: less land, less water, less tillage and lower CO₂ emissions. There is an urgent need for European policymakers to ensure European industry and European farmers can participate in responding to global and local agricultural challenges by having access to biotechnology through a predictable and functioning approval system. Despite our import dependency on GM products mainly in the feed but also in the food sector, the lack of predictability of the EU approval systems has resulted in serious asynchronicity of approvals with exporting countries creating barriers to trade, which have already translated in higher prices for key agricultural commodities imported into Europe. It is essential that the EU implements an action plan to eliminate the accumulation of dossiers now in the system (over 70) most of which have already been approved in other parts of the world and are being traded openly. An elimination of the backlog as well as correct and timely implementation of the product approval system for newly submitted dossiers are crucial in ensuring a level playing field for all feed and food chain operators in Europe and retaining our competitiveness in the global agricultural space.

Top ten countries planting GM crops

The top ten countries planting GM crops grew more than 1m hectare in 2012:



GMOs global planting since 1996



Source: James, C. (2012)

A promising R&D pipeline

Who are the new developers?

Rise of China, India, Brazil and other emerging nations

Public institutions and public private partnerships (PPPs)

What is being developed?

First generation: insect resistance and herbicide tolerance

Next generation: nutritional value, stress tolerance, disease resistance

New crops: emphasis on crops for developing world

New traits: climate change mitigation and adaptation

New techniques

Approval process

1. **Risk assessment** is done on a case-by-case and step-by-step basis.
2. When EFSA has safety assessment, its scientific opinion forms the basis of a **Draft Decision** to be proposed by the European Commission.
3. Member States vote on the European Commission's proposal.
4. Once released, GMOs are subject to **monitoring, traceability and labelling**: monitoring plans need to be approved prior to marketing the product. Traceability is ensured by labelling and administrative records throughout the food chain.
5. **Public information**: Information is provided to the public throughout the approval process.

Planting statistics for EU countries



Agricultural biotech can give farmers and consumers access to safe and affordable food while enabling more food to be grown using less land, less energy, less water and producing less CO2 emissions

- ▶ More than **18 million farmers** grew GM crops, on **175 million hectares** of land, globally in 2013.
- ▶ Agricultural biotech can **increase yields by 6%-30%** on the same amount of land, helping to protect biodiversity and wildlife.
- ▶ Agricultural biotech offers built-in protection against insect damage, resulting in a decrease in pesticide spraying.
- ▶ Agricultural biotech helps reduce fuel use and CO2 emissions by requiring less tillage and helps farmers grow more food, reliably, in harsher climatic conditions. In 2009, this was equivalent to **removing 17.7 billion kg of carbon**

dioxide from the atmosphere or equal to removing 7.8 million cars from the road for one year.

- ▶ Agricultural biotech produces food containing fewer toxins such as mycotoxins, a toxic fungus that infects plants damaged by pests.
- ▶ Agricultural biotech protects soil from erosion and compaction by enabling farmers to reduce the need to plough their fields and the need to travel up and down their fields to manage weeds or pests because the agricultural biotech plants protect themselves against both. By disturbing soil less, this also increases the efficiency of water usage by keeping the water in the soil.
- ▶ By offering new, improved and adapted agricultural crops such as drought or saline resistant plants, agricultural biotech can contribute to meeting the Millennium Development Goals on reducing poverty and can help increase food security for a growing global population.

Agricultural biotech Legislative overview

EU legislation on genetically modified organisms (GMOs) has been in place since the early 1990s. This specific legislation has always had the following two main objectives:

1. Managing possible human health and environmental risks
2. Avoiding trade barriers to internal trade within the EU (i.e., ensuring the free movement of approved GM products in the EU)

The entire corpus of GMO legislation was amended in the early 2000s, leading to the creation of a new legal framework which can be summarized as follows:

GM crops cannot be put on the market without prior EU approval, whether for importing a food or feed product

made from GM crops or for planting GM seeds. The EU approval system is widely recognized as one of the most stringent in the world and covers both so-called deliberate release i.e., cultivation under Directive 2001/18/EC and import and processing of GM food and feed through Regulation 1829/2003. Directive 2001/18/EC and the accompanying regulations are transposed and translated respectively into national laws across the EU so that each Member State may carry its specificities. Biotech crops that are produced without using genetic modification (as listed in Annex I of Directive 2011/18/EC), do not fall under the above-mentioned legislation.

As an overview, the GMO approval system consists of the following steps:

1. Risk assessment is done on a case-by-case and step-by-step basis fulfilling the requirements laid out in the legislation (Directive 2001/18/EC for cultivation and Regulation 1829/2003 for import and processing of GM food and feed).
2. When the European Food Safety Authority (EFSA) has completed the environmental, human and animal health safety assessment based on the risk assessment, its opinion, if positive, forms the basis of a Draft Decision for approval by the European Commission after voting in Standing Committees composed of representatives from the Member States.
3. Post-release monitoring plans need to be approved prior to marketing the product. Traceability is ensured by labelling and administrative records throughout the food chain. Food that is a GMO or is derived from GMOs must be labelled if the GMO(s) are present as an ingredient above 0.9% of the overall ingredient in the finished product.
4. Public information: throughout the approval process, information is provided to the public.

In the EU, unlike the above-mentioned approval system, coexistence between GM, conventional and organic farming is governed by the principle of "subsidiarity."¹ That means Member States are to adopt their own national strategies to promote coexistence.

Finally, the EU legislation (though not necessarily its practical implementation) is in line with the international trade agreements of WTO (it is clear, transparent and non-discriminatory) and with the trans-boundary movement rules of the UN Cartagena Protocol on Biosafety.

How long do applications take and what do they cost?

For GM food/feed products approved in 2011-2013, the EU authorization process took on average 48 months in total, of which 19 months were spent on processing and voting-related procedures after EFSA positive opinion. EU approval timelines are increasingly out of sync with timelines in the main producer countries of agricultural commodities. The EU's zero tolerance policy on not yet EU-approved products means that certain commodities cannot be traded, to the extent that even traces of such products can cause entire shipments to be rejected, despite the product not posing any safety concern. The cost resulting from rejection of a maize shipment of 50,000 tons is estimated at €25m, however less visible trade disturbances and constant business uncertainty for traders add to the cost. GM cultivation dossiers have been pending for many more years in the authorization system, which illustrates the

dysfunctionality of the approval process for cultivation in the EU, partly due to political differences among the Member States. Costs for applicant companies arise mainly from the large number of studies required and vary from €7m to €15m per crop.

In 2013, unprecedented delays at the very final stage in the process (after a Member State votes in two separate European Parliament committees) were incurred by the European Commission on certain product authorizations for import. The General Court of the EU concluded twice that the Commission has mismanaged the approval process. On 26 September 2013, it ruled that "the European Commission has failed to fulfil its obligations by failing to submit to Council" a GM dossier and added that "the Commission cannot, in a dilatory manner, repeatedly request opinions from EFSA."

An overview of agbiotech legislation

- ▶ Directive 2001/18/EC on the deliberate release into the environment of GMOs.² This directive is the main legislation which governs experimental releases and placing on the market of GMOs. Compared to the former legislation (Directive 90/220/EEC),³ the manner according to which permission for commercial releases of GMOs into the environment is given is tightened up, including limiting the period of authorization to a maximum of 10 years and requiring post-market monitoring of the impact of the organisms on the environment. The Directive provides for a step-by-step approval process on a case-

¹Defined as a principle the EU does not take action on a particular subject unless it is more effective than action taken at national, regional or local level (http://europa.eu/scadplus/glossary/subsidiarity_en.htm).

²Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. Official Journal of the European Communities L 106, 17.4.2001, p. 1.

³Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms. Official Journal of the European Communities L117, p. 15-27.





by-case assessment of the potential risks to human health and the environment. The environmental risk assessment and risk management of GMO relies on pre-commercialization biosafety research and post-commercialization monitoring.

- ▶ The placing on the market of GMO food and feed, or food and feed products containing or consisting of GMOs, is regulated by Regulation (EC) No. 1829/2003 on genetically modified food and feed.⁴ The regulation pursues the global objective of ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, while ensuring the effective functioning of the internal market.
- ▶ GMOs and food and feed products derived from GMOs, which are placed on the market, must also satisfy labelling and traceability conditions. These conditions are laid down in above-mentioned Regulation (EC) No.1829/2003 and Regulation (EC) No.1830/2003⁵ concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC. Regulation (EC) No.1830/2003 is a complement to Regulation (EC) No. 1829/2003. This regulation introduces a harmonized EU system to trace and label GMOs and to trace food and feed products produced from GMOs. In

particular the requirements are that business operators must transmit and retain information about products that are covered by the scope of the regulation at each stage of the placing on the market. This means that an operator will have a traceability management system in place to identify to whom and from whom products are made available. Regarding labelling, Regulation 1830/2003 stipulates that all food and feed containing or consisting of GMOs, food/feed produced from GMOs and food/feed containing ingredients produced from GMOs, must be labelled. The presence of GM material in conventional food/feed does not have to be labelled if it is below 0.9% and if it can be shown to be adventitious or technically unavoidable.

In the presence of a food/feed product containing GMOs or consisting of GMOs, the applicant has in reality a choice: (1) either the application in its entirety subject to Regulation (EC) No.1829/2003, applying the “one door, one key” principle, in order to obtain an authorization for the deliberate release of GMOs into the environment in accordance with the criteria laid down by Directive 2001/18/EC, and the authorization to use this GMO in food or feed in accordance with the criteria laid down by Regulation (EC) No.1829/2003, or (2) the application – or part of the application – is submitted both under Directive 2001/18/EC and Regulation (EC) No.1829/2003.

⁴Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. Official Journal of the European Communities L268, 18.10.2003, p. 1-23.

⁵Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC. Official Journal of the European Communities L268/24, 18.10.2003 p. 24

In practice, the main difference between the two procedures concerns the risk assessment. Under Directive 2001/18/EC, this is done by the competent authority of the lead Member State, in which the application for authorization is filed. EFSA only takes part in cases of disagreement of other national authorities and acts as an arbitrator. Under Regulation (EC) No. 1829/2003, EFSA performs the risk assessment itself (only for the environmental risk, EFSA has to ask a national authority to conduct a primary assessment). In addition, dossiers under the Regulation are voted in a different Regulatory Committee.

Intentional and unintentional movements of GMOs between Member States of the European Union and third countries are regulated by Regulation (EC) No. 1946/2003 on trans-boundary movements of genetically modified organisms, with the exception of intentional movements within the EU.

Other legal instruments have been adopted in connection with the above described legislation. These include:

- ▶ On 8 December 2013, the new Implementing Regulation (EU) No. 503/2013 on applications for EU market authorization of genetically modified (GM) food and feed submitted in the frame of Regulation (EC) 1829/2003 came into force. This Implementing Regulation has transferred the EFSA guidance for risk assessment of food and feed from genetically modified plants into a legally binding document. It covers general requirements and a detailed description of the data/study requirements.
- ▶ Commission Regulation (EC) No. 641/2004 on detailed rules for the implementation of Regulation (EC) No. 1829/2003 of the European Parliament and of the Council as regards the application for the authorization of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favorable risk evaluation.⁶
- ▶ Commission Regulation (EC) No. 65/2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms. All operators in the food and feed production chain will transmit and retain specified information on the GMOs. As a means to specify the identity of GMOs, a system of "unique identifiers" has been developed in this regulation.⁷
- ▶ Commission Recommendation 2004/787/EC on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No. 1830/2003.⁸
- ▶ Regulation EC 619/2011 harmonizing implementation of the zero-tolerance policy on non-authorized genetically modified (GM) material in feed to enter into force on 15 July 2011. It addresses EU businesses' uncertainty when marketing feed imported from non-EU countries.

⁶Same name, OJ L102, 7.4.2004, p.14-21.

⁷Commission Regulation (EC) 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for GMOs. OJ L 10, 16.1.2004, p. 5-1.

⁸European Commission (2004). Commission recommendation 2004/787/ EC of 4 October 2004 on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No. 1830/2003. Official Journal of European Union, L348, 18-26

Industrial overview

The industrial biotechnology industry explained

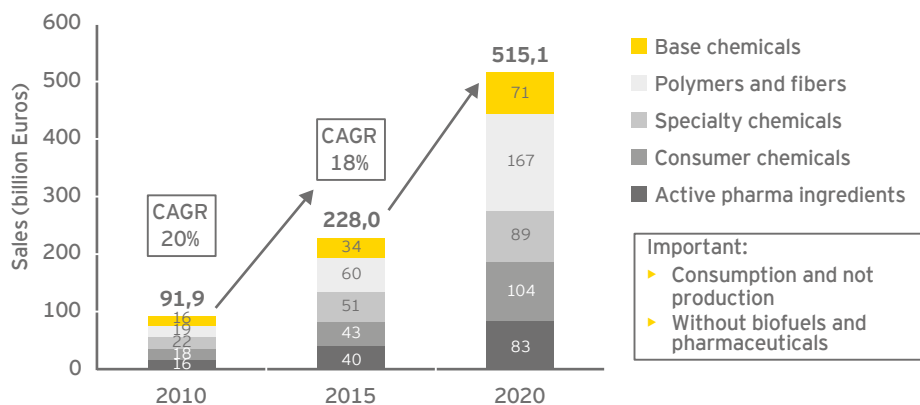
Industrial biotechnology is an industry in which Europe is a world leader, producing more than 60% of the world's enzymes. It uses these enzymes and other micro-organisms to make bio-based products in sectors, such as chemicals, food and feed, detergents, paper and pulp, textiles and bioenergy (such as biofuels or biogas). In doing so, it uses renewable raw materials and is one of the most promising, innovative approaches toward lowering greenhouse gas emissions and moving away from the dependence on fossil-based feedstocks. The application of industrial biotechnology has been proven to make significant contributions toward mitigating the impacts of climate change in these and other sectors. In addition to environmental benefits, biotechnology can improve industry's performance and product value

and, as the technology develops and matures, industrial biotechnology will yield more and more viable solutions for our environment. These innovative solutions bring added benefits for both our climate and our economy.

Bio-based industries are industries, which either use renewable resources and/or apply bio-based processes in their production processes. Industrial biotechnology is a key enabler of these types of industries. The "bioeconomy" as a whole is worth nearly €2 trillion and provides approximately 22million jobs in Europe alone across sectors as diverse as agriculture, forestry, fisheries, food, chemicals and biofuels.

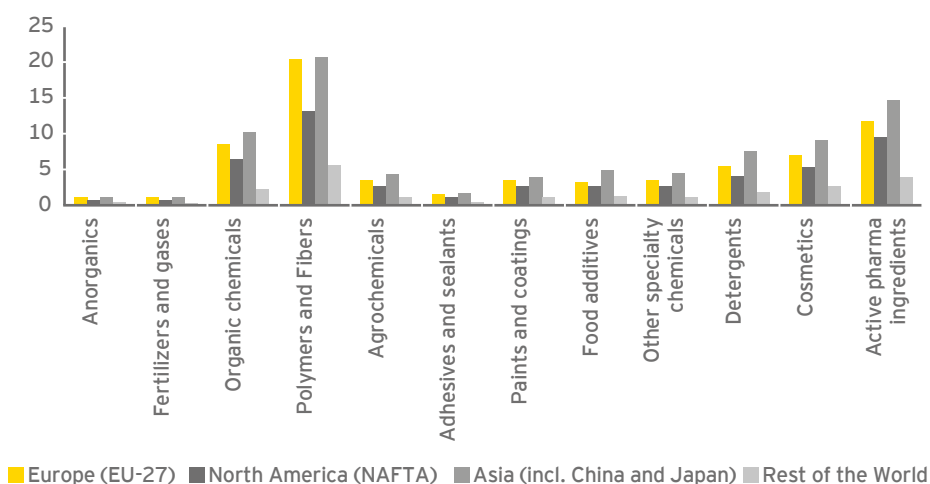
Industrial biotechnology continues to grow in the EU. Sales of products made by biotechnological processes in 2010 were €91.9b representing 6.2% of total chemical sales and are expected to continue to increase substantially in 2015 and 2020.

Figure 1
Sales of bio-based products in the EU



FESTEL CAPITAL: <http://www.festel.com/>

Figure 2



FESTEL CAPITAL: <http://www.festel.com>

In 2015, sales of products made by biotechnological processes will be around €228b representing 12.1% of total chemical sales resulting in a compound annual growth rate (CAGR) from 2010 to 2015 of 20%. In all segments and sub-segments it is expected that by 2015, the percentage of products produced using biotechnological processes will increase. It is estimated that base chemicals will account for €34b, polymers and fibers will strongly increase to €60b, specialty chemicals will have €51.4b, consumer chemicals €42.9b and API €39.7b⁹

In the industrial biotechnology area different company types, such as multinational enterprises (MNEs), small and medium enterprises (SMEs) as well as start-ups, which are dedicated to industrial biotechnology or diversified over a broader range of areas, can be found.

There has been a big shift in recent years toward more holistic policy initiatives for supporting the bioeconomy. While many activities are still conducted at a national level, the European Commission has introduced a series of initiatives to support and set in motion the roll out of the “Bioeconomy Strategy” which was adopted in 2012. Since then, the Strategy has grown stronger, through a number of support frameworks, outlined below:

Horizon 2020: with a budget of nearly €80b over seven years, it is the biggest EU research program to date, and one of the biggest publicly funded research and innovation programs worldwide. Policymakers agreed on three main pillars for the new funding program:

- ▶ “Excellent Science”, which is to receive 37% of the budget

⁹FESTEL CAPITAL: <http://www.festel.com/>

- ▶ “Industrial Leadership”, containing specific support for both SMEs and “Key Enabling Technologies”, is to receive 22.5%
- ▶ “Societal challenges”, including problems associated with an ageing society and environmental issues – receives 38%

Under the second pillar of “Industrial Leadership”, clear recognition was given to the industrial biotechnology sector by the Commission when it named industrial biotechnology a “Key Enabling Technology” (KET) that can boost the European economy, ensuring that the EU remains sustainable, globally competitive and a center for excellence in science. Europe is seeing a shift in EU funding policy away from support for research and applied research only, toward funding research linked to development and innovation. Thanks to these developments, bridging the “valley of death” from concept to market, becomes more of a reality.

Also important for biotechnology companies, a specific SME instrument within the Horizon 2020 program has now been set up to recognize the vital role high-tech SMEs play in boosting innovation creation in Europe, and 20% (or about €8.65b) of the program funds will be directed toward these smaller companies. A simplified model will also ease the application burden, cutting back on red tape and increasing the pool of potential applicants for funding. The new instrument aims to fill gaps in funding for early-stage, high financial risk research and innovation as well as spearheading novel innovation.

Support to SMEs is provided in three different stages covering the whole innovation cycle. Firstly, the feasibility part will allow for an assessment of the technological and commercial potential of an innovative idea (proof of concept). Secondly, if a grant is awarded it will support an innovation project focusing on activities such as pilot, demonstrations, testing and scale-up studies. Finally, the commercialization phase is supported indirectly through facilitated access to debt and equity financial instruments as well as various other measures, for example on IPR protection.

Bio-based industries public private partnership (PPP): This is a multi-sector initiative, with a vision of creating a society and economy which increasingly makes everyday products, such as food, feed, textiles, chemicals and fuels, from locally sourced biomass and wastes, rather than from fossil fuels. The initiative will create jobs in a broad range of sectors in Europe, triggering rural growth across regions while placing sustainability and the smart and efficient use of resources at its heart. In doing so, it will also aim to overcome the EU’s so-called “innovation valley of death” by bridging the gap between excellence in technology and success through EU commercialization of bio-based products. Worth €3.8b, the PPP aims to ensure smart, sustainable and inclusive economic growth, and should help Europe become a world leading bio-based economy. The proposal comes as part of an innovation investment package of new Joint Technology Initiatives (JTIs) under Horizon 2020.



The industry is organized in a Bio-based Industries Consortium. The Consortium currently brings together more than 70 European large and small companies, clusters and organizations across technology, industry, agriculture and forestry. They have all committed to invest in collaborative research, development and demonstration of bio-based technologies within the PPP.

Bioeconomy Observatory: In March 2013, the European Commission's Joint Research Centre (JRC) started the coordination of a three-year project to set up the Bioeconomy Observatory.

Data and information will be collected and disseminated regarding the three key pillars highlighted in the EU Bioeconomy Strategy:

- ▶ Investments in research, innovation and skills: research pillar
- ▶ Reinforced policy interaction and stakeholder engagement: policy pillar
- ▶ Enhancement of markets and competitiveness in bioeconomy: markets pillar

Biotechnology-the potential gains for Europe.

The number of European biotechnology firms in 2011 amounted to 3593.¹⁰ Below, we outline some of benefits that these companies are already bringing to Europe, and what's in the pipeline.

Industrial biotech minimizes mankind's impact on the environment, while also boosting manufacturing output and creating more jobs for Europe

- ▶ Industrial biotech is an industry in which Europe is a world leader. Europe produces about **60%** of the world's enzymes.
- ▶ Industrial biotech uses enzymes and micro-organisms to make products which improve the effectiveness of detergents so that clothes can be washed at lower temperatures and the production of paper and pulp, food, clothing, chemicals and bioenergy is done in a more environmentally efficient way using less energy, less water and producing less waste.
- ▶ Bio-based industries are industries, which either use renewable resources and/or apply bio-based processes in their production processes. Industrial biotechnology is the key enabler of bio-based industries. The bio-economy as a whole is worth nearly **€2t** and provides approximately **22 million jobs in Europe** alone across sectors as diverse as agriculture, forestry, fisheries, food, chemicals and biofuels.
- ▶ Industrial biotech avoids emitting **33 million tonnes of CO₂** – equivalent to more than 7 coal fired power plants or equivalent to the energy use of **2.5 million homes** per year.
- ▶ Biotechnology already allows you to save up to **30%** of the electricity used on laundry by washing at **30°C** rather than 60°C.
- ▶ By driving in a car fuelled with advanced biofuels, you can help to reduce CO₂ emissions by a minimum of **80%**.

¹⁰OECD Key Biotechnology Indicators – June 2013
<http://www.oecd.org/innovation/inno/keybiotechnologyindicators.htm>



- ▶ Parts of automobiles are today made from renewable sources; like bio-based plastics for car parts, tyres partially made from renewable rubber, and biofuels.
- ▶ Enzymes can improve the intake of many nutrients, reducing Phosphate output in manure, providing an environmental benefit to farms.
- ▶ Alternatives to antibiotics and overall improvement to animal nutrition are available, making the use of animal feed overall more effective.

Industrial Biotech Legislative overview

Industrial biotechnology – also known as white biotechnology – uses enzymes and microorganisms to make bio-based products. EU legislation has been in place since the Nineties to cover the contained use of genetically modified micro-organisms as is described below.

Contained use of genetically modified micro-organisms (GMMs)

Directive 2009/41/EC lays down common measures for the contained use of GMMs aimed at protecting human health and the environment.

ACT

2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of GMMs.

SUMMARY

Member States are required to take all measures necessary in order to avoid the contained use of GMMs having negative consequences on human health and the environment.

The directive does not cover:

- ▶ Genetic modifications resulting from the use of certain techniques or methods listed in Annex II, part A.
- ▶ Contained uses involving the GMMs listed in Annex II, part C. GMMs on this list meet the criteria laid down in Annex II, part B, establishing their safety for human health and the environment.
- ▶ The transport of GMMs by road, rail, inland waterway, sea or air.
- ▶ The storage, culture, transport, destruction, disposal or use of GMMs which have been placed on the market in accordance with **Directive 2001/18/EC on the release of GMOs** or pursuant to other community legislation which provides for a specific environmental risk assessment similar to that laid down in the said directive, provided that the contained use is in accordance with the conditions, if any, of the consent for placing on the market.

The assessment of GMM records will result in a **risk hierarchy of the contained uses consisting of four classes**. The containment measures to be applied will also be classified in a four-level hierarchy.

- ▶ Class 1: No or negligible risk, level 1 containment
- ▶ Class 2: Low risk, level 2 containment

- ▶ Class 3: Moderate risk, level 3 containment
- ▶ Class 4: High risk, level 4 containment

The contained use of GMMs requires an **examination of the containment and protection measures** taken, in order to avoid a release.

When contained uses are to be carried out in premises for the first time, the user will be required, before commencing such use, to submit to the competent authorities **a notification containing at least the information** listed in Annex V, Part A, B or C, as appropriate. Following notification to the competent authorities of a class 1 contained use, subsequent class 1 contained use may proceed without further notification. Users of GMMs in class 1 contained uses will be required to keep a record of each assessment, which will be made available to the competent authority on request.

If the premises have been the subject of a previous notification to carry out class 2 or a higher class of contained uses and any associated consent requirements have been satisfied, the class 2 contained use may proceed immediately following the new notification. However, the applicant may himself request from the competent authority a decision on the grant of a formal authorization. The decision must be made within a maximum of 45 days from the notification.

If the premises have not been the subject of a previous notification to carry out class 2 or a higher class of contained uses, the class 2 contained use may, in the absence of any indication to the contrary from the competent authority, proceed 45 days after submission of the notification or earlier with the agreement of the competent authority.

A class 3 or higher class of contained use may not proceed without the prior consent of the competent authority, which will communicate its decision in writing:

- ▶ At the latest 45 days after submission of the new notification, in the case of premises which have been the subject of a previous notification to carry out class 3 or a higher class of contained uses and where any associated consent requirements have been satisfied for the same or a higher class than the contained use with which it is intended to proceed.
- ▶ At the latest 90 days after submission of the notification, in other cases.

The annexes to the directive detail the **criteria for assessing the risks of GMMs to health and the environment**, as well as the protective measures for each of the four levels of containment.

If they so wish, Member States may provide for groups or the public to be consulted on any aspect of proposed contained use.

Before a contained use commences, Member States have to ensure that:

- ▶ An **emergency plan is drawn up** in order to react effectively in the case of an accident.
- ▶ **Persons at risk of being affected by an accident are informed** of all aspects related to their safety.

If an accident occurs, the user should immediately inform the competent authority and communicate the information necessary for assessing the impact of that accident and for taking the appropriate action. The Member State will also inform the Commission and any Member State that may be affected by the accident.

The Commission will create a register of accidents, including an analysis of the causes of the accidents, the experience gained and measures taken to avoid similar accidents.

The Commission will be assisted by a Committee which is to rule on matters related to the application of the directive and adapting it in light of technical progress.

Context

This directive replaces and repeals Directive 90/219/EEC. It is a formal

amendment aimed at bringing together the original directive and its successive amendments into a single act, without any changes to the fundamental provisions nor any new transposition into national law being made.

Finally, this directive lays down the **minimal standards applicable to the contained use of genetically modified micro-organisms**. Member States are permitted to take more stringent measures. They may also extend the scope of the directive to contained uses involving genetically modified plants, animals or fish.

Key terms of the Act

Genetically modified micro-organism: a micro-organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination; within the terms of this definition:

- ▶ Genetic modification occurs at least through the use of the techniques listed in Annex I, Part A
- ▶ The techniques listed in Annex I, Part B, are not considered to result in genetic modification

Contained use: any activity in which micro-organisms are genetically modified or in which such GMMs are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with, and to provide a high level of safety for, the general population and the environment.

Accident: any incident involving a significant and unintended release of GMMs in the course of their contained use which could present an immediate or delayed hazard to human health or the environment.

Directive 2009/41/EC; Entered into force on 10.06.2009; published in Official Journal OJ L 125 of 21.5.2009



EU country profiles



The establishment of a company: a country-by-country overview of start-up considerations



	Tax rate	Use of tax losses	R&D tax credits
Austria	25%	Yes – capped at 75% of income	10% subject to a cap of €1m for any outsourcing
Belgium	33% (lower rate 24.25% to 34.5% up to €322,550). In addition there is a 3% surtax.	Yes – unlimited carry forward, but no carry back	Investment deduction – 14.5% of acquisition value of qualifying asset or 21.5% of the depreciation amount. An alternative is the R&D credit – investment deduction multiplied by the tax rate.
Denmark	24.5% Reducing to 23.5% in 2015, 22% for 2016 and onward	Restrictions on carryforward – Offset in full up to DKK7.5m, 60% above DKK7.5m	100% deduction for qualifying expenditure. Tax credit for R&D activities enables a refund of negative tax (loss). The tax credit is calculated as up to 25% of DKK 5m (2015: up to DKK 25m)
France	33.33%	Yes – limit €1m, plus 50% of taxable profits exceeding the limit	30% up to €100m and 5% for qualifying expenses in excess of €100m
Germany	Effective rate 15.825% plus municipal (10%-18%)	Yes – limit €1m, plus 60% of taxable profits exceeding the limit	No
Hungary	19% and 10% on first €1.7m	Yes – up to 50% of tax base	Double deduction for R&D expenses
Ireland	12.5% and 25% (passive)	Yes – full relief	Yes – 25% (effective deduction 37.5%)
Italy	31.4%	Yes – up to 80% of tax base	50% tax credit on incremental R&D, within a maximum of €2.5m per year.



Patent/innovation box	Intellectual Property regime	Capital gains tax (CGT)	Other incentives	Incentives – grants/finance support
			6% and 20% training expenses	€200,000 non refundable and €1m loan
Yes – 80% of gross income, maximum effective tax rate 6.8%	Yes	CGT rollover relief available in certain cases. No CGT on shares save for a separate assessment of 0.412% subject to conditions	An 80% exemption from wage withholding tax for qualified personnel (e.g. researchers) is also available.	Several grants and subsidies available on regional and European level
		Exemption for group shares, subsidiary shares, own shares and unlisted portfolio shares		
	15% rate – amortization and financing cost allowed	Young Innovation Enterprise (YIE) – CGT exemption		
				No repayable cash grants
	50% dispensation for royalty income			VIP cash grant €10m
	Deduction for broadly defined IP		Three-year exemption from corporation tax for start up with carryforward of any unused relief beyond the initial three years	Enterprise Ireland €650,000
		Investor relief from CGT where proceeds rolled over into new investment		Commissione Nazionale per le Società e la Borsa (CONSOB) Ministero dello Sviluppo Economico (MISE)

	Rate	Use of losses	R&D tax credits
Luxembourg	29.22%	Yes	Yes – SME sector for certain costs
The Netherlands	25% and 20% on first €200,000	Yes – carry forward nine years, carry back one year	R&D tax credit (formerly known as WBSO) of 35% (50% for start ups) of the first €250,000 of the total wage costs for R&D and 14% of the remainder. RDA (Research & Development Deduction) of 60% for R&D costs/expenses.
Norway	27%	Yes – carry forward indefinitely	Yes – 18% or 20% for Small and Medium sized enterprises (SMEs) – maximum tax credit available is NOK8m
Poland	19%	5 years. Capped at 50% of loss in any one year	Innovation fund – 50% of eligible cost with approval
Portugal	23%	Yes – restricted to 70% of taxable profits	32.5% tax credit on qualifying expenses. €1.5/1.8m cap applies in certain circumstances.
Spain	30% and 25% on first €120,202 where prior year net revenue was less than €10m (group basis).	Yes – for a period of 18 years	Yes – general rate 25% (42% can be achieved)
Sweden	22.00%	Yes – carry forward indefinitely and available in group	Expenses deductible
Switzerland	12%-24%	Yes – carry forward seven years	Capitalized expenditure – write off or amortize
United Kingdom	23%, reducing to 21% on 1 April 2014 and 20% on 1 April 2015	Yes – carry forward full relief	Deduction of 225% of qualifying expenditure for small and medium sized enterprises (SME) with a 130% deduction for large companies.

These are general guidelines, refer to individual country information later in the chapter.

Patent/innovation box	Intellectual property regime	Capital gains tax (CGT)	Other incentives	Incentives – grants/finance support
Yes, partial income tax exemption of 80% of net income			Yes; if certain conditions are met, a range of tax incentives may apply.	Yes, incentives (other than tax incentives) or finance support are available.
Effective tax rate of 5%		CGT exemption or rollover available		Several non-tax incentives and grants
		No CGT for non-resident		Innovation Norway
			Exemption from tax in special economic zone	Maximum cash grant available PLN10m
		Available in certain circumstances	Reduced rate 5%/10%/15% in disadvantaged areas	National Strategic Reference Framework (NSRF)
60% of gross income				Multiple public funding, can achieve €500,000
		Yes, available in limited cases	Reduced payroll for employees engaged in research or development for at least 75% of their work time, or 15 hours per month	Proposals to encourage VC and investors
Canton of Nidwalden – effective rate of 8.8%		Yes – in certain circumstances	Tax holiday, 10 years – canton	Swiss National Science Foundation supports 8,500 researchers annually
10% rate being phased in over five years (10% will apply from 2017)		Entrepreneurs' Relief – 10% rate for lifetime gains up to £10m	Most dividends likely to be UK tax free	Multiple public funding opportunities including the Biomedical Catalyst

Austria

The entrepreneurial culture

Austria's federal and regional governments provide a variety of financing for early-stage companies and start-ups in biotechnology. This is complemented by other measures such as trade fairs, and support for intellectual property and business plans. With its Action Plan Biotechnology announced in June 2013, the Austrian Federal Ministry of Economy, Family and Youth presented a wide range of initiatives to support the biotech industry. These initiatives are strategically placed throughout the value chain and administered through various federal agencies, such as Austria Wirtschaftsservice (AWS) and the Austrian Research Promotion Agency (FFG).

AWS LISA

AWS LISA is a one-stop-shop support program that provides assistance throughout the value chain for life sciences startups. Comprised of four pillars – Foster, Finance, Fuel and Advance – LISA provides tailor-made support measures for every stage of a company's development (lifescienceaustria.at).

- ▶ Foster: As a way of fostering an entrepreneurial culture, AWS runs the business plan competition "AWS BoB – Best of Biotech" (bestofbiotech.at), every two years. Furthermore, AWS offers professional consulting and due diligence in the pre-startup phase.
- ▶ Finance: Focusing on startup ideas in biotechnology and medical devices, AWS provides financial support through two custom-designed funding programs: AWS PreSeed and AWS Seedfinancing.
- ▶ Fuel: LISA International Marketing promotes the Austrian life science sector on the international stage and is the first point of call for enquiries relating to it. Furthermore, companies will be supported in obtaining follow-up financing, as well as offering sector-specific lectures.
- ▶ Advance: AWS produces statistics, analysis and sector studies to help key decision-makers guarantee the competitiveness of the Austrian life sciences sector.

2. Forschungsförderungsgesellschaft (FFG)

FFG makes available project financing for companies conducting research and development (R&D). Apart from those, FFG offers thematically focused funding programs, such as funding for research into orphan diseases. The funding program Research Studio Austria supports the application and exploitation of research results in the preparation of industrial R&D in Austria (ffg.at).

Most federal states in Austria have regional funding banks that provide additional resources. The academic incubators in the federal states, AplusB-Centers, also give advice and financing for the founders of businesses (aplusb.biz).

Other organizations, such as the Investment Agency, Austrian Business Agency (ABA, investinaustria.at), as well as the Austrian Chamber of Commerce (WKO, wko.at) or the Austrian Biotech Industry Association (ABI, biotechindustry.at) offer a variety of support options for businesses. ABA-Invest in Austria,

the national company for investment, provides consulting services to firms interested in setting up operations in the country. As a government agency, it focuses on all issues relevant to selecting an appropriate location. In addition, it provides free information about Austria as a business location.

Taxation

Corporate income tax

All companies resident in Austria, and foreign companies with a branch or permanent establishment in the country, are subject to corporate income tax at a rate of 25%. Taxable income is based on the profit or loss shown in financial statements, which must be adjusted in accordance with special rules set out in the Austrian Tax Act. Note that the regime for group taxation allows parents and subsidiaries to consolidate their taxable income in certain circumstances.

A recent comparison of the effective tax burden in Austria compiled by economic researcher and consultancy BAKBASEL and the Center for European Economic Research (ZEW) concludes that the country has a total tax burden of 22.1%.

Austria's network of double taxation treaties ensures minimal taxation at the source for dividends, interest and licensing fees. In addition, firms may claim an education allowance of up to 20%, or claim a 6% credit for expenditure on education.

Tax losses can be carried forward indefinitely, but losses cannot be carried back. Under a general restriction, 75% of income can be set off against losses carried forward. So, 25% of the income

remains subject to tax, even if there are sufficient losses carried forward. In certain exceptions, 100% of the income can be set off against tax; for example, gains on the sale of a business unit or pre-group tax loss carry-forwards at a group member level.

A change in ownership may jeopardize tax losses carried forward. Indeed, this may be true if there is a material change in ownership, management or business. The tax losses carried forward are also at risk after a reorganization, if the assets or business units that generated the losses do not exist at the effective date of a reorganization.

Although, in general, shareholders are free to determine whether to finance their company with equity or loans, the tax authorities may reclassify loans granted by shareholders as equity if funds are transferred under the legal or other circumstances that typify equity contributions.

For third-party acquisitions only, interest expenses can be deducted against tax for debt financing in Austria as well as foreign corporations.

Incentives

Companies may claim a premium (or cash equivalent) for R&D equal to 10% of certain expenses on research or experimental development. Österreichische Forschungsförderungsgesellschaft mbH, a governmental "expertise institution" makes decisions on whether certain expenses qualify for a premium. The R&D must be conducted by an Austrian company or the local arm of a foreign one permanently established in Austria.

The R&D premium may also be claimed for contractual research conducted by third parties (Auftragsforschung). In such cases, however, the qualifying expenses are capped at €1m. Furthermore, the third party must be registered in the European Union or European Economic Area, while the R&D must be its main business. An R&D premium cannot be claimed if the third party is under the control of the principal or if the companies belong to a tax group.

Similarly, a premium of 6% can be claimed for training expenses. Instead of the premium, the company can deduct an additional, notional expense of 20% of the training expenses in its tax return. Annual fees for patents are levied only from a company's third year onwards.

Landscape for investors

1) Tax groups

Companies are allowed to establish a tax group so that a parent company and its subsidiaries can consolidate their income. The group's parent requires a majority of capital and voting rights in its subsidiaries from the beginning of the subsidiary's fiscal year. With a shareholding exceeding 50%, the parent company can claim 100% of the taxable profit or loss of the domestic group member, irrespective of the percentage of the shareholding. If there are foreign group members, only partial losses can be considered. If a company leaves a tax group before the end of a three-year period, the whole period is rolled up and the entities are taxed on a stand-alone basis (i.e., profits and losses are reallocated to the individual member of the group).

Available pre-group tax-loss carry-forwards can be fully offset against available profits at the level of the individual member.

The parent's loss carry-forwards, as well as those suffered within the tax group, are restricted by the rules on minimum taxation.

If an Austrian corporation acquires shares in an Austrian operating company from a third party, and subsequently enters into a tax group, the (negative or positive) goodwill is amortized for tax purposes at the level of the buyer over 15 years. The goodwill is determined as the difference between the purchase price and equity of the target company, reduced by hidden reserves in non-depreciable assets. The goodwill is further capped at 50% of the purchase price.

2) National dividend exemption and international participation exemption

Dividends received by an Austrian company from another such corporation are exempt from corporate income tax (and no minimum holding is required). Capital gains derived from the sale of shares in Austrian companies are treated as ordinary income and so are subject to corporate income tax.

An Austrian company is entitled to an international participation exemption (for dividends and capital gains) if, for more than a year, it holds at least 10% of the share capital of a foreign corporation that is comparable to an Austrian corporation. A reduction in the value of an international participation and capital losses are not tax deductible, but an Austrian company can opt for such tax deductibility. Capital gains are tax exempt under the international participation exemption; if an option was

exercised, capital gains are subject to corporate income tax.

Under the anti-abuse rule, the international participation exemption does not apply if:

- i. The subsidiary earns primarily specified types of passive income, i.e., interest, income from leasing property other than land and buildings and capital gains.
- ii. The subsidiary is not subject to income tax at an effective rate of more than 15% in its home country.
- iii. Advance ruling

Since 2011, it has been possible to obtain binding information from the tax authorities on actions that have yet to be realized (i.e., an advanced ruling). On the basis of the application filed by the taxpayer, the tax authorities issue an assessment related to the specific case. The authorities are then bound to this legal opinion in future. The system is limited to certain issues, i.e., reorganizations, tax grouping and transfer pricing.

Landscape for entrepreneurs

Austria's rates for individual income tax for 2013 are progressive and vary between 0% and 50%.

Finance

Austria Wirtschaftsservice

Focusing on startup ideas in biotechnology and medical devices, AWS provides financial support with its funding measures AWS LISA PreSeed and AWS LISA Seedfinancing. AWS LISA PreSeed (preseed.at) provides funding for the

phase before the setup of a life science company. Costs related to the scientific implementation and the economic application of a project can be funded. The maximum amount of this non-refundable financial support is €200,000.

Setting up an innovative and internationally competitive high-tech company needs a lot of know-how, courage and capital. AWS LISA Seedfinancing (seedfinancing.at) supports the startup phase of high-tech companies with up to €1m, combined with tailored advice and support.

Once the company is making profit or is sold, financial support must be refunded. Customary securities usually needed for bank loans are not necessary. However, the company must be partly and adequately funded through private capital.

With temporary management (aws.g.at/maz), AWS supports startup high-tech companies, which are already funded through the seed program, to overcome critical competence gaps. With up to €50,000, or a maximum of 50% of the costs, external advice in the areas of finances, sales or technology can be funded. The support measure usually lasts six to nine months.

For more mature companies, there are a number of loans and guarantees available through outlets such as Forschungsförderungsgesellschaft: Basisprogramme (which may provide up to €1m per year). Regional agencies and the academic incubators AplusB-Centers may also step in to help.

Furthermore, AWS has three initiatives to close the financing gap for young, innovative companies. AWS Business

Angel fund provides co-financing for equity investments; it is aimed in particular at startups. AWS gründerfonds provides risk capital to companies with high growth potential in the early stage, as well as in the growth phase. These instruments are complemented by the AWS Venture Capital Initiative which undertakes co-investments with institutional investors.

Availability of capital

Biotech companies in Austria are financed to a large extent by local business angels as well as international venture capitalists, mainly from France, Germany, the Netherlands and the UK.

Regulatory environment and incentives

Within the framework of the national R&D strategy from 2011 to 2020, the Austrian Federal Ministry of Economy, Family and Youth presented its ambitious Action Plan Biotechnology in June 2013. This plan aims to increase the size of this research-intensive sector significantly within the next five years, in particular through new financial support programs.

On patents, the Directive on Biotechnological Inventions has been implemented without national amendments. The London Agreement has not been implemented.

Market access regarding chemicals is based on the REACH System. For information regarding the reimbursement of pharmaceuticals, please refer to pharmaconsulting.at. Marketing of genetically modified organisms (GMO)

is partly restricted and does not follow European Union rules. Cultivation of GMO crops is hampered by a strict liability scheme, and by public opinion.

Structuring for the future

A common structuring arrangement is to establish an Austrian holding company for the acquisition of an Austrian target company. In the case of a third-party acquisition, related interest expense would be deductible at holding level. If the holding and target company enter into a tax group, a consolidation of taxable profits and losses is possible (for foreign group members, however, only partial losses can be considered). Additionally, if the operating Austrian entity was acquired from a third party, capitalized goodwill has to be amortized at group parent-level over 15 years.

Dividends distributed from the target to the acquisition vehicle are tax exempt under the national dividend exemption. At both levels, dividends and capital gains from foreign participations may qualify for the international participation exemption. Dividends distributed from the acquisition vehicle to its foreign shareholder(s) may benefit from Austria's excellent treaty network.

€1m



Belgium

The entrepreneurial culture

Situated at the center of Europe, Belgium is considered by many to be a prime location for business. Some 60% of the European Union's buying power is concentrated within a 500km radius of the country.

Belgium has the densest road and rail network in the world, and its waterways link Antwerp, Europe's second-largest sea port, to industrial clusters across the rest of the country and beyond. As well as hosting many of the institutions of the European Union, Brussels is where NATO and many other European and international organizations are headquartered.

According to the OECD, Belgium has some world-class universities and a fairly high share of publications in top scientific journals. It is no surprise, therefore, that it was voted the best country for biotechnology within the Organisation for Economic Co-operation and Development (OECD) in the organization's Science, Technology and Industry Outlook for 2008. According to the EUROSTAT statistics, Belgium ranks third in the list of highest shares of innovative enterprises during the period 2008 and 2010.

In Belgium, business and the academic world have a tradition of working together. Such cooperation is supported by several research bodies on regional levels. Partly as a result of these organizations' efforts, spending on R&D is high in relation to the country's size. According to the OECD, this puts Belgium among the leading European Union venture capitalist investors.

The dynamic atmosphere of biotech companies in Belgium was highlighted again in 2012 when the journal *New Scientist* mentioned that *"for such a small*

country, Belgium boasts an astonishing 300 biotech companies, all working closely with universities, research institutes and hospitals."

According to the annual Global Innovation Index, Belgium was ranked 21 on the 2013 ranking and performing well in particular on education and the quality or scientific research.

Belgium is a federation with three regions (Brussels-Capital Region, Flanders and Wallonia). The region's competencies are separated and they respectively account for 8%, 67% and 25% of total R&D. The Federal Government committed itself already in 2008 to reduce the employment costs of researchers, to support the creation and development of small and medium-sized enterprises, and to increase R&D intensity. All competent Belgian authorities have included the EU strategy 2020's 3% target and aim to increase expenditures on R&D.

The country's proactive innovation policies target leading-edge sectors. In this respect, Flanders in Action focuses on research talent and the commercialization of research results in strategic fields. The Innovation Centre Flanders concept note approved in May 2011 defines a long-term vision for innovation policy based on six vertical and transversal "innovation crossroads." The Walloon Marshall Plan 2. Green seeks to strengthen human resources and to consolidate regional cluster policy for sustainable development. The Creative Wallonia plan was also launched in 2010 to make Walloon society more conducive to innovation; a strategy for an integrated research policy was approved in March 2011. The Brussels 2006-11 Regional Innovation Plan includes

a focus on sector-oriented clusters, internationalization of the innovation system, and better economic returns to innovation.

Moreover, Belgium's Federal Government provides incentives to foster R&D and innovation. Various organizations provide advice and guidance to those wanting to start (or expand) their activities in Belgium.

Foreign companies considering setting up in Belgium should contact the Service for Direct Investments via the following websites:

- ▶ ib.fgov.be
- ▶ investinlanders.be
- ▶ investinwallonia.be
- ▶ investinbrussels.com

There are also various industry federations. Essenscia, an umbrella organization, represents the chemicals and life sciences industry. Pharma.be, or the Belgian Pharmaceutical Industry Association, represents the country's pharmaceutical interests. Bio.be is the Belgian association for bioindustries. It aims to develop a climate in which companies can expand their businesses, make new investments and gain access to markets. In doing so, Bio.be enables the various regions to attract investments into biotechnology. Bio.be is a member of EuropaBio.

At a regional level, there are bodies such as FlandersBio, Brusselsliftech, Greenwin and Biowin in Wallonia. They support activities such as training, networking and development.

Taxation

Corporate income tax

Companies resident in Belgium are subject to tax on their worldwide income whereby foreign source income may be exempt under the Dividend Received Deduction (see below) or the double tax treaty branch exemption. Non-resident companies are only subject to tax on income sourced from Belgium. A company is resident in Belgium if it has its registered office, its principal place of business or its place of management or administration located in Belgium.

The normal rate of corporate income tax is 33.99% (a 3% surcharge included) both for resident companies and for branches of overseas ones. Income below €322,550 is taxed at rates ranging from 24.98% to 35.54%. These statutory rates are generally reduced by applying several deductions, such as the notional interest deduction.

Indeed, Belgian companies and foreign companies with a permanent establishment in the country automatically benefit from the notional interest deduction. This tax deduction, which is not reflected as such in the financial accounts, is a unique tax incentive allowing companies, irrespective of their size, industry or activity, to deduct a percentage (2.630% for tax year 2015) of their equity (or risk capital) from their taxable income. This reflects the broad objective of the incentive, which is to align the tax treatment of debt financing (where interest is in principle tax deductible) with the tax treatment of equity financing (where no such deduction is available) and

thus, allowing companies to strengthen their capital structure, without giving up the benefit of a tax deduction. Risk capital equals total equity, including retained earnings as reported in the non-consolidated closing balance sheet of the financial year preceding the relevant tax year and excluding items such as, for example shares held in other companies. As a result, the notional interest deduction reduces the effective tax rate, in particular for companies engaged in equity intensive activities such as research and development.

Under the Dividend Received Deduction, 95% of the dividends received by a Belgian company or the Belgian branch of a foreign company are exempt from tax. The remaining 5% is subject to the standard rate of corporate income tax which can however be partly or fully reduced by other deductible expenses such as for example interest expenses incurred upon the acquisition of the shares. The exemption only applies if a participation test and a subject-to-tax test are satisfied. In this respect, the recipient of the dividends must own in full ownership a minimum of 10% in the capital of the subsidiary or a participation with an investment value of at least €2.5m for an uninterrupted period of at least one year. The subject-to-tax test contains a number of clauses looking at the tax regime of the subsidiary, its income, income from its branches and lower tier subsidiaries. Income derived by a Belgian company through its foreign branch is generally exempt in Belgium under the double tax treaties entered into by Belgium.

The net amount of capital gains on shares is exempt from corporate income tax, save

for a separate taxation of 0.412%, provided the above-mentioned subject-to-tax is met and a minimum holding period of one year is complied with. The separate taxation of 0.412% is not applicable in a case where the company transferring the shares is considered to be a small or medium-sized enterprise.

In Belgium, all other capital gains are in principle taxed at the ordinary rate. If the proceeds are reinvested in depreciable fixed assets within three years (or five years, for certain assets), and if certain conditions are met, taxation of the capital gains is deferred over the depreciation period of the newly acquired assets.

Belgian source dividends are generally subject to a 25% withholding tax. Exemptions or reduced rates are, however, available under the country's double tax treaties or domestic legislation, in particular the implementation of the European Parent-Subsidiary Directive. Moreover, under similar conditions, dividend withholding tax is not imposed on dividends paid to a qualified treaty parent, i.e. one which has, or commits itself to have, a shareholding of at least 10% in a Belgian company for an uninterrupted period of 12 months. In this respect, it is worthwhile mentioning that Belgium has an excellent double tax treaty network with close to 100 treaties signed including multiple beneficial treaties, in particular with the United States of America and with key jurisdictions in the African and Asia-Pacific region such as Hong Kong and mainland China.

Belgian source interest or royalties are also generally subject to a withholding tax of 25%. However, also for these types of income, reductions or exemptions apply

under a double tax treaty concluded by Belgium or by virtue of domestic law.

A Belgian company that receives interest or royalty income from foreign sources subject to a foreign withholding tax can claim a credit in Belgium in order to avoid double taxation if certain conditions are met.

In principle, depreciation rates are determined on the useful economic life of the assets. The following straight-line rates are generally accepted:

- ▶ Office buildings: 3%
- ▶ Industrial buildings: 5%
- ▶ Chemical plants: 8% to 12.5%
- ▶ Machinery and equipment: 10% to 20%
- ▶ Office furniture and equipment: 10% to 15%

The declining-balance method and rules of accelerated depreciation are also allowed in certain circumstances.

Tax losses can be carried forward indefinitely if a company remains a going concern. There is no carryback available. Belgium has no rules on tax consolidation or grouping. Of particular relevance to those in life sciences and biotechnology is the fact that, in principle, all R&D expenses are fully tax deductible.

Belgium has rules on thin capitalization. A debt to equity ratio of 5:1 applies to payments made to either a group company or to a foreign entity, if the latter entity is either not subject to tax or is subject to a regime that is significantly more advantageous than Belgium's ordinary tax regime. Companies engaged in cash pooling or treasury activities may benefit from a netting regime whereby the

amount of interest potentially subject to the thin capitalization rule is limited to the difference between the amount of interest paid and the amount of interest received.

Tax incentives

i. Patent income deduction (or patent box)

The Belgian patent income deduction (PID) is an incentive allowing companies to deduct 80% of their qualifying patent income from their taxable basis, reducing the effective tax rate on such income to a maximum of 6.8% (i.e., 20% of the Belgian statutory corporate income tax rate of 33.99%). The PID is automatically applicable to Belgian companies as well as foreign companies having a permanent establishment in Belgium, irrespective of their size or industry.

Combined with other attractive features, the PID ranks Belgium as a tier one jurisdiction for companies carrying out research and development activities resulting in patents. Advance tax rulings can be requested in order to secure the tax treatment.

The PID is applicable to qualifying income from:

- ▶ Patents, fully or partially self-developed by Belgian companies or Belgian permanent establishments of foreign companies in qualifying R&D centers
- ▶ Patents acquired or licensed from related or unrelated parties provided they are further fully or partially developed in qualifying R&D centers (irrespective of the fact that such developments lead to additional patents).

The PID is not open to patents that were commercialized prior to 1 January 2007. A key advantage is that the PID is not restricted to Belgian patents. European patents, US patents or patents valid in other jurisdictions can also qualify. Other intellectual property, such as copyrights, trademarks or brands, does not qualify for the PID.

The R&D center, through which patents have to be developed or further improved, should qualify as a branch of activity, i.e., a division which is capable of operating autonomously. Although an appropriate and relevant level of operations and functions has to be available in such a center in order to perform and supervise R&D activities, certain activities in connection with the development or improvement of patents may be outsourced to related or unrelated subcontractors. The requirement to have an R&D center is not applicable to small and medium-sized enterprises making this incentive even more accessible for these types of companies and in particular for new startups.

The PID applies to income derived from the licensing of patents but is also applicable to related patent income that is embedded in the sales price of a patented product or a service.

For patents that are licensed to related or unrelated parties, 80% of the gross (arm's length) income received may be deducted from the taxable basis. It applies to variable income streams, fixed income streams, upfront fees, milestone fees, etc. Capital gains realized on the sale or disposal of patents fall outside the scope of the PID.

When a company uses patents to sell or produce goods or to deliver services, 80% of a deemed arm's length royalty (i.e., the equivalent to the royalty which the company would have received if it had licensed the patents used) may be deducted from the taxable basis.

The PID is calculated as a percentage on the gross patent income but is taken against a company's net income, i.e., after depreciation expenses, interest expenses, wages, other R&D expenditure, etc. Therefore the qualifying patent income is generally subject to an effective tax rate lower than 6.8%. This can result in excess PID which can be offset against other taxable income. Note that the unused PID cannot be carried forward to subsequent years. In case patents are acquired or licensed, the depreciation expenses or license expenses incurred are to be deducted from the gross patent income before applying the 80% deduction.

In summary, the PID is straightforward, automatically applicable and does not require a special ruling or election. It contains some key features which make it a very attractive regime, also in comparison with other European regimes. Indeed, the PID applies in addition to the deduction of incurred business expenses such as research and development expenditure, interest expenses and wages. There is no recapture of previous incurred R&D expenses. Finally, the PID can be combined with other incentives such as the notional interest deduction, the investment deduction for research and development and patents which may further reduce the net cost of performing R&D activities in Belgium.

ii. Tax credit or deductions for R&D

The investment deduction for research and development entitles a Belgian company or a Belgian permanent establishment of a foreign company to apply a deduction in addition to the annual depreciation expense of qualifying assets.

The investment deduction can be calculated either as a percentage of the acquisition value of the qualifying asset ("one time" deduction) or as a percentage of the annual depreciation amount in which case the investment deduction is spread over the depreciation period ("spread" deduction). These percentages vary annually. For assessment year 2014, the "one time" deduction amounts to 14.5% of the acquisition value of the asset while the spread deduction amounts to 21.5% of the annual depreciation.

The investment deduction applies to:

- ▶ Tangible and intangible fixed assets used for research and development of new products and technologies that do not have a negative impact on the environment ("green investments"), including research and development expenses capitalized under Belgian GAAP
- ▶ Patents ("one-time" deduction only).

As an alternative to the investment deduction, companies can also opt for a tax credit which is deductible from the corporate income tax due. The tax credit is equal to the investment deduction multiplied by the standard corporate tax rate of 33.99%. Therefore, although the calculation is different, the advantage is equivalent. Excess tax credits are carried

forward and can be used subject to certain limitations. The remaining balance after five years is refunded, which results in a cash benefit.

ii. Employment-related incentives

A partial exemption of wage withholding tax of 80% is available for universities, scientific institutes and companies (including young innovative companies). As a result, the employer is only required to transfer 20% of the withholding tax due to the tax authorities. The remaining 80% is a direct cash benefit for the employer and thus significantly lowers the salary cost for the employers and is neutral for the employee concerned.

In order to apply the partial wage withholding tax, the employee should have a qualifying PhD or Master degree and he or she must be employed in a research and development program. A notification procedure is required and some documentation should be provided to support the notification process.

Foreign executives and researchers who temporarily work in Belgium can also enjoy a special tax regime. A person who is classified as a foreign executive or researcher is considered to be a nonresident in Belgium from a tax point of view and, consequently, is only taxed on his income relating to professional activities carried out in Belgium. Moreover, certain expense allowances (called expatriate allowances) that relate to the temporary nature of the employment in Belgium are fully exempt.

The tax landscape for investors

As mentioned above, there are incentives for those investing in Belgium. These include the notional interest deduction, the patent income deduction, a deduction (or equivalent credit) for investments in R&D and patents, and other incentives.

i. Principal companies

A low effective rate of tax can be achieved in Belgium through a combination of the above mentioned incentives and transfer pricing based rulings. The transfer pricing based approach is based on a transfer pricing provision, which introduced the internationally accepted arm's length standard to Belgium's tax legislation. It provides a downward revision of taxable profits to the extent that these exceed a pure stand-alone entity's profit level.

ii. Holding companies

Belgium has a long history of attracting holding companies. And it continues to do so, not least because of its extensive network of tax treaties (amounting to 100 in all) as well as other features:

- ▶ No capital duties, stamp duties or taxes on net worth
- ▶ Capital gains on shares are exempt, except for a separate tax assessment of 0.412%
- ▶ Dividends received may be exempt up to 95%

- ▶ No dividend withholding tax to qualifying treaty parents
- ▶ Interest expenses relating to the acquisition of shares are generally tax deductible

In addition, there is no legislation regarding "controlled foreign corporations" i.e., those owned and controlled from outside the country but registered to do business in Belgium. Companies may adopt a foreign currency for accounting purposes. They are also eligible for check-the-box elections, a simplified system for declaring tax in the US. And there are many exemptions from withholding tax for both domestic and overseas companies.

iii. Well-established ruling practice

In order to obtain advance certainty on the application of one or more of the tax incentives above or the tax implications of a certain transaction in general, an advance ruling can be obtained. Such a ruling is a unilateral written decision by the Belgian tax authorities at the request of a (potential) taxpayer about the application of the tax legislation in a specific situation that has yet to occur. Obtaining a ruling typically takes three months. This period may be longer in complex situations. A ruling is generally valid for a period of five years and is renewable upon the taxpayer's request.

A pre-filing meeting, which is possible on a no-name basis, can also be scheduled with the tax authorities before an application is filed. In principle, a verbal indication may already be obtained after such a meeting.

Finance

In Belgium, various initiatives are available on a regional and European level with the objective to stimulate (scientific) research and industrial development. Subsidies may be granted as direct financial support or through subordinated loans with favorable terms and conditions. The grants or loans depend on several criteria (e.g., the size of the company and the activity for which the support is requested). The amount of support may also depend on the region where the work is done and are generally provided after submitting a project application.

Support may be requested for everything from feasibility studies for innovative ideas to the recruitment of researchers, and for research related to the application of an idea or the field of development. Other activities that may be covered include: efforts to evaluate new processes and products, tests involving universities and research institutions, and research in pursuit of new processes, products or services, or to improve existing ones.

In many regions, support for small and medium-sized enterprises is given priority. In Flanders, for instance, this support includes help for start ups up to the point where they file a patent. As well as supporting individual firms, bodies such as the Agency for Innovation through Science and Technology (IWT) provide a focal point for collective research in areas highlighted by industry groups, such as FlandersBio or CNBIOS.

In the south of Belgium, companies can receive subsidies up to 80% of the total amount invested. Biowin offers subsidies of up to 100% of the cost of research undertaken by universities, up to 70% for that undertaken by small and medium-sized companies and up to 50% for that undertaken by larger ones. Similar support programs are available for enterprises located in the Brussels-Capital Region.

Availability of capital

According to the European Union's Innovation Scoreboard for 2014, Belgium qualifies as an "Innovation follower" with an innovation performance above or close to that of the European Union's average. Strongholds are international scientific co-publications and the collaboration between innovative small and medium-sized enterprises. In 2012, 28% of venture capital invested in Belgium was

deployed in life sciences, and the average amount invested in the sector is the largest anywhere in the EU. The Belgian Government supplies seed capital for qualifying ventures through the Flemish Innovation Fund, which is managed by PMV, an independent investment company. The latter also runs a new Transformation, Innovation and Acceleration fund (TINA) with the aim to accelerate knowledge transfer by supporting collaborative projects. In 2011, Flanders introduced SOFI to support spin-off companies from the strategic research centers. The Technological Innovation Partnership in Wallonia and the Brussels-Capital Region's strategic platforms also aim to encourage collaborative research.

In addition, the Government holds a 27% interest in GIMV, an investment company with shares listed on Euronext Brussels. GIMV, which specializes in private equity and venture capital, focuses mainly on Europe and is an important investor in life sciences.

Regulatory environment and incentives

Biotech for health care

The cost of clinical trials in Belgium is low compared to the US and to other countries in the EU. The majority of the clinical studies in Belgium are initiated by pharmaceutical companies; the remainder by academics. Belgium's Federal Agency for Medicines and Health Products (FAMHP) is known for its effective and speedy procedures. Applications for medicinal products involving biotechnology (including advanced therapy medicinal products) follow a centralized route and are covered by the relevant EU directives and regulations. In addition, the Directive on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and the distribution of human tissues and cells, as well as the Belgian law of 2008 on the procurement and use of human biological material for medical applications and scientific research, which implements this directive, define the framework for activities performed with human cells and tissues.

It is the role of Bio.be in technology and pharma.be in biopharmaceuticals to propose changes to the country's federal rules and laws on science. Bio.be and pharma.be consult their members on what needs to change in order to sustain the pace of innovation. The outcome of this consultation then influences negotiations with the relevant minister to change the existing legislation.

Biotech for industrial use

Belgium is adopting European legislation to improve its sustainability. But some responsibilities are regional, not federal.

For those generating electricity, Belgium has set up a scheme of green certificates and has guaranteed minimum prices to support the development of energy generated from renewable sources, including biogas made from waste. To promote biofuels, including the use of bioethanol in transport, the federal authority has set up a scheme of biofuel quotas which are exempt from tax. It has also introduced the mandatory use of biofuels in mixes of fuel.

Biotech in agriculture

Agriculture is a matter for Belgium's regions. In Flanders, the universities

are heavily involved in research into the genetic modification of plants, and as a result, the regional Government is receptive to the use of biotechnology in agriculture. The regional Government in Wallonia is opposed to genetic modification and so imposes different rules.

Structuring the future

If an idea proves successful, Belgium is also a good place in which to plan to capitalize on it. If one would be considering starting or developing operations in Belgium, one should:

- ▶ Prepare a sound business case and ensure that the company has a presence in the country
- ▶ Design the business carefully, including how to distribute the product or service
- ▶ Make use of the available tax incentives such as the NID, PID and "excess profit" incentive
- ▶ Consider whether other businesses or processes could be transferred to Belgium in order to create extra leverage or synergies

Denmark

The entrepreneurial culture

The Danish biotech industry has developed at a rapid pace since the late 1990s. Today, it comprises approximately 100 companies.

The biotech industry in Denmark has benefited from having a number of pharmaceutical and biotechnology companies headquartered in Denmark, such as Novo Nordisk, Novozymes, LEO Pharma, Chr. Hansen and Lundbeck. This has secured a firm base of industry knowledge and expertise.

As such, Denmark has a strong biotech environment. This is especially concentrated in the cluster of companies operating around Copenhagen – home to around 80% of Danish biotech firms. Together with south Sweden, this Copenhagen biotech zone is known as the Medicin Valley Area (MVA).

Other biotech clusters are found around other university cities and towns such as Aarhus and Odense. In the Copenhagen area, biotech companies may establish themselves in one of the science parks, like Scion-DTU, Symbion, CAT or COBIS (Copenhagen Bio Science Park), the latter focusing entirely on biotechnology companies. All of these science parks provide laboratories and “plug and play” facilities, which can be useful for newly established firms.

The association of biotechnology companies in Denmark, DANSK BIOTEK, is focused on the general industry conditions

in the country and is keenly engaged in the debate around the industry’s development. Many of the Danish biotech entrepreneurs are engaged in the association. In life sciences more broadly, the Medicin Valley Alliance is constantly trying to improve the conditions of the sector in the area.

Denmark also has a number of biotech venture funds, such as Novo Venture, Novo Seeds, Sunstone Capital, Lundbeckfond Ventures, Lundbeckfond Emerge and Seed Capital Denmark.

In 2012, Copenhagen Spin-Outs was established as a new, publicly supported collaboration between academia and industry, with a focus on innovation and the commercialization of biotech research in the Copenhagen area.

Taxation

Corporate tax

In general, the amount of tax paid by a biotech company in Denmark follows the usual rules under tax law.

The Danish Government has introduced a new growth-plan for the economic growth of Denmark. Among other things, the growth-plan reduces the corporate income tax rate gradually from 25% (2013) to 24.5% in 2014, 23.5% in 2015 and 22% for income year 2016 and onward.

Under Danish law, losses may be carried forward indefinitely for tax purposes, but not backward. Losses may not be offset

against interest and other capital income, net of interest paid, if more than 50% of the shares in the company have changed ownership since the beginning of the year in which the loss was incurred.

In addition, tax losses are lost entirely if a change of ownership occurs at a time when the company is without business activities. The utilization of tax loss carry-forwards is limited, though. For income years with a taxable income exceeding DKK7.5m, the income may only be reduced by 60%. The rule applies on a group level.

Furthermore, in Denmark, there are three rules limiting interest. All three should be examined, since they focus on different bases, unless a company's net expenses are below DKK21.3m. In such circumstances, these expenses would always be deductible, unless the company is deemed to be thinly capitalized (i.e., it has more debt than equity). In such circumstances, the rules restrict interest and capital gains on controlled debt where the interest ceiling and the limit on earnings before interest and taxation (EBIT) limit a company's net financial expenses. So firms should first make the calculation for thin capitalization because, if it applies, interest is excluded from the net financial expenses, which are limited in relation to the interest ceiling and the rule covering EBIT.

For thinly capitalized companies, a debt-to-equity ratio of 4:1 must be observed. The ratio is calculated every year-end and is generally based on fair market values

(not on book values). The equity is made up of the assets minus the liabilities. Controlled debt is debt that is provided by group entities or external debt secured by such entities.

For the interest ceiling, only net financial expenses not exceeding the taxable value of the company's assets (multiplied by a fixed interest rate of 3% for the income year starting in 2013) are deductible. However, an amount of DKK21.3m can be deducted, subject, of course, to the rules on thin capitalization.

Under the EBIT rule, a company's taxable income can be reduced by 80% as a consequence of net financial expenses. However, an amount of DKK21.3m is deductible (subject again to the rules on thin capitalization and the interest ceiling).

Tax incentives

In general, Denmark has not had incentives open to biotech companies. Relevant for the industry though, is that the country allows for a 100% deduction of expenses from R&D activities in the year they are incurred, or for them to be divided between the current year and the subsequent four years.

However, as of the income year 2012, tax credits have been introduced. The Danish tax credit scheme is also highly relevant for the biotech industry.

The tax credit enables companies with R&D activities to obtain a refund of negative

tax (loss) relating to R&D activities. Hence, the tax value of a loss related to specific types of R&D costs can be paid out. The tax credit is calculated as up to the applicable corporate income tax rate (CIT) of DKK 5 million R&D in the relevant income year. From 2015 the DKK 5m limit will be raised to DKK 25m. As a result of the above mentioned change in CIT, the maximum limit for payment of tax credit will be increased from DKK1.25m to DKK5.5m, which represents 22% (CIT rate) of the R&D cost of 25m in 2016. Please note that for jointly taxed entities, the tax credits are applied at joint-taxation level.

Tax landscape for investors

As noted above, there are no specific concessions on tax for those investing in biotech in Denmark. However, structures in which at least 10% of the shares are owned by corporate investors are commonly used for holding investments. This is because, when sold, such shares are exempt from tax (provided no companies are considered to be intermediary holding companies according to special anti-avoidance rules). Furthermore, dividends paid to shareholders attract no tax for shareholders with more than 10% of the capital.

Tax landscape for entrepreneurs

In general, entrepreneurs receive no concessions under Denmark's tax rules. However, new rules have been enacted effective from 1 January 2013, which provides that a corporate shareholder's disposal of unlisted portfolio shares (less than 10% shareholding) should be tax-exempt, provided that certain requirements are met.

Structuring for the future

Protection of intellectual property within Denmark is largely the same as in other parts of the European Union.



France

The entrepreneurial culture

There are already more than 23,000 foreign companies doing business in France. In 2011, there were 446 companies active in France's biotechnology industry; among these, almost 400 were historical biotech companies, together employing around 11,000 people, over half of whom work in research and development (R&D).

The French biotech industry's increasing turnover – €261m in 2011 and only €186m in 2010 – and the increasing number of initial public offerings (IPOs) – 8 new listed companies in 2012 – shows that this dynamic industry has continued to grow significantly over the years.

All told, there are 71 clusters of innovation in France, including partnerships between private businesses, public sector research laboratories, universities and academic institutes. Of these, seven focus on biotechnology or health. The clusters are what are known as "business ecosystems," which already boast about 60 foreign businesses among their members.

Between 2006 and 2008, the clusters received €1.5b in funding from the state and received a similar amount to support their R&D between 2009 and 2011. This was mainly due to a special fund that is also open to foreign companies. In addition, both French and foreign companies investing in France enjoy an attractive regime on intellectual property (IP), which has recently been enhanced and extended.

The Invest in France Agency (IFA), created in 2001, is a public-private body responsible for promoting, prospecting

and facilitating international investment in France. The agency works in partnership with regional development agencies to offer international investors opportunities and customized services. More details are available from invest-in-france.org.

Taxation

Corporate tax

The standard rate of corporate income tax (CIT) in France is 33.3%. A social security surtax of 3.3% is assessed on income exceeding €763,000, resulting in a marginal effective rate of 34.4%. Furthermore, for financial years ending between 31 December 2011 and 30 December 2013, companies with a turnover exceeding €250m will be subject to a 5% surcharge on outstanding corporate income tax. Therefore, for such taxpayers, the maximum standard rate is 36.1%. As per the current version of the Draft Finance Bill for 2014, this surcharge is very likely to be increased to 10.7% for financial years ending between 31 December 2013 and 30 December 2015. Then, the maximum standard rate should reach 38% for such taxpayers.

There is a reduced rate of 15% (15.5% with the 3.3% social security surcharge, 16.2% for companies with a turnover exceeding €250m in financial years that end between 31 December 2011 and 30 December 2013, and even 17.1% for companies with a turnover exceeding €250m in financial years that end between 31 December 2013 and 30 December 2015, should the current version of the Draft Finance Bill for

2014 be enacted). This has been applied to incomes or gains derived from the licensing or sale of patents, patentable rights and related know-how, as well as, for fiscal years beginning on or after 1 January 2011, for improvements to patents or patentable rights – provided that the IP rights qualify as fixed assets.

As a matter of principle, royalty payments are deductible in full as expenses. However, depending on the terms of the agreement that grants to the licensee the right to exploit some patents' rights and know-how, royalty payments could be treated as the acquisition cost of an intangible asset and thus as capital expenditure, which may be eligible for depreciation and amortization.

The tax treatment of non-refundable signing fees and upfront fees, and milestone payments, mainly depend on whether the related outcome is uncertain. Depending on the circumstances, they can be treated as either deductible expenses or capital expenditure, possibly eligible for amortization and depreciation.

Intangible rights that benefit from a limited legal protection, or whose exploitation will terminate at a specific date, may be amortized for tax purposes. Under the parent-subsidiary regime, dividends are 95% exempt from CIT.

Losses can be carried forward indefinitely, but can only be used during the years that follow within an annual limit of €1m, plus 50% of the profit of the year exceeding this limit. Losses can also be carried back

against the profits of the previous fiscal year, but only up to €1m.

Under France's rules on thin capitalization, the deductibility of interest paid to related parties is limited when the debt-to-equity ratio exceeds 1.5:1. This is also the case when the interest expenses paid to related parties exceed 25% of adjusted earnings before interest, tax, depreciation and amortization, or the interest received from related parties.

French tax law also provides for a general interest-deduction capping mechanism based on the amount of the net financial interest expenses. If the net financial interest expenses exceed a €3m threshold, only 85% of the net financial interest expenses incurred in financial year 2013 is tax deductible, and 75% for expenses incurred in financial years 2014 and onward.

Dividends are subject to a domestic withholding tax of 30% (with exemptions within the European Union (EU) under certain conditions). Royalties are subject to a domestic rate of 33.3% (with exemptions within the EU under limited conditions). There is no withholding tax on interest (unless it is to Non-Cooperative Countries and Territories (NCCT)). Rates for withholding tax may be reduced under tax treaties. For groups of companies, the rules on tax consolidation allow a French parent company to be liable for the corporate income tax for the entire consolidated group.

In addition, dividends and/or deemed dividend distributions made by companies, entities or organizations that are liable to CIT in France, are in principle subject to a 3% tax (among various exceptions, the tax notably does not apply to distributions realized within a tax-consolidated group).

Indirect taxation

As from 1 January 2014, in France the standard rate of VAT is 20%. However, various reduced rates apply to certain products or services. For instance, as from 1 January 2014, drugs are subject to reduced rates of either 2.1% or 10% (2.1% or 7% until 31 December 2013).

Incentives

In France, there are no specific tax incentives exclusively designed for biotechnology companies, but they are eligible for incentives offered to companies in other industries. Biotechnology companies generally look for one or more of the following incentives:

1) R&D tax credits

France's tax credit for R&D is the most advantageous in the world. It represents 30% of eligible R&D expenses up to €100m (and 5% beyond €100m) borne by a company in France and in other EU countries. It covers human and material resources dedicated to eligible R&D activities, subcontracted R&D,

technological watch, patenting or patent protection and more. There is a cap of €10m for expenses contracted out to non-related parties, and of €2m to related parties, and a limit of three times the company's other R&D expenses.

To be eligible, the activity must:

- (i) Be part of a recognized R&D process (i.e., fundamental, applied or experimental research).
- (ii) Outrun general practices used in the field of application and rely on advanced professional skills from scientists and engineers, distinct from common knowledge in the profession. Consequently, companies cannot rely on the design and implementation of conventional solutions. The activity must also be commercially relevant: the simple fact that the activity is new or innovative is not enough to make it eligible for the tax credit.

The tax credit may be offset against the amount of corporate income tax due for the current financial year and for the three subsequent years. The remaining credit may be refunded after three years. Note that a ruling may be obtained from the French tax authorities in order to secure the benefit of this tax credit before R&D expenditure is borne.

Moreover, the tax credit for R&D has been extended to small and medium-sized enterprises (SMEs) for innovation

expenditures, for financial years from 1 January 2013. The tax credit is limited to 20% of such expenses within a limit of €400,000. Thus, the maximum tax credit on these expenses amounts to €80,000.

R&D tax credits are also extended to academic research, where expenses are accounted for twice their actual cost.

2) Intellectual property

Under France's IP regime, amortization allowances and financing costs can be deducted at the standard rate of 33.3%.

A rate of 15% applies to income derived by a French corporation from the licensing or sale of patents or patentable rights, subject to certain conditions (i.e., the character of the fixed assets and a two-year holding period for acquired IP). Investors also receive support in France. This depends on the type of investment project (i.e., whether it is a productive investment, R&D, innovation or training); the location of the project (whether, for example, it is in a priority zone for development); and on the size of company.

The French authorities support projects that entail investment and job creation by large companies in economically disadvantaged regions and those undergoing industrial redevelopment (according to the EU's Regional Aid Zones map). The scheme covers businesses involved in R&D, professional training

for employees, job creation for defined populations, investment and the creation of jobs by SMEs in all parts of the country, as well as certain schemes to protect the environment.

State aid is available from the national government or regional and local authorities, particularly in the form of subsidies, tax exemptions and tax credits. There is a maximum limit for applicants who receive assistance from several different sources. EU law requires support to act as an incentive, so applications must be made before the project gets under way.

Tax landscape for investors

There are also tax benefits for investors available in France. For eight years after their inception, SMEs can elect to be part of the Young Innovative Enterprise (YIE) scheme if:

- (i) Half of their shares are directly or indirectly held by individuals or certain types of companies in venture capital, registered public associations or organizations, public research institutions, or another YIE.
- (ii) If 15% of their total annual tax-deductible expenditure goes on R&D (the R&D expenditure to take into account is the same as the one eligible for the R&D tax credit, with a few notable exceptions regarding innovation and technology-watch expenses).

The main benefit of this regime is total exemption from CIT for the first profitable year and 50% relief for the following year within the limit of the EU de minimis aid regulation (note that the exemption does not apply to certain types of income, such as dividends, grants and debt forgiveness). Companies can also claim for the immediate refund of any unused tax credits relating to R&D.

Those within the YIE also enjoy, among other things, an exemption from social security for all employees and for legal representatives involved in R&D projects, as well as a full and uncapped exemption (except the limit of the EU de minimis aid regulation) from business contribution on property and property tax for seven years for YIE created until 31 December 2013 (the Finance Bill for 2014 should extend it to YIE created until 31 December 2016), providing that a company's local authority has been consulted. Note, too, that the YIE can benefit from the tax credits on R&D.

Individuals holding shares of a young innovative company, issued as from 1 January 2004, can elect, before the end of the year during which they sold their shares, to benefit from a full and uncapped capital gain tax exemption if they:

- (i) Held the shares for at least three years during which the company qualified for the YIE scheme.
- (ii) Did not hold (with their families, directly or indirectly) more than 25% of the shares of the company.

Tax landscape for entrepreneurs

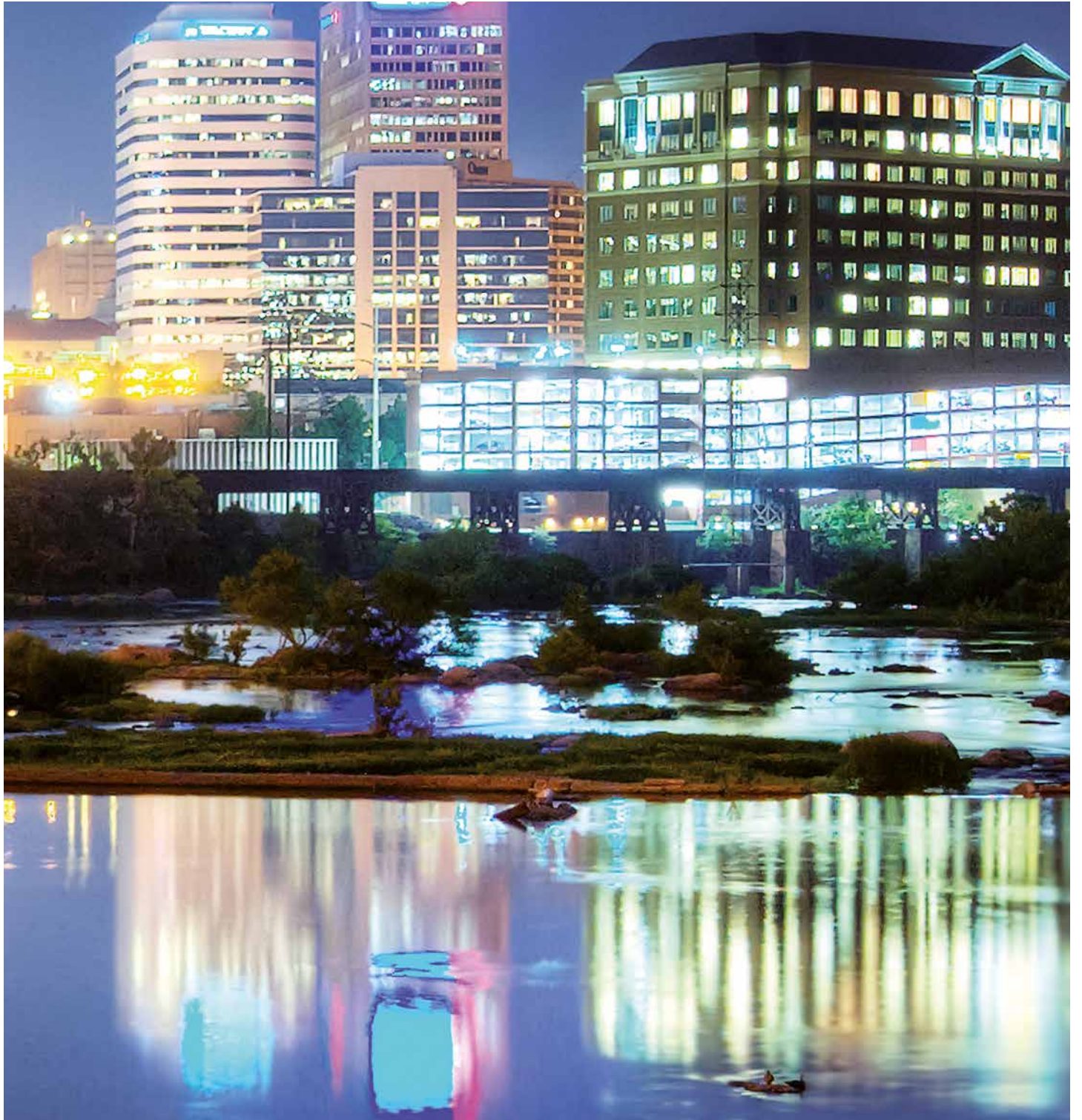
Expatriates employed in France benefit from one of the most advantageous tax regimes in Europe. They enjoy an exemption from tax on income earned

abroad. Employees can opt for exemption from income tax on up to 50% of their total income (through an expatriation bonus plus a proportion of the remuneration received for work carried out abroad). Expatriates are exempt from wealth tax on assets or estates held outside France for five years. There is also an exemption of 50% on income from "passive" sources, such as dividends, interests and fees, and on capital gains on equity transfers from foreign sources. In addition, from their taxable income, expatriates can deduct retirement premiums paid to supplementary retirement schemes subscribed to in their home countries until the fifth year following the first year of their work in France.

Regulatory environment

France has a variety of legal provisions covering biotechnology. Laws regulate, among other things, therapeutic products, reproductive and transplant medicine (for research on humans), genetic engineering, agriculture, the protection of the environment, and food.

French law also provides for an effective protection of IP rights, such as patents and trademarks, as well as copyrights and related protection rights. Biotechnology enterprises may thus seek to protect their innovations and turn their ideas into industrial property. The authority for registering and protecting IP rights in France is the National Intellectual Property Institute (inpi.fr).



Germany

Germany has a history of encouraging new ideas and new biotechnology companies. There are a number of agencies and initiatives that provide support and funding for companies in the industry – such as the BioEconomy Research and Technology Council (biooekonomierat.de), Go-Bio (go-bio.de), High-Tech Gruenderfonds (high-tech-gruenderfonds.de) and Health Research, part of Research in Germany (high-tech-strategie.de).

Advice is also available through the Federal Ministry of Education and Research (bmbf.de) and the Federal Ministry for Economic Affairs and Energy (bmwi.de). Germany Trade & Invest (gtai.com) is the foreign trade and inward investment agency. It provides up-to-date information to German companies seeking to expand their businesses abroad; and it supports, with expert advice, those companies looking to enter Germany.

There are also funding programs and initiatives in various federal states. The German BioRegions – the regional initiatives for the advancement of the economic application of modern biotechnology – can act as a go-between and first contact.

Taxation

Corporate tax and trade tax

Corporations, limited by shares (owned by the shareholders) (Aktiengesellschaft, or AG) and limited liability companies (Gesellschaft mit beschränkter Haftung, or GmbH), that have either their statutory seat or their place of management in Germany are considered resident

companies. As such, they are subject to corporate income tax (Körperschaftsteuer) and trade tax (Gewerbesteuer) on their worldwide income as far as it is not exempted by tax treaties. Income from a foreign permanent establishment may be tax-exempt under a German tax treaty.

Corporate income tax is levied at a rate of 15% on taxable income, regardless of whether the income is distributed or retained. A 5.5% surcharge is imposed on corporate income tax, resulting in an effective tax rate of 15.825%.

Trade tax on income is imposed by the municipalities in which the company has got a business presence, to the extent that taxable income is allocable to the respective municipality. Different municipalities impose different rates, generally varying between 10% and 18%. For the determination of taxable income for trade tax purposes, certain adjustments are made. Primarily, these adjustments include the following:

- ▶ A 25% add-back of interest on debt
- ▶ A 6.25% add-back for license payments
- ▶ A 5% add-back of lease payments for movable assets
- ▶ A 12.5% add-back of lease payments for immovable assets

Tax losses may be carried forward indefinitely. Taxable income of up to €1m can be fully offset against losses carried forward from prior years. Only 60% of taxable income exceeding €1m can be offset against such losses. As a result, 40% of the excess always triggers tax (minimum taxation). This rule on minimum taxation applies to both corporate income tax and

trade tax on income. For the purposes of corporate tax, but not for trade tax on income, losses can and must first be carried back into the preceding business year, up to an amount of €1m.

Tax losses expire proportionally if, within a five-year period, more than 25% of the shares of a loss-making entity are directly or indirectly transferred to one acquirer or entities related to such an acquirer or a group of acquirers pursuing the same interest. If, within the five years, more than 50% of the shares are transferred, the entire remaining loss expires. These rules also apply to fact patterns comparable to a share transfer, e.g. a share capital increase with the new shares being issued to a new shareholder holding more than 25% or more than 50% in the loss-making entity after the share capital increase. For share transfers after 31 December 2009, under a built-in gain exception, a loss carry-forward survives the change in ownership in an amount equal to the built-in gains of the loss-making company. When calculating the built-in gains, the only assets included are assets whose disposition would trigger German taxable gain in the hands of the loss-making entity (not, for example, shares in subsidiaries of the loss-making entity). Under a group restructuring exemption, a transfer of shares may not be considered harmful if “the same person” directly or indirectly owns 100% of the transferor and the transferee. For ownership changes made before 1 January 2008, different rules under the previous regime continue to apply as well. Under the Reorganization Tax Act, if a company with tax losses is merged into another company, its remaining tax losses generally expire and are not transferred to the surviving company.

The interest limitation rule disallows “excess net interest expense,” which is defined as the excess of interest expense over interest income if such excess exceeds 30% of the taxable earnings before (net) interest, tax, depreciation and amortization (EBITDA). Unused EBITDA can be carried forward five years upon application, and excess net interest expense disallowed under the interest limitation rule can be carried forward into subsequent years for deduction. Unused carry-forwards are affected by reorganizations, such as business disposals, mergers and share transfers, and may fully expire in such instances.

The limitation rule does not apply if any of the following conditions are satisfied:

- ▶ The annual net interest expense is less than €3m.
- ▶ The company is not a member of a consolidated group, i.e., a group of companies that can be consolidated under International Financial Reporting Standards (“group clause”). This may not apply to companies that have received loans from: a direct or indirect shareholder who holds more than 25%; a party related to such a shareholder; or a third party having recourse to such a shareholder or related party.

Or

- ▶ The equity ratio of the German subgroup is no more than 2% lower than the equity ratio for the group as a whole, as shown on the balance sheet of the preceding fiscal year (“escape clause”).

60%

Incentives

Financial support for R&D is based on cash grants and low interest loans for innovative projects. Eligible costs are generally related to a specific project and can include personnel costs and costs for materials, subcontractors, travel, amortization and overheads. In general, in Germany, there are no tax incentives in the form of tax credits or alike available for R&D activities.

In particular, there are dedicated funding opportunities (cash grants) for R&D performed by companies and other R&D institutions in the biotechnology sector in Germany.

Both, the National Research Strategy BioEconomy 2030 and the Health Research Framework Program, started by the German Federal Government at the end of 2010, are providing sustained financial and political support for the German biotechnology sector. Funding of around €8b has already been made available as part of these initiatives.¹

Under the umbrella of the above named framework programs currently specific calls for proposal in the context of the "Innovation initiative for industrial biotechnology" as well as the "Bio-economy" initiative are being published. To participate in Government R&D support programs, companies or R&D institutions must define a project with clear objectives and a fixed time line. The application should highlight the innovative character of the project and the technological risks involved.

An application for R&D funding also has to set out a plan, detailing how the results of the research will be turned into products,

processes or services that generate additional turnover or employment in the region where the project is to take place. Public funding for R&D projects is regularly awarded in a competitive process

The total incentives that a project may receive depends on the size of the company (small, medium-sized or large), on whether the project is conducted in cooperation with other companies or research institutes, and on the type of research. Depending on the specific program and on the applicability of the products, the funding quota ranges between 25% and 75% of the eligible costs. Large enterprises receive in general up to 50% funding of the eligible costs.

Please note furthermore, that there are additional programs to support market access for small and medium-sized enterprises. The requirements for intellectual property can also vary.

Additionally, under the new guidelines on regional state aid for 2014-20, the creation of new R&D centers (or production premises) can be funded in specific regions in Germany. Depending on the potential of creating new permanent jobs in the region, on the region itself and some further funding conditions, capex investments of large enterprises can be funded up to 15%. In this context, Germany Trade & Invest, a government agency charged with regional economic development, may act as facilitator.

Tax landscape for investors

In Germany, it is generally possible for the user, but not the investor, to receive grants for investments. However, Germany offers numerous other incentives for investors.

¹<http://www.bmbf.de/de/biooekonomie.php>, <http://www.bmbf.de/de/gesundheitsforschung.php>

Germany has a wide network of tax treaties. Most confer the right to tax a gain from a sale of the shares in a German corporation (AG or GmbH) to the state of residence of the foreign-resident investor. For foreign corporate investors that hold a minimum participation in a German corporation, dividend withholding tax may be reduced to zero (compared with a domestic rate of 26.375%).

Dividend income received by a German corporate entity from its German and foreign subsidiaries is basically exempt from corporation income and trade tax. However, the exemption requires a 10% minimum shareholding (15% for trade tax) and is tied to some further prerequisites. Five percent of the tax-exempt dividend income is deemed as a non-deductible expense, while the expenses actually incurred in connection with such dividends are deductible. Consequently, only 95% of the dividend received by a corporation is effectively exempt from tax.

For individuals, different rules apply. There are no special tax incentives for individuals resident in Germany with investments in biotech companies.

Structuring for the future

Tax-efficient structures

If the corporate seller is resident outside Germany in a country with which Germany has a tax treaty, the right to tax such a gain is conferred in most cases to the state of residence of the investor.

Depending on the country of residence of the investor or investors, it may be possible to structure the investment so that a tax-efficient disposal can be achieved. There may be opportunities to design a tax-efficient disposal tailored to the circumstances of the investment.

The regulation of intellectual property depends on the funding in question. Generally, the terms are made clear in the approval letter of the funding authority.

Biotech is certainly one of the focal points for funding in Germany. The Bio-economy Research and Technology Council is also to receive more support. License income from licensees resident in another state is normally taxable in Germany. R&D costs incurred are generally tax deductible. However, under certain circumstances development costs may be capitalized.

Hungary

The entrepreneurial culture

Hungary's Government and tax regime provide several opportunities to support new investment. There were a number of programs initiated under the National Development Agency (nfu.hu) in 2007-13, which were co-financed by the European Union (EU), and similar programs are to come in the new 2014-20 EU budget cycle.

The Nemzeti Külgazdasági Hivatal (Hungarian Investment and Trade Agency, or HITA, hita.hu) began operating at the beginning of 2011. Its task is to encourage foreign companies to invest in Hungary and to support foreign trade by small and medium-sized enterprises (SMEs).

Taxation

The principles of the Hungarian tax system are similar to those in Western Europe. For individuals, the tax year is the same as the calendar year and for companies, it is the same as either the calendar year or the business year. In general, tax returns must be filed annually. However, quarterly or monthly filing may be required for value-added tax and payroll taxes. Companies have to submit their corporate income tax returns by 31 May following the end of the calendar (or within 150 days of the year-end for companies whose business year differs from the calendar year). In 2010, Hungary has introduced a competitive corporate income tax rate (10% or 19%) and has offered a number of tax holidays and special tax incentives on collecting dividend and royalty income. In addition, attractive incentives and cash grants are available both for greenfield investments and developing existing establishments.

Corporate tax

As a general rule, the liability for corporate income tax is 19% of the taxable base. Nevertheless, a preferential rate of 10% can be applied to the first HUF500m (€1.7m) of the taxable base.

A company's profit before tax can be modified in several ways. For example:

- ▶ Development tax allowance can be applied in certain circumstances. The value of the investment should reach HUF3b (EUR10.5m) or HUF1b (EUR3.5m) in certain regions or HUF100m (€350,000) in special areas. The allowance, which must be used within 10 years, reduces the company's annual liability for corporate income tax by a maximum of 80% of the tax payable.
- ▶ Loss carry-forward: tax losses can be carried forward from previous tax years and taken into consideration as a decreasing item in subsequent years – up to 50% of the tax base in the current tax year. This means that the corporate income tax base, calculated from the pre-tax profit after taking into consideration all tax base adjustments other than the tax loss itself (for example, research and development (R&D) costs, depreciation, non-deductible costs) can be decreased by up to 50% only by applying tax losses. In other words, if a company utilizes tax losses to offset its taxable profit, it still will have to pay corporate income tax on at least 50% of its tax base.
- ▶ Royalty income: if taxpayers collect royalties in Hungary, they may be entitled to deduct 50% of the income from pre-tax profit when calculating the base for corporate income tax while still

being able to deduct related costs, such as amortization of intellectual property. This deduction is capped at 50% of the pre-tax profit.

- ▶ **Optional exemption on IP gains:** Tax payers may opt to exempt from tax gains on intellectual property assets on disposal of those assets.
- ▶ **Thin capitalization:** if the daily average amount of debt is greater than three times the daily average of the taxpayer's equity, the interest expense on the excess debt cannot be deducted for the purposes of corporate income tax (i.e., the debt-to-equity ratio must be 3:1). Rules on thin capitalization also apply to interest expenses incurred on the pooling of cash.
- ▶ **Transfer pricing:** if, in transactions between related parties, a higher or a lower consideration is applied than would arise between independent parties in comparable circumstances, a taxpayer may need to modify its pre-tax profit by the difference between the market price and the price that was used.

R&D double deduction

A company's pre-tax profit can be reduced by direct costs associated with R&D or by the depreciation of the capitalized costs of R&D. Both relate to R&D activities carried out within the scope of the taxpayer's own activity. As a result, the R&D costs or the depreciation for capitalized costs for R&D can be deducted twice (first as recognized expenses and secondly as a deduction against the base for corporate income tax).

In addition, if R&D activities are jointly performed with universities or an academy as part of a written agreement, the base for corporate income tax can be reduced by three times the amount of the R&D, with a cap of HUF50m (€170,000). The rule does not apply either to R&D costs financed from subsidies or to those purchased from Hungarian taxpayers (with certain exceptions).

Local business tax

Local municipalities may impose taxes on entrepreneurial activity carried out in their jurisdictions. One of the most important local taxes is local business tax. The maximum rate of local business tax is 2% of the tax base. The direct costs of the R&D activities can also reduce the base for local business tax.

Tax landscape for investors

The Hungarian tax system has been focusing on attracting inbound investments in regional activities, such as holding and licensing, and local manufacturing. In order to achieve this, Hungary has historically had a low corporate income tax rate (between 10% and 19%) and has offered a number of tax holidays and special tax incentives on collecting dividend and royalty income. In addition, attractive incentives and cash grants are available both for greenfield investments and developing existing establishments. Hungary has also made ongoing efforts to reduce both employment burdens and administration on employees.

Tax landscape for entrepreneurs

Hungary levies no withholding tax on dividend, interest and royalty payments made to companies, while tax treaties may reduce tax rates applicable to these payments made to individuals, and on such payments from abroad to Hungary.

Capital gains deriving from the sale of certain investments (reported shares) are exempt from corporate income tax.

Finance

As a member of the EU, Hungary can offer a broad range of subsidies. An investment in an enterprise – depending on the location – may be entitled to receive state subsidies of up to 50% of the investment costs.

The available subsidies for companies operating in the biotechnology industry are as follows:

VIP cash grant:

- ▶ The most beneficial cash grant opportunity currently available for large investors deemed strategic by the Hungarian Government.
- ▶ Supports asset investments, job creation, establishment of shared service centers and R&D projects.
- ▶ The investment value should reach €10m – if there is an available EU tender this amount should be €25m.

Development tax allowances:

- ▶ Exemption from 80% of the corporate tax payable for 10 years following the fulfillment of the investment.
- ▶ Investment volume minimum of HUF100m.

Training subsidy:

- ▶ Twenty-five percent to sixty percent of eligible training costs to a maximum of €1m (HUF300m) if job creation is between 50-500 to a maximum of €2m (HUF600m) if job creation is less than 500.

Job protection action plan:

- ▶ A tax allowance: the social tax payable can be decreased for five prioritized labor groups. The claim of the allowance is to be indicated in the tax documentation.
- ▶ The social tax is in this case either 0% or 14% (instead of the general 28.5%) depending on the type of labor group.

Other R&D incentives:

- ▶ R&D direct costs or depreciation of activated or accounted R&D can be 100% deducted from corporate tax base.
- ▶ Three hundred percent of direct R&D expenses – maximum HUF50m (c.€160 K) – can be deducted from the corporate tax base if the operation of the company's R&D unit is located at a university or public research institute.
- ▶ Social tax-free employment of research staff with PhDs (up to a monthly wage of HUF500,000).

- ▶ Tax allowance for corporate donations to organizations of public benefit supporting exclusively public-duty R&D activities.
- ▶ Tax-free development reserve for four years – 50% of pre-tax profit (to a maximum of HUF500m (c.€1.6m)).
- ▶ Tax benefit on credit agreements is the only type of incentive besides the cash and development tax allowance, which is set by the regional intensity ratio as set by the European Commission.

EU cash grant programs:

- ▶ They support large asset investment with complex technology development and employment creation.
- ▶ They support R&D investments (basic research, applied research and experimental research).

Availability of capital

Hungary pays special attention to investments in certain industries deemed important for its economy. It focuses, for example, on the health industry and the green economy, as well as engineering and medical, agricultural and natural sciences.

Under the framework of the JEREMIE program, private investment funds specifically finance SME investments. The preferred industries are IT, telecommunications, biotechnology and energy.

In addition, under the framework of Széchenyi Plan programs, SMEs can apply for loans and guarantees.

According to the Ministry for National Economy, the total cumulative value of foreign direct investment (FDI) in Hungary is €77.7b (as of end-2012). Most of the investment has flowed from EU countries into services and industries associated with vehicles and professional and scientific activities. Around 80% of it comes from the EU and just under 25% from Germany alone.

Structuring for the future

Hungary has a wide network of tax treaties with other countries, which can benefit investors seeking to reduce their liability for tax. Successful companies engaged in biotechnology may be able to use a holding company based in the country. In this way, investors can take advantage of exemptions from tax for income derived from royalties as well as capital gains.

Tax-efficient structures

Tax legislation in Hungary grants a number of opportunities to support a centralized structure for R&D. These include a 50% dispensation for royalty income as well as allowances for the cost of development in connection with R&D activities. Capital gains on intellectual property may be fully exempt from tax. There are also EU grants to encourage R&D available for relevant activities undertaken in Hungary.

Ireland

The entrepreneurial culture

Ireland has a respected regulatory regime with a thriving sector specializing in research, development and innovation. With strong support from the Irish Government, there is productive collaboration between industry and academia.

Ireland also enjoys easy access to Europe, the Middle East and Africa and is a global functional hub for several multinational companies. The country has clusters of leading global companies in life sciences with 9 of the top 10 pharmaceutical companies and 8 of the top 10 medical device companies having operations here. During the past few years, Ireland's competitiveness has improved significantly, with a striking reduction in business costs, such as those for payroll, energy, office rents and services.

There are a number of government agencies, led by Enterprise Ireland, which help entrepreneurial activities. There are also county and city enterprise boards, totaling 35, which support small business. In addition, Business Access to State Information and Services (BASIS) provides businesses with a single access point to government (basis.ie).

The National Institute of Bioprocessing and Training (NIBRT) is a global center of excellence for training and research in bioprocessing. Located in a new, world-class facility in Dublin, it is purpose-built to closely replicate a modern bioprocessing plant with state-of-the-art equipment. NIBRT is based on collaboration between University College Dublin, Trinity College Dublin, Dublin City University and the Institute of Technology in Sligo. It offers facilities of an international standard (nibrit.ie).

Science Foundation Ireland (SFI) is the national foundation for research in Ireland. SFI invests in academic researchers and research teams who are most likely to generate new knowledge and leading-edge technologies and competitive enterprises in the fields of science and engineering underpinning three areas: biotechnology, information and communications technology (ICT), and sustainable energy and energy-efficient technologies (energy). Guided by the National Research Prioritisation Exercise (NRPE) and the Action Plan for Jobs, SFI continues to play a complementary role to that of the IDA Ireland and Enterprise Ireland in creating an environment conducive to the attraction, retention, expansion and initiation of industry and the creation of jobs in Ireland. For example, last year, 72% of the job announcements made by the IDA had a prior collaboration with an SFI funded research group.

Taxation

Corporate tax

One of the key features of Ireland's tax regime is the 12.5% corporate tax rate. There is a three-year exemption from corporation tax for startups, provided certain conditions are met. The maximum annual tax liabilities for which shelter is available under this scheme is €40,000, again, on the proviso that certain conditions are met. Marginal relief is available where liability is between €40,000 and €60,000.

Ireland has a corporate tax rate of 12.5% for active business and 25% for non-trading or passive income, such as investments and rental income. Trading losses can be offset against profits, with relief at the group level and the ability to carry them

forward. In addition, there is a tax credit of 25% for research and development (R&D), which may be refunded over a period of three years. Effectively, a 37.5% deduction for R&D expenditure can be achieved. The tax regime also provides a write-off for broadly defined acquisitions of intellectual property (IP). And holding companies are exempt from capital gains tax on disposals of shares in subsidiaries.

There is an effective exemption through a tax rate of 12.5% for qualifying foreign dividends with a flexible, onshore pooling of foreign tax credits. There is also an extensive network of tax treaties with other nations, together with access, as expected, to other members of the European Union (EU). The country's domestic law provides for many exemptions from withholding tax. And, in certain circumstances, companies may obtain what is known as VAT 56 (formerly 13A) authorization, which allows a zero rating on purchases of goods and services, where a company is mainly manufacturing.

Some recent tax policy changes include the Special Assignment Relief Programme (SARP). This is a tax incentive for executives of foreign firms working in Ireland to avail themselves of an exemption from income tax on 30% of salary between €75,000 and €500,000. School fees, and travel expenses are tax deductible at corporate level.

Incentives

Ireland has had a scheme offering tax credits for R&D since 2004. Qualifying expenditure generates a 25% tax credit to offset against corporate taxes, in addition

to a deduction at a rate of 12.5%. The purpose of the scheme is to encourage both foreign and indigenous companies to undertake new or additional R&D in Ireland. The tax credit is available to Irish resident companies and branches on the extra cost of in-house R&D undertaken within the European Economic Area (EEA), provided such expenditure is not otherwise eligible for tax benefits elsewhere within the EEA. Incremental spend is calculated in comparison to a base year of 2003 for R&D expenditure. So, for new entrants to R&D, the credit is essentially based on the volume of work undertaken.

Certain conditions need to be met to qualify for this tax credit. Broadly speaking, applicants must seek to achieve a scientific or technical advancement. The work must also help to resolve scientific or technological uncertainty. Both revenue and capital expenditure may qualify. In practice, this includes wages, related overheads, the cost of plant and machinery and buildings.

The credit regime also provides for outsourcing. This means that up to 5% of the expenditure on R&D can be passed on to European universities, including Irish ones. In addition, 15% of the expenditure can be subcontracted to other unconnected parties (i.e., giving a total of 15%), or €100,000, whichever is the greater amount. The tax credit can be refunded over three years where there is insufficient corporate tax liability to utilize the full credit in a particular year, or otherwise can be carried forward.

Since 2012, a company with an entitlement to the R&D Tax Credit can surrender a portion of the credit to workers who meet

the definition of a “key employee.” Subject to certain conditions, the employee can use the benefit of the tax credit to reduce their own income tax liability.

Tax landscape for investors

CGT entrepreneurial relief

A new CGT incentive is being introduced to encourage entrepreneurs (in particular “serial” entrepreneurs) to invest and re-invest in assets used in new productive trading activities.

The measure will apply where an individual, who has paid capital gains tax on the disposal of assets, makes investments in a new business in the period from 1 January 2014 to 31 December 2018 and subsequently disposes of this investment no earlier than three years after the date of investment. The CGT payable on the disposal of this new investment will be reduced by the lower of:

- (i) The CGT paid by the individual on a previous disposal of assets in the period from 1 January 2010.
- (ii) Fifty percent of the CGT due on the disposal of the new investment. Commencement of this measure is subject to receipt of EU State Aid approval.

Start your own business (SYOB)

An exemption from income tax up to a maximum of €40,000 per annum will be provided for a period of two years to individuals who set up a qualifying, un-incorporated business, and have been unemployed for a period of at least 15 months prior to establishing the business.

Tax landscape for entrepreneurs

Employment and investment incentive (EII)

Subject to certain conditions, relief from income tax is available by way of a deduction from income to individuals who invest long-term risk capital in ordinary shares of unquoted companies resident in the state or resident in the European Economic Area with a qualifying establishment in the state and who are engaged in trades in the state. In addition, R&D projects, undertaken with a view to carrying out such trades can also qualify for relief. The maximum aggregate amount of investment for which a person can get relief in any one year is €150,000.

A further relief for seed capital means that individuals who leave employment to start up their own businesses may claim a refund of tax on previous income for up to six years in respect of the investment in the new business. Individuals can select the tax years for which they may claim refunds from any or all of the six years prior to the year of investment. The maximum relief is €100,000 per annum at the individual’s top rate of tax.

Finance

A range of services and incentives, including funding and grants, are available to those considering foreign direct investment in Ireland. These are offered to both new and existing clients by IDA Ireland, an agency that promotes inward investment.

IDA assists in the process via a range of services, which include: information and statistics on business sectors and locations within Ireland; assistance in setting up a business; and introducing potential investors to industry in Ireland, to government representatives and to those providing services and research. Where required, the agency may also offer advice on property for international investors (idaireland.com).

Enterprise Ireland (EI) is the state agency responsible for supporting the development of manufacturing and international service companies. The agency provides funding and support to everybody from entrepreneurs with plans for a startup to large companies planning to expand their activities or seeking to increase their exports. There are a number of schemes available; for example, a large company undertaking a substantial R&D project could receive €650,000. EI (enterprise-ireland.com) also provides funding and support for college-based researchers to assist in the development, protection and transfer of technologies to industry via licensing or through spin-out companies.

Science Foundation Ireland (SFI) invests in academic researchers and teams likely to generate new knowledge, technologies and competitive enterprises in science and engineering. It also aims to encourage a culture of entrepreneurialism and promote partnerships (sfi.ie).

Financial support is also available from the county and city enterprise boards. The maximum grant payable is 50% of the

investment, or €150,000, whichever is the lesser, provided certain conditions are met.

Availability of capital

Despite the economic difficulties in Europe, capital is still available for startups and other enterprises from state agencies such as IDA and EI, as well as investors, venture capitalists and banking institutions.

Regulatory environment and incentives

Under European and Irish legislation, all medicinal products must be authorized by the Irish Medicines Board (IMB) before being marketed in Ireland (imb.ie).

Authorization to market a product or service produced through biotechnology may be obtained by taking one of several routes:

- (i) A direct approach to the IMB. This should be used only to market the product in Ireland and not in any other member state of the EU, or as the basis for a future application for mutual recognition to other member states.
- (ii) So-called mutual-recognition and decentralized procedures. Both aim to facilitate access to a single market by relying on the principle of mutual recognition.

(iii) A centralized procedure. The European Medicines Agency (EMA) is responsible for the scientific evaluation of applications made in this way. Companies are required to submit a single application for authorization to the EMA.

Structuring for the future

Thanks to its attractive tax rate and the regime for holding companies described above, Ireland's status as a world-class location for international business is well established. And reinforcing this are the country's regulatory and legal regimes, combined with its open and accommodating attitude to business. In recent years, too, Ireland has emerged as a favored onshore location for multinational corporations seeking to establish regional or global headquarters to manage their business, international functions and shareholdings associated with their businesses.

Tax-efficient structuring

As such, Ireland also provides an efficient base from which to manage the disposal of businesses. Another benefit is the

exemption from capital gains tax for holding companies and no Irish tax cost on foreign dividends. For repatriation, 0% withholding tax is available under the many domestic law provisions, as well as the EU parent/subsidiary directive or tax treaties.

There are no thin-capitalization or controlled foreign company rules and consequently tax efficient financing of Irish operations, as well as interest relief on borrowings, is possible.

The support offered by the country's tax policy, and the tax credits on research and IP, also encourage companies to use Ireland as a focal point for R&D in general. Indeed, the strong regulation and a clear legal framework for protecting and exploiting IP make Ireland a preferred location for many companies looking to centralize their R&D (patentsoffice.ie).

€650,000



Italy

The entrepreneurial culture

Despite the lack of dedicated incentives in the biotech industry, based on publicly available data, Italy boasts the third-largest number of biotechnology companies and has the highest rate of growth in pure biotechnology. The development of biotechnology industries is a priority for some Italian regions, which not only has the effect of grouping existing biotechnology operators in certain locations, but also helps to attract new companies. As in other European countries, biotechnology in Italy is often carried out by small and medium-sized enterprises (SMEs), partly because such activities do not require a great deal of startup capital.

Indeed, since it began in the 1990s, Italy's biotechnology industry has grown steadily. In fact, at the end of 2013, there were a total of 264 organizations operating as "pure biotechnology" companies. Of the total, 146 firms operate in the human health sector, with "red" biotechnology their core business. About 77% of all companies in the sector are "micro," with fewer than 10 employees, or are "small," with less than 50 employees. Those seeking guidance when setting up a new biotechnology business in Italy, as with entrepreneurs in other sectors of industry, may turn to Invitalia, a reference point for companies seeking advice on investing in Italy (invitalia.it).

Entrepreneurs needing advice on setting up locally should contact the local Camera di Commercio (camcom.gov.it). Foreign entrepreneurs interested in entering the Italian market can also contact the Italian Trade Agency (ITA italtrade.com) which offers insights into the country and facilitates scientific projects (ice.it).

There are also two private organizations that, depending on the nature of the business, help those starting up new enterprises: the Italian Business Angel Network (IBAN, iban.it) and Italian Private Equity and Venture Capital Association (AIFI, aifi.it). Finally, specific information about Italy's biotechnology industry may be obtained from the Italian biotechnology companies' association, Assobiotec (assobiotec.it).

Taxation

Corporate tax

Italy's tax regime does not provide specific incentives for biotech companies. Indeed, other than those granted through tax credits, biotech companies are subject to corporate tax under the same rules as all other companies.

Assuming that a biotechnology company would expect to make losses during its early years, and would also need debt financing, the fact that tax losses (NOLs) and interest expenses may be deducted against tax may be of interest to them. It should also be noted that, in order to help companies facing difficult economic and financial times, the rules have been changed. On the basis of Legislative Decree (D.L.) 98/2011, taxable losses incurred by a company may be carried forward with no time limits, and may be used to offset up to 80% of future taxable income. However, NOLs incurred in the first three years (startup losses) may still be carried forward with no time limits and may be used to offset future taxable income, irrespective of the 80% limit.

It must be noted, however, that the new rules on carrying losses forward do not apply to Italian partnerships, which are still subject to the old regime. Under this, NOLs may be carried forward for five years, unless they were incurred in the first three tax years. The latter are known as evergreen NOLs and may be carried forward with no time limit.

As with the rules covering the deduction of interest expenses, starting from 2008, the thin-capitalization rule was replaced by a 30% threshold for earnings before interest, tax, depreciation and amortization (EBITDA). This means that Italian companies are now entitled to deduct interest expenses (net of interest income) up to the 30% threshold for EBITDA. Interest expenses exceeding the threshold may still be carried forward with no time limit and may be deducted in any future tax year in which the 30% threshold exceeds the interest expenses incurred in the same fiscal year.

Moreover, earnings up to the threshold not fully absorbed by the interest expenses in a given year may be carried forward with no time limit and used to deduct future interest expenses that exceed the annual amount. Again, however, this does not apply to Italian partnerships, which in principle are entitled to deduct all interest expenses incurred in the fiscal year, regardless of their EBITDA.

Starting from FY 2011, Italian companies and commercial entities can deduct from their corporate income tax base an amount of notional interest (i.e., a yield fixed at 3% for years 2011-13, while at 4%, 4.5% and 4.75%, respectively for 2014, 2015 and 2016) calculated on their equity increases

compared to the equity in their balance sheet as of 31 December 2010 net of the profits of the same year.

In more detail, the relevant increase is determined by the equity contributions and by the retained earnings less the following items:

- (i) Reductions of the net equity with assignment to shareholders
- (ii) Investments in controlled companies
- (iii) Business acquisitions

If the allowance for a year is higher than the net IRES taxable base, the difference will be carried forward to the next period.

The measure is aimed at reducing the cost disadvantage of equity in the capital structure of Italian businesses and it is also applicable to Italian branches of foreign subjects.

Incentives

Tax credit for R&D activities

Until 2012, only research and development (R&D) investments commissioned to external entities were eligible for tax credits (i.e., companies had to entrust universities or other research bodies to carry on the work).

In 2013, a new enterprises' tax credit mechanism both for R&D activities carried out by universities and research entities or directly by the enterprises has been issued. Starting from 2014, this decree provides for a 50% tax credit on incremental R&D investments that are borne by any company, within a maximum of €2.5m per year.

However, the new discipline is subject to implementing decrees that will provide details about measure and conditions of the incentive.

In addition, it is worth noting that the above mentioned incentive is provided within a limited timeframe. More in particular, the incentive is in force between FYs 2014-2016.

Tax credit for qualified human resources

This is an incentive consisting of a tax credit of 35% of the costs (up to the amount of €200,000 per year per enterprise) for new permanent hiring of highly qualified personnel, i.e.:

- (i) Holders of PhDs from an Italian university or a foreign university recognized to be of equivalent standing under current legislation
- (ii) Holders of masters degrees in technical or scientific masters subjects employed in R&D activities

The credit is subject to certain procedural fulfillments. It is not included in the IRES or IRAP taxable base, and can only be used to offset direct and indirect taxes, substitute taxes, withholding taxes and social security contributions. The funds for this incentive allocated for 2013 are €50m.

In addition to those for R&D, other tax credits may be available, either for certain investments made or in return for hiring disadvantaged employees in Italy's southern regions. It must be noted that the incentive in question requires

further regulatory decrees in order to gain full operability. In addition, the above mentioned incentive is provided on a permanent basis, starting from FY 2012.

Cost of R&D employees' deduction for IRAP purposes

As a general rule, personnel expenses are not deductible for IRAP purposes. Nonetheless the cost of personnel performing R&D activity is fully deductible (wages and social security contributions) for IRAP purposes. The deduction is granted under the condition that the effectiveness of these expenses is certified by a qualified third party (e.g., President of the Board of Statutory Auditors, Chartered accountants). In addition, the above mentioned incentive is provided on a permanent basis, starting from FY 2005.

Tax landscape for investors

A domestic provision, introduced in 2008, yet so far little used, provides an incentive for investors selling their shareholding in one company while investing in another operating in the same sector. It works by exempting any capital gain realized through the initial disposal. There may also be ways to structure holdings in a tax-efficient way (e.g., through corporate tax fiscal unity, value-added tax grouping, branches acting as holding entities and partnerships).

Tax landscape for entrepreneurs

Entrepreneurs' income is subject to tax (either individually at progressive rates or at a corporate rate of 27.5%). Certain companies operating in the oil, electricity and energy sectors (including renewable energies) may be subject to a corporate tax surcharge that, for three tax periods starting from fiscal year 2011, is 10.5%. From FY 2014, the surcharge is 6.5%.

In addition, entrepreneurs are liable for a regional tax (IRAP), which is levied at 3.9% on the value added, which is roughly equal to the earnings before interest and taxation. (The actual rate of tax may vary according to the region in which the firm operates and on the nature of the business).

Starting from fiscal year 2012, companies qualified as non-operating companies are subject to an additional tax rate of 10.5% on taxable income (i.e., total IRES rate equal to 38% instead of 27.5%). The additional tax in question also applies to companies that repeatedly present a negative tax result.

Other direct taxes may apply, depending on the assets held by the entrepreneur (such as municipality tax, ranging from 0.6% to 1.06% charged on the properties' value). Starting from FY 2014, a new service tax grouping the former municipal taxes existing at the end of FY 2013 has been issued. The new maximum service tax rates have been set forth by the 2014 Stability Law. In specific cases, the minimum rates might be amended by each municipality.

Overall, tax on entrepreneurs in Italy can be burdensome. Not only is the system complicated, the tax authorities are also focusing on business in general in a renewed attempt to tackle tax evasion and abuse.

Finance

Grants and other support

Most of Italy's biotech companies fund their business in one of three main ways:

- (i) Debt
- (ii) Grants (national and regional as well as those available through European and international sources)
- (iii) Venture capital and private equity funds

As funding through grants decreases, more and more biotech companies are resorting to venture capital or private equity firms for funding. That said, the most popular option is debt. An increasing number of firms are also considering a public issue of shares on a stock exchange.

Companies specializing in red biotech often receive grants or other forms of funding from a combination of official sources: the Italian Ministry of Education, University and Research (MIUR); the Ministry of Health (MDS); and the Italian Ministry for Economic Development (MSE). A big role is played by the regional governments, which are autonomous in deciding on policies to encourage biotech incentives.

Availability of capital

As to national support for the industry through the Ministry of Education, University and Research (MIUR), no new significant funds were granted in 2013 and, currently, there are no open competitions with regard to the other R&D programs financed by MIUR.

Finally, I would be inclined to drop this expression under the EU's Decision no. 1982/2006, the Seventh Framework Program (in force from 2007-13), a total of €1,935m was earmarked to support new biotech ventures across Europe.

Regulatory environment and incentives

Intellectual property (IP) rights on biotech inventions in Italy are ruled by Law no. 78 (2006), which enacted the Directive 98/44/CE. However, many, including Assobiotec, believe rights to IP on biotech products and tech-transfer processes should be increased and improved. One of the main hurdles is the difficulty in transferring technology from universities or research centers to companies.

Furthermore, the costs of depositing and registering patents are, in Assobiotec's opinion, still too high, especially for SMEs.

Structuring for the future

Tax-efficient structures

One of the main choices facing entrepreneurs setting up biotech businesses is the vehicle through which the operation is established in Italy (e.g., a company, partnership, permanent establishment, holding company and so on). How a company is financed is also important. Multinationals, in particular, should plan their transfer pricing policies (e.g., royalties for the right to use intangibles) and bear in mind that, under Italy's tax rules, the deduction of expenses incurred by Italian entities from "black-listed" countries may be challenged. (Note that, as far as the Italian authorities are concerned, some Swiss companies may be so affected.)

When disposing of a business, it is usually more tax efficient for owners to sell shares rather than assets directly. Provided that the investment in the Italian company shares has been held for at least 12 months and other conditions are met, the capital gain realized by an Italian holding company through the sale of a participation may be up to 95% exempt from corporate tax (IRES). Nor would it be subject to IRAP.

A full exemption is granted with respect to capital gains realized by individuals on the disposal of participations in companies and partnerships, provided that:

- (i) The participating entity has been established within the preceding seven year period.
- (ii) The participation disposed was held for at least three years.
- (iii) The capital gains realized are reinvested within two years from the disposal in another resident company or partnership operating in the same business sector and established within the preceding three-year period. Capital gains realized on the disposal of a going concern are usually subject to a rate of 27.5% IRES. The disposal of operations through a merger or contributions is tax neutral.

In principle, Italy's regulators support the idea of a centralized structure for R&D so that rights to IP can be placed under one roof.

Yet, unlike other jurisdictions, income derived from the licensing of IP is usually subject to nominal rates of tax under IRES and IRAP. In addition, any remuneration for the licensing of IP rights to related foreign parties may be subject to an "arm's length" principle under Italy's transfer pricing rule.

New measures for the development of innovative startups

The Growth Act 2.0, issued by Italian Government in October 2012, is aimed at generating sustainable renewal from a structural context of emergency.

Given its objective of promoting sustainable growth, technological development, new entrepreneurship and employment, the Growth Act is certainly a step forward in the process of modernizing the Italian industrial system. Indeed, the Act immediately contributes something tangible, by introducing for the first time in the Italian law the definition of "innovative start-up."

In fact, the Growth Act provides a series of facilitating measures for the first four years of activity of an innovative company. These measures are designed to allow more functional management of a number of corporate law requirements, and easier access to investment channels. Included among the main measures are the following:

- 1) Specific exceptions with regard to corporate law, such as the possibility to also apply to a startup company that has been established as an S.r.l. (limited liability company) those provisions which are specifically

reserved to stock corporations (S.p.A.). This gives the possibility to offer and trade participations in the share capital of the company, regardless of the legal form under which the latter was constituted. The act also provides for a reduction of the costs of launching new innovative entrepreneurial initiatives, through the exemption from stamp and secretariat duties for registration to the Companies' Registrar, as well from the annual fee to be paid to the Chamber of Commerce.

- 2) More flexibility in the use of temporary employment contracts, with the possibility to enter into temporary employment relationship, for a fixed term of between six months and four years (renewable several times also without interruption), with a considerable advantage in terms of allowing adequate flexibility in planning the company's organization.
- 3) Alternative forms of contributions for employees and suppliers (stock options and work-for-equity): startups may transfer their own shares – or a participation in their share capital – to directors, employees, consultants or service providers. Revenues originating from these securities or rights will not

contribute to the composition of the assessable income, both for fiscal and for social security purposes.

- 4) Introduction of specific tax incentives to encourage investors to support R&D activities, in connection with the high risk profile which is intrinsic for any startup company. More specifically, in fiscal years 2013-16, those individual persons that have invested in an innovative start-up are eligible for a deduction from gross tax equal to 19% of a maximum amount of €500,000. For legal persons, the deduction from the taxable income is 20% of a maximum amount of €1.8m. Both deductions are subject to the maintenance of the participation in the company's share capital for a minimum of two years.
- 5) New fund raising channels: through dedicated online portals, the management of which is entrusted to Commissione Nazionale per le Società e la Borsa (CONSOB), the public authority responsible for regulating the Italian securities market, the Growth Act aims at introducing crowdfunding as a new channel for raising capital from a wider pool of small investors.

- 6) Increased support for internationalization: innovative startups will benefit from the services provided by ICE (Agency Trade Promotion Agency) and by Desk Italia, the first interface for foreign investors, promoted by the Italian Ministry of Economic Development.
- 7) Easier access to credit: startups will enjoy free of charge, and in a simplified way, the services of the Central Guarantee Fund for SMEs, thus benefitting from the application of more favorable conditions in terms of coverage and maximum guaranteed sum.

These measures are applicable to any innovative startup that the Decree itself qualifies as an Italian non-listed company, which has been in operation for not more than 48 months and has its principal place of business in Italy. Furthermore, starting from the second year of operations, total annual revenues should not exceed €5m, with no distribution of profits. The key feature for any innovative startup is obviously to have as an exclusive or predominant purpose the development

and marketing of innovative products and services, with a high technological value.

In addition, in order to be considered as an innovative startup, the company must meet at least one of the following three requirements:

- ▶ R&D costs must be equal to or greater than 15%.
- ▶ At least one-third of employees must be represented by highly educated personnel.
- ▶ The company must be the owner or the licensee of a patent.

Overall, the Act represents a significant step forward in terms of stimulus and support for the creation of new business ventures with a high rate of innovation.

However, it does not meet all needs, especially in those areas where the results of the investment in R&D are located in the medium to long term, as in the case of biopharmaceutical companies for which the development time of a new molecule is far beyond the four years required by the legislator.

Luxembourg

The entrepreneurial culture

The Grand Duchy of Luxembourg, a founding member of the European Union, lies at the heart of Europe, between France, Germany and Belgium. It is home to several international institutions, including the European Investment Bank and Eurostat, the statistics office of the EU. It also hosts the European Court of Justice.

This politically stable country has 500,000 inhabitants, 44% of whom are foreign, giving it a very young, international and multilingual workforce. Luxembourg has three official languages – Luxembourgish, French and German – but English is also commonly used, even in dealings with the Luxembourg Government.

The Luxembourg Cluster Initiative ([clusters.lu](#)), launched in 2002 by the Luxembourg Government, actively encourages networking between the private and public sectors. The focus is placed on key technologies that have been identified as important for the future sustainable development of the Luxembourg economy, such as health care and biotechnologies. The initiative is a key element of the National Research and Development (R&D) Innovation Policy, which brings together various clusters and innovation networks established in Luxembourg.

The Luxembourg Cluster Initiative is coordinated by Luxinnovation ([luxinnovation.lu](#)), the National Agency for Innovation and Research, whose members include the Ministry of the Economy and Foreign Trade, the Ministry for Higher Education and Research, the Luxembourg Chamber of Commerce and the Chamber of Trades. The aims of

this initiative are to strengthen the R&D and innovation potential of companies and to reinforce corporate links with public research organizations and academia through effective innovation networks. The Luxembourg BioHealth Cluster ([biohealthcluster.lu](#)) is a recently established cluster, which aims to reinforce and capitalize on the Government's national strategy to achieve scientific excellence in molecular diagnostics – the cornerstone of personalized medicine – and to enhance Luxembourg's reputation as a recognized and attractive environment for biomedical research, development, innovation (RDI) and business. The cluster includes R&D companies, public research organizations, laboratories, hospitals and other actors (such as patients associations and providers of capital and services) based in Luxembourg whose activities are related to health sciences and technologies. With a principal focus on molecular diagnostics, the cluster also covers other RDI and business domains that are important for an integrated, patient-based and personalized approach to medicine, such as new therapeutics, bioinformatics, medical device and telemedicine.

Taxation

Corporate tax

Luxembourg resident and non-resident taxpayers with a taxable presence in Luxembourg are subject to Luxembourg Corporate Income Tax (CIT) and Municipal Business Tax (MBT) on their taxable income. A company is resident in Luxembourg if either its legal seat

or its central administration is located there. Resident companies are taxed on their worldwide income. A non-resident taxpayer is only taxed on its Luxembourg source income. On 1 January 2014, the combined income tax rate is 29.22%. This consists of 21% CIT with an additional 7% of employment fund surcharge and 6.75% municipal business tax for companies located in Luxembourg City with a taxable income greater than €15,000. A CIT rate of 20% (plus surcharges) will be applicable on taxable income up to €15,000. Since 1 January 2013, all Luxembourg resident entities in corporate form are subject to a minimum tax regime. However, income derived from qualifying participations (dividends and capital gains) may be tax exempt (under conditions), as well as intellectual property (royalties and capital gains) may benefit from an 80% income tax exemption if certain conditions are met. Accordingly, the qualifying net income derived from IP (i.e. the gross revenue less directly related expenses, depreciation, and write-downs) will be taxed at an effective rate of 5.84%.

The net wealth tax rate is 0.5% and will annually be imposed on the adjusted net asset value as of 1 January. Qualifying IP rights and shareholdings are exempt from net wealth tax.

Taxpayers may request upfront clearance on the Luxembourg tax treatment of their envisaged plans from the Luxembourg tax authorities.

Luxembourg does not levy royalty withholding tax or interest withholding tax (save for the application of the EU Savings Directive; automatic exchange of information as regards interest

payments should be applied as from 1 January 2015 according to a government announcement). In addition, there is no Luxembourg dividend withholding tax (subject to conditions) for dividends distributed by Luxembourg companies to qualifying parent companies established within the EU, the European Economic Area or one of Luxembourg's double tax treaty partners. Currently, Luxembourg has 68 double tax treaties in force, and the treaty network is steadily growing. The withholding tax exemptions allow for an easy repatriation of funds to shareholders and investors. Luxembourg does not levy branch remittance tax either.

Luxembourg has transposed into national law the provisions of the Parent-Subsidiary Directive ("participation exemption" or "Schachtelprivileg") providing for a full tax exemption of qualifying dividends. Luxembourg has furthermore extended this exemption to capital gains.

Value Added Tax (VAT)

On 1 January 2014, Luxembourg has the lowest standard VAT rate of the European Union, at 15%. A special 3% rate applies to pharmaceuticals. VAT exemptions include health and medical services. Although the standard VAT rate is expected to increase to 17% on a midterm basis (remaining anyway the lowest standard VAT rate in the EU), the super-reduced rate of 3%, applicable to pharmaceuticals, among others, should remain unchanged.

Incentives

(a) IP regime

Since 2008, Luxembourg has offered a beneficial IP tax regime aiming to

strengthen Luxembourg's position as a hub for IP regimes. Income derived from qualifying intellectual property (royalties and capital gains) may be 80% income tax exempt if certain conditions are met. The effective tax rate on qualifying net IP income is hence 5.84% (2013 and 2014).

The Luxembourg IP regime has a very broad scope which applies not only to patents, but also to trademarks (including domain names and service marks), designs and models, and software copyrights.

The Luxembourg IP regime applies to both the self-developed and acquired IP rights, without the restriction to further develop these or to have an R&D branch of activity in Luxembourg. This allows for a beneficial acquisition platform for qualifying IP rights from group companies or third parties. A notional deduction of 80% for the use of a self-developed patent by a company for its own activity is also granted.

The Luxembourg IP tax regime requires that the IP right must have been granted or acquired after 31 December 2007. The IP tax regime does not apply to IP acquired from an "associated company," which is restrictively defined as being: (i) a company holding a direct participation of at least 10% in the share capital of the company invoking the benefit of the regime; (ii) a company whose share capital is held directly for of at least 10% by the company invoking the benefit of the regime; or (iii) a company that is directly held by a third company which holds a direct participation of at least 10% in the share capital of the company invoking the benefit of the regime.

The 80% tax exemption applies not only to royalties received on licenses or royalties embedded in the sale of products, but also to capital gains realized upon the sale of the IP rights by the Luxembourg taxpayer.

The qualifying net income derived from IP is defined as the difference between gross revenue and any expenses directly connected with such revenue, including amortization and write-offs. A recapture regime will apply, along similar lines to the participation exemption applied to capital gains on shares. This recapture will imply that the reduced basis for the computation of the capital gain is increased by 80% of the sum of the expenses incurred in connection with the transferred IP rights for which relief had been given during the tax year of the disposal or during any previous tax year. Finally, notwithstanding the 80% exemption, foreign royalty withholding taxes are fully creditable up to the amount of Luxembourg tax due on the income. The remainder of the amount is deductible from the Luxembourg tax basis.

(b) Investment credit

A tax credit of 12% is granted for additional investments in qualifying assets. Qualifying assets consist of depreciable tangible fixed assets other than buildings physically used in EU member states, Iceland, Liechtenstein and Norway (EEA). Certain assets are excluded from the additional tax credit in the year of their acquisition, such as motor vehicles, assets that have a useful life of less than three years and secondhand assets. In addition, a 7% credit is granted for qualifying new investments up to €150,000, and a 2% credit is granted

for investments over that amount. If investments are made to create jobs for disabled persons, these rates are increased to 8% and 4%, respectively.

Investments may qualify for both credits. The rates for the general investment tax credit are increased from 7% to 8% and from 2% to 4% for certain investments intended to protect the environment. The credit reduces corporate income tax and may be carried forward for 10 years.

(c) Aid for innovation and R&D

The benefits are currently foreseen by two different laws, the law dated 5 June 2009 on the promotion of R&D and innovation (all enterprises) and the law of 30 June 2004 in favor of the sector of SMEs. Aid is granted in the form of a capital subsidy or interest subsidy.

Under the law of 5 June 2009, R&D and innovation aid for eligible businesses and projects may not exceed the following amounts:

- ▶ Fundamental research: maximum 100% of eligible expenses
- ▶ Applied industrial research: maximum 50% of eligible expenses
- ▶ Experimental development activities: maximum 25% of eligible expenses

The following increases may be granted:

- ▶ An increase of 10% where the beneficiary is a medium-sized enterprise or a private research organization fulfilling the criteria of a medium-sized enterprise.
- ▶ An increase of 20% where the beneficiary is a small enterprise or a private research

organization fulfilling the criteria of a small enterprise.

- ▶ An increase of 15% provided the total degree of aid does not exceed 80%, where:
 - ▶ The project or program is based on cooperation between at least two enterprises or private research organizations independent from one another and provided that none of them bears alone more than 70% of the eligible costs and the project or program is realized in cooperation with at least one SME or the project involves cross-border cooperation, i.e., the research or development activities are performed in at least two member states of the EU.
 - ▶ The project or program is based on cooperation between at least one enterprise and one public research organization independent from one another and provided that the public research organization bears at least 10% of the eligible costs and has the right to publish the results of the project or program.
 - ▶ In the field of industrial research, the results of the project or program are widely broadcast through technical and scientific conferences, published in scientific or technical publications, kept in generally accessible registers or made available via free software.

Under the law of 30 June 2004, R&D and innovation aid for eligible businesses and projects may not exceed the following amounts:

- ▶ Fundamental research: maximum 75% of eligible expenses

- ▶ Applied research: maximum 50% of eligible expenses
- ▶ Pre-competitive development activities: maximum 25% of eligible expenses

The following increases may be granted, provided that the total degree of aid does not exceed 100% for fundamental research, 75% for applied research and 50% for pre-competitive development activities:

- ▶ An increase of 10% where the beneficiary is an SME fulfilling the criteria of a medium-sized enterprise.
- ▶ An increase of 10% where the investment or research project involves cross-border collaboration with at least one independent partner from another EU Member State but does not fall within the scope of the objectives of the EU framework program for R&D.
- ▶ An increase of 15% where the investment or research project involves cross-border collaboration with at least two independent partners from two other EU Member States and where it falls within the scope of the objectives of a project or program of the EU framework program for R&D.
- ▶ An increase of 25% where, in addition to meeting the conditions of cross-border R&D, the results of such a project are widely disseminated.

- ▶ An increase of 25% where the aid is granted for the monitoring of technological development or a feasibility study carried out prior to applied research or pre-competitive development activities.

In principle grants are paid in a lump sum after completion of the investment program. However, payments in one or more tranches may be granted in specific cases as the project progresses, in particular where the beneficiary resorts to financing by leasing.

Interest rate subsidies and interest relief amount to the difference between the market interest rates in force at the time the aid is granted, applicable to the category of operation concerned and the reduced interest rate effectively paid by the beneficiary. The interest rate may not be reduced by more than 4% points, nor may it be reduced to below 1%.

Aid may only be allocated once to the same economic entity over a period of 10 years, including successive takeovers by different natural or legal persons. Aid must be requested within a period of two years from the payment of the expenses for which aid is requested.

To benefit from R&D and innovation aid under this law, the business must:

- ▶ Be established in Luxembourg
- ▶ Offer sufficient guarantees in terms of viability
- ▶ Hold a business permit granted by the Department of small and medium-sized businesses
- ▶ Be soundly managed
- ▶ Actively contribute to and form part of the country's economic structure

Finance

Local authorities may be willing to provide additional incentives and to facilitate investment projects.

The SNCI grants medium-term and long-term loans to industrial enterprises and service providers whose activity represents a significant impact on economic development and whose equity amounts to at least €25,000. The loans are intended to finance tangible and intangible assets that are subject to depreciation and land used for professional purposes only. Parts of buildings used for non-professional purposes, automotive equipment and inventory may not be financed by medium-term and long-term loans. Medium-term and long-term loans may only be requested in respect of investment projects with a value of at least €100,000.

Other

R&D activities performed outside Luxembourg, e.g., on a contract R&D basis, can benefit from the Luxembourg IP regime, providing an effective tax rate of 5.84% on qualifying net income. This can be achieved in situations where the Luxembourg taxpayer acts as the IP principal and licenses the IP rights to third parties.

It is important to note here that IP which is acquired from group companies (except associated companies, see above) or third parties can also qualify for the Luxembourg IP regime, and this without the need to further develop it.

Finally, it is not required for the Luxembourg company to legally own the IP rights; it must however have the economic ownership benefit from the Luxembourg IP regime.

The Netherlands

The entrepreneurial culture

The Netherlands has an active innovation policy, which focuses on nine priority sectors – one of which is life sciences and health. To support this sector, the Government has established the organization Topsector Life Sciences & Health.

This organization aims to encourage cooperation between academia, companies and government. Its governance structures represent these three groups. Topsector Life Sciences & Health carries out work in a number of fields, including R&D, international cooperation, human capital, risk capital and regulatory work. More information can be found on lifescienceshealth.com. The Netherlands has a number of strengths, not least its telecommunications and transport infrastructure.

HollandBIO

HollandBIO is the Dutch biotech industry association. It represents, connects and supports biotech companies and research organizations operating in the Netherlands. For more information go to hollandBIO.nl.

Netherlands Enterprise Agency (Rijksdienst voor Ondernemend Nederland) encourages entrepreneurs in sustainable, agrarian, innovative and international business. It helps with grants, finding business partners, know-how and compliance with laws and regulations. The aim is to

improve opportunities for entrepreneurs and strengthen their position. The Agency works at the request of ministries and the EU.

Netherlands Enterprise Agency is part of the Ministry of Economic Affairs. The organization has been in existence since 2014 and is the result of a merger between Agency NL and the Dienst Regelingen. Some activities of the Commodities Boards are also included. Netherlands Enterprise Agency focuses on providing services to entrepreneurs. It aims to make it easier to do business using smart organization and digital communication. The Agency works in The Netherlands and abroad with governments, knowledge centers, international organization and countless other partners. For more information go to RVO.nl.

Taxation

Corporate tax

Corporate income tax is levied on resident and non-resident companies. Resident companies are those incorporated under Dutch civil law, including subsidiaries of foreign companies, European companies (Societas Europaea, or SEs) and European cooperative societies (Societas Cooperativa Europaea, or SCEs) that are established in the Netherlands, even if their management and statutory seat is abroad. In addition, companies are

resident if they are effectively managed and controlled in the Netherlands, even if they are incorporated under foreign civil law. Resident companies are subject to tax on their worldwide income. Non-resident companies – primarily branch offices of foreign companies doing business in the Netherlands – are taxable only on specific income items, such as real estate and business profits in the Netherlands. The standard rate of corporate tax is 25%. A tax rate of 20% applies to the first €200,000 of taxable income. An effective tax rate of 5% is available for income related to qualifying intellectual property (IP). Rulings are agreements concluded with the tax authorities on the future consequences of transactions or situations involving Dutch taxpayers. For certainty in advance on transfer pricing, an advance pricing agreement (APA) can be concluded with the tax authorities. APAs provide taxpayers with certainty about the arm's length nature of transfer prices. For almost all other matters, such as the applicability of the participation exemption, the tax consequences of hybrid finance structures or permanent establishment in the Netherlands, an advance tax ruling (ATR) can be concluded.

The period for which a ruling applies depends on the type of ruling. Some apply to a specific case and therefore, in principle, apply indefinitely. However, in general, ATRs are valid for a period of

four to five years. If the facts on which the APA or ATR was based do not change, then, in principle, the APA or ATR can be renewed indefinitely. No distinction is made in the Netherlands between capital gains and other income. In certain cases, capital gains are exempt or a rollover is available, based on case law or under the reinvestment reserve. The standard rate of withholding tax on dividends is 15%. However, several exemptions and reductions, as described below, may apply.

Under the participation exemption, dividends paid by resident companies to other resident companies are usually tax free. Dividend withholding tax is not imposed on dividends distributed from a Dutch company to a qualifying entity in another EU member state, that owns at least 5% of the nominal paid-up share capital of the payer. The qualifying entities are specified in the EU Parent-Subsidiary Directive. The threshold of 5% may be lowered in certain circumstances. Under an extensive network of Dutch treaties, the rate of dividend withholding tax is typically reduced to as low as 0%.

All corporations located in the Netherlands (except qualified investment companies that are subject to a rate of corporate income tax of 0%), including holding companies, are, in principle, exempt from Dutch corporation tax on all benefits connected with certain qualifying shareholdings (participations). Benefits

include cash dividends, dividends in kind, bonus shares, hidden profit distributions and capital gains realized on the disposal of the shareholding. A capital loss that might result from the disposal of the shareholding is similarly non-deductible (but a liquidation loss of a subsidiary company is, in principle, deductible). The participation exemption applies to all holdings of 5% or more of the nominal paid-up capital of the subsidiary, unless the participation is a portfolio investment.

In principle, depreciation is based on historical cost, the service life of the asset and the residual value. From January 2007, depreciation is limited on buildings, goodwill and other assets. Despite these restrictions, a write-down to a lower market value remains possible.

Goodwill must be depreciated over a period of at least 10 years. As a result, the maximum annual depreciation rate is 10%. If the goodwill is useful for a longer period, this period must be taken into account. For other assets, such as inventory, cars and computers, the depreciation is limited to an annual rate of 20% of historical cost, unless the accelerated tax depreciation mentioned above is applied.

Incentives

In the Netherlands, a taxpayer may deduct immediately from taxable income, subject to the regular rate of corporate income tax, the costs of developing intangible assets. As a result, such costs do not need to be capitalized.

In addition, if certain conditions are met, a taxpayer can elect to apply the Innovation Box. The aim of this box is to encourage innovation and investment in research and development, including that of software. The Innovation Box is the successor to the Patent Box, which applied from January 2007, and was converted into the Innovation Box, as of 1 January 2010. In the Innovation Box, by reducing the tax base by about 80%, net income from qualifying IP is effectively taxed at a rate of 5%. The 5% rate applies only to the extent that the net earnings derived from the self-developed intangible assets exceed the development costs. The development costs are deductible at the standard rate of tax and form the threshold. If the Innovation Box regime is adopted for a particular intangible asset, the other intangibles are not required to be allocated to the box. The Innovation Box, unlike the Patent Box, does not impose a limit on the amount of income from intangible assets that can be taxed at the reduced rate. As of 2013, it is also possible to opt for a fixed profit allocation if, in the current or previous two years, a qualifying intangible asset has been developed (yearly benefit is limited to €5,000). The purpose of this new regulation is to make the Innovation Box more easily accessible for start ups and SMEs.

An important condition of the Innovation Box is that the taxpayer must have been granted a patent or R&D declaration (by Netherlands Enterprise Agency). In order to apply for the Innovation Box, applicants must also meet the following requirements:

1. An intangible asset has to be owned and developed by (i) the Dutch taxpayer, (ii) through contract research or (iii) through a cost contribution arrangement.

2a. The first sale of the intangible asset for which a patent has been granted has to take place after 31 December 2006. This includes plant variety rights.

Or

2b. the first sale of the intangible asset for which a R&D declaration has been granted by Netherlands Enterprise Agency has to take place after 31 December 2007.

3. Expected profits must originate to a large extent from the patent or R&D declaration.

Trademarks, logos and similar assets do not qualify. Contracted R&D for qualifying intangible assets is allowed. ATRs and APAs are also available. Where there is a treaty, withholding tax on foreign royalties can normally be credited against Dutch corporate income tax, but the amount of the credit is limited to the Dutch corporate income tax attributable to the relevant income on royalties. The research and development tax credit (formerly known as WBSO) provides a tax facility for companies, research centers and self-employed persons who perform R&D work. Under the scheme, there is a contribution toward the wage costs of employees directly involved in R&D. The

facility involves a reduction in the total deduction of tax on wages and social security contributions by the R&D institute, subject to compulsory deductions. The reduction amounts to 35% (50% for start ups) of the first €250,000 of the total wage costs for R&D and 14% of the remainder. As of 2012, the R&D declaration could also give access to a new tax incentive, the Research and Development Deduction (RDA). The RDA grants the taxpayer an additional deduction for R&D costs (not including labor costs) and expenses that are directly related to projects for which an R&D declaration is granted. For 2014, the additional deduction is set at 60% of the qualifying costs and expenses.

The tax landscape for investors

Foreign investors, including those in big pharma and biotech, have not only chosen the Netherlands for foreign direct investment, but also as a location from which to organize, fund, own and grow their overseas companies and businesses. Investment companies (Fiscale Beleggingsinstelling or FBI) enjoy a beneficial tax regime if certain requirements are met. Under this regime, profits are not subject to tax, provided the net investment income is distributed within eight months of the following financial year. There is a commonly used structure, which is tax effective, for holding investments, where the interest on a loan,

contracted due to a takeover purchase of the company, is deductible. From 2012, this structure has been discouraged and – in some cases – not all the interest can be deducted. However, in certain situations deductions continue to be permitted.

The tax landscape for entrepreneurs

For entrepreneurs, there are many reasons for setting up in the Netherlands. Among the main advantages are:

- ▶ A 25% rate of corporate income tax
- ▶ No taxation of dividends and capital gains from qualifying subsidiaries (participation exemption)
- ▶ No withholding tax on interest and royalties
- ▶ No withholding tax on dividends when using a Dutch cooperative
- ▶ No capital tax or stamp duty
- ▶ An extensive network of tax treaties as well as access to EU directives

As a result of these advantages, companies pay a low level of withholding tax on distributions from investments to foreign recipients and receive favorable tax treatment for foreign employees. Companies may also receive accelerated

depreciation of business assets to stimulate their investments. Companies may also be able to use hybrid loan structures. Companies can use ATRs and APAs to obtain certainty on international tax structures. In addition, companies can carry forward tax losses for nine years, and can also carry tax losses back. Not only is there certainty up front from the Dutch tax authorities, by way of formal agreements, there is also a tried and-tested structuring for multinational companies, private equity and investment funds. What is more, Dutch corporate income tax returns can be filed in another currency – as a functional currency.

Finance

Local authorities may be willing to provide additional incentives and to facilitate – usually large-scale – investment projects.

Regulatory environment and incentives

The Netherlands is party to all major treaties and conventions for protecting and registering IP. It has a strong and efficient infrastructure to register patents and trademarks. Patents from the Netherlands Patent Office give international protection.

Structuring for the future

Tax-efficient structures

The Netherlands also has advantages when it comes to disposing of businesses. There is an exemption under which benefits such as dividends and capital gains derived from a qualifying participation are exempt from corporation tax. The exemption generally applies if the parent company holds at least 5% of the shares in the subsidiary and if this subsidiary is not considered a “low taxed passive investment subsidiary.” Capital gains from the sale of a qualifying participation are also exempt from corporate taxation. Capital gains realized upon mergers and split-offs may be rolled over under special provisions. Capital

gains realized on the disposal of business assets may, under certain circumstances, be placed in a reinvestment reserve or be taxed at a lower rate, provided the income qualifies for the Innovation Box. It is possible to establish a centralized R&D structure in another country and to license the IP through the Netherlands to a third country. The IP, other than the legal ownership of patents, may also be held in the Netherlands.

Norway

The entrepreneurial culture

Innovation Norway may, upon application, assist with startup finance (innovasjon norge.no).

Taxation

Corporate tax

The general corporate tax rate is 27% flat. Losses may be carried forward indefinitely.

Apart from the general SkatteFUNN¹ research and development (R&D) incentive, there are no particular incentive tax regimes for biotechnology startups.

As a starting point, costs incurred in order to acquire, maintain or safeguard taxable income (hereunder R&D costs) are deductible for tax purposes. However, business assets with a useful life of at least three years and a cost price of more than NOK15,000 must be capitalized for tax purposes.

Cost incurred pursuant to procured or self-performed R&D can normally be deducted from the taxable income. However, after it has become probable that the project will lead to a business asset, R&D costs have to be capitalized (if the cost is more than NOK15,000 or the asset will be useful for more than three years). There is some uncertainty in relation to exactly when the obligation to capitalize R&D costs arises.

The tax authorities commonly question the tax treatment of R&D costs during tax audits.

Incentives

According to the SkatteFUNN tax incentive regime, a company that has incurred R&D costs is entitled to a tax relief (a tax credit) in addition to the ordinary deductions. A condition for receiving this tax deduction is that the project has received advance approval from the Research Council of Norway (RCN) as being a R&D project under the terms of the law.

For the tax year 2014, the maximum tax credit is 18% (or 20% if the taxpayer is a small or medium-sized company) of R&D costs. The eligible costs may normally not exceed NOK8m per year. However, in the case of R&D cooperation with an approved R&D institution, the cap is NOK22m.

A company entitled to relief that is not in a tax paying position will receive the same amount as a governmental refund.

Tax landscape for investors

There are no specific incentives or tax concessions available for investors.

However, in general, there is no Norwegian tax on capital gains on shares in a Norwegian company accruing to a non-Norwegian tax-resident.

Furthermore, dividends accruing to a corporate shareholder resident within the EU or the European Economic Area (EEA) are not subject to withholding tax (WHT) – provided that certain requirements are met. For example, the EU or EEA resident company must actually be established (i.e., have real substance) and be engaged in genuine economic activity.

¹SkatteFUNN is a tax credit. The credit is not granted but a credit that the enterprise is entitled to.

Also, neither capital gains nor dividends accruing to a Norwegian limited liability company on shares in a Norwegian company or a company established within the EU or EEA are taxable.

Arm's length interest expenses are in general deductible, provided there is no thin-capitalization issue. There is no WHT on interest income accruing to non-resident creditors.

Finance

There is no specific support for biotechnology, yet agencies such as Innovation Norway, the Research Council of Norway and the Industrial Development Corporation of Norway offer advice and incentives. Innovation Norway (innovasjon Norge.no) may help with start-up finance.

Availability of capital

Its underlying economic strength has meant that Norway has not been particularly affected by the current situation in the financial markets. However, the banks are becoming increasingly reluctant to fund high-risk projects.

Structuring for the future

A common way of setting up a Norwegian business is to incorporate it in a limited liability company, which is held directly by an EU or EEA resident company, or by an intermediate Norwegian holding company.

To make sure that dividends are not subject to WHT, the first tier non-resident holding company should be tax resident within the EU or EEA and have a substantial stakeholding (e.g., offices and employees) in that country.

Additionally, where the holding company is resident in a country with which Norway has a tax treaty, WHT may not be levied subject to the relevant treaty provisions.

An arm's length debt finance should render the interest deductible in Norway. Furthermore, no WHT is levied in Norway on the interest.

Tax-efficient structures

There is no capital gains tax on the disposal of shares made by a non-resident with no PE situated in Norway.

Norwegian personal tax residents pay 2% capital gains tax.

Careful consideration should be given to selecting a Norwegian company to hold ownership of intellectual property (IP). Such ownership may be better located in an alternative EU or EEA country that has a more favorable IP tax regime. The trend is to emigrate IP from Norway and continue production activities in the country as a contract manufacturer.

That said, in Norway, it is also possible to set up a centralized structure that owns IP and which can be licensed to users outside the country.

Poland

Support from EU funds

Poland has been granted €72.9b in funding under the EU cohesion policy for 2014-20. Support is not yet available for companies because the implementation rules of the policy are still being prepared. Funding will be allocated to national and regional operational programs, and entrepreneurs will be able to apply. The first opportunities to benefit are likely to be announced in the second half of 2014.

It is expected that entrepreneurs will be able to receive support in a number of areas, including:

- ▶ Improvements to R&D infrastructure
- ▶ Financing of R&D and innovation
- ▶ Implementation of the results of R&D

Other grants are currently available to entrepreneurs from domestic programs.

Grants from domestic programs

The Polish Government provides a cash grant called the Multi-Annual Support Program (MASP) to support mainly large investments that are considered crucial to the country's economy. The level of support offered is based on the number of jobs created, and it ranges from PLN3,200 to PLN15,600 per job created. There are no application rounds; applications can be filed throughout the year. In order to benefit from this form of aid, a company should first talk to the Polish Information and Foreign Investment Agency (PAIIZ) and with the Ministry of Economy (MoE). The terms of the grant are set out in a bilateral agreement between the MoE

and the investor, and grants are made in cash. MASP grants are greater for those entrepreneurs planning an investment in what the Government has identified as one of the priority sectors.

So, for example, the Government would look favorably on an application from a biotechnology company spending a minimum of PLN40m over two years, creating more than 250 jobs. Similarly, a planned investment of at least PLN3m to create a center for R&D, which would create 35 jobs for highly educated researchers, would also be likely to win favor, as would an investor planning to spend, say, PLN160m to create at least 50 jobs.

Those in the biotechnology industry may also benefit from another public aid program – Innomed. This program is designed to support companies performing R&D related to innovative solutions for medicine, such as:

- ▶ Searching for new innovative medicines
- ▶ The development of innovative medicines and therapies
- ▶ The personalization of therapy and disease prevention
- ▶ The development of innovative technology for the production of generic drugs

The program has a budget of PLN195m, which will be awarded in three rounds. Companies will be able to receive cash grants up to PLN10m. The first call for applications will most likely be made in mid-May 2013. However, no official announcement has yet been made.

Another government program of interest to those in the biotechnology industry is Innotech. This program is divided into two parts:

- ▶ In-tech, which supports cooperation between scientists and business
- ▶ Hi-tech, which provides backing for the development of advanced industrial technology

A summary of main rules of Innotech is provided in the table on the next page.

The National Centre for Research and Development (NCBR) has announced a call for projects in the framework of the STRATEGMED program. Its main areas of focus are prevention practices and the treatment of civilization diseases. The program intends to address the challenges of an aging society, the growing incidence of chronic diseases and, ultimately, to deal with the issue of rising medical service costs. It aims to stimulate innovation and competitiveness in the Polish economy, particularly in the areas of biotechnology and biomedical engineering. It will do this via projects oriented to the development and implementation of new methods in prevention, diagnosis, medical treatment and rehabilitation. The allocation dedicated by the NCBR to the selected projects amounts to PLN360m. Applications may be submitted by academic consortia that include at least one enterprise.

Taxation

Corporate law

Under Polish law, only those businesses operating in one or more of the special economic zones can be granted an exemption from corporate income tax. Businesses seeking to operate in these zones require a permit from the Ministry of Economy.

At present, there are 14 such zones in Poland. An investor may choose either to enter an existing zone or to apply for an existing zone to be extended to private land.

The holder of a permit avoids corporate income tax, which stands at a rate of 19%. The exemption will stand for as long as the zone exists (provisionally until 2020, although an extension beyond 2020 is now being considered).

Permits for those seeking to enter an existing zone can usually be obtained within six to eight weeks. Investors can apply for the permit at any point – there is no formal call for applications. It may take up to eight months to extend a special economic zone to private land.

Under another scheme, companies may apply for R&D center status. This status allows a company to create an innovation fund of up to 20% of its monthly revenues, which are then deductible for the purposes of corporate income tax. The main requirement is that the fund must be used to cover expenses linked to R&D. Other benefits include exemptions from real estate tax, forestry tax and agricultural tax. The total exemption can amount to €200,000 over a period of three consecutive years.

To qualify for an R&D center status, a company must, in the year prior to filing an application, generate net revenues of at least €1.2m from the sale of goods and products and from financial operations. A minimum of 20% of this revenue must be generated from sales of products developed from the company's own R&D. Applicants must also have no outstanding liabilities for tax or social security.

The Innotech program

In-tech	Hi-tech																																																								
<ul style="list-style-type: none"> ▶ Support is granted in the form of a cash grant for projects including: <ul style="list-style-type: none"> ▶ R&D ▶ Preparation for the implementation of R&D, including documentation, tests, the protection of industrial rights, certifications and market research 	<ul style="list-style-type: none"> ▶ Support is provided in the form of a cash grant for projects including: <ul style="list-style-type: none"> ▶ R&D ▶ Preparations for R&D, such as purchasing consulting services connected with innovation 																																																								
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Portugal

The entrepreneurial culture

Portuguese public policy places a strong emphasis on the importance of entrepreneurship, which is the focus of +e+i, the Strategic Program for Entrepreneurship and Innovation. The program provides funding to initiatives that promote innovation and stimulate entrepreneurship, and it supports a large number of projects.

P-BIO, Portugal's Biotechnology Industry Organization, was founded in 1999. The organization, which focuses on R&D, involves 40 companies active in the sector. Most of these companies are involved in the health care and medical sectors, but some are in agri-food and environmental biotechnology.

Much of the R&D carried out in the country depends on the work of Portuguese scientists. Many are internationally recognized for their achievements in the field of biotechnology, both at foreign and at Portuguese universities.

Taxation

Corporate tax

In Portugal, corporate income tax (IRC) is levied on resident and non-resident entities. From 2014 onward, entities whose principal activity is commercial, industrial or agricultural will be subject to IRC of 23% on worldwide profits, but a foreign tax credit may reduce the amount payable: direct foreign tax may be credited against the liability for Portuguese tax up to the amount of IRC attributable to the net income from foreign sources.

Companies or other entities that operate in Portugal through a permanent establishment will be subject to IRC of 23% on the profits attributable to the permanent establishment. Companies or other entities without a permanent establishment in the country are subject to IRC on income that is deemed to have derived from Portugal.

In addition, such entities are subject to an additional municipal surcharge of 1.5%, with some exceptions.

A state surcharge of 3% is levied on taxable profit between €1.5m and €7.5m and 5% on taxable profit exceeding €7.5m.

Double tax treaties may further limit the risk of double taxation as a result of clearly defined permanent establishment rules in Portugal. From 2014 onward, tax losses can be carried forward for 12 years, provided that certain conditions are met. The new rule will only apply to tax losses generated after 1 January 2014. For previous tax losses, the carry forward period would be 4 or 5 years, depending on their origin period. However, Portugal has limited the deduction of losses to 70% of the taxable profit.

Incentives

Biotechnology companies may benefit from a variety of incentives, including the following:

- ▶ SIFIDE – a tax incentive system for corporate R&D. This aims to provide companies in Portugal with tax benefits that promote R&D, with the accent on boosting productivity, economic development and the qualification levels of the workforce. Expenses on R&D

qualify for a tax credit that is made up of two components:

- i. A base rate of 32.5% of expenses incurred during the current tax year
- ii. An incremental rate of 50% of expenses incurred during the period, in comparison with the simple average of the two previous tax years, with a limit of €1.5m. This limit may increase to €1.8m when considering expenses incurred in the hiring of PhDs.

- ▶ Regime Fiscal de Apoio ao Investimento (RFAl): is a special tax regime to support investment in land, plant, equipment and certain intangibles. It is available to businesses in a number of sectors, including agriculture, forestry, agro-industry, energy, manufacturing and the extractive industries. The credit amounts to 20% on qualifying investments of up to €5m and of 10% on qualifying investments above €5m. In addition, if certain requirements are met, RFAl provides an exemption from or a reduction of the municipal holding tax for buildings and an exemption from or a reduction of the property transfer tax, and a similar dispensation from stamp duty for contracts necessary to make the investment, including financing agreements.

Contractual incentives are also available for qualifying new investment projects established before 31 December 2020. To qualify, the project must satisfy a number of requirements:

- i. It must have a value exceeding €3m.
- ii. It must be in a sector considered of strategic importance to the Portuguese economy.
- iii. It must be designed to reduce regional economic imbalances, create jobs and stimulate technological innovation and scientific research in Portugal.

The incentives may include the following: a tax credit of 10% to 20% of the eligible investments made (which is deducted against the taxable profit of the project); an exemption from or a reduction of the municipal holding tax for buildings used in the project; an exemption from or a reduction of the property transfer tax for buildings used in the project; and an exemption from or a reduction of the stamp duty for acts and contracts necessary to complete the project, including financing.

The tax landscape for investors

Provided that certain conditions are met, investors may benefit from an exemption to domestic capital gains tax on the disposal of shares in foreign investments.

Investors may also benefit from double taxation treaties signed by Portugal with more than 60 other countries.

Also available is an exemption from withholding tax on dividends paid to EU shareholders eligible under the Parent-Subsidiary Directive, again provided that certain conditions are met. In order to benefit from exemptions from withholding tax as well as other reliefs, investors should consider using a holding company based in the EU.

In addition, there are benefits for those who are not permanent residents of Portugal. These apply to non-residents who have been in Portugal for the previous five years and who decide to become resident (and so taxed) there. This involves a special flat tax rate of 20% applicable to net income derived from activities that are considered to generate high added value of a scientific, artistic or technical nature. There are also exemptions for income from foreign sources, provided certain requirements are met. Employment income earned abroad from high-added-value activities may benefit from an exemption if it is subject to effective taxation abroad. Under the double tax treaties, dividends, interest, rental income and capital gains may also benefit from an exemption, provided they are subject to taxation in the country they are sourced from.

It is also worth noting that, from 2014 onward, corporate income derived from contracts relating to the transfer or temporary use of property rights on patents and industrial designs will contribute to the determination of taxable profit for just half of its value. To benefit

from this regime, several conditions must be met. One important condition is that this regime is only available to those whose property rights result from the R&D they have performed or contracted.

Finance

As a result of the transition into the new National Strategic Reference Framework (NSRF), effective from 2014 through to 2020, the existing incentives programs will be reshaped to satisfy the new EU regulations. Portugal will continue to have most of its territory eligible for EU-funded incentives, which will have to focus on innovation and research, as a result of the EU's Europe 2020 strategy.

Financial incentives programs are available to companies in most sectors, without any limitations based on the origin of capital. The new incentives programs are likely to focus on:

- ▶ R&D

EU's regulations on state aid apply to Portugal because it is part of the EU. This means that R&D expenses are normally eligible for the highest applicable funding.

- ▶ Innovation

Investments that accelerate the adoption of innovative processes or that result in the expansion of capacity for new products and services will continue to be eligible for loans at preferential interest rates. And cash grants are also available to assist in the reduction of investment costs.

▶ Job creation

There are many incentive schemes in place that aim to encourage job creation and the establishment of professional internships. These schemes will continue to support companies that are looking for new talent or that are expanding their activities.

▶ SMEs

Following EU guidelines on support for small and medium-sized enterprises, Portuguese public policy will continue to focus on these companies' efforts to modernize and to secure international competitiveness.

The reduced rates are limited to ceilings of taxable income, which are linked to the number of existing jobs. However, an administrative order was enacted by the Madeira Autonomous Region, granting more flexibility on the definition of a job.

If an EU holding structure is put in place, investors may get an exemption from withholding tax paid on distributed dividends and an exemption from or a reduction in withholding tax on interest payments. Also applicable are relief on capital gains on the disposal of shares in a Portuguese company, and relief on stamp duty paid on financing.

Structuring for the future

Structures that provide a tax-efficient base for successful operations include the tax-free zone of Madeira, a Portuguese archipelago.

Portugal offers benefits if an investment is made through Madeira. The zone offers a reduced rate of corporate income tax of 5% (for the years 2013–20). This applies to foreign income (i.e., that does not have a Portuguese source) that is derived from a licensed activity.

Spain

The entrepreneurial culture

The Spanish biotechnology sector continues to make very impressive progress.

- ▶ In 2011, the number of companies that claimed to perform biotechnology activities had risen to 3,025, an increase of 76.4% on 2010. This underscores how there is now a stronger “sense of belonging” in the biotech sector.
- ▶ A total of 660 companies said that biotechnology is their main or sole activity, representing an increase of 7% on 2010.
- ▶ The sector employed 202,250 people in 2011, creating 38,724 new jobs on 2010, an increase of 23.7% on 2010.
- ▶ However, focusing solely on biotech companies, employment has dropped by 7.61%.
- ▶ Despite the adverse economic situation, the turnover for companies that use biotechnology has increased by 26.5% in 2011, to reach €76.069b.
- ▶ In 2011, the shared GDP of biotechnology-using companies amounted to 7.2%, compared to 5.7% for the previous year (or 3% in 2008).

These positive movements can be seen as a sign that the sector is undergoing consolidation. This is due to the increasing visibility of biotechnology as a source of innovation and competitive improvement

in many different sectors that were traditionally considered to be mature. Furthermore, the number of biotech companies (one of the indicators used to assess the size of the sector) shows a year-on-year growth of 7%.

Industrial property and knowledge generation

In Spain as a whole, 1,064 patents were published in the biotechnology sector in 2012, representing an increase of 15.4% over 2011. Of these patents, 72.4% correspond to applications, while 27.6% correspond to patent awards. Table 6 shows, in absolute terms, the analysis according to the scope of protection (Spanish, European, North American, Japanese or international patents).

Internationalization remains a top priority for Spanish biotech companies. The launch of new products is another priority – this indicator has been very positive in comparison with the previous year, reaching a total of 132 new products (defined as “biotechnological products or services” Spanish Bioindustry Association (ASEBIO)).

When considering the process of internationalization, it is important to realize that biotech is a young industry, with only 15 years’ experience. However, unlike other productive sectors of the Spanish economy, for biotech,

internationalization is an important factor, since the success of these companies depends largely on their ability to export products, establish partnerships and technology-exchange agreements, and obtain international funding.

Spanish biotechnology companies (ASEBIO members) continue to expand with plenty of strength internationally. Many companies are establishing subsidiaries abroad: this has increased from a total of 64 entities in 26 countries in 2009, to 136 enterprises in 41 countries in all 5 continents in 2012. The overseas presence of ASEBIO members is concentrated in Europe (49% of the total), South America (21%), North America (18% – primarily in the US) and Asia Pacific (12%). In the course of 2012, a total of 41 companies (+32% on 2011) signed 76 international partnerships (+58%).

The biotechnology sector in Spain offers an interesting investment opportunity and is a means to help the domestic biopharmaceutical sector during a time of crisis, and when internal sustainability is needed.

Useful links:

asebio.com

mineco.es

ine.es

cdti.es

investinspain.org

Taxation

Corporate tax

Corporate tax is imposed at the rate of 30% on the income of resident companies, and non-resident companies with a permanent establishment in Spain. Small and medium-sized enterprises (SMEs) are taxed at a rate of 25% on profits up to €120,202 and at the general rate of 30% on the tax base exceeding this amount.

Taxable base is deemed to be the company's income for the year determined from the annual financial statements prepared under Spanish GAAP and adjusted for certain statutory tax provisions.

Tax losses may be carried forward and offset against future taxable income for a period of 18 years. For newly established enterprises, the 18-year period begins in their first profitable year for tax purposes.

The Spanish Government has recently approved the Royal Decree Law (RDL) 4/2013. This RDL establishes that start-ups will have a reduced tax rate (in their first two profitable years) depending on the amount of the taxable base. In this sense, for the part of the taxable base between €0 and €300,000, the applicable tax rate will be 15% and for the rest of the tax base the Applicable rate will be 20%.

On income tax, the RDL has also introduced a 20% tax deduction from the net positive income applying to taxpayers who apply for an economic activity from 1 January 2013.

Incentives

There are no specific tax incentives for biotech SMEs, other than general research and development (R&D) incentives. Start-up finance is available through ESBAN, an association of business angels. But the Spanish regions have taken perhaps the biggest steps in encouraging investment. Virtually all regional governments have developed programs to support entrepreneurs and give them access to funding.

According to Spanish corporate income tax (CIT) regulations, companies engaged in R&D activities have the right to apply for a tax credit on their expenses and certain investments made on R&D during the year. Spanish legislation distinguishes between R&D projects and Technologic Innovation (IT) projects. In view of the different applicable rates, whether a project qualifies as R&D or IT has a significant impact on the amount of the potential tax credit available.

To determine whether a company's activities qualify for R&D or IT tax credits, an in-depth technical analysis that requires knowledge of the business and products should be made by experts. The Spanish legislation provides the possibility of requesting a certificate from certain authorized organisms on classification as R&D or IT.

R&D tax credit is calculated by the application of a fixed percentage on the R&D expenses for the year. The general applicable rate is 25%, but if the yearly expenses exceed the average expense of the preceding 2 years, 42% will be applicable to such excess. An additional 17% credit is available for personnel

expenses corresponding with qualified researchers and 8% for investment in assets (excluding real estate) exclusively affected by R&D. In addition, a tax credit of 12% of the expenses incurred in the tax period on technological innovation can be taken off the tax liability.

The tax credit base is made up of the amount of R&D expenses and, if applicable, investments in tangible fixed and intangible assets, excluding real estate and land. Expenses, including the depreciation of assets used in R&D activities, are deemed to be R&D expenses if they are directly related to, and are actually applied to, the pursuit of those activities, and are separately registered by project.

In tax periods beginning from 1 January 2013, companies that apply for this tax credit because of an insufficient amount of CIT due could ask the administration to pay them the necessary amount of the R&D tax credit. The amount of the tax credit applied or paid cannot jointly exceed €3m annually. This limit will be calculated on a group level for companies. This new measure would affect the R&D tax credit, but not the tax credit for technological innovation activities. Certain requirements must be fulfilled in order to apply this option.

The IT tax credit is also calculated by the application of a fixed percentage (12%) on the IT expenses.

The tax credits base is reduced by 65% of the subsidies received for those activities which are attributable as income in the tax period.

In the past, R&D and IT expenses relating to activities pursued abroad only qualified for the tax credit if the main activity

was carried out in Spain under certain circumstances. However, for financial years starting after January 2008, this limitation does not apply for EU Member States.

Amounts paid to carry out activities in Spain at the request of the company, either individually or jointly with other entities, are also deemed to be R&D expenses.

The amount of tax credit may not exceed in aggregate (R&D and IT) 35% (temporarily 25% for years 2012 and 2013) of the gross tax due, net of domestic and international double taxation tax credits and of tax reductions. However, this limit would be increased to 60% (50% for years 2012 and 2013), if the tax credit corresponding to expenses incurred and investments made in the tax period exceeds 10% of gross tax due, net of domestic and international double taxation tax credits and of tax reductions.

The excess can be carried forward for 18 years (modified by RDL 12/2012 from 15 years to 18 years). For newly incorporated companies, the 18-year period computation does not start until the first year of profits.

Patent box

Law 16/2007 introduced a patent-box type of incentive regime into the Spanish tax system. This regime was designed to conform with EU provisions. However, on 13 February 2008, the European Commission announced that the regime is compatible with EU state aid rules and, consequently, the regime entered into force retroactively for tax years starting from January 2008.

This tax incentive is applicable to the tax base and the aim is to encourage the creation, protection and exploitation of intangible assets with business potential. Under this scheme and according to the new Law 14/2013 of 27 September, to support entrepreneurs and their internationalization, 60% of gross revenues arising from the transfer of the rights of patents, designs or know-how, is exempt from taxable income.

Qualifying assets include patents, designs or models, plans, or information concerning industrial, commercial or scientific experience.

This regime is applicable within tax groups formed by companies, and is also compatible with R&D tax credits.

Finance and incentives

Biotech industry aid is mainly grants, credits and zero-interest rate advances. These types of aid can either come from Europe or the Spanish Central Government (as well as regional entities).

At the European level, Horizonte 2020 is the main instrument for funding investigation projects and technological development on the EU for the years 2014-20. With a budget of €79,400m, the program is structured into three main pillars. Horizonte 2020 is of great interest to the biotech industry as a whole, including in Spain.

On a national level, the varied public support depends on specific programs approved and investment activities. For example:

▶ R&D projects (PID):

This initiative is based on low (EURIBOR) interest rate credits given to multi-year projects with a minimum budget of €175,000 or €500,000 in the case of "International Technological Cooperation Projects" run by a consortium or an EIG. De-centralized, funded international projects (under EUREKA, IBEROEKA and other bilateral programs) are granted with special, "soft" conditions in which credits become partially non-reimbursable.

▶ Innovation Hotline:

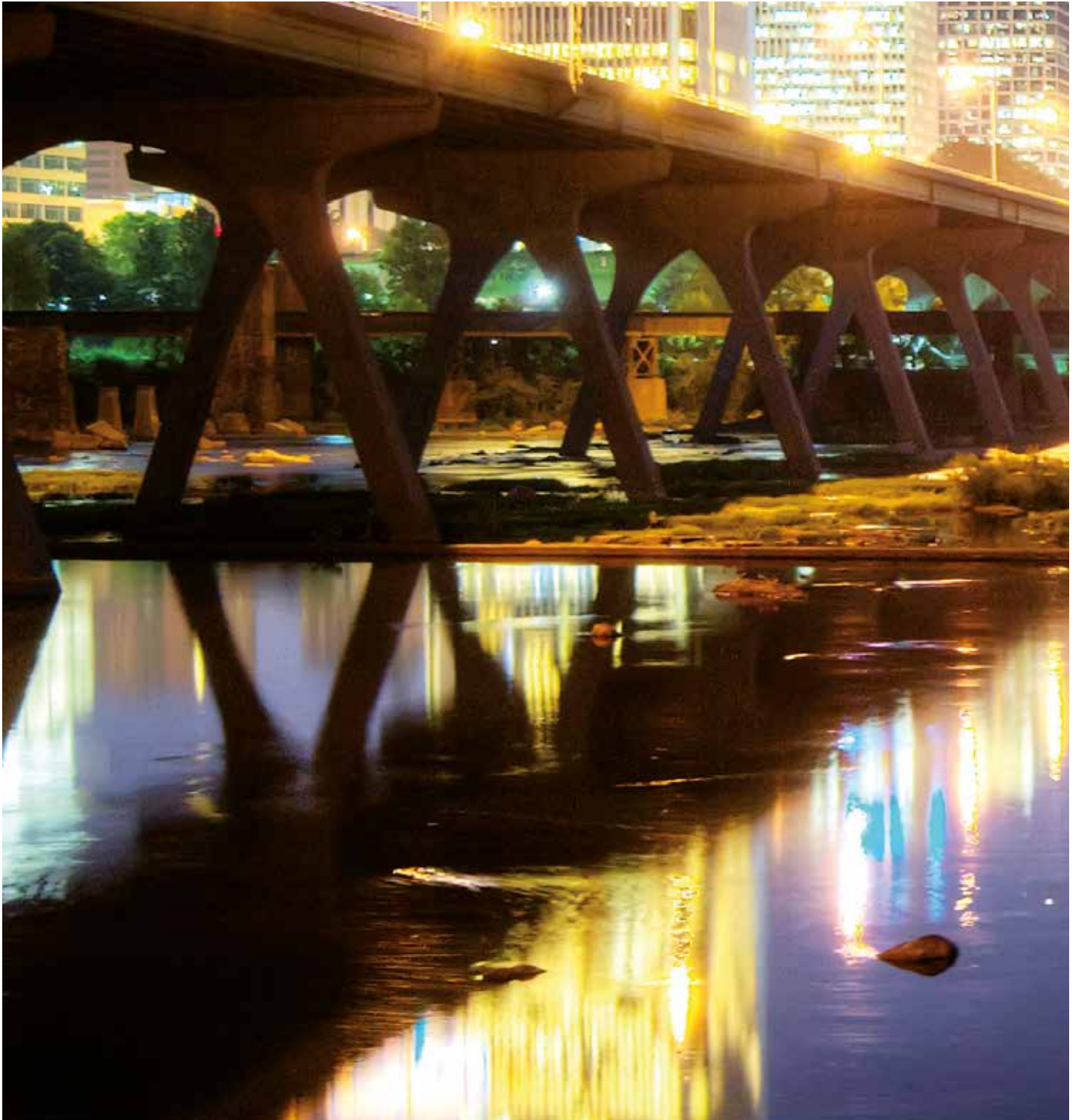
This program offers a subsidized (2%) interest rate financing offered to innovation activities that improve competitiveness, as long as the technology built is considered to be "emerging" in the sector. The minimum budget of the project must be at least €175,000.

▶ NEOTEC Initiative for the creation and consolidation of technology-based companies:

This initiative subsidizes necessary expenses for a company incurred for implementation (except from land purchase and civil construction) by €250000.

▶ Technological Fund of ICEX-INVEST IN SPAIN:

This includes a diverse set of measures, all aimed at promoting R&D and innovation in companies with foreign capital that wish to set up operations in Spain, or those already established in the country who wish to begin R&D and innovation activities. This is a non-returnable subsidy, with aid percentages varying from 25% up to 80%, depending on the type of project and company size.



Sweden

The entrepreneurial culture

Innovation drives Sweden's economy. The Innovation Union Scoreboard in both 2012 and 2013 named Sweden one of the leaders of innovation in Europe. The life science sector contributes to nearly 20% of Sweden's net exports and the Government is actively working with an innovation agenda that targets the life sciences sector.

SwedenBIO – the National Swedish Life Science Industry Organisation is the industry's voice and helps innovative companies succeed. The organization produces Nordic Life Science days, an annual investment, partnering and network meeting that attracts a large international attendance (nlsdays.com).

More than 20 incubators, science parks and regional biotech organizations are working to stimulate growth in the life sciences sector by bringing together companies, universities, health care organizations, and society as a whole, to find new ways to advance the sector's competitiveness both nationally and internationally. Strong life science clusters are found in the Malmö-Lund area in southern Sweden, around Gothenburg, in the Stockholm-Uppsala region and in Umeå in northern Sweden.

For general information about starting a business in Sweden visit the webpage verksam.se. The initiative is a collaboration between several government agencies and facilitates the establishment and development of commercial companies.

Advice is available through Business Sweden: The Swedish Trade and Invest Council, which promotes Sweden as a

business location (business-sweden.se).

In addition, regional business promotion agencies, such as Business Region Stockholm (stockholmbusinessregion.se), Invest in Skåne (investinskane.com) and Business Region Gothenburg (businessregion.se), are important organizations with a special focus on life science. Their mission is to connect international companies with business opportunities and to help Swedish companies in the regions to internationalize their businesses.

The Swedish Government has several initiatives designed to support entrepreneurs and companies – this includes funding and loans. Some of the initiatives are:

- ▶ The Swedish Governmental Agency for Innovation Systems (VINNOVA), invests around SEK2b per year and has about 200 employees, working from offices in Stockholm and Brussels. VINNOVA manages programs for improving innovation in Sweden. Its programs have different specialisms and cover several areas of society and industry. Innovative small and medium-sized enterprises (SMEs) and health care are two of VINNOVA's strategic areas. Read more about VINNOVA at vinnova.se.
- ▶ Tillväxtverket, the Swedish Agency for Economic and Regional Growth, is responsible for strengthening regional development and facilitating enterprise and entrepreneurship throughout Sweden. Read more at tillvaxtverket.se.
- ▶ Almi complements the market by providing risk-bearing loans where nobody else does. In its decision-making,

Almi sees the viability of an idea and a company's potential as more important than its real assets. An entrepreneur's or company's ability to develop and exploit its idea or the investment is also important. Almi is owned by the Government and regional public owners, and is near to its customers in 40 locations around the country. It works with businesses in all commercial phases, from ideas-stage startups to successful companies. It offers two forms of venture capital – seed capital and expansion capital. Read more at almi.se.

- ▶ Industrifonden is a foundation initiated by the Swedish Government operating on a commercial basis without external capital contributions. The foundation's capital is kept intact. All surpluses are used for new investments. Industrifonden offers capital, usually by investing in the equity of Swedish SMEs with international growth potential. Industrifonden also provides various types of risk-sharing loans.

Taxation

Corporate tax

There are no corporate tax regulations in Sweden that apply specifically to biotech companies, either in the start-up phase or for existing businesses. A limited company established in Sweden pays business tax of 22% on the profit the business had during the year.

Tax losses are carried forward and can be offset toward future taxable income without time limitations. The unlimited carry-forward period of tax losses is an

advantage compared with other countries, as it is common for time limitations to apply to the utilization of losses carried forward. Moreover, current-year tax losses can generally be offset against group profits through group contributions from Swedish group companies (limitations can apply after change of control). Group contributions are tax deductible for the paying company and taxable income for the receiving company.

Unlike several other jurisdictions, there are no thin-capitalization rules in Sweden. There are, however, restrictions on deduction of interest on intercompany loans. These restrictions were extended from 1 January 2013.

Incentives

Costs for research and development (R&D) are deductible for tax purposes, according to a specific regulation in the Swedish Tax Act. This includes research performed in the taxpayer's own business, as well as contributions paid to another company that performs research activities, on the condition that the research performed by the latter company is of reasonable interest for the contributor's business. The term "reasonable" was added to the wording of this section from 1 January 2012 in order to broaden the scope of the rule.

There are currently no tax incentives specifically aimed at biotech companies in Sweden.

There is no established monetary limit on contributions from one company to another company performing R&D activity.

Moreover, from 1 January 2014, it has been possible for companies to pay a reduced fee for a special employers' contribution for employees working in R&D. The deduction is a maximum 10% of the salary to each employee and a maximum SEK230 per group per month.

In general, expert tax relief is granted for foreign experts, researchers or key personnel. Expert tax relief is only granted to individuals who intend to work in Sweden for no longer than five years. However, the actual tax relief is only granted for the first three years of the employment period. The individual must be non-resident in Sweden (when the assignment in Sweden starts and must not have been resident in Sweden in any of the last five years before the assignment) and must not be a Swedish citizen. The application must be filed within three months of the employee's arrival in Sweden.

If approved, 25% of the employment income is exempt from taxes and Swedish employers' social security contributions. In addition, the following benefits can be provided tax free: moving expenses to Sweden and back home, two home trips for the whole family per year, and school fees for children (below university level).

Sweden introduced amended rules for expert tax relief on 1 January 2012. According to these new rules, an employee will be eligible for expert tax relief if his monthly salary exceeds SEK88,800 (i.e., SEK88,800 per month for income year 2014) including benefits. The applicant must file a formal application (a one-page document) and a copy of his or her employment or assignment contract. The applicant must also specify his or her

monthly salary. It is no longer necessary for applicants to document their levels of expertise, but they must still fulfill all other criteria for expert tax relief described above.

The amended rules were introduced mainly because previously it was hard to predict if an expert tax application would be approved. The old rules also required extensive documentation to show that an employee qualified as an "expert" or "key person." Employees who do not meet the criteria for the monthly income can apply for expert tax relief under the old rules. In order to qualify as an expert the individual needs to fulfill one of the following three requirements:

- ▶ Works with special tasks with a high degree of competence that is very difficult to find in Sweden
- ▶ Conducts qualified research or development projects with a specific competence or at a specific competency level that is difficult to find in Sweden
- ▶ Performs top management or executive work or similar tasks that ensure a key position in the company

Under Swedish law, the compensation should normally be paid by a Swedish company or a permanent establishment in Sweden of a foreign company. Compensation paid from a foreign payer can, under certain circumstances, be subject to expert tax.

Tax landscape for investors

Unlisted participations held by corporations are normally exempt from tax under the Swedish participation exemption, which

creates an effective tax environment for holding structures. However, it is important to note that capital losses and write-downs on such participations are correspondingly not deductible.

Individuals are normally taxed at 25% on dividends or capital gains from shares in unlisted companies. For listed shares, the tax rate is 30%. Please note, however, that very special rules apply for owners who are operative in closely held companies (see below).

Tax landscape for entrepreneurs

The taxation of individuals depends on how individuals choose to establish their businesses (sole proprietorship, partnership, limited liability company, etc.). The owner of a limited liability company is taxed on salary for work done or dividends on shares. A progressive tax rate between approximately 30% and 58% applies to income from employment.

However, very special taxation rules apply to owners who are operative in closely held companies in Sweden. These are taxed for dividend or capital gains on the shares in part as capital income and in part as employment income. Tax rates vary between 20% and 58%. A closely held company is defined as four or fewer people together owning at least 50% of the share of a company's voting power. If the owners are operative in the company's business, these specific rules could be applicable on their shareholdings. Note that the rules are very detailed and complex, and are continuously subject to amendments. For example, family members are, in this regard, treated as one person. The same goes for operative owners.

However, if an external investor (not operative in the company) owns more than 30% of the voting powers of the company, these special rules are not applied. This means that dividends or capital gain on shares are normally taxed at 25% for an owner who is an individual. The lower tax rate of 20% on dividends or capital gains for individuals is the lowest rate in Sweden. Consequently, these rules can result in a very favorable tax treatment if sufficient tax planning – before startup and ongoing throughout the holding – is carried out.

Finance

In addition to those sources already outlined above, public support may be obtained from the European Union (EU) via, for example, the FP7 program. Swedish biotech companies have been successful in this respect.

Availability of finance

Sweden has a strong economy and profitable banks. Moreover, the Sw. Företagsskatte-kommittén has submitted two first progress reports as part of the current corporate tax investigation. One of the reports (Tax incentives for venture capital, submitted in January 2012) proposes two alternative tax incentives for venture capital related to new capital invested in a company, either at establishment or in connection with a new share issue. The proposals are designed to promote venture capital investment among Swedish individuals and companies.

Regulatory environment and incentives

There appear to be no regulatory incentives (tax or otherwise) specifically targeted at biotech companies.

The Swedish Patent and Registration Office handles all issues relating to the registration and protection of patents, trademarks and design in Sweden. Currently, there is no mutual recognition of rights patented in Sweden. You can apply for a European patent at epo.org (visit the Swedish Patent and Registration Office's homepage).

The Medical Products Agency is responsible for regulations governing the approval and control of technical pharmaceutical and medicine products. Swedish medicinal legislation is essentially the same as in the rest of the EU. Read more at lakemedelsverket.se.

Compliance with the rules on chemicals is monitored by the Swedish Chemicals Agency (KemI). European Community legislation is harmonized in EU Member States, including Sweden. However, specific environmental concerns and aspects of worker protection could provide scope for deviations from the requirements in European Community regulations and directives. Read more at kemi.se.

Exemption for teachers

The legislation relating to the right to employee inventions (LAU 1949:345) regulate the extent to which the employer may be entitled to take over the rights of an employee's patentable inventions.

Paragraph one states that, "teachers at universities, colleges of higher education and other institutions with the right to teach" are exempt. This means that they are not considered to be employees as defined by the legislation.

In Sweden, teachers, researchers and doctoral students are exempt, which means that these groups own the right to their own patentable inventions, even if they are made during working hours.

However, teachers, researchers and doctoral students may agree to give up this right to those funding their research.

However, due to the Swedish participation exemption, setting up a structure with a Swedish holding company might be suitable.

Due to the very special rules regarding closely held companies, it is very important to consider whether the Swedish holding company should be owned by individuals if they would be taxable in Sweden for dividends or capital gains and, in that case, if these special rules are applicable. Without the correct tax planning, it could be expensive for individual owners to receive dividends or capital gains on shares in closely held Swedish companies.

Note also that, from a Swedish perspective, it is important to structure and localize the intellectual property (IP) to the appropriate company and jurisdiction from the start. A transfer of assets from a Swedish company to a foreign associated company is taxed as if performed to market value, which could create a taxable profit in Sweden.

On transfer pricing, Sweden generally complies with the Organisation for Economic Co-operation and Development's guidelines.

Tax-efficient structures

As described above, unlisted participations held by companies are normally exempt from tax under the Swedish participation exemption. This creates an effective tax environment for holding structures. The most usual structure is a Swedish holding company to which the acquisition debt is allocated, and one or more operative subsidiaries. Please note, however, that from 1 January 2013, extended restrictions apply on interest deductions on intercompany loans.

Structuring for the future

As discussed, Sweden has no special tax or other regulatory incentives for IP or biotech companies. However, there is currently an intense debate between industry and government on these issues. Sweden regards itself as a "knowledge-based economy" and realizes that measures need to be taken to improve conditions for business. This debate is likely to result in the implementation of new tax incentives for R&D activities in the foreseeable future.

Switzerland

The entrepreneurial culture

Switzerland encourages entrepreneurs, including those in biotechnology. There are research and development (R&D) clusters in the cantons of Basel/Baselland, Zurich, Geneva/Vaud and Ticino. All have a high concentration of companies that invest heavily in R&D. Teaming up with academic centers such as universities is common. Indeed, with its world-class universities, Switzerland offers a pool of scientists and other personnel. The Government may also reform the country's corporate tax laws to include extended credits for R&D.

The Swiss Biotech Association (SBA) is the industry's focal point (www.swissbiotech.org). In Switzerland, promoting the economy is mainly the preserve of the 26 cantons, most of which have departments responsible for doing the job.

The Swiss Technology Transfer Association (swiTT, switt.ch) is the association of technology transfer professionals who are active in the transfer of technology from institutes of public research and education, university hospitals, and other not-for-profit research organizations to the private sector. swiTT maintains swiTTlist, a portal for projects that are licensable.

Location Switzerland is the national agency that promotes Switzerland as a business location (s-ge.ch).

As the Confederation's innovation promotion agency, the Commission for Technology and Innovation (CTI) lends support to R&D projects, to entrepreneurship, as well as to the development of startup companies. CTI helps to optimize knowledge and technology transfer through the use of thematic and regional networks and platforms.

Support is generally available for R&D projects relating to scientific innovations in all disciplines. Project proposals are submitted using the bottom-up principle and are mainly selected on the basis of their innovativeness and market potential.

CTI's Venturelab program offers made-to-measure training modules for up-and-coming entrepreneurs. These modules provide the knowledge, skills and methodology needed to establish a new company and successfully transform their promising business ideas into marketable products and services. Young entrepreneurs can also benefit from professional coaching. New knowledge-intensive and technology-based companies with considerable market potential are eligible.

The CTI supports the transfer of knowledge and technology between higher education institutions and industry in a targeted and results-oriented manner. Professionally run R&D and Knowledge and Technology Transfer (KTT) networks offer small and medium-sized enterprises services that help channel technological know-how through higher education institutions and also by providing solutions for business-specific needs. In addition, innovative Swiss businesses and researchers should have development opportunities through access to international programs and networks such as EUREKA, ERANet and FP7, or European Technology Platforms (ETP).

Cluster strength

In biotechnology, Switzerland runs an interesting initiative, led by the SBA, called 1Nation1Cluster. The aim is to connect all important stakeholders for mutual progress.

Taxation

Corporate tax

In Switzerland, net income is subject to corporate income tax at federal, cantonal and municipal levels. This results in a combined effective ordinary tax rate of between 12% and 24% depending on the location. Lower rates are available in special tax regimes, i.e., for holding, principal and mixed companies (for details on the latter two see below). Unlike anywhere else, taxes qualify as a tax-deductible expense.

At the cantonal and communal level, there is an annual "capital tax." This is charged on a corporation's net equity at book value. Rates vary between 0.001% and 0.525%, depending on the canton and the tax regime applicable. Some allow corporate income tax to be credited against capital tax. Value added tax (VAT) is levied at the standard rate of 8% or at a reduced rate of 2.5% for certain industries, such as pharmaceuticals, fertilizers, pesticides and seeds.

Capital gains are generally taxed at the same rate as other income. However, capital gains from disposals of qualifying investments in subsidiaries are subject to participation relief (provided there is a minimum investment in the equity of 10%, which is held for a minimum of one year).

Relief is also granted with regard to taxes on dividends from qualifying participations (i.e., those with a minimum equity investment of 10% or where the investment has a fair market value of at least CHF1m). The tax liability may be reduced according to the proportion of net dividend income to total taxable income.

Income of the current year may be offset against losses incurred in the preceding seven years, to the extent that such losses have not yet been used to absorb profits of prior years (i.e., under a carryforward provision). Losses cannot be carried back.

There are federal guidelines on thin capitalization that are also applied by most cantons. Under these, a minimum capitalization is calculated based on the fair market value of the individual assets held. For each type of asset, only a specified percentage may be financed with debt from related parties (e.g., cash, 100%; participations, 70%; intangibles, 70%).

Depreciation may be calculated using either the straight-line (SL) method or one based on declining balance (DB). At federal level, maximum rates for intangibles are 40% (for DB) and 20% (under SL). Some cantons have favorable provisions (e.g., an immediate or one-time allowance for depreciation).

Withholding tax is levied on dividends and certain interest payments (generally on bank accounts and bonds) at a rate of 35%. No withholding tax is generally levied on interest on commercial loans. In addition, there is no withholding tax on royalties. Furthermore, it should be noted that the applicable rates may be reduced under an agreement between Switzerland and the European Union (EU) or under other similar double tax treaties. In the majority of parent subsidiary situations, including most of the significant Swiss treaty countries, the withholding tax may be reduced to 0%. In addition, actual payment and subsequent reclaim of the tax may be avoided if the respective notification formalities are followed.

Except for the purposes of VAT, the concept of a consolidated or group return is unknown in Swiss tax law. Each corporation is treated as a separate taxpayer and files its own return.

Incentives

Biotech companies may benefit from a range of general incentives:

1) Tax holidays

For up to a maximum of 10 years, cantons are free to grant full or partial relief from corporate income tax and capital taxes to newly established companies, those relocating a new business to Switzerland, and those contemplating a significant expansion of an existing business. In order to qualify for such relief, it is usually necessary to be creating new jobs, promoting innovative economic activities or sustainably developing an economic area.

At federal level, tax incentives are limited to ventures in the "Economic Renewal Areas." In these areas, companies may receive full or partial exemption from tax for up to 10 years. Tax relief is usually granted to industrial companies and production-related service firms, creating new jobs or preserving existing ones on a long-term basis. In general, tax holidays will be granted with claw-back provisions. This means the tax holiday may be revoked if the requirements for relief are not met.

2) Provisions

Federal and cantonal regulations provide that a company may record a tax-deductible reserve amounting to one-third of the value of its inventories. At the federal level and in most cantons, too,

provisions for future third-party R&D costs are allowed up to 10% of taxable profit or up to a maximum of CHF1m. Provisions to cover doubtful accounts receivable and expected liabilities are generally allowed for tax purposes if they are justified commercially. Certain lump sum provisions for accounts receivable are possible without substantiation.

3) Capitalization of R&D expenses

Under these provisions, R&D costs may be expensed or, if justified, capitalized and amortized over their useful lifetime. If the R&D expenses are capitalized, the limitation on losses carried forward for seven years can be mitigated. In that respect, it should be noted that, in general, the treatment for accounting purposes is the basis for the tax treatment.

Tax landscape for investors

In Switzerland, capital gains from the sale of shares held as a private asset by individuals are usually tax free. Furthermore, there is usually no withholding tax on interest on commercial loans, including those made by foreign parents to Swiss subsidiaries. In order to reduce economical double taxation (of corporate income as well as that from dividends), the partial taxation of dividends was introduced for Swiss residents holding a minimum of 10% of the capital of a company. The rule applies both at the federal level and the cantonal and municipal level.

As part of the latest tax reform, the capital contribution principle (CCP) was introduced at the beginning of 2011. Under this system, repayments of capital contributions directly received from shareholders after 31 December 1996

12%-24%

and disclosed in a separate account in the balance sheet of the distributing company are exempt from income tax (at the level of Swiss individual shareholders). They are also exempt from withholding tax. Any repayment of equity that fails to qualify either under the above rules or as a repayment of paid-in share capital is, however, subject to income and withholding tax.

Tax landscape for entrepreneurs

In Switzerland, tax rates vary widely because of the multilayered system. The maximum overall rate of federal income tax is 11.5%. On top of that, cantonal and municipal taxes are levied at progressive rates. The maximum combined rates (including all three levels) range from approximately 19% to 46%, depending on the location. In addition, cantons and municipalities levy net-wealth taxes.

For expatriates, an annual lump sum deduction of CHF18,000 at the federal level is allowed to cover housing fees and other such expenses (e.g., moving expenses). Similar allowances may be granted at the cantonal level. Otherwise, only minor standard deductions are available.

That said, a number of mandatory contributions are fully deductible against tax. These include the Confederation's old-age, survivors and disability insurance with a contribution rate of total 10.3% as well as the cost of insurance against

unemployment, all split equally between employee and employer. Also deductible are contributions to the (mandatory) company pension fund. Rates vary according to the plan, gender and the age of the employee. The employer must bear at least half of the total contribution. Some contributions toward individual savings are also tax-deductible up to a certain level.

Finance

The Swiss National Science Foundation (SNSF) is Switzerland's leading provider of scientific research funding. Annually, the SNSF supports some 8,500 researchers, almost 80% of whom are aged 35 or younger. With its federal mandate, it supports basic research in all disciplines, from philosophy and biology to the nanosciences and medicine.

The focus of its activities is the scientific endorsement of projects submitted by researchers. The best applicants are funded by the SNSF with an annual total amount equaling approximately CHF750m.

Established in 1952 as a foundation under private law, the SNSF has the autonomy it needs to promote independent scientific research. The SNSF is committed to promoting young scientists and works to ensure that scientific research in Switzerland has the most favorable conditions for developing internationally. It also encourages dialogue between scientists and representatives in society, politics and the economy.

Availability of capital

In general, capital is available in Switzerland, either from business angels family offices or specialist venture capitalists. In addition, compared to some of their competitors, Swiss banks are in good health, which may be of advantage in financing discussions.

See also the data analysis presented in the Swiss reports on biotechnology (swissbiotechreport.ch), published annually since 2004.

Regulatory environment and incentives

There are a variety of legal provisions in Switzerland relating to biotechnology, particularly for research. Federal laws and ordinances regulate therapeutic products and medicines as well as genetic engineering, agriculture, protection of the environment and food. There are also supervising authorities. The cantonal ethics committees, the Swiss Agency for Therapeutic Products, Swissmedic, the Federal Office of Public Health (FOPH) and the Federal Office for the Environment (FOEN) are responsible for implementation of the Human Research Act (HRA). Additional information on the implementation of the HRA can be found at kofam.ch.

Swiss law provides for the protection of intellectual property (IP), such as patents and trademarks, as well as copyright and related protection. So enterprises may protect their innovations and turn their ideas into industrial property (ige.ch).

There is also support for start-ups. The Swiss National Science Foundation in Bern (snf.ch) is the point of contact for basic and targeted research. The Commission for Technology and Innovation deals with applied R&D (kti-cti.ch). Individual cantons also offer help to firms starting up.

In addition, Switzerland takes part in programs such as the EU Framework Program for Research and Technological Development or the European Cooperation in the field of Scientific and Technical Research (euresearch.ch and www.hfsp.org respectively).

Structuring for the future

Tax-efficient structuring

As mentioned, in Switzerland, there is usually no capital gains tax levied on shares held as a private asset when disposed of by individuals. At a corporate level, tax relief is granted for capital gains on investments if certain requirements are met.

In certain circumstances, a securities transfer tax can apply on an acquisition/disposal, dependent upon the particular holding structure applied.

Federal guidelines provide for a special tax regime for what are known as principal companies, which can apply to those specializing in biotechnology. A Swiss company within an international group may be treated as a principal company if:

- (i) The firm assumes risks and responsibilities for activities such as purchasing, R&D, manufacturing, marketing, distribution and logistics.

8,500

(ii) Manufacturing is usually performed outside Switzerland on a contract or toll basis.

(iii) Sales are conducted outside the country through related parties that operate as commissionaires or limited risk distributors and meet certain other requirements.

In such cases, taxable income may be reduced by a maximum of 50% at the federal level and taxation is as a mixed company at the cantonal level. This results in an overall effective tax rate of between 4.5% and 9%, depending on activities and location.

Another benefit is that, subject to certain requirements (see above), companies may qualify for tax holidays. This may reduce the effective tax rate in the best case to 0% for a period of up to 10 years.

The status of a mixed company is, as discussed above, available at the cantonal and municipal level. To secure such a status, a company needs to be engaged predominantly abroad, with only minor involvement in the Swiss domestic market. Usually, this means having at least 80% of its income sourced from abroad and a similar percentage of expenses

related to foreign activities. However, the requirements vary from canton to canton. In the best case, the status secures an effective tax rate of as low as 8%-12%, depending on the location.

A company with its statutory seat in the Canton of Nidwalden is entitled to run, within its normal business, a "license box" to which IP and R&D activities, as well as related income and royalties, can be attributed. So far, the arrangement is only available in Nidwalden, but there is talk of other cantons doing the same. The definition of "royalties" matches that in article 12 of the convention drawn up by the Organisation of Economic Cooperation and Development. Income from both domestic and foreign sources may benefit equally from the license box, including capital gains. In addition, expenses incurred for R&D and other activities in connection with the license income are deductible. The residual income is subject to an effective tax rate of 8.8%.

Although some of the above tax regimes, in particular the concept of the mixed company, are currently under scrutiny by the EU, alternatives are being sought for and should be available in time, before the current regimes are phased out.

The United Kingdom

The entrepreneurial culture

The UK Government is very keen to support entrepreneurs and tech spin-outs, and constantly reviews the fiscal environment and environment for doing so. Support for entrepreneurs can be seen in the tax framework, where a tax-efficient enterprise management incentives share scheme has been recently reformed to allow a 10% rate of tax on gains for employees. Changes have also been made to entrepreneurs' relief to ensure share options can also be taxed at a lower rate.

Spin-out companies' ability to raise finance is supported by the tax breaks afforded to investors through the Enterprise Investment Scheme, and more recently the Seed Enterprise Investment Scheme, which provides a very favorable tax structure for equity investors.

The UK Intellectual Property Office provides intellectual property support to new companies (ipo.gov.uk).

The UK Government has a single website for all aspects of trade and industry, bis.gov.uk. Business Link is the UK Government's online resource for businesses. It contains all essential information, together with details about support and services for business, whether for a large organization or one that is just starting up (businesslink.gov.uk).

StartUp Britain is a campaign run by entrepreneurs for entrepreneurs, which was launched in March 2011. Designed to celebrate, inspire and accelerate enterprise in the UK, has broad Government support (startupbritain.org).

The Technology Strategy Board (TSB) is the UK's national agency for innovation. Its goal is to accelerate the pace of economic growth by stimulating and supporting business-led innovation. To this end, the TSB manages a number of publicly funded programs, including Knowledge Transfer Partnerships (innovateuk.org).

Enterprise Zones help areas with problems to create new businesses and jobs. Companies operating from such zones benefit from flexible planning regulations. They also pay lower business rates (bis.gov.uk).

Taxation

Corporate tax

The main rate of corporation tax is 23% reducing to 21% effective 1 April 2014 with a further reduction to 20% effective 1 April 2015.

There has been a confirmation of the increase in the annual investment allowance to £250,000 for two years, with effect from January 2013. This provides immediate tax relief for the first £250,000 of capital spend each year. It will be of particular relevance to groups looking to make material capital investments.

Patent box

The patent box regime offers a 10% headline tax rate in respect to qualifying profits. The patent box has been in the UK tax reform pipeline since 2009, but the rules have now been enacted and the regime has been live since 1 April 2013. Now more than ever, groups need to assess the impact of the regime and make sure

that they meet the qualifying criteria to harness the benefits (hmrc.gov.uk/ct/forms-rates/claims/patent-box.htm).

Tax losses

In the UK, there is no limit on the extent to which tax losses, including those for start-ups, can be carried forward. Nor is there a limit on how much of the loss can be utilized in any one year. The UK currently gives full relief on interest costs arising from financing structures, providing they are charged at arm's length and providing they are not restricted by the worldwide regulations on debt caps. Broadly, these rules restrict interest cost where the UK net debt is greater than 75% of a group's external gross debt worldwide.

Incentives

R&D credit

From April 2013, the R&D credit regime for large groups has been significantly enhanced. The new Above The Line (ATL) credit will help fund UK R&D. As a consequence, the UK Government hopes to make UK R&D centers more attractive and globally competitive.

Under the current regime, R&D credit is given as a 130% super-deduction for qualifying R&D spend.

The ATL credit will be:

- ▶ Available at the headline rate of 10%
- ▶ Taxable
- ▶ Fully payable, net of tax, to companies with no corporation tax liability (subject to cap)
- ▶ Administered and settled through the corporation tax system

The ATL credit will be introduced alongside the existing super-deduction in April 2013 and fully replace the super-deduction from April 2016 onward.

The ATL credit will be particularly attractive to companies that are loss-making for UK tax purposes, as the credit will be payable in cash. Currently, the R&D credit only increases the company's loss pool.

The payable credit will be limited to the amount of a company's total Pay As You Earn (PAYE) and National Insurance contribution liabilities in relation to staff engaged in qualifying R&D activities in the accounting period. This cap will apply to the credit after the offset of the claimant's current-year corporation tax liability. The amount up to the cap can be utilized in a variety of ways, including being group relieved or offset against the company's other tax liabilities. The excess over the cap will be treated as an ATL credit in the following accounting period, and can be carried forward indefinitely.

For small and medium enterprises, the 225% super-deduction will remain. This credit provides targeted support for early-stage companies investing in R&D in the UK.

Tax landscape for investors

The UK is increasingly a more attractive holding location for corporate investors due to:

- ▶ A low headline rate of corporation tax
- ▶ The broad-based exemption from UK corporation tax on dividends received by UK companies

Under tax law that came into effect on 1 July 2009, dividend income of a UK company that comes from both UK and non-UK sources should be exempt from corporation tax if a number of qualifying conditions are met. Although it is necessary to undertake some due diligence to ensure that one of the qualifying conditions will apply, the exemption is broad-based and is a full, 100% exemption, which does not contain a “minimum shareholding” test, a “period of ownership” test, or a requirement that considers the activities of the payer or how the payer is taxed. On the assumption that a UK holding company controls a group company or it holds 100% of the ordinary share capital of a group company, it should be possible for the UK holding company to qualify for this exemption, such that dividend income received from the group company should not be subject to corporation tax.

- ▶ No outbound dividend withholding tax
- ▶ An extensive treaty network

The UK has tax treaties with more than 100 jurisdictions and benefits from access to the European Union (EU) Interest and Royalties Directive and EU Parent-Subsidiary Directive.

- ▶ Generous interest deductibility rules

Traditionally, the UK has been viewed as a beneficial territory for tax-efficient financing, due to its relatively generous provisions available for interest deductions, notwithstanding the anti-avoidance provisions in place to stop “excessive deductions” (thin cap, arbitrage, debt cap, unallowable purpose, etc.). This can produce a much more favorable and commercial result than the rules in territories that apply strict limitations, or mathematical formulae-based approaches.

- ▶ Exemption (by election) of foreign branch profits from corporation tax

With effect from 1 January 2012, UK companies may elect to exempt the profits earned by their foreign branches from corporation tax. This exemption will be attractive to companies with branches in low-tax foreign locations, where additional “top up” UK corporation tax would be payable in the absence of the election.

- ▶ Controlled foreign corporation (CFC) reform

CFC reform has been on the agenda as part of the wider overhaul of the taxation of foreign profit since June 2007. There are a number of factors that have driven the need to reform the CFC regime, including a stated desire to create the most competitive tax system in the G20, the need to update an old piece of legislation to reflect modern business practice, and the requirement that the regime is EU-law compliant.

It is intended that the new regime will target situations that pose a high risk of artificially diverting UK profits and will ensure that if a CFC charge arises it will only be applied to the proportion of overseas profits that have been artificially diverted from the UK.

► **Substantial Shareholding Exemption (SSE)**

The SSE exempts any gain on the disposal of a qualifying holding of shares for the requisite period. Any disposal of shares in a group company by a UK company will be regarded as a taxable disposal. A taxable gain will initially arise to the extent the consideration or market value of the shares disposed of exceeds their acquisition cost (less indexation allowance). However, this taxable gain can, under many circumstances, be exempt from UK corporation tax where the conditions of the SSE are satisfied. In most cases involving the disposal by trading groups of shares in companies that carry out trading activities rather than investment activities, the SSE will typically apply.

► **Enterprise Investment Schemes and Venture**

Capital Trusts also offer tax incentives to stimulate personal investment. These schemes were recently further extended.

Tax landscape for entrepreneurs

The recent increase in the lifetime limit for entrepreneurs' relief on tax from £5m to £10m has given the UK an advantage over many competitors.

Finance

The UK Government provides a number of grant funding opportunities for biotech companies, primarily through the TSB.

The most important of these has been the Biomedical Catalyst, a £180m fund to support translational research through non-dilutive grants at various stages of development (including feasibility, early and late) of up to £2.4m. These provide 50% of project funds, with the remaining 50% matched by the company. Since its launch in April 2012, the fund has supported over 100 projects and raised almost £70m of additional private finance. The Biomedical Catalyst was provided with extra funding to continue into 2015/16 as part of the recent UK Government Spending Review in June 2013. It is a key part of the UK funding landscape.

The TSB also runs other specific funding platforms. Health care is the biggest expenditure within its budget. This includes, for example, specific grant funding opportunities for regenerative medicine companies.

The UK has also established a number of "catapult" centers to advance collaborative research in specific areas. These include a Cell Therapy Catapult and a Stratified Medicines Catapult to support the regenerative and stratified medicine sectors, respectively.

The UK Government has invested £100m into the Genomics England initiative to support the genome sequencing of 100,000 cancer and rare-disease patients and provide a stratified medicine platform for the UK to make use of the move toward regenerative medicine.

The UK Government is investing £28m in the National Biologics Industry Centre, which will provide cutting-edge facilities and expertise for companies to engage with on biological manufacturing.

Local enterprise partnerships are held between local authorities and businesses that play a role in determining the priorities facing a community. Not only are they a means of spurring decentralization, they are also a way for local authorities and businesses to work together in order to quicken the pace of economic recovery ([businesslink.gov.uk/finance and communities.gov.uk/localgovernment/local/localenterprisepartnerships](https://businesslink.gov.uk/finance-and-communities.gov.uk/localgovernment/local/localenterprisepartnerships)).

Other useful websites include:

- ▶ bis.gov.uk/RGF
- ▶ innovateuk.org

Regulatory environment and incentives

Apart from offering incentives for R&D, as described above, the UK's tax regime also provides for relief on the amortization of intangible assets, such as patents, trademarks and other forms of intellectual property.

Recent changes to the UK's regulatory system could also be seen as advantageous to companies looking to operate there. However, they are at an early stage. The changes include switching to a single regulator for research and a streamlined process of approval at a local level.

The UK Government has established the National Office for Coordination of Research Infrastructure (NOCRI; nih.ac.uk). This new body has been set up to help the public, as well as those in charities and industry, to work in partnership with government.

NOCRI supports partners by research signposting; for example, helping them to navigate clinical research and find experts, as well as facilities and technologies. NOCRI also helps to develop collaborative research partnerships. A model agreement has been developed to streamline contracting for partnerships involving those within pharmaceuticals and biotechnology, as well as universities and organizations in the National Health Service (NHS).

Significant funding has been provided to the National Institute for Health Research and NOCRI to support NHS infrastructure to the tune of about £800m over five years.

An Innovation Office has been created within the Medicines and Healthcare Products Regulatory Agency to provide more active support and guidance for the development and regulation of ground-breaking and innovative products.

The UK Government has now introduced the Early Access to Medicines Scheme (EAMS). The scheme envisages a three step process to speed medicines to patients in an unlicensed setting and outside of ongoing clinical development for areas of unmet medical need. The EAMS includes a new Promising Innovative Medicine (PIM) designation. Such a PIM will be an important signal for a company to give to potential patients and investors that

they are developing an innovative product in an expedited and efficient regulatory process. Achieving a PIM designation and going through the new EAMS route will allow for companies to receive a “all hands on deck” approach from the UK regulatory and public bodies. The EAMS also comes with a commitment to create a new route for NICE assessment and rapid commissioning post-license to speed uptake and reimbursement for those products and is likely to have a positive effect on the companies developing these products and the investment community’s perception of them.

Structuring for the future

From the perspective of an individual shareholder, the key to setting up new ventures in biotechnology is to structure shareholdings correctly from the outset. This may help an applicant to not only qualify for entrepreneurs’ relief, but also help offer incentives for management, so that the company is able to manage its affairs for the medium and long term.

Tax-efficient structures

In the UK, there are structures that provide for the sale of operations free of tax for corporate holders disposing of shares in a biotechnology company. Similarly, there are structures that enable investors to benefit from entrepreneurs’ relief for individual shareholders in such companies.

Finance Company Partial Exemption (FCPE)

The FCPE, which forms part of the overhaul of the CFC regime, generates an opportunity to establish a low-tax platform for non-UK lending with limited tax risk. Where the exemption is available it will, in most situations, give rise to an effective 5.75% corporation tax rate on profits from overseas intergroup finance income by the year 2014. There are also limited situations where a full exemption is achievable.



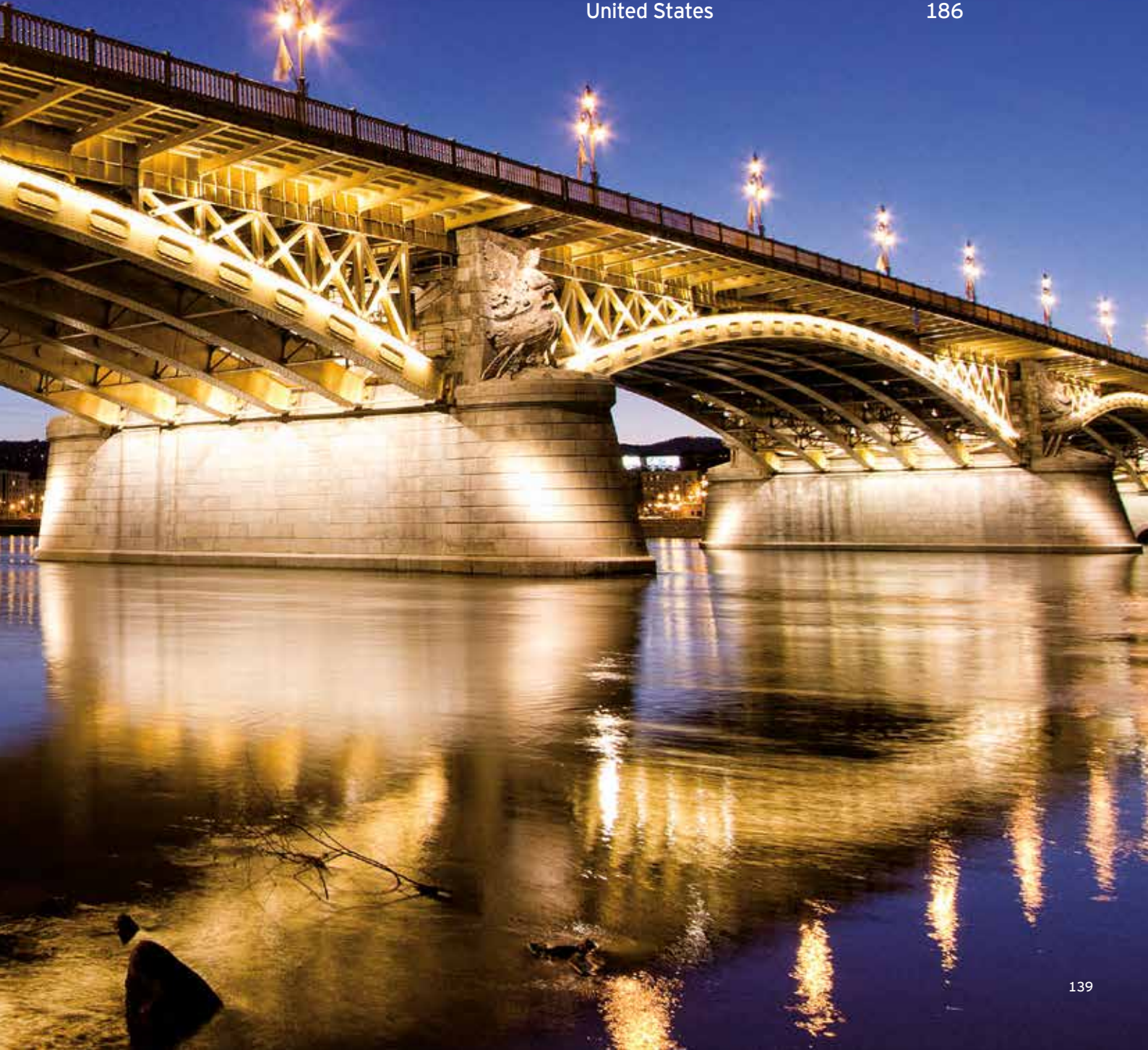
Non EU country profiles





Index

Australia	140
Brazil	144
Canada	148
China	152
India	162
Japan	174
Singapore	178
South Korea	182
United States	186



Australia

This chapter is based on information current as of 1 September 2013.

Overview

The Government introduced R&D incentives programs in order to encourage Australian industry and undertake R&D activities. The programs form part of the creation of an environment that is conducive to increased commercialization of new process and product technologies developed by eligible companies. The current R&D Tax Incentive regime has been in operation since 2011, superseding the previous R&D Tax Concession regime introduced in 1986.

Currently, a 45% refundable tax offset is available to eligible R&D entities with a turnover of less than €20 million per annum. A non-refundable 40% tax offset is available for all other eligible R&D entities. Foreign-owned R&D may qualify for the 40% or 45% tax offset depending on its group turnover.

2013 tax rates

Top corporate income tax rate (federal and state average)	30% ¹
Standard goods and services (GST) tax rate	10% ²

¹ Subsection 23(2) of the Income Tax Rates Act 1986.

² Section 4 of the A New Tax System (Goods and Services Tax Imposition – General) Act 1999.

Incentives available

Names of incentives	R&D Tax Incentives
Types of incentives	Tax credits

R&D tax incentive

Description of benefits

- ▶ A 45% refundable tax offset is available for eligible R&D entities with a turnover of less than \$20 million per annum.
- ▶ A nonrefundable 40% tax offset is available for all other eligible R&D entities.
- ▶ Foreign-owned R&D can qualify for the 40% or 45% tax offset depending on its group turnover.
- ▶ It has been proposed that from 1 July 2013 there will be an exclusion to the R&D Tax Incentive, whereby companies with aggregate assessable income of \$20 billion or more would no longer be eligible to access the 40% nonrefundable tax offset. However, at the time of writing, this proposal had not yet been passed into law.
- ▶ Unutilized tax credits may be carried forward indefinitely.

Guidelines around incentive applications

The R&D Tax Incentive program is applicable to current investments. Claiming the benefit is a two-part process:

- ▶ The R&D activities are registered by lodging an application with AusIndustry.
- ▶ The R&D Tax Incentive schedule is lodged in the company tax return using a unique registration number from AusIndustry.

Companies are required to register eligible R&D activities within 10 months of the end of the income year in which the activities were conducted.

Eligibility requirements

Eligible R&D activities are categorized as either “core” or “supporting” R&D activities. Generally, only R&D activities undertaken in Australia qualify for the new R&D Tax Incentive program. Core R&D activities are broadly defined as experimental activities whose outcome cannot be known and which are conducted for the purpose of acquiring new knowledge. Supporting activities may also qualify if they are undertaken to directly support the core R&D activities. Exceptions that are required to pass a higher dominant purpose test are supporting R&D production trials and other “excluded” activities as defined. Software-related projects may also be core or supporting R&D activities unless their dominant purpose is one of internal administration, in which case it will be classified as an excluded activity. An additional eligibility test may apply.

Eligible expenditure is defined as expenditure incurred by an eligible company during an income year, including contracted expenditure, salary expenditure and other expenditure directly related to R&D. Core technology, interest expenses, some plant and equipment costs, and feedstock costs are not eligible.

Eligible companies are those incorporated in Australia or foreign companies resident in a country that has a double taxation treaty with Australia carrying on business through a permanent establishment in Australia. An entity whose entire income is exempt from income tax is not eligible. No industry sectors are specifically excluded.

IP and jurisdictional requirements

Generally, companies must demonstrate that R&D activities are undertaken on their own behalf in order to claim the incentive. Activities conducted by the R&D entity for one or more foreign corporations that are related to the R&D entity (called foreign-owned R&D) may qualify for the R&D tax incentive provided the R&D contract arrangement is undertaken with a company resident in a country with which Australia has a double taxation agreement. Eligibility of work performed outside the country requires pre-approval through an Overseas Finding Application. The IP regimes are effective as of 1 July 2011.

Role of governmental bodies in administering incentives

The R&D Tax Incentive operates on a self-assessment basis and is jointly administered by the Australian Taxation Office (ATO) and AusIndustry. AusIndustry regulates and monitors compliance activities in the assessment of the technical eligibility of activities, while the ATO regulates and undertakes compliance activities in relation to notional deductions and correlated tax offsets.

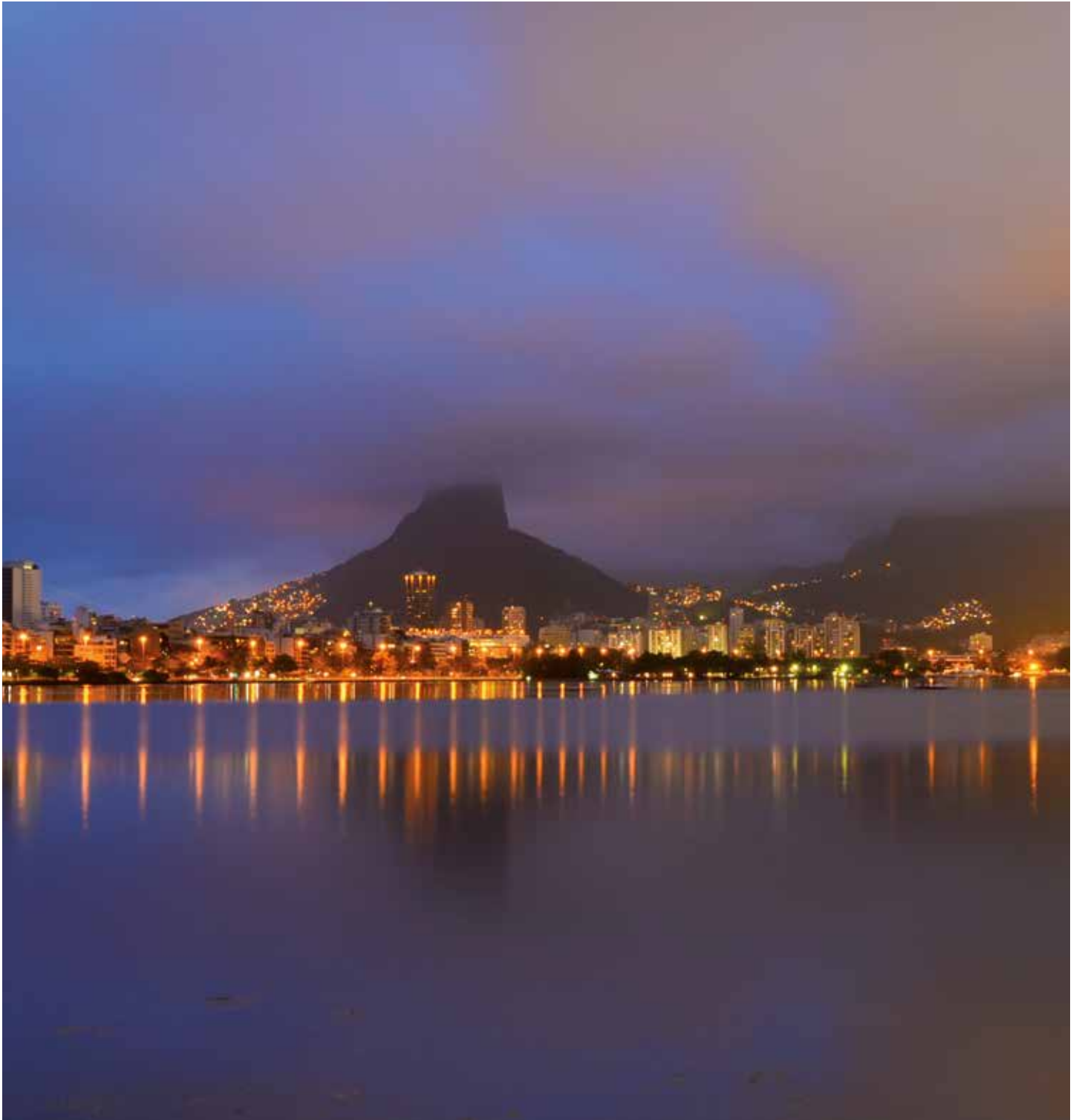
Administrative requirements

Companies must register annually with AusIndustry within 10 months of the relevant corporate financial year-end. Also an advance finding ruling process is available, which enables companies to seek certainty on project. This provides companies with eligibility certainty for a period of up to three years.

Companies must maintain contemporaneous records in order to substantiate their R&D Tax Incentive claim. The company's records must be sufficient to show that the claimed activities took place and that they meet all aspects of the definition for either core or supporting R&D activities.

Statutory reference

- ▶ Statutory reference – Division 355
- ▶ Year of statutory regime – 1 July 2011



Brazil

This chapter is based on information current as of 1 September 2013.

Overview

The Brazilian Government has been a strong supporter of R&D activities in various segments in Brazil. At the end of 2005, the Government created a tax incentive for R&D, which commenced in 2006. Currently, the Government offers super deductions of 160%-200% to taxpayers with eligible R&D expenses, financial support to new R&D investments and accelerated depreciation on qualifying R&D assets. Through the R&D incentives, the Government attempts to achieve technological innovation, product innovation and enhanced R&D activities.

“Technological innovation” refers to the design of a new product or manufacturing process and addition of new functionalities or characteristics to the product or process that leads to incremental improvements and an effective quality or productivity gain. “Product innovation” refers to the improvement of new and/or existing products in the domestic or international markets. “Enhanced R&D activities” refers to basic research, applied research, experimental development, basic industry technology and technical support services.

2013 tax rates

Top corporate income tax rate (federal only)	34%
Standard VAT (ICMS) rate	
▶ General rates 0%-25% transactions	17%-19% ¹
▶ ICMS rate on interstate transactions	4%-12% ²
Federal VAT (IPI) rates	0%-20% ³
Federal social contributions (VAT-type taxes) on revenues (PIS/COFINS)	3.65%-9.25% ⁴

¹ Article 3, Law 9,249/1995, and Article 3, Law 7,689/1988.

² Each state determines its respective ICMS rates.

³ Decree 7,660/2011. Higher rates are applied on luxury or superfluous goods.

⁴ Article 2, Law 10,637/2002, and Article 2, Law 10.833/2003.

Incentives available

Names of incentives	R&D deduction*	Accelerated depreciations	Funding authority for studies and projects
Types of incentives	▶ Super deduction	▶ Accelerated depreciation on qualifying R&D assets	▶ Financial support

*Although not based upon scientific analysis, EY clients report that this incentive delivers the most beneficial results to investors.

R&D deduction

(Inovação Tecnológica)

Description of benefits

A super deduction of 160% to 200% is available to taxpayers with eligible expenses. If a company has additional researchers compared to the previous year, it may apply for the extra deduction (from 160% to 180%). In addition, if a company registers IP in Brazil, an extra 20% deduction is available. The R&D deduction is applicable to expenses incurred by Brazilian entities and contract research or greenfield investments are not normally eligible. Unused R&D deductions may not be carried forward or carried back. In order to receive the R&D deduction, taxpayers are required to present Tax Clearance Certificates to the tax authorities, however, no pre-approval process is required in order to obtain the R&D deduction.

Taxpayers can also receive a reduction on IPI, Imposto sobre Produtos Industrializados (federal excise tax), for eligible R&D activities. Under the IPI reduction, 50% reduction is available on the IPI levied on instruments, equipment, machinery, apparatus and tools imported

by Brazilian companies or dedicated to R&D activities performed in Brazil. In order to receive the IPI reduction, taxpayers are required to claim the incentive upon requesting the acquisition.

Guidelines around incentive applications

The R&D deduction is applicable for current year investments; for example, if a company has R&D expenses in 2013, they may apply for the incentive considering expenses occurred from January to December of 2013. The R&D deduction is claimed in the income tax return; for instance, expenses occurred in 2012 should be claimed on the tax return delivered to the Brazilian IRS (Receita Federal do Brasil), in 2013.

Accelerated depreciation

(Depreciação Acelerada)

Description of benefits

R&D legislation allows the companies to accelerate the depreciation on R&D assets for tax purposes only. Depreciation of 100% is available on eligible R&D assets in the year of their acquisition.

Guidelines around incentive applications

Accelerated depreciation is applicable to current investments. The incentive is claimed in the income tax return; for instance, expenses occurred in 2012 should be claimed on the tax return delivered to Brazilian IRS in 2013.

Funding authority for studies and projects

(Financiadora de Estudos e Projetos (FINEP))

Description of benefits

Financial support with reduced interest rates is available to new R&D investments of Brazilian companies. The fund provided by the Government can provide such funding for up to 90% of the total project costs. The incentive requires a preapproval process to be followed.

Guidelines around incentive applications

Financial support is applicable to current and future investments. In order to claim the incentive for future investments, taxpayers are required to follow procedures set out by the Government. In addition, taxpayers are also required to meet with specific requirements set by FINEP.

Eligibility requirements

Eligibility is not limited to a specific industry. Under Law No. 11.196/2005, technological innovation is defined as "the conception of a new product or production process, as well as the inclusion of new functionalities or characteristics in the product or process resulting in additional improvements, effective quality or productivity increase, as well as competitiveness increase in the market."

Generally speaking, innovation activities eligible for tax benefits are related to scientific and technological stages adopted by taxpayers in the development and implementation of products and/or processes, resulting in productivity gain and incremental improvements. Qualifying expenses include payroll costs, materials, machines, equipment, raw materials for tests and some local expenses directly related to the R&D in Brazil. Third-party costs can also be considered; however, there are specific rules to follow in order to obtain the incentive.

IP and jurisdictional requirements

The IP must be registered and owned locally to obtain the increased R&D tax incentive of 20%. However, the company can apply for the R&D tax incentive locally without registering IP in Brazil.

Role of governmental bodies in offering incentives

The Ministry of Science and Technology (MCTI) fulfills an important role in administering the incentives because it must approve and control the application of tax benefits by qualifying the applicable projects. Only MCTI has the appropriate skills to analyze the projects presented by companies. The Brazilian IRS maintains its audit role in relation to incentives with tax impact and may (or may not) investigate some accounting and fiscal aspects focused on the R&D incentives.

Administrative requirements

Only companies that adopt the methodology of "taxable profit" (Lucro Real) on a quarterly or annually basis may apply for the R&D tax incentive. The companies should fill out the income tax return annually in order to maintain compliance. Also, companies that apply for this incentive should have tax clearance certificates that are valid for the full period (January to December of the respective year). In addition, companies must annually complete a specific R&D form and submit it electronically to MCTI.

Statutory reference

- ▶ The Federal Law No 11.196 – year 2005
- ▶ Decree No. 5.798 – year 2006
- ▶ Normative Instruction No. 1.187 – year 2011

Canada

This chapter is based on information current as of 1 September 2013.

Overview

The federal Scientific Research and Experimental Development (SR&ED) program is a tax incentive program designed to encourage economic development and job creation in Canada. The SR&ED program is the largest source of federal funding for industrial R&D performed in Canada and is well regarded by business. The program is a tax incentive program (as opposed to a grant program) and is demand driven. There is no ceiling on how much the Government may pay out to claimants in any particular year.

Legislation governing the program is contained in the federal Income Tax Act and Income Tax Regulations and, is therefore the responsibility of the Department of Finance. However, the Canada Revenue Agency (CRA) is responsible for the program's

administration. In recent years, the CRA has been working on administrative improvements directed at simplifying the claim process, increasing the scientific capacity of the program and improving consistency with respect to processing SR&ED claims across the country.

The federal Government has provided tax assistance for R&D since 1944. Although investment tax credits (ITCs) were introduced for SR&ED expenditures in 1977, the program as it exists today was developed in the 1980s.

2013 tax rates

General corporate income tax rate (federal/provincial/territorial average)	27.59% ¹
Standard VAT rate (federal/provincial/territorial average)	5%-15% ²

Incentives available

Names of incentives	SR&ED*	Accelerated capital cost allowance (CCA) rate and manufacturing or processing (M&P) tax credit
Types of incentives	Tax credit	Accelerated depreciation and tax credit on the R&D Asset

*Although not based upon scientific analysis, EY clients report that this incentive delivers more beneficial results to investors.

¹ EY Canada corporate tax rates June 2013. The federal rate on general income is 15%, and the provincial/territorial rate on general income ranges from 10% to 16%, resulting in income earnings and earnings derived from manufacturing and processing. A combined federal-provincial average tax rate of 27.59%. The federal Government and the provincial and territorial governments may apply lower tax rates to active small business.

² EY Canada summary.

SR&ED

Description of benefits

A 20% federal tax credit is available on eligible activities and expenditures. This federal tax credit will decrease to 15% for taxation years ending after 2013 and will be pro-rated for taxation years straddling 1 January 2014. The credit rate is increased to 35% for small Canadian-controlled private corporations (CCPCs) on the first C\$3 million of expenditures per year. CCPCs in general must be private corporations, resident in Canada not controlled directly or indirectly by one or more nonresident persons or public corporations. The 35% credit is 100% refundable for non-capital-related expenditures and 40% refundable for capital expenditures. The C\$3 million expenditure limit is reduced where the preceding year's taxable income for the corporation and associated corporations exceeds a threshold linked to the maximum small business deduction business limit for the year and when the taxable capital of the corporation (or associated group) for the preceding year exceeds C\$10 million. In addition, the annual expenditure limit must be shared among associated corporations. Unused R&D tax credits may be carried forward to 20 years and carried back for three years.

For the provincial and territorial incentives, tax credits range from 4.5% to 37.5% depending on the provincial or territorial jurisdiction. The majority of provincial and territorial jurisdictions offer refundable credits.

Guidelines around incentive applications

SR&ED is applicable to retroactive and current investments provided they are claimed within 18 months of the fiscal year-end. To benefit from the SR&ED tax incentives, a claimant generally must carry on business in Canada in the year; perform eligible SR&ED work that is related to the business of the claimant; and complete and file Form T661, Scientific Research and Experimental Development Expenditures Claim, as well as Form T2SCH31 (Schedule 31), Investment Tax Credit – Corporations, or Form T2038 (IND), Investment Tax Credit (Individuals), as applicable. The reporting deadline is 12 months after the filing due date of the return for the fiscal period in which the expenditures were incurred.

Accelerated capital cost allowance (CCA) rate and manufacturing or processing (M&P) tax credit

Description of benefits

The year 2013 was the last year when certain R&D qualifying assets will be eligible for immediate deduction and SR&ED tax credits under the SR&ED program. However, to the extent certain R&D assets are used in connection with a taxpayer's eligible manufacturing and processing activities these assets may qualify for Class 29 property classification. Class 29 assets may be depreciated over a three-year period. The same assets may also qualify for federal and/or provincial manufacturing or processing investment tax credits ranging from 5% to 10% (or more) of the qualifying expenditures. Certain R&D assets may be eligible for other accelerated depreciation property classes such as Class 50 computer hardware which has a 55% capital cost allowance depreciation rate.

Guidelines around incentive applications

The opportunity for capital assets used in SR&ED activities to qualify for accelerated depreciation property classes (e.g., Class 29 and 50) is applicable to current, prior and future year projects. A taxpayer may amend prior year corporate tax filings (i.e., revise capital asset classifications) to access classification opportunities to the extent the years are not statute barred. With respect to property that is eligible for M&P tax credits, the credits must be claimed by the taxpayer on their corporate

tax returns (federal and/or provincial) within 18 months of the year the property was acquired.

Eligibility requirements

SR&ED is defined as a systematic investigation or search that is carried out in a field of science or technology by means of experiment or analysis that is basic research, applied research or experimental development and includes work undertaken by or on behalf of the taxpayer with respect to engineering, design, operations research, mathematical analysis, computer programming, data collection, testing or psychological research where the work is commensurate with the needs and directly in support of the basic research, applied research or experimental development. The work must be undertaken in Canada. Qualifying SR&ED expenditures may include labor, materials consumed or transformed, subcontracts (SR&ED performed on taxpayer's behalf), leased equipment, other expenses directly related and incremental to the SR&ED, third-party payments and capital equipment. Starting in 2013, the inclusion rate for subcontractor costs was reduced to 80%. Starting in 2014, lease and capital costs are no longer eligible. The SR&ED incentive is not limited to particular industries.

IP and jurisdictional requirements

SR&ED must be carried on by the taxpayer in Canada.

Role of governmental bodies in administering incentives

The legislation governing the SR&ED program is contained in the federal Income Tax Act and Income Tax Regulations, which are the responsibility of the Department of Finance. The CRA is responsible for the program's administration, including review and assessment.

Administrative requirements

Form T661, Scientific Research and Experimental Development Expenditures Claim, as well as Form T2SCH31 (schedule 31), Investment Tax Credit (Corporations), or Form T2038, Investment Tax Credit (Individuals), must be completed and filed with prescribed information. The reporting deadline is 12 months after the filing due date of the return for the fiscal period in which the expenditures were incurred.

Statutory reference

- ▶ Canadian Income Tax Act – Section 37, 127, Regulation 2900
- ▶ Canadian Income Tax Act – Sections 20(1)(a), 127(9), Regulations 4600, 5202, Schedule II of Regulations – Class 29, 50

China

This chapter is based on information current as of 1 September 2013.

Overview

Most of the R&D incentives have been available in China for many years, and overall, the regime is becoming more mature with constantly issued laws and regulations. However, as some regulations are still not explicit, authorities in different locations may have different interpretations and treatments regarding R&D incentives.

The Government encourages R&D activities, while taking a stringent position on the approval of R&D incentives. A pre-approval or information registration is required to claim R&D tax benefits. Taxpayers need to submit all relevant information including the R&D project budget, descriptions of specific R&D projects, categories of R&D expenditure, and management or board meeting documents authorizing R&D project(s) to the Government as early as possible.

China offers incentives to taxpayers eligible for the technologically advanced service enterprise (TASC) and the high-new technology enterprise (HNTE) status. TASC and HNTE refer to those companies with advanced technologies and qualified personnel to produce products or provide services. It also provides pre-tax super deductions of 150% on qualifying R&D expenditures incurred during the year. In addition, China provides CIT exemption for the transfer of qualified technologies.

2013 tax rates

Top corporate income tax rate (federal and state average)	25% ¹
Standard VAT rate	17%, 13%, 11%, 6%, 0% ²

¹ Article 4 of China CIT Law, effective from 1 January 2008.

² According to VAT pilot arrangements, the applicable VAT rates for general VAT taxpayers regarding VAT pilot services are as follows: 11% – according to VAT pilot arrangements (Caishui 2013 No.37), the applicable VAT rates for general VAT taxpayers regarding the transportation services will be subject to 11% VAT rate; 6% – according to VAT pilot arrangements, the applicable VAT rates for general VAT taxpayers regarding certain modern services (including R&D and technology services, information technology services, cultural and creative services, logistics auxiliary services and authentication and consulting services) will be subject to 6% VAT rate; 0% – according to VAT pilot arrangements (Caishui 2013 No.37), the applicable VAT rates for general VAT taxpayers regarding the taxable services specified by the Ministry of Finance and State Administration of Taxation, such as providing international transport services or R&D services and design services to overseas entities will be subject to 0% VAT rate. In addition, most of the goods exportation will be subject to 0% VAT rate.

Incentives available

Names of incentives	Incentives for technologically advanced service company (TASC) status*	Incentives for high – technology and new-technology enterprises (HNTE) status	R&D expenses super deduction	Incentives for qualified technology transfer income
Types of incentives	<ul style="list-style-type: none"> ▶ Reduced tax rates 	<ul style="list-style-type: none"> ▶ Reduced tax rates ▶ Tax holiday ▶ Tax exemptions 	<ul style="list-style-type: none"> ▶ Super deduction 	<ul style="list-style-type: none"> ▶ Tax exemption and reduction

*Although not based on scientific analysis, EY clients report that this incentive delivers the most beneficial results to investors.

Incentives for TASC status

(技术先进型服务企业)

Description of benefits

- ▶ The reduced CIT rate is 15% to TASCs.
- ▶ The deduction limit of employee education expenses increases to 8% of total salaries and wages (compared with normal rate of 2.5%) for CIT purposes.
- ▶ A business tax (BT)/VAT exemption applies on qualified offshore outsourcing service income.
- ▶ A pre-approval process is required to obtain the incentives.

Guidelines around incentive applications

The incentive is applicable for current investments. A company with TASC certifications may enjoy a 15% reduced CIT rate within the validation period of the certification. The relevant information or documents should be submitted for tax

bureau review each year for the TASC status. The incentives related to the 8% deduction limit of employee education should be claimed in the annual CIT filing return, which is due within five months after the end of the tax year (the statute annual filing deadline). The application package should be submitted with the relevant forms in the CIT filing return, which include the Basic Information Form on Taxpayers, Appendix 5 and Supplementary Table 7 of the return.

Incentives for HNTE status

(高新技术企业)

Description of benefits

- ▶ A reduced CIT rate of 15% is available to HNTEs.
- ▶ For a qualified HNTE newly established in a special economic zone³ or Shanghai Pudong New Area on or after 1 January 2008, the enterprise

³ "Special economic zone" refers to those in Shenzhen, Zhuhai, Shantou, Xiamen and Hainan.

may be entitled to a tax holiday of “two years’ exemption and three years’ half deduction” from the first year in which it derives production or operating income.

- ▶ A preapproval process is required to obtain the incentive.

Guidelines around incentive applications

The incentive is applicable for current investments. A company with HNTE certifications may enjoy a 15% reduced CIT rate within the validation period of the certification. The relevant information or documents should be submitted for tax bureau review each year that HNTE status is requested, which is due within five months after the end of the tax year (the statute annual filing deadline). The relevant forms in the CIT filing return should be submitted, including the Basic Information Form on Taxpayers, Appendix 5 and Supplementary Table 3-5 of the return.

R&D expenses super deduction

(研发费加计扣除)

Description of benefits

- ▶ According to CIT Law, resident enterprises are allowed to deduct 150% of qualified R&D expenses for CIT purpose (hereinafter referred to as “R&D expenses super deduction”).
- ▶ A pre-approval process is required to obtain the incentive.

Guidelines on incentive applications

The incentive is applicable for current investments. The incentives related to the R&D expenses super deduction should be claimed in the annual CIT filing return, which is due within five months after the end of the tax year (the statute annual filing deadline). The application package should be submitted with the relevant forms in the CIT filing return, which include the Basic Information Form on Taxpayers, Appendix 5 and Appendix 5(1) of the return.

Incentives for qualified technology transfer income

Description of benefits

- ▶ According to CIT Law, CIT can be exempted and reduced for qualified technology transfer income.
- ▶ A pre-approval process is required in obtaining the incentive.

Guidelines on incentive applications

The incentive is applicable for current investments. The incentives related to qualified technology transfer income should be claimed after the end of each tax year, and the claim is due no later than five months after the end of the tax year (the statute annual filing deadline). The relevant forms in the CIT filing return should be submitted, including the Basic Information Form on Taxpayers, Appendix 5 and Appendix 5(3) of the return.

Eligibility requirements

Incentives related to HNTE status

- ▶ Key considerations:
 - ▶ The HNTE certificate must be obtained before applying for preferential tax treatment from the in-charge tax authority.
 - ▶ The recognition of HNTE is jointly managed by the Ministry of Science and Technology (MOST), the Ministry of Finance (MOF) and the State Administration of Taxation (SAT), with MOST carrying out initial checks.
 - ▶ HNTE status certificate is valid for three years from the date of issuance.
- ▶ Major recognition criteria of HTNE:
 - ▶ Core IP rights ownership
 - ▶ Fall in the catalog of key high-technology and new – technological territories
 - ▶ Headcount requirement for R&D personnel (30% graduates with an associate degree or above, no less than 10% for R&D)
 - ▶ Minimum R&D expenses requirement (3% to 6% of turnover)
 - ▶ Minimum revenue requirement from high-technology and new-technology products or services (60% of total annual revenue)
 - ▶ Four analyses are required on the number of proprietary IP, capability to convert R&D findings

into IP, ability of execution and management of R&D activities, and growth of revenue and total assets

Incentives related to TASC status

- ▶ Major recognizing criteria of TASC:
 - ▶ For the CIT incentive:
 - ▶ Qualified technologically advanced outsourcing services (information technology outsourcing (ITO), business process outsourcing (BPO) and knowledge process outsourcing (KPO))
 - ▶ Location of operation (21 model cities⁴)
 - ▶ Qualified operating history
 - ▶ Minimum education level requirement for employees (50% graduates with an associate degree or above)
 - ▶ Minimum revenue requirement from qualified technologically advanced services (50% of annual total revenue)
 - ▶ Minimum revenue requirement from qualified outsourcing services (50% of annual total revenue)
 - ▶ For business tax (BT) exemption/VAT exemption on the qualified offshore outsourcing service income:
 - ▶ Qualified technologically advanced outsourcing services in ITO, BPO and KPO fields
 - ▶ Location of operation (21 model cities)

⁴ The 21 Model Cities include Beijing, Tianjin, Dalian, Ha'erbin, Daqing, Shanghai, Nanjing, Suzhou, Wuxi, Hangzhou, Hefei, Nanchang, Xiamen, Jinan, Wuhan, Changsha, Guangzhou, Shenzhen, Chongqing, Chengdu, Xian.

R&D expenses super deduction

- ▶ Scope of qualified R&D expenses:
 - ▶ Design expenditures for new products; expenditures for formulating new techniques and procedures; expenditures for technical books and materials, including translation expenditures, that are directly related to the R&D activities
 - ▶ Expenditures of direct materials, fuel and power consumed during the R&D activities
 - ▶ Wages, salaries, bonuses, subsidies and allowances for research personnel
 - ▶ Depreciation and lease expenditures for equipment
 - ▶ Devices used specifically for the R&D activities
 - ▶ Amortization expenditures for intangible assets, such as software, patent rights and certain non-patented technologies used specifically for the R&D activities
 - ▶ Expenditures incurred to develop and fabricate prototypes and trial models
 - ▶ Site-testing expenditures for exploration activities
 - ▶ Expenditures incurred on assessment, review, inspection and certification of research results

Incentives related to the qualified technology transfer income

- ▶ Relevant CIT incentives:

- ▶ If the resident enterprise's income from its technology transfer does not exceed RMB5 million (about US\$163,000), CIT may be exempted.
 - ▶ For the part of the enterprise's income exceeding RMB5 million, the enterprise income tax will be half exempted.
 - ▶ Criteria for CIT incentives:
 - ▶ The company must be resident in China.
 - ▶ The technology transfer will fall into the scope specified by the MOF and the SAT.
 - ▶ The technology transfer within China will be recognized by the provincial-level science department or above.
 - ▶ The transfer of technology to overseas will be recognized by the provincial-level commercial department or above.
 - ▶ There may be other criteria specified by the relevant in-charge authorities.

IP and jurisdictional requirements

The IP must be registered and owned locally. The company claiming the R&D incentive must have effective ownership of the IP.

Technology or innovation zones

There are many National Economic and Technological Development Zones (NETD Zones) in China, and various preferential treatments of financial subsidies are provided to companies established inside the NETD Zones. R&D incentives provided by each NETD Zone are diverse, according to the different development status and development policies of each NETD Zone. There are no specific uniform R&D incentives to these zones other than the incentives listed.

R&D incentives are mainly provided by local authorities of NETD Zones by way of rewards or subsidies. The types of R&D incentives include land/office price reduction, one-off subsidy and financial subsidies to attract the R&D headquarter/center or technological companies, technology innovation project/program financing, additional subsidies to the original R&D incentives, subsidies to the talents engaging in scientific and technological innovation, and rewards for the technology innovation honors.

Role of governmental bodies in administering incentives

Incentives related to HNTE status

- ▶ Involved government agencies:
 - ▶ MOST, MOF and SAT
- ▶ The recognition of HNTE is jointly managed by MOST, MOF and SAT, with MOST carrying out initial checks. When the company is granted the HNTE status,

it will submit the relevant application documents to the in-charge tax bureau.

Incentives related to TASC status

- ▶ Involved government agencies:
 - ▶ MOF, SAT, the Ministry of Commerce (MOC), MOST, and the National Reform and Development Commission (NRDC).
- ▶ Eligible companies should submit application documents to the local science and technology authority, which will jointly manage the recognition of TASC with local authorities of commerce, finance, tax, and national reform and development. When the company is granted the TASC status, it will submit the certificate and relevant application documents to the in-charge tax bureau in order to claim the tax incentive in its CIT annual filing.

R&D expenses super deduction

- ▶ Involved government agencies:
 - ▶ Science and Technology Committee and Tax Bureau
- ▶ The company should submit the required documents to the in-charge tax bureau in order to claim the super deduction for R&D expenses, and the tax bureau will conduct relevant assessments, mainly focused on whether the expenses fall into the eight categories of qualified R&D expenses. The tax bureau may seek help from the local Science and Technology Committee in the qualification assessment of R&D expenses. Any R&D claim is initially processed by the tax bureau when the taxpayer submits the annual CIT return. Tax bureaus routinely

conduct examinations (both scheduled and unscheduled) to ensure compliance.

Incentives related to the qualified technology transfer income

- ▶ Involved government agencies:
 - ▶ Science and technology department, commercial department and tax bureau

Administrative requirements

Government pre-approval is required to claim R&D tax benefits. Taxpayers are required to submit all relevant information to the Government as early as possible, including the R&D project budget, descriptions of specific R&D projects, categories of R&D expenditures, and management or board meeting documents authorizing R&D project(s).

Annual compliance requirements

Incentives related to HNTE status

- ▶ In general, HNTE companies should submit relevant documents to the in-charge tax bureau prior to their annual CIT filing. Relevant documents mainly include the HNTE certificate and specified forms about R&D expenditure ratio and sales/service income analysis.

Incentives related to TASC status

- ▶ In general, TASC companies should submit relevant documents or information to the in-charge tax bureau during annual CIT filing. For example, relevant documents include the total revenue on technologically advanced

services and specified forms about the offshore outsourcing service revenue ration.

R&D expenses super deduction

- ▶ In order to enjoy the tax incentive, the following documents need to be submitted to the in-charge tax bureau during annual CIT filing:
 - ▶ R&D super deduction form in the annual filing package
 - ▶ Notification with registration number
 - ▶ Breakdown of R&D expenses for commissioned R&D projects (where applicable)
 - ▶ Financial statement, cost allocation and profit allocation of cooperative R&D projects (where applicable)
 - ▶ Reports on the projects' application
 - ▶ Annual Filing Return Form 5-1
 - ▶ Other materials required by the in-charge tax bureau

Incentives related to the qualified technology transfer income

- ▶ A company that makes a technology transfer transaction should submit relevant documents to the in-charge tax bureau for the record after the end of the tax year and before submitting CIT annual filing returns.

The certification requirement

Incentives related to HNTE status

- ▶ The recognition of HNTE is jointly managed by MOST, MOF and SAT, with MOST carrying out initial checks. Typically, there are six steps in the HNTE recognition procedure:

1. Online self-assessment
2. Online registration
3. Document submission
4. Assessment by MOST, MOF and SAT
5. Public opinion solicitation
6. Application for preferential tax treatments (if there is no objection incurred in Step 5, and the HNTE Certificate is issued)

- ▶ An HNTE certificate is valid for three years from the date of issue but is eligible for renewal through a reassessment procedure three months prior to its expiration.

Incentives related to TASC status

- ▶ A company qualified for TASC should apply to the local authority of MOST. The recognition of TASC is jointly managed by local authorities of MOF, SAT, MOC, MOST and NRDC. Typically, there are seven steps in the TASC recognition procedure:

1. Online registration
 2. Online declaration and submission of documents
 3. Primary examination and recommendation by the prefecture-level offices of MOF, SAT, MOC, MOST and NRDC
 4. Assessment and TASC list confirmation by the provincial-level offices of MOF, SAT, MOC, MOST and NRDC
 5. Public opinion solicitation
 6. Submission to the state-level offices of MOF, SAT, MOC, MOST and NRDC for the record
 7. Declaration and TASC certificate issuance.
- ▶ A TASC certificate is valid for three years from the date of issue but is eligible for renewal through a reassessment procedure three months prior to its expiration.

Qualified technology transfer income

- ▶ A registration certificate for the technology transfer contract is necessary when applying for tax incentives at the tax bureau. An agreement for technology transfer within China should be registered with the authorities of science and technology at the provincial level or above, while the cross-border technology transfer should be registered with commerce authorities at the provincial level or above. If the cross-border technology transfer agreement involves technology

that was developed with government financial support, it should be subject to approval from departments of science and technology at the provincial level or above. The documents to be submitted mainly include the agreement, and scanned copies of the involved intellectual property certificates. The registration requirement may vary between authorities in different provinces.

Statutory reference

Regulations	Effective year
Incentives related to HNTE	
Article 28 of CIT Law	2007
Article 93 of Implementation Regulation of CIT Law	2007
Guo Ke Fa Huo [2008] No. 172	2008
Guo Ke Huo Zi [2008] No. 128	2008
Guo Ke Fa Huo [2008] No. 362	2008
Guoshuihan [2009] No. 203	2009
Caishui[2011] No. 47	2011
Guo Ke Fa Huo [2012] No. 1220	2012
Incentives related to TASC	
Caishui [2009] No. 63	2009
Caishui [2010] No. 65	2010
R&D super deduction	
Guo Shui Fa [2008] No.116	2008
Incentives related to the qualified technology transfer income	
Article 27 of CIT Law	2007
Guoshuihan [2009] No. 212	2009
Caishui [2010] No. 111	2010

India

This chapter is based on information current as of 15 October 2013.

Overview

The Government of India has a progressive outlook toward R&D activities undertaken in India, and continues to promote such activities, focusing strongly on the science and technology fields. This is evident from the ambitious programs the Government has launched covering the following objectives:

- ▶ Increase in support to R&D
- ▶ Improvement in pool of scientific manpower
- ▶ Improvement in India's R&D infrastructure
- ▶ Implementation of flagship programs at the national level in order to improve technological competitiveness of Indian industries
- ▶ Establishment of research facilities and centers of scientific excellence on par with some of the most globally renowned facilities

Further, the Government has been continuously supporting R&D activities and seeks to provide an environment that offers growth of a knowledge-based economy by implementing effective fiscal policies and offering tax and other benefits in R&D. The Government offers various tax benefits in the form of super deductions on revenue expenditure, accelerated depreciation on capital expenditure, tax exemptions, tax holidays for setting up units in specified areas and indirect tax benefits, such as

customs duty exemptions on import of specified goods for the agrochemical sector and for companies having in-house R&D unit and excise exemptions available for research institutes. In addition to the above, the Government has also created a Technology Development Board to provide financial support to industrial concerns from undertaking R&D activities in the field of technology.

Alongside the fiscal incentives provided by the federal Government, various states in India offer incentives, such as stamp duty waiver and concessions, VAT-related subsidies and soft loans, exemptions or refund of entry taxes and octroi (a local tax which is collected on various articles brought into a district for consumption) and subsidies related to social security contributions.

2013 tax rates

Top corporate income tax rate (national and local average)	
▶ Domestic companies	33.99% ^{1,2}
▶ Foreign companies	43.26% ³
Standard/reduced VAT rate	
▶ Central excise duty is levied on goods manufactured in India – generic effective rate	12.36% 4%/5% or 12.5%/15% (depending on the nature of goods)
▶ State VAT on sale and purchase of goods	

¹ *Budget Plus 2013*, EY India, 2013.

² The tax rate of 33.99% is applicable where the total income is more than INR 100 million. However, where the total income is more than INR 10 million but less than INR 100million the tax rate is 32.45%. Further, tax rate of 30.90% is applicable where the total income is equal to or less than INR 10 million.

³ The regular tax includes surcharge and cess of where the total income is more than INR 10 million and up to INR 100 million; 41.2% where the total income is equal to or less than INR 10 million.

Incentives available

Names of incentives	Deductions for expenditure on scientific research	Deductions for expenditure on scientific research by manufacturing entities*	Deductions for contributions for R&D	Tax holiday on export profits earned by units set up in Special Economic Zones (SEZs)*	Funding for R&D activities in technology	Customs duty exemption and concession	Excise duty exemption (research institutes)
Types of incentives	<ul style="list-style-type: none"> ▶ Super deduction 	<ul style="list-style-type: none"> ▶ Accelerated depreciation on qualifying R&D assets 	<ul style="list-style-type: none"> ▶ Super deduction 	<ul style="list-style-type: none"> ▶ Tax holiday 	<ul style="list-style-type: none"> ▶ Cash grants ▶ Loans ▶ Financial support 	<ul style="list-style-type: none"> ▶ Tax exemptions ▶ Reduced tax rates 	<ul style="list-style-type: none"> ▶ Tax exemptions

*Although not based on scientific analysis, general industry consensus is that these two incentives deliver the most beneficial results to investors.

Deductions for expenditure on scientific research

Description of benefits and eligibility requirements

A 100% deduction is available to all industries on revenue and capital expenditures (other than expenditures incurred for the acquisition of land) paid out or expended in scientific research related to the business. Further, where any expenditure is incurred before business commences in order to pay salaries to employees engaged in scientific research or to purchase materials used in scientific research, all such expenditures as certified by the Director General of Income Tax (Exemptions) (DGIT(E)) and the Department of Scientific and Industrial Research (DSIR) within three years immediately preceding

the commencement would be allowed. NOL resulting from the deductions may be carried forward for eight years.

Guidelines on incentive applications

To claim the deduction for retroactive investments, the expenses should be incurred within three years of the commencement of business. The deduction may be claimed in connection with retroactive investments in the year of business commencement by filing a tax return within the time prescribed for the financial year in which the expenditure is incurred.⁴ Retroactive expenses incurred prior to the commencement of business may be claimed if they are certified by the DGIT(E) and DSIR.

⁴ As per the current tax laws, the due date of filing a return of income is 30 September following the end of the relevant financial year where transfer pricing provisions are not applicable. However, the date is further extended to 30 November, following the end of the relevant financial year where transfer pricing provisions are applicable.

Deductions for expenditure on scientific research by manufacturing entities

Description of benefits and eligibility requirements

A weighted deduction of 200% is available for scientific research on in-house R&D expenditure as approved by the DGIT(E) and DSIR, including capital expenditures (other than land and buildings) by companies engaged in manufacturing and the production of articles and things except for those articles or things specified in the Eleventh Schedule⁵ or for companies engaged in the biotechnology business. Expenditures on scientific research include expenses incurred performing clinical drug trials, obtaining approvals from regulatory authorities and filing patent applications. NOLs resulting from the deduction amount may be carried forward for eight years.

Guidelines around incentive applications

- ▶ The incentive is applicable to future investments. The deduction may be claimed in the year the expenditure is incurred in by filing the details of the expenditure for the relevant financial year before the DSIR on or before 31 October following the end of the relevant financial year and by claiming the deduction in the income tax return within the time prescribed for the relevant financial year.

- ▶ Per current tax laws, the deduction will be available for capital and revenue expenditure (other than the cost of land and buildings) incurred in an in-house R&D center on or before 31 March 2017.
- ▶ Specific DSIR approval is required in order to take advantage of super deduction benefits.
- ▶ The company will be eligible for the super deduction only if it enters into an agreement with the DSIR for cooperation in an R&D facility and for audit of the accounts maintained for that facility.

Deductions for contributions for R&D

Description of benefits and eligibility requirements

Deductions may be granted only in relation to the approved entities to which a donation or contribution is being made. The deductions available are as follows:

- ▶ Weighted deduction of 200% is granted to assesseees for any sums paid to a national laboratory, university or institute of technology, or specified persons with a specific direction that the said sum would be used for scientific research within a program approved by the prescribed authority. The prescribed authority in the case of a national laboratory, university or institute of technology is the head of the institution, and in the case of a specified person, it is the Principal Scientific Adviser to the Government of India.
- ▶ Weighted deduction of 175% is available for contributions made to approved

⁵ Examples of items specified in the Eleventh Schedule include beer, wine, alcoholic spirits, tobacco and tobacco preparations, cosmetics and toilet preparations, toothpaste, dental cream, tooth powder and soap, aerated waters, confectionary and chocolates, gramophones, projectors, photographic equipment and office machines such as calculators and cash registers.

institutions (e.g., research associations, universities and colleges) to be used for scientific research. An approved institution is a research association, university or college that has been approved and notified in the Official Gazette, by the Central Government.

- ▶ Weighted deduction of up to 125% is available for contributions made to any company engaged in scientific research. However, the following conditions must be satisfied in order to claim the deduction:
 - ▶ The company must be registered in India.
 - ▶ The main object of the company must be scientific R&D.
 - ▶ The company must be approved by the Chief Commissioner of Income Tax.
 - ▶ Weighted deduction of up to 125% is available for contributions made to approved institutions (e.g., research associations, universities, colleges that undertake research in social science or statistical research) to be used for research in social sciences or statistical research.

To obtain approval, these entities must file the relevant forms before the prescribed authorities. NOLs resulting from the deductions can be carried forward for eight years.

Guidelines on incentive applications

The incentive is applicable to future investments. The deduction may be claimed based on the amount of contribution made to the approved entities by filing the income tax return within the prescribed time for the relevant financial year.

Tax holiday on export profits earned by units set up in special economic zones (SEZs)

Description of benefits and eligibility requirements

Incentives are offered to companies engaged in providing R&D services under a service arrangement by way of export of services to a foreign principal. Such companies may set up their units in SEZs in order to secure the tax benefits. SEZ units engaged in export of goods and services from 1 April 2006 onward are eligible to claim a 15-year, phased tax holiday (refer table below) on all export linked profits earned.

Quantum of deduction to SEZ unit	Period of deduction
100% of export profits	First five years
50% of export profits	Next five years
50% of export profits, provided the profits are transferred to a Special Economic Zone Reinvestment Reserve Account for the purposes of acquiring plant or machinery within three years.	Next five years

Export profits of SEZ units are calculated as follows:

- ▶ Profits of SEZ unit x [Export turnover of unit/Total turnover of unit]

Guidelines on incentive applications

Incentives are available to any unit set up in SEZs provided such unit is not formed by splitting up or reconstructing existing businesses. In addition, such an SEZ unit must not be formed by the transfer of previously owned plant and machinery. An enterprise may claim the deduction or benefit by filing its income tax return within the time prescribed for the relevant financial year.

The unit in an SEZ can be set up for following purposes:

- ▶ Manufacturing
- ▶ Providing services (which in turn, may include R&D services)
- ▶ Trading and warehousing

To set up a unit in an SEZ, preapprovals are required from the applicable development

commissioner. A detailed application and procedural process is to be followed for seeking an approval.

Investment proposals in an SEZ qualify for bringing in funds in India under the automatic route, and no prior approval is required from the Exchange Control and Regulatory authorities for infusion of funds in India.

Separately, tax benefits may also be available to an enterprise engaged in the business of biotechnology or IT hardware on setting up a manufacturing facility (unit) anywhere in the Northeastern states of India. Tax holiday is available to such a unit for a period of 10 consecutive years; however, the deduction is restricted to profits of the unit on a stand-alone basis.

Funding for R&D activities in technology

Description of benefits

Support in the form of grants is provided by the DSIR to industrial R&D projects through the Technology Development Program (TDP) of DSIR. As per the project funding guidelines of TDP, the Technology Development Board (TDB) invests in the equity capital or gives loans to industrial concerns and research associations that are attempting development and commercial application of indigenous technology or adapting imported technology to wider domestic applications. The TDB also provides grants. However, this mode of funding is not particularly popular with multinational corporations, and grants are provided by the TDB only in exceptional cases.

Guidelines on incentive applications

- ▶ Indian companies, cooperatives and research associations are eligible to seek funding from the TDB. Further, domestic R&D institutions such as national and state laboratories, academic institutions, cooperative research associations, in-house R&D units recognized by the DSIR and commercial R&D companies recognized by the DSIR can also apply for funding.
- ▶ The most common form of TDB funding is concessional loan assistance, which comes with a number of conditions, including payment of royalty on sales generated during the term of the loan.
- ▶ A second mode of funding provided by the TDB is equity participation. Illustrative conditions for securing funding by way of equity include pledging of shares by promoters to the TDB for a value equal to equity subscription by the board.
- ▶ A further mode of funding is TDB grants. However, the TDB provides grants only in exceptional cases. The recipient of the grant may be required to pay the TDB an amount equivalent to the grant received by it or share the profit proportionate to the grant received.

Customs duty exemption and concessions

Description of benefits and eligibility requirements

A customs duty exemption is available on the import of specified goods for use by the agrochemical sector for R&D purposes or by companies with an in-house R&D unit, subject to conditions. Similarly, a concessional rate of customs duty is available on import of specified instruments, equipment or components by research institutions (other than hospital), subject to conditions.

Guidelines around incentive applications

Customs duty exemptions and concessions are applicable to current investments made. No particular forms have been prescribed under the Indian Customs legislation for claiming the aforementioned customs duty exemption or concessional rate of duty. However, certificates and approvals (as per relevant notification) would need to be produced for customs authorities at the time of clearing the imported instruments, equipment or components to avail such exemption or concession as the case may be.

The customs duty exemption and concession is available subject to fulfillment of specified conditions prescribed under the relevant notification, such as:

- ▶ The goods imported should not be sold or transferred within five years from the date of importation (or seven years from date of installation in the case of the agrochemical sector).

- ▶ The unit or institute importing the goods must be registered with DSIR and other governmental authorities (as the case may be).
- ▶ Certification from relevant authorities or agencies is required regarding the value of exports and goods imported for R&D purpose, essentiality of imported goods for R&D activities, etc. (to avail the exemption/concession benefits).

Excise duty exemption (research institutes)

Description of benefits

An excise duty exemption is available for the local procurement of specified instruments, equipment, components, etc., by research institutions (other than hospitals), subject to conditions.

Guidelines around incentive applications

The excise duty exemption is applicable on supply of specified instruments, equipment or components manufactured in India to research institutions (other than hospitals). Further, the manufacturer and seller is required to obtain the relevant certificates and approvals (as per relevant notification) from such research institutions and produced for excise authorities to claim the exemption.

The excise duty exemption is available subject to fulfillment of specified conditions as prescribed under the relevant notification, such as:

- ▶ The institute must be registered with the Government in the DSIR, and certification from the DSIR is required.
- ▶ In the case of a publicly funded research institute under the administrative control of the Department of Atomic Energy or the Department of Defense Research and Development of the Government of India, a certificate from the concerned department must be provided to the manufacturer of the goods.
- ▶ The goods should not be sold or transferred within five years from the date of installation.
- ▶ The head of the institute must provide certification stating that the goods are essential and used for research purposes.

State-level incentives

- ▶ Many states are keen to attract investments to set up new units and expand existing units to develop infrastructure, education and employment opportunities. For these purposes, the states offer many investment-linked incentives.
- ▶ The types of incentives offered include stamp duty waiver and concessions; state VAT-linked subsidies, soft loans and exemptions; exemption or refund of entry taxes and octroi; subsidies linked to social security contributions, and more.
- ▶ Incentives may be offered to specified industry sectors based on the size of the eligible investment, location, employment generation, nature of products, etc. No specific plan is provided for R&D; however, R&D companies are eligible to apply.
- ▶ The incentives offered may vary from state to state (under respective state industrial policies) with customization for megaprojects or investment in backward areas based on negotiations with the relevant state government.

IP and jurisdictional requirements

Where the Indian company carrying out research does not own the IP (e.g., under a contract R&D model), there could be challenges in securing approvals claiming the weighted deduction of 200%, and it

may not be effective because the weighted deduction could be restricted to “net expenditure.” Apart from this, there are no restrictions with respect to holding IP rights to secure tax-related benefits.

Role of governmental bodies in administering incentives

Incentives related to expenditure on scientific research, expenditure on scientific research by manufacturing entities and contributions to R&D

Involved government agencies: DSIR part of the Ministry of Science and Technology, Director General of Income-tax (Exemptions).

The Government of India established the DSIR, an autonomous body and India’s largest R&D organization. Further, the Government established the DSIR with a broad mandate to promote industrial research and to carry out activities relating to technology development. The DSIR is part of the Ministry of Science and Technology and carries out the activities relating to promotion, development, utilization and transfer of indigenous technology. The DSIR has carried out various programs and schemes aimed at promoting R&D. Because India provides various incentives and benefits to the private sector for R&D, the DSIR also acts as a nodal agency for the approval of benefits claims. The DSIR approves all scientific R&D activities carried out

by research associations, colleges, universities, etc. Further, on completion of the R&D activity, the DSIR obtains a completion certificate from the research associations and considers a report of the activities carried out, results obtained and its further application for commercial exploitation.

Incentives related to export profits earned by units set up in an SEZ

Involved government agencies: Ministry of Commerce and Industry, Department of Commerce.

The administration of each SEZ is governed by a three-tier administrative set-up.

The Board of Approval is the apex body comprising 19 members from various ministries of the Government of India and headed by the Secretary, Department of Commerce. The Approval Committee at the zone level deals with approval of units in the SEZs and other related issues. Each zone is headed by a Development Commissioner, who is ex-officio chairperson of the Approval Committee.

The Board of Approval and the Central Government approve the setup of SEZs. Subsequently, units are permitted to be set up in the SEZ. All the proposals for setting up units in the SEZ are approved at the zone level by the Approval Committee consisting of the Development Commissioner, Customs Authorities and representatives of state government. All post-approval clearances, including grants of importer-exporter code numbers,

change in the name of the company or implementing agency, broad banding diversification, etc., are given at the zone level by the Development Commissioner. The performance of the SEZ units is periodically monitored by the Approval Committee, and units are liable for penal action under the provision of Foreign Trade (Development and Regulation) Act, in case of violation of the conditions of the approval.

Incentives related to funding for R&D activities

Involved government agencies: Technology Development Board, Department of Science and Technology

The Technology Development Board manages and administers the fund created by the Government for technology development and application.

The TDB accepts applications for financial assistance from all sectors of the economy and approves the granting of funds to the industrial concerns after a detailed evaluation.

Incentives related to customs

Involved government agencies: Central Board of Excise and Customs

Regarding customs duty and excise duty (including customs and excise duty incentives in the form of exemptions and concessional rate of duty), the Ministry of Finance has established the Central Board of Excise and Customs to issue guidelines and notifications to administer the incentives.

Administrative requirements

Incentives related to expenditure on scientific research, contributions to R&D and for units set up in the Northeastern states of India

No particular forms have been prescribed under the tax laws for claiming a tax incentive. However, the assessee may claim the deduction by filing a tax return within the time prescribed for the financial year in which the expenditure is incurred.

Incentives related to expenditure on scientific research incurred by manufacturing entities

As noted, specific DSIR approval is required to secure the benefit of a weighted deduction of expenditures incurred by manufacturing companies with an in-house R&D facility. The DSIR, in most cases, conducts an inspection of the R&D unit before granting an approval. To secure a deduction for expenditures incurred on in-house R&D units, the following conditions must also be met:

- ▶ The R&D facility must not exist purely to carry out market research, sales promotion, quality control, testing, commercial production, style changes, routine data collection or activities of similar nature.

- ▶ Separate audited accounts (i.e., certified by a chartered accountant) for each R&D center must be maintained for each approved facility.
- ▶ A yearly statement must show the progress of implementation of the approved program to be submitted to the DSIR.
- ▶ The amounts of expenditures as certified by the DSIR and advised to the DGIT(E) are entitled to the weighted deduction. The weighted deduction is available on the "net" expenditure.
- ▶ Assets acquired with respect to developing scientific R&D facilities will not be disposed of without the approval of the DSIR.
- ▶ On completion of the R&D activity, a completion certificate must be given to the DSIR with a report of the activities carried out, results obtained and further application for commercial exploitation.

Incentives related to export profits earned by units set up in an SEZ

Units set up in an SEZ are governed by the terms of the letter of permission granted by the Development Commissioner. Apart from the approval procedure listed earlier, compliances for an SEZ unit include the following:

- ▶ Filing of an annual performance report with the Development Commissioner of the SEZ. The annual performance report includes details of imports, exports, capital goods and ECB borrowings. The contents of the report have to be certified by a chartered accountant.
- ▶ On the basis of the annual performance report submitted by the unit, the Approval Committee undertakes an annual review of the unit's performance and compliance with the conditions of approval as provided in the letter of permission.

Incentives related to customs and excise

- ▶ Under customs legislation, there is a provision for conducting on-site audits, during which the authorities may check compliance with the conditions stipulated while granting and availing incentives by the assessee. The authorities may verify whether the conditions prescribed in the corresponding notification, such

as whether the goods are transferred or otherwise, have been adhered to. In the case of import by agrochemical sector units, a certificate from the jurisdictional assistant or Deputy Commissioner of Central Excise (in cases of units registered under Central Excise) or from an independent chartered engineer (in cases of unregistered units) must be produced before the Assistant or Deputy Commissioner of Customs certifying that the imported goods are installed in the R&D wing of the importer within six months from the date of importation. Certification from the competent authority is required.

Statutory reference

Accelerated depreciation

- ▶ Section 35(1) of the Income Tax Act, 1961 (the Act)

Super deductions

- ▶ Section 35 of the Act

Tax holiday for export profits for units in an SEZ

- ▶ Section 10AA of the Act

Funding for R&D activities in technology

- ▶ Project Funding Guidelines issued by the Technology Development Board

Customs duty exemption (related to the agrochemical sector)

- ▶ Customs Notification No. 12/2012, dated 17 March 2012

Customs duty exemption (related to in-house research units)

- ▶ Customs Notification No. 50/1996, dated 23 July 1996 (as amended from time to time)

Concessional rate of duty (related to research institutes)

- ▶ Customs Notification No. 51/1996, dated 23 July 1996 (as amended from time to time)

Excise duty exemption (related to research institutes)

- ▶ Central Excise Notification No. 10/1997, dated 1 March 1997 (as amended from time to time)

Japan

This chapter is based on information current as of 1 September 2013.

Overview

R&D tax incentives are a cornerstone of Japanese industrial policy, and are designed to increase the competitiveness of Japanese industry. With the second highest nominal corporate income tax rate in the world (and also high effective corporate tax rates) R&D incentives are an important policy measure for business. The Japanese R&D tax regime may be considered mature as it was introduced in 1967. Initially, tax credits had been applied to incremental R&D expenditures. A tax credit of up to 10% was introduced in 2003 and applied generally on qualified R&D expenditure. The credit has been consistently granted over the past 10 years.

R&D incentives are mainly granted in the form of tax credits against National Corporate Tax and are subject to certain limitations. In addition, incremental and increased tax credits are available. To promote the globalization and integration of Japanese companies in international markets and academic programs, offshore activities are also eligible for R&D incentives.

2013 tax rates

Top corporate income tax rate (national and local average)	38.01% ¹
Standard VAT rate	5% ²

Incentives available

Names of incentives	R&D Tax credit*	R&D income deduction under Asian Business Location Law
Types of incentives	▶ Tax credit	▶ Tax deduction

*Although not based on scientific analysis, EY clients report that this incentive delivers more beneficial results to investors.

¹ Ministry of Finance (MOF), 2012 Tax Reform Guide, July 2012. The rate includes local corporate taxes and Special Corporate Tax for Reconstruction.

² Consumption Tax Laws, Art 29, and Local Tax Law, Art 72-83. The rate consists of the national rate of 4% and local rate of 1%. The rate will increase to 8% from 1 April 2014; 10% from 1 October 2015.

R&D Tax credit

(Shikenkenyu no sogaku ni kakaru zeigaku
kojo seido)

Description of benefits

There are two layers of R&D credits available in Japan: (i) base credit and (ii) additional credit. The base credit is available as long as a company incurs qualified R&D expenses. In addition to the base credit, an additional credit will be available only for fiscal years beginning on or before 31 March 2014 in cases when (i) the current year's qualified R&D expenses exceed average annual R&D expenses over the past three years and the largest annual R&D expenses in the past two years and/or (ii) the current year's qualified R&D expenses exceed 10% of average annual sales amount over the recent four fiscal years including the current year.

Base credit

- ▶ The base credit is a gross type credit equal to gross R&D costs multiplied by 8% to 10% (for large corporations) or 12% (for SMEs).
- ▶ Under the base credit, the R&D credit is available up to 20% of the corporate tax liability amount. For any two consecutive fiscal years starting on or after 1 April 2013, the R&D credit limitation on base credits is increased from 20% to 30% of total the National Corporate Tax liability.

- ▶ If the amount of gross R&D costs multiplied by the credit rate exceeds 20% (or 30%) of the corporate tax amount, such excess portion may be carried forward for one year. Carry back of the excess credit is not permitted.

Additional credit

- ▶ Taxpayers may choose either "incremental type credit" or "excess type credits."
- ▶ Incremental type credit equals to incremental R&D costs multiplied by 5%.⁴
- ▶ Excess type credit equals the excess R&D costs of more than 10% of average sales, multiplied by a certain percentage.
- ▶ Under the additional credit, the R&D credit is available up to 10% of total the National Corporate Tax liability.
- ▶ Carry forward/back of the excess credit is not permitted for additional credit.

Guidelines around incentive applications

To claim the R&D tax credit, certain forms must be used (schedule 6(6), 6(7), fiscal years beginning on or before 31 March 2014. The filing due date of the corporate tax return is two months (one month extension is generally allowed) from the fiscal year end.

³ An extension of applicable period by three years to 31 March 2017 has been proposed.

⁴ An increase of the credit rate (up to 30%) has been proposed.

R&D income deduction under Asian Business Location Law

(Shikenkenyu no sogaku ni kakaru Shotoku Kojo)

Description of benefits

An income deduction of up to 20% is available to companies meeting both of the following conditions:

- ▶ Newly established blue-return filing⁵ Japanese subsidiary of foreign multinationals that exclusively conducts R&D.
- ▶ Newly established blue-return filing Japanese subsidiary of foreign multinationals that employs at least 10 employees at the beginning and 25 when the incentive ends.

The 20% income deduction is granted for 5 years for certified companies, which results in an approximate seven percentage point effective tax rate reduction.

The income deduction is applicable to each fiscal year ending within five years of date of approval of its R&D business plan granted between 1 November 2012 and 31 March 2014.

A company enjoying an income deduction under the Asian Business Location Law is not entitled to combined income deduction and R&D tax credits in the same fiscal year.

Guidelines on incentive applications

To be qualified for the 20% income deduction, the company is required to submit an R&D business plan and to obtain pre-approval from the Minister of Economy,

Trade and Industry. The income deduction is claimed through filing corporate tax returns, to which a specific form (schedule 10(3)) is attached. The filing due date of the corporate tax return is two months (one month extension is generally allowed) from fiscal year end.

Eligibility requirements

Eligible R&D expenditure includes the cost of material, salaries and wages and other related expenses of employees who have expert knowledge and skills and are engaged exclusively in experimental and research work, as well as a depreciation allowance for machinery and equipment used for such work. Personnel who have expert knowledge and skills refers to those having a technical background and who are directly involved in R&D activities (e.g., managers and assistants in charge of R&D activities). Administrative staff, janitors, security guards, etc, who may be involved in some way with R&D activities, do not qualify.

Qualifying Research Expenses (QRE) are defined as expenses incurred in experimental and research work in order to manufacture products or to improve, design or invent techniques. Research activities may occur within or outside of Japan. Contract fees received do not qualify and are to be netted against QREs, while for contract fees paid, R&D credits may be taken.

In order to be eligible for a deduction from the corporate income tax base under the Asian Business Location Law:

- ▶ R&D should be related to advanced knowledge and technology and will

⁵ According to Japanese income tax law, a taxpayer can elect a "blue-return filing" status by submitting the election to the tax authority. By electing the "blue-return filing" status, a tax payer can maintain its accounting records to a standard acceptable by the tax authority.

be subject to a business plan review by the Ministry for Economics, Trade and Industry.

- ▶ No affiliated company should already be engaged in the planned R&D activities in Japan.
- ▶ The company must be newly established in Japan and employ at least 10 employees at the beginning and 25 when the incentive ends.
- ▶ The company must be solely engaged in R&D activities.

Role of governmental bodies in administering incentives

The National Tax Agency administers the R&D tax credit and income deduction (i.e., the eligibility for tax credit or income deduction is scrutinized by tax authorities upon future tax audit). As for R&D income deduction, a company is required to obtain an approval from the Minister of Economics, Trade and Industry for its R&D business plan to be qualified for the deduction.

Administrative requirements

Tax credit

To claim a tax credit, certain forms (schedule 6(6), 6(7), 6(8) and/or 6(9)) must be attached to the corporate tax returns, which are due on two months after fiscal year end (one month extension is generally allowed).

Income deduction

Application for pre-approval with The Ministry of Economics, Trade and Industry is required and the income deduction is granted for five years upon obtaining the approval. To claim the deduction, a certain form (schedule 10(3)) has to be attached to the corporate tax returns.

Statutory reference

Tax credit

Article 42-4 and 42-4-2 of Special Taxation Measures Law.

Income deduction

Special Measures Law for the promotion of R&D by multinational companies, Article 61 of Special Taxation Measures Law.

Singapore

This chapter is based on information current as of 1 September 2013.

Overview

Since 2008, the Government has strengthened its focus on R&D and has continually revisited the available R&D programs and support mechanisms. These R&D incentives are used as a key policy enabler to boost productivity and also recognize the significant contribution that R&D plays in building globally competitive companies.

Discretionary R&D incentives in Singapore have been in existence for over 10 years and, accordingly, are relatively mature in terms of the underlying policy and drivers.

For statutory incentives, these have only been around for four years and are still maturing.

Currently, the Government offers a tax deduction of up to 400% that is available for qualifying R&D expenditure on R&D activities performed in Singapore or abroad. Partial government grants are also available for approved R&D projects.

2013 tax rates

Top corporate income tax rate (national and local average)	17% ¹
Standard VAT rate	7% ²

Incentives available

Names of incentives	Enhanced R&D deduction	Research Incentive Scheme for Companies (RISC)	Double tax deduction for R&D expenses
Types of incentives	Super deduction	Cash grants	Super deduction

¹ The 2013 Worldwide Corporate Tax Guide, EY, 2013.

² Ibid.

Enhanced R&D deduction

Description of benefits

As a primary R&D incentive in Singapore, the enhanced R&D deduction provides for a 150% enhanced tax deduction on qualifying R&D expenditure in Singapore. The R&D tax deduction is further enhanced from 150% to 400% for the first S\$400,000 of eligible R&D expenditure for years of assessment 2011-15. Eligible businesses also have the option to convert up to S\$100,000 of their qualifying expenditures into cash at a conversion rate of 60% for years of assessment 2013-15. Unutilized losses may be carried forward indefinitely, subject to satisfaction of the shareholding test.

Guidelines around incentive applications

The enhanced R&D deduction is applicable to current investments. As the incentive is statutory-based, the claims follow the corporate tax filing timeline. The enhanced tax deduction is claimed against taxpayers' taxable profits in the year the expenditure was incurred. Corporate tax returns are filed on a preceding-financial-year basis.

RISC

Description of benefits

The RISC is a Government cash grant co-fund to encourage and assist companies in setting up R&D centers in Singapore and develop their in-house R&D capabilities. The support is typically 30% or 50% of total qualifying cost, such as manpower-related costs, equipment and materials,

professional services and IP rights. The grants have been provided selectively to large projects in certain strategic technology areas identified by the Singapore Government. However, projects awarded the cash grant are not announced nor made public. Taxpayers are required to seek pre-approval in order to obtain the incentive.

Guidelines on incentive applications

RISC is applicable for future investments, and typically, approval is granted only on projects that have not yet commenced.

Double tax deduction for R&D expenses

Description of benefits

The incentive provides a 200% tax deduction on R&D expenditure incurred on approved projects. No R&D projects may be approved for this incentive after 31 March 2015. Unutilized losses can be carried forward indefinitely subject to the satisfaction of the shareholding test. Taxpayers are required to seek the preapproval in order to obtain the incentive.

Guidelines on incentive applications

The double tax deduction for R&D expenses is applicable to future investments, and typically, approval is granted only on projects that have not yet commenced.

Eligibility requirements

Enhanced R&D deduction

R&D is defined as any systematic, investigative and experimental study that involves novelty or technical risk carried out in the field of science or technology with the objective of acquiring new knowledge or using the results of the study for the production or improvement of materials, devices, products, produce or processes (with specified exclusions). Activities that directly support core R&D activities may also qualify.

Eligible expenditure includes staff costs, consumables and contracted R&D expenditure, net of government grants or subsidies. Where the R&D work is contracted to an R&D organization or is performed under an R&D cost-sharing agreement (CSA) and a breakdown of the expenditure is not available, the eligible R&D expenditure is deemed to be 60% of fees payable to the R&D organization or under the CSA.

Any business carrying on qualifying R&D projects in Singapore is eligible for the enhanced tax deduction. No industry sectors are specifically excluded. However, research in the social sciences or the humanities cannot be claimed unless they are activities that support a qualifying project.

RISC

There is no specific definition of R&D. Eligible expenditure typically includes manpower-related costs, equipment and materials, professional services and intellectual property rights. There is no eligibility restriction on specific industries; however, as it is a discretionary incentive, grants are provided selectively to large projects in certain strategic technology areas identified by the Singapore Government.

Double tax deduction for R&D expenses

The definition of R&D is same as that provided for the enhanced R&D deductions. Eligible expenditure may cover various types of expenditure (other than capital costs) and subject to agreement by the relevant authority. This may include staff costs, consumables, overheads, testing costs and professional services. No industry is specifically excluded. However, as it is a discretionary incentive, grants are provided selectively to large projects in certain strategic technology areas identified by the Singapore Government.

IP and jurisdictional requirements

For the enhanced R&D deduction, qualifying R&D activities are not restricted to those conducted in Singapore. However, only the qualifying activities performed in Singapore are eligible for the 150% enhanced tax deduction. Qualifying R&D expenditure associated with overseas activities is only eligible for the

400% enhanced tax deduction (capped at S\$400,000 per year of assessment). For RISC and double tax deduction for R&D expenses, there are no specific IP requirements.

Role of governmental bodies in administering incentives

The expenditure claimed is processed by the Singapore tax authorities, i.e., the Inland Revenue Authority of Singapore (IRAS), for the enhanced R&D deduction. The IRAS also monitors the activities that are claimed to ensure compliance with the R&D enhanced tax deduction regime.

The Singapore Economic Development Board (EDB) administers discretionary incentives, including cash grants and the 200% tax deduction.

Administrative requirements

Companies are not required to seek Government preapproval for the R&D enhanced tax deduction. For the other discretionary tax incentives, approval must be granted by the EDB. To be eligible for the enhanced tax deduction, a company must submit the claim in its income tax return and tax computation with the completed R&D claim form, by the annual filing deadline of 30 November. Where a company incurs at least S\$150,000 of R&D expenditure (net of government grants and subsidies), it is required to provide a detailed description of the R&D project undertaken, based on prescribed guidelines. Where a company wishes to claim more than 60% of the sum payable to an R&D organization or under a CSA as eligible R&D expenditure, the claimant must submit to the IRAS copies of invoices

issued by the R&D organization detailing a breakdown of the expenditure items.

For the R&D cash grant, companies must submit documentation in relation to making claims and reporting on the progress of the project. Claims may be made on a quarterly basis using the prescribed format as provided by the relevant authority once the R&D cash grant has been awarded. Companies are also required to submit a yearly progress report and a final report at the end of the project.

For the double tax deduction for R&D expenses, companies must, in the first year of assessment when a new tax incentive commences, complete and submit with their income tax return, the Evaluation Checklist for a Company Awarded with Tax Incentives(s) form. For subsequent years of assessment, the completed checklists are required to be submitted only when requested by the IRAS.

For certification, the EDB must grant approval for the discretionary tax incentives. For discretionary incentives, in addition to the negotiation process, the relevant application forms must be completed. These forms are not publically available but will be provided by the EDB during the negotiation process.

Statutory reference

- ▶ Income Tax Act, Section 14D, Section 14DA and Section 14E.
- ▶ In respect of Section 14DA, the enhanced deduction is available for the years of assessment 2011 to 2015. It is expected that Budget 2014 (to be delivered in February 2014) will address the future of this incentive.

South Korea

This chapter is based on information current as of 1 February 2014.

Overview

The R&D tax incentives in South Korea are mature, having existed for more than 10 years. The Tax Incentives Limitation Law (TILL) that currently governs R&D tax incentives has been effective since 1 January 1999. The R&D tax incentives aim to encourage the investment in R&D activities or facilities that enhance productivity and competitiveness of

national industries. Currently, there are various R&D incentives in South Korea to encourage R&D activities; however, the R&D tax credit and R&D facility tax credit are the most notable R&D incentives in South Korea.

2013 tax rates

Top corporate income tax rate (national and local average)	24.2% ¹
Standard VAT rate	10% ²

Incentives available

Names of incentives	R&D tax credit	R&D facility tax credit
Types of incentives	Tax credits	Tax credits

R&D tax credit

Description of benefits

Two types of tax credits are available under the R&D tax credit program for qualifying companies in Korea:

- ▶ Growth industry and source technology R&D credit: 20% tax credit for R&D expenditure incurred by new, high-growth companies with original technology. The credit is increased to 30% for SME.
- ▶ Ordinary R&D credit:
 - ▶ Large corporations (non-SMEs): the credit equals the greater of: (i) 40% of current-year R&D expenditures exceeding the average of the three prior years (two prior years for

2014 and prior year for 2015) R&D expenditures, or (ii) the R&D expenditures for the current year multiplied by 3% plus an additional rate defined as 50% of the R&D expense ratio, capped at 4%.

- ▶ SMEs: the credit equals the greater of either: (i) 50% of current-year R&D expenses exceeding the average of the three prior years' (two prior years for 2014 and prior year for 2015) R&D expenditures, or (ii) 25% of current R&D expenditures.

Unutilized R&D tax credits can be carried forward for up to five years. Amendment of a prior R&D credit is available so long as the amended corporate income tax return for claiming a refund of R&D credit is filed within three years of the original filing due date.

¹ Article 55 of South Korea's Corporate Income Tax Law.

² Article 55 of South Korea's Corporate Income Tax Law.

Guidelines on incentive applications

The R&D tax credits are applicable for current investments. A domestic corporation that intends to apply the R&D tax credit is required to file, along with its annual corporate income tax return, an application form (Form 1 under the TILL), a detailed statement of R&D expenses (Form 3 under the TILL) and an R&D plan to the competent tax office within three months of the end of its fiscal year.

R&D facility tax credit

Description of benefits

To encourage investment in the development of new R&D facilities, an additional credit of 10% for small size corporations (a credit of 5% for medium and 3% for large corporations) on the cost of developing a new R&D facility may also be available in the year that the R&D facility is completed. R&D facilities include:

- ▶ Facilities for qualified research and experiment
- ▶ Facilities for qualified vocational training
- ▶ Facilities for commercialization of qualified new technology

Unutilized R&D facility tax credits can

be carried forward for up to five years.

Amendment of a prior R&D credit is available so long as the amended corporate income tax return for claiming refund of R&D credit is filed within three years of the original filing due date.

Guidelines on incentive applications

The R&D facility tax credit applies to current investments. A domestic corporation that intends to apply the R&D facility tax credit is required to file, along with its annual corporate income tax return, the application form (Form 1 under the TILL) to the competent tax office within three months of the end of its fiscal year.

Eligibility requirements

Qualifying activities include R&D activities conducted by a dedicated R&D center of the corporation or the corporation's internal R&D center, both of which should be registered with the Government (i.e., Ministry of Science, Information and Communication Technology and Future Planning in Korea).

Eligible R&D expenditure is defined as contracted, salary and material expenditures that are directly related to R&D. Additionally, manpower development

expenditure is eligible where it directly relates to R&D so long as it is incurred by R&D institutes or R&D-dedicated departments.

Ineligible expenditure includes:

- ▶ General management and supporting activities
- ▶ Market research and promotional activities or general quality testing
- ▶ Repetitive information gathering activities
- ▶ Activities to improve management or staff efficiency
- ▶ Legal and administrative activities such as protection of patent rights, etc.
- ▶ Exploration and investigation activities related to reserves of natural resources including minerals
- ▶ Research activities on contract basis

IP and jurisdictional requirements

R&D activities resulting in new IP may be performed outside of South Korea, and the IP does not have to be registered or owned locally. However, the company claiming the R&D incentive must be the beneficiary of the results of the R&D activities and be incorporated in Korea.

Technology or innovation zones

There are no technology or innovation zones providing R&D incentives in South Korea.



Role of governmental bodies in administering incentives

Each year, the Korean National Tax Service reviews R&D tax incentive applications that have been submitted with a corporate income tax return and processes the expenditure claims. The R&D expenditure claims may also be subject to written information requests or a tax audit in the future.

Administrative requirements

According to the Technology Development Promotion Law, the company is required to claim and register with the Ministry of Science when the company incorporates an R&D department or an R&D center.

Statutory reference

- ▶ Reserve for R&D expenditure – article 9 of the TILL
- ▶ R&D tax credit – article 10 of the TILL
- ▶ Tax credit for investment made on R&D facilities – article 11 of the TILL



United States

The US research tax credit expired on 31 December 2013. Under the American Taxpayer Relief Act of 2012, the credit was extended from 1 January 2012, through 31 December 2013. In his Fiscal Year 2015 Budget, President Obama proposed a permanent extension of the research credit, as he has typically done in prior fiscal year budgets. US Ways and Means Chairman Dave Camp (R-Mich.), while expressing his preference to address tax extenders as part of a broader tax effort, has also proposed making the research credit permanent. US Senate Finance Committee Chairman Ron Wyden (D-OR.) supports a retroactive extension of many of the expired tax extender provisions, including the research tax credit, and his Committee has recently approved legislation that would retroactively extend for two years (1 January 2014 to 31 December 2015) the research credit (as well as other tax extender provisions).

While the approval of tax extenders legislation is a significant development in overall efforts to renew or extend the research tax credit, it remains uncertain whether or when the US Congress will take final action.

Overview

In the US, a nonrefundable tax credit is available for certain qualified research expenses (QREs) incurred in the US that exceed one of two computed base amounts. This tax credit may be used by a business to reduce its federal tax liability. There is also a deduction allowed for 100% of the costs of R&D (other than costs associated with the acquisition of

depreciable property). The QREs eligible for the research credit are a subset of the costs eligible for the deduction, as QREs are generally measured as direct costs of R&D without including overhead costs or indirect costs. In general the deduction for R&D expenditures is required to be reduced by the entire amount of the credit, unless a special election has been made to reduce the amount of the credit. Most of the 50 US states permit a deduction for R&D costs that is identical to the federal deduction. Around two-thirds of the states also offer a research credit for state tax purposes. Many states model their research credit on the federal credit; however, the credit is generally permitted only for QREs incurred within the state and the state credits can vary dramatically between jurisdictions. Some state credits do not require a business to increase its QREs (as the federal credit does) in order to receive a credit. Often the types of costs that qualify for the credit are different, and the percentages of QREs used to compute the credit also differ. For most businesses, their federal research credits are larger than their state research credits, but that is not always the case.

The federal research credit has always been a temporary provision in law, and was allowed to expire at the end of 2013. Since 1981, the credit has only technically expired for a one-year period, during which time it ceased to be in effect; all other times it has been extended and renewed, retroactively effective from the prior date of expiration. Generally, most state research credits are permanent.

2013 tax rates

Top corporate income tax rate (federal and state average)	39% ¹
Standard VAT rate	0% ²

Incentives available

Names of incentives	Research credit	Tax deduction*
Types of incentives	Tax credit	Tax deduction

*Although not based upon scientific analysis, EY clients report that this incentive delivers more beneficial results to investors in general, however, the results depend on the taxpayers' facts and circumstances.

Research credit

Description of benefits

Federal and state research credits for certain QREs incurred in the US may be used by a business to reduce its federal and state tax liabilities. These are statutory tax incentives with specific amounts and applicability defined in statute at either the federal or state level. In general the federal credits are nonrefundable, while some state credits are refundable. In addition, some state credits may have the potential to be purchased or sold to the benefit of the taxpayer.

The federal research credit is designed to reward a business for an increase in its spending on research; thus, a taxpayer must determine the increment of its current-year QREs over a computed base amount in order to claim the research credit.

There are two methods for computing the research credit:

- ▶ Regular credit: The regular credit is computed by measuring spending as a percentage of a business's gross receipts. Thus, if a business is increasing its QREs as a percentage of gross receipts measured against a historic period, a percentage of the increment will likely be eligible for the regular credit. The maximum cash benefit in tax savings for the regular credit is about 6.5% of a business's QREs, but the benefit may be smaller.
- ▶ Alternative Simplified Credit (ASC): The ASC is a much simpler way to compute the research credit. Generally, the credit is equal to 9.1% of a business's increase in QREs in the current year, over 50% of the average QREs for the prior three years.

¹ The Council of State Governments, The Book of the States, 2002 edition, Range of State Corporate Tax Rates. The tax rate includes the federal rate and the average of state rates (which range from 0% to 12%).

² Many state and local governments impose sales taxes.

In general, the research credit is limited to a maximum of 25% of the regular tax liability. Unutilized research credits may be carried back for one year and carried forward for 20 years.

Guidelines around incentive applications

The research credit is applicable to retroactive investments and current investments. The research credit is claimed on the original corporate income tax return by completing Form 6765 and electing either the regular credit or the ASC. It must be filed by the due date of the return with extensions. A retroactive research credit may be filed by amending the income tax return for the open year for which the credit is being claimed. In general, taxpayers may claim the incentive retroactively for three years. Unless an ASC election was made on the originally filed return for that year, only the regular credit may be used.

Tax deduction

Description of benefits

The tax deduction is permitted for 100% of R&D costs (other than costs associated with the acquisition of depreciable property) for federal and state tax purposes.

Guidelines around incentive applications

The deduction is applicable to retroactive investments and current investments. The

deduction for research expenditures must be made on the originally filed income tax return. Taxpayers may claim additional deductions for research expenditures on amended returns if the taxpayer has established a method of accounting to deduct its research costs and merely erred in not deducting them on the original return. In general, taxpayers may claim the incentive retroactively for three years.

Eligibility requirements

There are four criteria that a research activity must meet in order to qualify for the credit:

- ▶ The activity qualifies as a deductible research expense.
- ▶ The research is undertaken for the purpose of discovering information that is “technological in nature” (relies on new or existing principles of the physical or biological sciences, engineering, or computer science).
- ▶ The objective of discovering the information is for its use on the development of a new or improved “business component” (any product, process, computer software, technique, formula, or invention) of the company using the credit.
- ▶ Substantially all of the research activities constitute a “process of experimentation” (the theoretical and physical evaluation of design alternatives for a business component).

The credit is available for in-house and contract costs incurred for qualified research. Qualifying expenses for the federal research credit (and most state credits) are defined as taxable wages paid to employees directly involved in R&D consumable supplies (not depreciable property) used directly in R&D and/or 65% of amounts paid to third parties for research services. Qualifying expenses for the federal and state deductions are defined as direct and an allocable portion of indirect costs for R&D.

Role of governmental bodies in administering incentives

Generally speaking, the taxing authorities may audit research credits and deductions claimed by any taxpayer after the filing for the credit or deduction. Although there is no special audit or preapproval process required, there are special procedures, such as Pre-filing Agreements (PFAs), available to taxpayers who wish to have their federal research credit and/or deduction audited in advance of filing their tax returns.

Administrative requirements

As with any credit or deduction, a taxpayer must maintain business records to support credits and deductions claimed. There are no special procedures for R&D credits or deductions. No preapproval process is required for the R&D incentives.

Statutory reference

- ▶ Federal research credit: Section 41 of the Internal Revenue Code
- ▶ Federal R&D deduction: Section 174 of the Internal Revenue Code
- ▶ State credits and deductions: various provisions based on each state's statutory framework



Outlook for biotechnology



Biotechnology is geared at enhancing quality of life and responding to society's grand challenges, such as an ageing and ever increasing population, health care choice and affordability, resource efficiency, food security, climate change, energy shortages and economic growth. With a track record in scientific know-how, talent and innovation, Europe has the potential to be a world leader in the field of biotechnology.

Indeed, biotechnology has been a cornerstone of Europe's competitiveness in terms not only of research and innovation but also in terms of industrial growth, number of jobs and new companies created in member states.

However, the right policies and incentives for R&D development are essential to grow the industry. In this report, we examine some key themes for the industry; is enough being done to encourage innovation and promote a culture of entrepreneurship, are member states doing enough to support the development of the biotechnology industry with tax policies, incentives and sustainable finance. Challenges remain with scale up and cost competitiveness. Are EU academic institutions turning ideas into something real, what can Europe learn from other key biotechnology locations?

We hope this report can be used as an exchange of best practice between member states and their associated regulatory authorities, so that a holistic approach to policy is developed and the technology and its applications can flourish to continue to provide solutions for society's grand challenges while creating jobs, economic growth and intellectual capital in Europe.

We asked key stakeholders in the biotechnology industry to share insights and views on the outlook for the future:

Health care biotechnology



Emmanuel Chantelot, Head of International Government Relations and Public Affairs, Shire

EY: Where does Shire, a multinational biotechnology company, see the biggest opportunities in Europe – in R&D, in sales ... ? Do you think your company's position is generally representative of similar companies?

Chantelot: For Shire, the biggest opportunity areas for the future lie in our continued efforts to develop innovative treatments for patients with high unmet medical need. We have established a leadership position in the rare disease field and clearly prioritize this area for further expansion. The vast majority of more than 7,000 known rare diseases are not treatable today – this represents a substantial opportunity. And, in many cases, Shire is developing first-ever treatments for different rare diseases. In Europe, companies such as Shire benefit from a special regulatory and incentive framework (the EU Orphan Medicinal Products Regulation), which provides a strong stimulus for investments into rare diseases. This is a very important factor that makes Europe an attractive place to be in the area of rare diseases.

EY: Do you think European biotechnology has enough resources at its disposal to compete internationally, in developing as well as developed markets?

Chantelot: Sustainable financing is critical to sustainable development of biotechnology innovation in health care. A very substantial proportion of biotech companies in Europe are micro and small companies that play a vital role in forging innovation. However, many of these enterprises never make any profits and represent quite risky undertakings. Traditionally, it has been more difficult for European companies to obtain venture financing as compared to their US competitors. The lack of strong venture capital tradition in Europe, coupled with higher risk aversion and less entrepreneurial business community, has positioned European companies at a disadvantage. At the same time, the EU Framework Programs, such as FP7 and soon Horizon 2020, may provide alternative sources of research funding for the resource-scarce smaller biotech companies.

EY: Is enough being done to create incentives for European biotech start-ups? What sort of incentives are most beneficial? How can governments best contribute? What about the private sector?

Chantelot: Many Member States provide various financial and fiscal incentives for biotech companies as part of their industrial development plans. Another opportunity lies in public private partnerships that target development of new medical technologies. The best example is the European Union's Innovative Medicines Initiative (IMI), which is now the world's biggest public-private endeavor with a clear focus on R&D projects that can benefit biotech startups.

There is much more to be done to trigger expanded interest in biotech startups within the European investment community, with a particular role for the European Investment Bank and the new financing instruments they are putting in place.

EY: Is there enough understanding at a general level of the benefits of medical biotechnology? If not, what could be done to improve it?

Chantelot: Health care biotechnology has been making a very substantial contribution to medical treatments and improvements in Europe and worldwide, yet not everyone seems to recognize that. We need to improve understanding by policymakers, the medical community and the general public of the value of biotechnology products, the complexity behind their development and production, and the key differences compared to small molecule products (e.g., biosimilars versus generics). Better understanding of those nuances should help guide public policy development for the future, which in turn should be supportive of the health care biotech industry. There is an important role to play for organizations such as EuropaBio, its member associations across Europe and biotech companies to establish a sustainable, multi-stakeholder communication platform to support favorable policy developments for the future of the biotech sector in Europe.

EY: What are the biggest obstacles to the ongoing growth of the European medical biotechnology industry (e.g., cost pressure, talent shortages, lack of investment money, inconsistent or over-stringent regulations)? What can be done to overcome them?

Chantelot: There are a few challenges facing the European biotech sector along

the entire innovation value chain, both on the supply and demand side of innovation.

First, as science and technology become increasingly complex and ever more specialized, there is a need for increased collaboration among a broad base of stakeholders, including industry, academia, teaching hospitals and patients. Europe needs to develop vibrant life science clusters, such as the Boston Area in the US, which create unique and critical capabilities for innovation to flourish.

Second, the rapidly evolving innovation landscape in the biotech sector is also putting pressure on the current regulatory and value assessment systems. Regulatory processes in Europe are no longer fit for purpose, as new, complex and very innovative technologies are being developed. We need more flexibility in the EU regulatory system and ensure it adapts to the changing technological landscape. Close collaboration between industry, regulators and patients is a must. We also require more consistency in terms of data requirements and critical parameters for product approval so that new promising technologies can become available to patients without unnecessary and costly delays. Lastly, value assessment through HTA needs to reflect the changing nature of biotech innovations that are often highly specialized treatments targeting small patient populations. Such products cannot be assessed in the same way as regular, large patient population products anymore.

Third, it is about the market uptake of the new biotech medicines, which offer great value to patients but which also often come at a higher price per patient. Payers and health care policymakers will have to consider how to best allocate investments within health care budgets so that patients can benefit from new biotech products in a timely manner across all EU 28 markets and ensure that the innovation model

pursued by biotechnology companies can be sustained in the long term.



Carlo Incerti, Chief Medical Officer, Genzyme

EY: As part of a very innovative company like Genzyme, what do you see as the biggest opportunities for biotech in Europe?

Incerti: If one looks at the regulatory constraints and the challenges of access, with the European governments imposing very strict rules on reimbursement and the evolution of technology assessments, one might seriously ask if Europe is still a place to be for any novelty biopharmaceutical company. For us, the answer is definitely yes, it is. We're growing significantly in Europe when it comes to revenues so we still expect Europe to play a fundamental role for our company.

Europe is receptive to innovation that can translate into a real benefit for patients; the challenge that we have is to keep the pipeline of innovation as strong as possible. However, we do see Europe as challenging from an R&D perspective: by cost, bureaucratic impediments, attitude and lack of true support from Member State governments; the European Commission is doing a lot but the translation by Member States is very challenging. So, R&D is limping a little.

EY: Which startup industries do you think biotechnology could learn from?

Incerti: The IT industry has been able to portray the benefits to society that an increased implementation and adoption

of these types of devices could have, sometimes of course exaggerating, but they've done a very good job. We haven't been able to replicate this successful messaging in the health care industry.

There is a perception that instead of big pharma, one now talks of big biopharma. But the image is not one of people that are, let's say, investing to improve people's lives, but rather one of exploiting diseases to make profit. That's a stigma that probably dates back to the 80s and 90s. We need to do more to dispel this myth. I believe that companies like ours, and others that are working in the area of specialty therapeutics, personalized medicine, that are really close to the patients, will be able to change attitudes, thus creating a healthy environment for innovative enterprises.

EY: Are lines being blurred between biotech and other similar sectors, including medtech, as a way of delivering better care to patients?

Incerti: It's happening, and I would say it will be a precondition for future success. Firstly, we're all shifting from being medtech manufacturers, drug developers, diagnostic manufacturers, into service providers because the concept now is that we all strive to address a service in a more holistic way – addressing "the patient journey". So, we're investing a lot in patient education, because better understanding by the patient could lead to, early diagnosis and early access. And in many progressive diseases, the earlier you treat, the better the outcome. Then there's the therapeutic phase, which is another part of the journey, and that leads to the access to the medicine, and then monitoring. It's a complete journey, and companies have to be able to address it in its entirety. This is why we're seeing so many alliances in

this industry. This collaborative type of approach is something that is becoming more and more the norm rather than the exception.

EY: Is there still a fairly healthy appetite for entrepreneurial R&D within the academic sector?

Incerti: When it comes to ideas and scientific excellence, I think that Europe is still an extremely attractive place to be. But the challenge is how to translate ideas into something with a real chance of success. Today, you need to be able to clearly demonstrate what's in it for the patient to be accepted by the reimbursement authorities; relative clinical effectiveness is the name of the game. This needs to be well understood by the young entrepreneurs of Europe who will be the ones facing the biggest challenges.

EY: So how should entrepreneurs go about obtaining that sort of reimbursement strategy knowledge?

Incerti: I'm one of the people trying to disseminate this information – it's now inevitable that the tracks of regulatory approval, development and payer acceptance are no longer separate. We're becoming a society that wants to understand value. This is the biggest discussion – the sustainability of a system that is in danger of not knowing how to pay for innovation. We have to be able to assess, document and release information on the value of our therapies that is measurable. In many company departments, Evidence Value Development is replacing the old terms, such as Health Economic and Outcome Research, because evidence generation first, then evidence translation afterward, are becoming more important. And I'm not so sure that this is really understood by the new generation of entrepreneurs.

Industrial biotechnology



Stephan Tanda – Royal DSM Board member – Netherlands

EY: Where does DSM, a global biotech company, see the biggest opportunities in Europe?

Tanda: We're active in the pharma, the nutrition and the industrial biotechnology spaces and the answer would be slightly different for each sector. I think one thing is clear, that, from an R&D point of view, Europe has a lot to offer, a lot of scientific know-how and talent.

When it comes to scale-up, particularly in industrial biotech, the competitiveness of Europe is much more of a challenge. Energy costs are extremely high, particularly compared to the US, but also Latin America. Of course, you can work with regulators and governments; in many countries, industry has different energy costs to consumers, but there needs to be an understanding that the competitiveness of Europe as a manufacturer, including as a biotech manufacturer, hinges very much on having competitive energy costs.

Industrial biotech uses cleaner manufacturing processes that fit into the overall goals of Europe – sustainable growth, reduction of greenhouse gas emissions. So if there's an industry that Europe wants to promote, it is the industrial biotech or bio-based industry.

Agricultural biotechnology is almost not present in Europe because of the

prohibitive regulatory regime. I think pharma biotech and industrial biotech are doing well, but access to biomass and raw material from agriculture is another issue. A lot more has to be done to connect farmers across Europe with the new markets that industrial biotechnology offers.

EY: What sort of relationship do you have with startups or early-stage biotech in Europe?

Tanda: We increasingly source innovation from outside the company, from start-up companies we take a stake in and maybe sit on the board and either license products in, or mentor people. We also work collaboratively with a number of universities across Europe, including Germany, the Netherlands, Switzerland and France. And I think this is one of the strong suits of Europe.

DSM operates two industrial park type sites where we host a lot of young companies. They benefit from our facilities, and we benefit from their creative minds and good ideas – an open innovation ecosystem where you have the infrastructure of big industry and the dynamics of young companies.

EY: What are the big obstacles in the way of success for biotech in Europe?

Tanda: Firstly, we lack entrepreneurship; not necessarily people in universities, but serial entrepreneurs with experience of more than one company. Secondly, capital: finding early-stage seed capital that allows that crucial first jump into an entrepreneurial venture and an additional few millions of venture capital; both seed and venture capital are extremely difficult. We don't have a culture like the US, where both serial entrepreneurs and people with deep pockets finance young companies. In Europe there are not many listed biotech companies, where last year in the US 50 or so started. So, that's really a concern.

EY: Do you think you have a leadership role to play in improving the general perception of biotechnology in Europe?

Tanda: Yes; industrial biotech is a very strong tool for manufacturing and providing solutions that are more sustainable in terms of having less environmental impact but also creating great business opportunities. So, we advocate for that very strongly by providing leadership to industry organizations or by working together with industry to create, for example, public/private partnerships with bio-based industries (PPP BBI). There's a better way of fulfilling our needs for materials and energy than just being hooked onto petroleum; we can instead use renewable grown resources.

EY: Do investors and startups have enough understanding of investment requirements and regulatory requirements?

Tanda: There needs to be a certain predictability that if you make the technology work, if you make the scale-up work, that markets will be there. In many other places – US, Brazil, China – the predictability of market mechanisms is much higher; the US Government, for example has a bio-preferred sourcing program that ensures markets will be there. Once you have market predictability, it's easier to attract investment, and I think that's where Europe still has some way to go. Having said that, I would like to acknowledge that a lot of progress has been made, Europe's vision for 2020 is very supportive for biotechnology. Also, the BBI public/private partnership really will focus on demonstrating the technologies and scaling up the bio-based economy, whereas in the past, Europe was focusing on research, forgetting about deployment. So it's a lot better than a few years ago but there's still a long way to go compared with other parts of the world.

Europe probably leads the thinking about the need for a more sustainable way of doing business, but the sad thing is that we're actually falling behind in terms of scaling that up. We have all the know-how here, the intellectual capacity, the talent, but it's the scale-up, the actual production or industrial activities that are lagging. However, the obstacles are not insurmountable, they can be addressed and, with that, Europe can lead the way.

Agricultural biotechnology



André Goig, Regional Director EAME (Europe, the Middle East and Africa) Syngenta AG.

Syngenta is a global agri-business that has set out to integrate the full range of its products, solutions, and agronomic expertise, to support the seed grower in exploiting opportunities created by the need to sustainably increase production in Europe and around the world. From our point of view, these opportunities are greatest in the east and south-east of Europe where it is possible to take big steps forward simply by getting existing technologies into the hands of growers and helping them to use such technologies sustainably. But there are also opportunities across the rest of Europe which can be unlocked through research and development in areas such as hybridization of seeds, seed care and breakthrough crop protection solutions.

Our confidence in the European marketplace is reflected in the fact that we continue to invest more than a third of our global R&D spend in this region.

Of course, agricultural biotechnology is one of a range of solutions that we offer to growers around the world. To date, this has mainly been focused on corn and soybean crops, and no solution has yet emerged for the huge cereal market that exists in Europe, which is why you've not really seen the same grower-led demand for the technology that emerged in North and Latin America.

Like anywhere else, we want to develop solutions, conventional or biotech based, which enable farmers and growers to produce safe, healthy, affordable food in as sustainable a way as possible.

But, for this to happen we need a robust, predictable and science-based approach to regulatory decision-making. Unfortunately, we have seen this process become increasingly politicised, especially in the EU, over the past decade and more. It started and continues to impact on biotechnology but also extends into crop protection (pesticides). This increasingly politicised decision-making needs to change because it will choke innovation, as we have already seen in green biotech, and will deny Europe access to the very technologies which can help farmers to produce more whilst better managing natural resources.

Global trends in GMOs mean that much more efficient action by EU policymakers is needed to avert trade disruption.

The number of GM product approval requests around the world and in the EU is increasing rapidly. The growing gap in authorization timelines between the EU and other parts of the world – and the need

to assess more stacked products (where multiple traits are combined) – means that more efficient processing of GM applications is needed in the EU.

The EU's top priority should be to make sure the GM product authorization system works, with more efficient processing of GM applications to achieve better synchronicity with exporting countries'.

Due to this lack of predictability in policy and regulation, agricultural biotech SMEs are virtually non-existent. In such an unstable, unpredictable and negative environment, who would be willing to take the risk of setting up a company in this space?

And we should remember, that if Europe continues to hinder innovation, based on its intrinsic hazard (as opposed to considering whether the risk can be managed, as we do in every other sector), we could end up damaging the use of technologies, like biotech, which are making a huge impact on the quality and sustainability of life.

On the other hand, I am becoming more positive about the prospects for agricultural technology in Europe, including agricultural biotech. You can see the progressive attitude of a growing number of EU Member States as well countries outside the EU, like Russia.

Tax policy

Across the world, many of the tax policies unveiled for 2014 indicate an increasing tax burden across virtually every type of tax.

In the area of corporate income taxes, some countries have (so far) announced statutory CIT rate reductions for 2014, and many seem to be targeting a rate of around

20% in the future. This indicates that the increased burden will be the result of other changes to the tax base; known legislative changes (and proposals) for 2014 certainly seem to bear this out.

Broadly speaking, the same overall trends (fewer headline rate changes, base expansion and higher tax burden) are also occurring across personal and indirect taxes.

While many new tax measures share the objective of continued deficit consolidation, 2014 sees a dramatic increase in the number of national developments designed to tackle base erosion and profit shifting (BEPS) in advance of recommendations from the OECD in this area in 2014 and 2015.

Companies will have a busy year

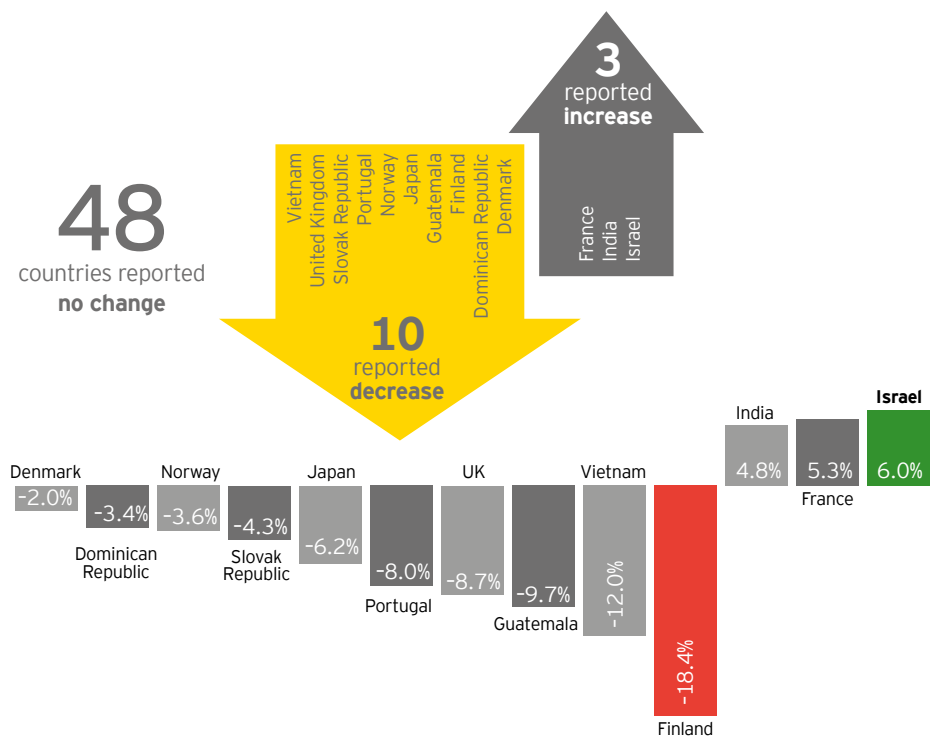
monitoring tax changes in 2014; all countries are trying to both expand and protect their tax base. Many are either making or planning wholesale tax reforms. And at the supranational level, not only will the OECD BEPS project undoubtedly drive change, but similar activity by the European Commission will require close attention, too.

Corporate income taxes: rates and burden in 2014

A recent EY study of tax policies for 2014 (covering 61 countries) indicates that while many countries continue to lower statutory CIT rates, a greater number of countries are actually increasing the overall CIT burden via other measures that expand the tax base. Examples of measures used to expand the base are largely consistent

Corporate income tax (CIT) rate

Globally, **Finland** had the largest decrease (24.5% to 20%, an 18.4% decrease), while **Israel** had the largest increase (25% to 26.5%, a 6.0% increase) in the CIT rate.



across countries and regions.

Countries decreasing their statutory CIT rates outnumber those who are increasing them by a ratio of more than 3:1. Of the 61 countries surveyed, 10 countries already have or will lower their statutory CIT rates in 2014, while only 3 (France, India and Israel) have passed legislation to increase them.

Statutory corporate income tax rates across those G20 members who tax corporate income vary dramatically; the United States has the highest rate (35%) while Canada has the lowest federal rate (15%) – although additional provincial rates increase the effective tax rate to between 25% and 31%.

The United Kingdom (21%) has one of the lowest effective tax rates of the G20 nations. Many other countries now seem to be viewing the rate of 20% as a medium-term target.

How countries are manipulating their corporate tax base to encourage the knowledge economy.

There are a number of common ways in which countries are choosing to manipulate their corporate tax base in the

year ahead. That said, not all countries are moving in the same direction as the common trend. As an example, many countries are using more generous R&D and other business incentives to attract foreign direct investment, such as the biotechnology sector.

In Norway, the initial depreciation rate available to certain assets increased in 2014. In Finland, though, long-term (i.e., usage time of at least 10 years) movable fixed assets must now be depreciated using straight-line depreciation, asset-by-asset, instead of over their economical usage time – currently 25% per year on a pooled basis. So while the types of measures identified may be largely consistent, their use can be very different, depending on the particular country and its overall objectives, revenue raising or encouraging the biotechnology sector.

Some common measures, identified as part of the EY study, that countries will be using in 2014 to continue to manipulate the corporate tax base (shown in order of prevalence):



Changes to (or focuses on) tax enforcement, including disclosure, substance requirements, GAAR



Higher corporate income tax burden overall



Changes to R&D incentives



Changes to interest/business expense deductibility (including payments to low-tax jurisdictions)



Changes to other business incentives (i.e., non-R&D)



Significant transfer pricing changes



Decreasing the statutory CIT rate



Changes to the tax treatment of losses



Changes to CFC rules/thin capitalization

Europe and the Innovation box

A key attribute of a biotechnology company's business model is the ability to developing IP or acquire IP and protect it. A patent confers upon the holder, for a period of time, the right to exclude others from exploiting (make, use, sell, import) the patented rights except with the consent of the owner. With the commercialization of this IP, the innovation incentive enables companies to avail of a lower rate of corporation tax on profits earned from its patents and certain other innovations.

The growing popularity of innovation incentive within the EU

Prior to 2007, France really stood out with its R&D tax credit system and specific tax IP related incentives providing for favorable tax treatment of income

from patents. Also, Hungary had a specific IP tax incentive but in the last six years, the French example served as a model for the other IP incentives in nine other EU countries (and one Swiss Canton), becoming a major instrument of the EU countries to offer incentives to R&D activity.

In 2007, the Netherlands, Belgium and Spain introduced their respective IP tax incentive, followed by Luxembourg (2008), Ireland (2009), Malta (2010), the Swiss Canton of Nidwalden (2011) and Cyprus (2012) leveraged from the popularity of IP incentives. Finally, in 2011, the UK announced its patent box incentive and Portugal in 2014. Although there are many differences between the various European IP incentives influenced by domestic considerations, such as existing policies and a strong industry presence, a common trait they display is the desire to become knowledge-driven

economies by stimulating R&D investment and increasing innovation and growth of R&D as well as creating – and retaining – high-value jobs and activities associated with the development, manufacture and exploitation of IP rights within the local jurisdiction.

One of the key points of all the IP (and R&D) tax incentives in the EU is that, while recognizing the competency of the EU Member States for national tax policy, they have to be general measures¹ from an EU law perspective, to conform with the fundamentals of EC treaty freedoms², the principle of non-discrimination and the Community State Aid rules.³ This ensures domestic rules cannot exclude enterprises from conducting or outsourcing their R&D elsewhere in (or outside) the EU.

With such a policy of free movement enshrined in the EU treaty, R&D and IP incentives within the EU cannot have territorial restrictions, there is however the potential migration issue related to highly mobile IP rights, resulting in policymakers of many EU countries developing specific rules to avoid a shift of investments to other EU countries that did already implement specific R&D and IP incentives.

Consequently, it can only be expected that other EU (and non-EU) countries will soon follow in improving their domestic legislation to both attract and retain IP rights and investments in the local jurisdiction.

IP incentives are an addition to – and not a substitute for – the typical up front tax incentives, such as R&D credits and super

deductions, which are granted during the years when R&D expenditures are actually incurred, trying to offer incentives and support activities designed to result in innovation.

In addition to innovation incentives and R&D tax credits, consideration should also be given to grants and incentives whether they take the form of an employment or capital cash grant. These grants and incentives can originate from EU subsidies directly or indirectly and from countries on central or regional basis.

Companies will also need to be mindful of any claw-back provisions for R&D tax credit or grants and incentives they receive and should understand what can trigger such a claw back.

However, at the time of writing this report, the UK Patent Box regime is under review to determine whether it might be regarded as a harmful tax measure under the EU Code of Conduct. The Council of Economics and Finance Ministers (ECOFIN) has also tasked the EU Code of Conduct Working Group to assess or consider all patent boxes in the EU, including those already assessed or considered before, in 2014, ensuring consistency with the principle of equal treatment, also against the background of international developments, including those in relation to the OECD BEPS initiative.

VAT and other indirect taxes

A similar picture of extensive base broadening is also occurring in the sphere of indirect taxes. In the same manner as

¹ The incentives cannot be selective and have to be open to all enterprises, irrespective of size, sector of activity or location.

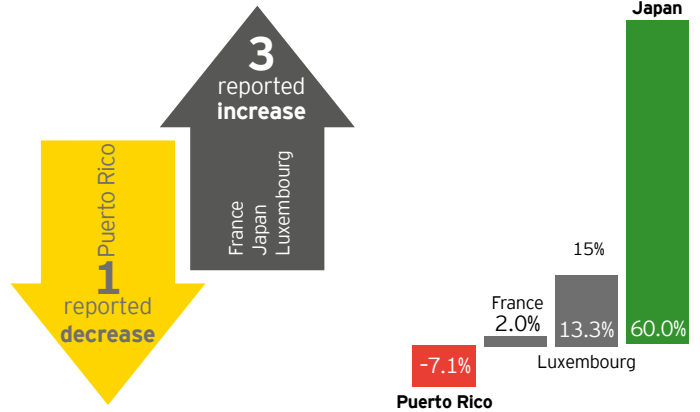
² More specific, the freedom of establishment (article 43 EC Treaty) and the freedom to provide services (article 49 EC Treaty).

³ According to article 87 (1) of the EC Treaty, "any aid granted by a [EU] Member State or through State resources in any form whatsoever which distorts or threatens to distort competition by favoring certain undertakings or the production of certain goods shall, insofar as it affects trade between [EU] Member States, be incompatible with the common market."

Standard VAT/GST/ sales tax rate*

Globally, only Puerto Rico has so far announced a VAT decrease for 2014 (7% to 6.5%, a 7.1% decrease), while **Japan's** increase from 5% to 8% represents a 60% increase.

56
countries reported
no change



for corporate taxes, this phenomenon is also accompanied by a dwindling volume of headline rate changes when compared to prior years. Only three countries (France, Japan and Luxembourg) report a standard rate increase (and Japan's increase amounts to a 60% rise).

China is one example of a jurisdiction aiming to broaden the tax base via greater use of VAT; in fact, in the short term, the overall indirect tax burden will likely be lowered because China has converged VAT and Business Tax (BT), which allows for input tax credit under VAT that would not have been available under the BT system.

Customs and global trade

In the past, global biotechnology companies' main business focus was in developed markets, where no customs duty applies to finished pharmaceutical, biotech, medical device and many consumer health products. Further, the World Trade Organization's Pharmaceutical Agreement eliminated duty from most APIs and intermediates. Additionally, unlike in today's market, the majority of clinical trials were also held in developed markets.

Now, however, the industry has fundamentally changed over the last

10 years with supply chains being re-engineered to deal with diversified portfolios, such as vaccines, animal health and generics. This re-engineering will help take advantage of the very significant current and future growth potential of emerging markets (currently 12%-15% annually).

This means that companies now have to deal with markets levying import duties on their products of up to 27%. Their first experience of such markets is usually for clinical trial projects with their related difficult valuation issues, very urgent timelines and irrecoverable duty and VAT issues.

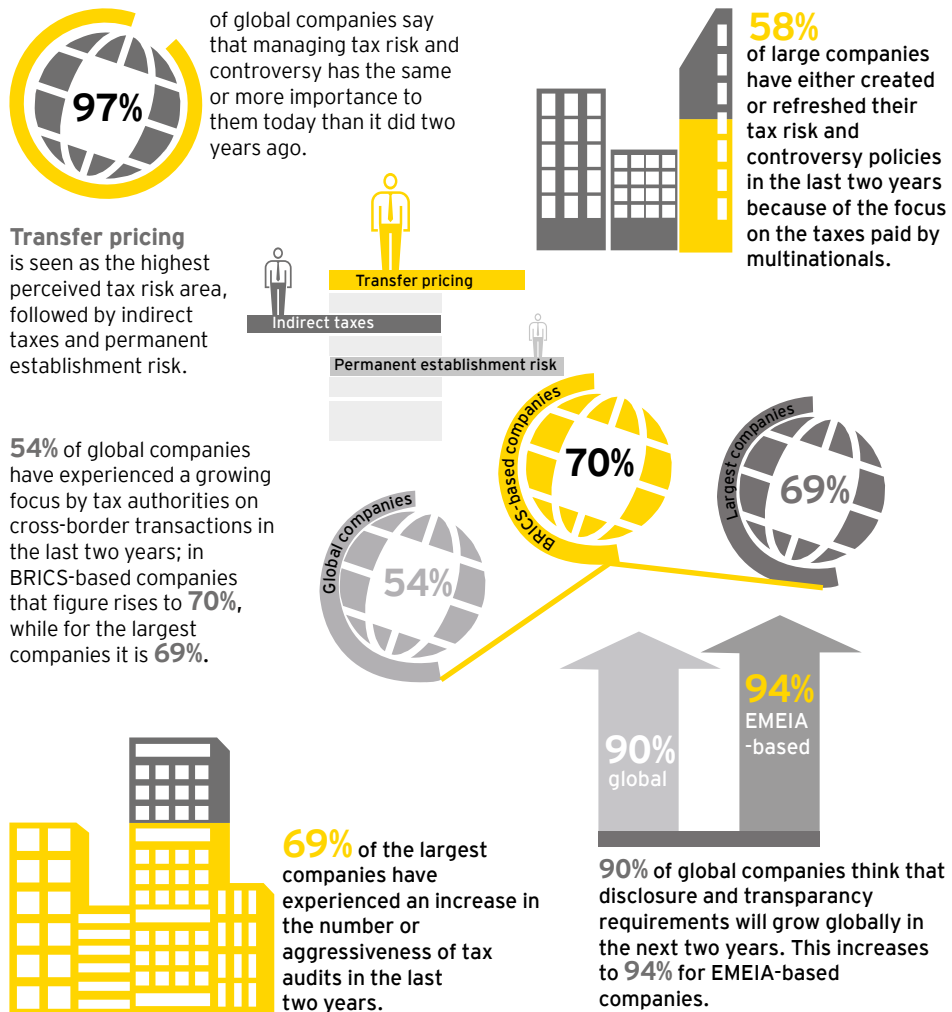
At the same time, the growth in customs and trade security programs all over the World such as AEO (EU Authorized Economic Operator) and C-TPAT (US Customs-Trade Partnership Against Terrorism) coupled with a boom in Free Trade Agreements have generated significant pressure on companies to invest in greater internal compliance controls, particularly within the biotechnology industry. The biotechnology industry has a significant desire to minimise any reputational risks that might arise from any adverse publicity from an exposure in the

supply chain. Also an increased focus on compliance from the US Sarbanes Oxley Act to Foreign Corrupt Practices Act (FCPA) and increased scrutiny and enforcement by customs authorities are adding to the pressure on companies to invest in greater internal compliance controls.

Many companies are now moving to reposition the customs and trade role to where it is more pro-active and provides significant input to key business decisions across the enterprise, from cost reduction to strategic planning to end-to-end trade compliance security.

Increasing tax enforcement in 2014

Virtually all countries are increasing overall tax enforcement levels; this is also borne out by what our clients tell us.⁴ Here, 69% of the world's largest companies have experienced an increase in the number or aggressiveness of tax audits in the last two years, while 58% have either created or refreshed their tax risk and controversy policies because of the focus on the taxes paid.



⁴ A survey of 771 EY clients that was open during November 2013-January 2014; the full results of this survey will be published in EY's 2014 Tax risk and controversy survey.

Significant transfer pricing changes

The OECD report on base erosion and profit shifting (BEPS) is a key development recently driven by a view that some elements of the cross-border tax architecture may not have kept pace with changes in global business practices, in particular in the area of intangibles.

The report identifies relevant work that has been completed by the OECD and states that a holistic approach is necessary to properly address the issue of BEPS.

As part of the surge in tax authority's initiatives to address BEPS concerns, the authorities in many countries released a broad package of measures with far-reaching consequences with regard to transfer pricing and international taxation.

European Union measure to stimulate the economy

Since 1 January 2014, Horizon 2020 is the European Commission's financial instrument implementing the Innovation Union, a Europe 2020 flagship initiative aimed at securing Europe's competitiveness. Horizon 2020 replaces the previous Framework Programme for Research & Development known as FP7 program.

Available from 2014-20 with a budget of nearly €80b, the EU's new program for research and innovation will be part of the drive to create growth and new job opportunities in Europe. It is designed to bring business into the research and innovation chain throughout its various

components and is the financial instrument which is aimed at connecting previous R&D funding with creation of innovation in line with the Europe 2020 strategy of fostering growth and jobs.

The main features of Horizon 2020 are:

- ▶ Reorganization, bringing together the Framework Programme for Research, the innovation part of the Competitiveness and Innovation Framework Programme (CIP) and the European Institute for Innovation and Technology
- ▶ Simplification and standardization of funding schemes and administrative rules
- ▶ Increased funding

Many companies may be eligible for Horizon 2020 funding and there will also be provisions for single-company funding for SMEs under specific calls (e.g., Biomarkers).

Horizon 2020 which is focused on funding research and innovation to respond to society's Grand Challenges, offers opportunities of funding in the fields of nanotechnologies, biotechnology (all sectors), advanced manufacturing and processing and health. Horizon 2020 also makes provision for a number of public private partnerships (PPP), two of which are specifically focused at the development of biotech sectors: the bio-based industries PPP and the innovative medicines industries PPP.

The average grant a participating organization can potentially secure will range between €200,000 and €1.5m per project, with funding up to 100% of eligible

project costs. There is no limitation on the number of projects for which a company can apply and additionally, Horizon 2020 funding can typically be complimented with local tax and non-tax incentives. The program is available in the EU Member States and associated countries and collaborations can include third countries.



Thomas Saylor, CEO Arecor Ltd., UK

EY: How has the environment for start-ups in biotech changed since you began your career?

Saylor: Perhaps the greatest change has been the increasing public attention and support of biotechnology. I've seen national, regional and local governments give an increasing priority to development of their biotech sectors through a growing number of tax, grant and other initiatives.

However, finance has become increasingly constrained. Over the last decade, there's been very limited access in Europe to public and private markets for biotech companies. While we are seeing some encouraging signs of change, the gap remains substantial. That's in stark contrast to the US where, although markets have their ups and downs, access to finance is much more available particularly for public companies or private companies going public. That's extremely important because public markets allow companies to finance products to a higher value point and to bring products to market, allowing companies to achieve sustainability.

Another change in the environment

is the many fundamental discoveries that are opening up new opportunities for application of biotechnology. This is reflected in the range of commercial applications of science. My own company, Arecor, has made advances in understanding the mechanisms affecting protein structure to improve the stability of protein and peptide drugs, as well as, vaccines improving the cost, availability and convenience of biologics. We work closely with major pharmaceutical companies to reformulate or develop stable formulations of biologics to enable new products and provide improved formulations of existing products. I am hugely impressed with the innovation that is taking place based on the emerging scientific insights.

Finally, there has been a growing symbiosis between large companies and biotech companies. Products producing over half of the sales of major pharmaceutical companies originated in academia or biotech companies. I expect that proportion to grow. A strong pharmaceutical industry in Europe is increasingly dependent upon a strong community of small and medium-sized biotech companies and is a source of innovation and "risk mediation."

EY: How have you seen entrepreneurialism develop in Europe in the time since you've been here?

Saylor: What stands out in Europe is the high quality of the science. Europe has been a leader in many areas of basic sciences but the science was not being commercially exploited as extensively as in the US. This is changing. There has also been a growing interaction between biotech and academia; from a reluctance to pursue commercial opportunities in the application of the sciences to a point where a growing number of key academics have built companies and raised the

profile of the commercial opportunities in the application of biotechnology.

There's also a new generation of people willing to take entrepreneurial risk. I have also seen a growing number of experienced entrepreneurs many of who have been involved in the development of multiple companies.

The culture has changed to be more supportive of entrepreneurs and failure. I've had five ventures; the first went down and the other four succeeded. I consider the one that went down my most valuable experience. In Europe, I think, the tolerance of failure, and recognition of the benefits of experience of failure, is becoming more tolerated.

EY: What do you think are the more effective sorts of ways for government to get involved in biotech?

Saylor: Grants can be useful to get to a proof of concept, so that you can actually go out and negotiate venture capital finance or other private support. There's also been more of an effort to create a continuity of grants; a pathway to put more serious money behind promising technologies.

Regarding tax policy, there are three angles. One is the enterprise, and there's a range of incentives, such as the R&D tax credit here in the UK and which is being replicated in other countries throughout the European community. The Patent Box providing tax incentives for development and protection of intellectual property is a more recent innovation that's now being implemented in several European countries.

From the entrepreneur's point of view, tax incentives can also be very important. Entrepreneurs taking a substantial risk and incentives, such as reduced tax on long-term capital gains can be very important to

encourage the best managers to come into the sector.

For investors, it's absolutely critical to have incentives for putting up risk capital and there have been a number of programs that relate to that. In the UK, there's the Enterprise Incentive Scheme, to provide favorable treatment to investors. The UK Bioindustry Association is also promoting tax benefits for the average tax payer to make investments in more risky ventures. France has already implemented a similar scheme.

EY: What are EuropaBio's ambitions regarding SMEs and how might it evolve over time to address the changing landscape?

Saylor: EuropaBio is the broadest coalition of companies with interests in biotechnology. Through the National Associations Council, EuropaBio represents over 1800 SMEs. At the same time, EuropaBio membership includes most of the large companies in the sector. EuropaBio's membership includes the most important sectors commercially implementing biotechnology: agriculture, pharmaceuticals and industrial biotechnology – it's a very broadly representative organization. The SME Platform which is part of EuropaBio seeks to identify constraints and to build initiatives to improve the climate for SMEs.

Funding is always priority for biotech SMEs. We seek to promote the accessibility of the grant programs available at the European level to biotech SMEs and to encourage policies which attract investors and entrepreneurs into the sector. We have been working with EY over the past several years to catalogue best practices as a policy agenda for Member States to encourage the development of biotechnology in their countries. In addition, we seek to promote

public understanding and support of biotechnology through such initiatives as EuropaBio Biotech Week.

EY: How well do you think European startups grasp the idea of reimbursement?

Saylor: One of the weaknesses in Europe is that we don't have a unified policy on pricing and reimbursement and it makes it difficult for large and small companies to introduce products. Personally, I feel that SMEs typically don't give enough attention to pricing reimbursement, health technology assessment policies in the early stages of their development to shape their commercial strategies. Very few SMEs would expect to take the product all the way to market, therefore they're considerably removed from pricing and reimbursement decisions. But they need to be aware, because they're going to license it on to companies that are going to be making decisions on pricing reimbursement and health technology assessment. A better understanding of the market place is crucial.



G. Steven Burrill, CEO Burrill & Company, US

EY: What does Europe look like as a place to invest in the biotech sector?

Burrill: I'd say Europe may be more attractive than it has historically been because of its more mature integrated health care system. But it's challenging as well, particularly for its lack of robust capital markets. I think at the science level you have high quality. The overall

R&D spend, broadly across Europe, is not at the level it is elsewhere in the world, certainly if you look at Asia, which is rapidly increasing. And if you look at America, we spend enormous amount at the research level, and that provides a much broader base for technology development than you see in Europe.

Sadly for the Europeans, many of the multinational pharmaceuticals, particularly the Swiss, German and French, are decreasing their R&D presence in Europe, favoring instead US, China, and elsewhere in the world.

EY: How could European biotech maximize interest in the area?

Burrill: The VCs aren't going to invest if there's no downstream capital to help carry the companies through, and so in the US where, because of NASDAQ and other security markets, we have robust access of the capital markets for developing companies, and even pre-profit or pre-revenue companies. That certainly has provided an attractive vehicle for earlier-stage investors.

Most authorities continue to focus, in my view, on the wrong end of the equation: they try and stimulate the startup end of the capital. The most important thing may be to work on the other end of the equation to see that the equity markets are available for this industry and developing companies.

Additionally, I think in Europe, broadly speaking, we don't see anywhere near the public participation in the public equity markets as we have, historically, in the US. And I think that's something that policymakers can look at.

I think the other place that policymakers can make a difference is in the commercial marketplace, to reward companies for innovation. If we spend hundreds of millions, maybe billions of dollars or euros, in the development of a technology, there





has to be some period of time in which investors and the company gets the right to return that investment for profitability to the shareholders to make it attractive. And where the price paid for much of this technology is at commodity levels, there's little incentive to develop that product and bring it to the market, because essentially there's no reimbursement for it.

EY: Is there any location in your mind that Europe could learn from and if so what is it they're doing?

Burrill: Americans and other parts of the world are looking at the Europeans as they try to get their arms around the value equations. Certainly, if you look at AmNog in Germany and NICE in the UK, you have authorities looking in-depth at value and outcomes and deciding what they pay for and why. Conversely, there are lots of places where the Europeans are looking at the Americans for opportunities and guidance for the capital markets and innovations and so on.

So you see some reciprocal relationships between the two major economic spheres. People tend to put China and India in a common bucket. They're highly populated with very big markets, but China is a rich market, and India poor. There are enormous differences around the globe in terms of how they pay for and invest in innovation, the culture in which they exist, how health care is delivered and paid for, and the incidence of disease. I'm not sure I can say that anybody is doing it completely right. Most people would think the US is, by and large, doing it right, but it's a highly complex system.

Twenty years, 30 years or 50 years from now, I think the US will still own innovation. We have a culture and an opportunity set that sees complexity as opportunity, and will continue to be innovative. Whether we capture the value in the US for that innovation, or elsewhere in the world,

I think we'll always lead, and if there's anything that Europe really needs to do it's to develop its innovation culture, and do those things that stimulate capital markets, and stimulate entrepreneurs, allow risk to exist, and recognize that some things don't work, and that's okay.

It's hard to change a culture over a generation but I think the competitive advantage that the Americans have, unlike anybody else in the world, has largely to do with this culture that is not averse to risk.



**Jos Peeters, Managing Partner,
Capricorn Venture Capital**

EY: How do you think the general environment for biotech investment has changed over the last 20 years?

Peeters: With the internet bubble that imploded and the financial crisis in 2008, the environment for venture capital in Europe is tougher than it was 20 years ago, not helped by the increased regulation from the European Commission. A serious pan-European operator wanting to attract institutional money from more than one country has to cope with the red tape imposed by the Directive, which contributes nothing to the success of the venture industry. Discussions at the Commission today center around how investment should be regulated rather than how they should be encouraged to flourish. Although it's not so easy to raise a drug development fund today, I think it will change in two, three years because in the past 12-18 months we've seen a lot of interest in new drugs, from big pharma and from investors. But it's in the early stages.

EY: Do you think the boom in US biotech is starting to percolate through to European markets?

Peeters: Yes, but in Europe, we don't have the depth of institutional investors following these type of growth companies. We don't have the specialized investment banks, or a dedicated stock market anymore. If European companies want to tap into that pool of liquidity, they have to go public on the NASDAQ stock market or turn to the US. Things will change, as money flows in the stock market and successes are shown.

EY: How do you see European biotechnology competing internationally, in terms of R&D, entrepreneurialism, and the ability of companies to think about the end stage and reimbursement?

Peeters: When it comes to innovation Europe is as good as anybody, if not better. We don't have an issue in attracting competent people, either. I've seen deals not done or not being successful because they were short of money; but never because they were short of managerial or entrepreneurial talent.

Reimbursement is a nightmare for small companies. Young companies should remember to reflect on the health economics of what they do before they spend a lot of money. We added that to our investment criteria a few years ago and we take a hard look at what the economics are for the governments that have to reimburse this eventually.

On the biotech side, there's quite a bit of seed money around in Europe from a number of business angles, and some larger funds such as Sofinnova, Index, LSP and others. It's not always easy for companies to raise their next fund but at least there are some significant pools of money around.

Big pharma has learned to play the option game, working with small biotech companies to get engagement at a very early stage; pay some money and then pay more and more as the program becomes successful.

The chemical or materials industry isn't there yet. So, what you see with industrial biotech is they have to prove, all the way up to industrial scale, that their process works, or that their end products work and are economically viable, before they get engagement from big chemical companies. And in terms of value creation and exit potential for venture capitalists involved in these types of companies, that's a different challenge.

EY: Do you think Europe should still be seen as a viable sales market?

Peeters: Yes. On the direct side Europe is 30% or 40% of the global market. Also we have an ageing population and a fairly wealthy middle class that continues to push for better medication. I think the development of companion diagnostics – more selectivity in the drugs that are administered (personalized medicines) – will help budgets and will also bring better health care. I think it's a significant market opportunity. We have an excellent research base, and should foster that. We have young people with the creativity and innovation power to develop new things, and we have schemes in place to encourage that type of research and to create spin-offs from that.

EY: What's the forecast like for deal-making, moving forward, in your opinion?

Peeters: The fact that so much is happening in the biotech sector recently in the US markets will bring more US funds looking at Europe and will awake some activity here. We usually follow a little bit behind. I'm not too pessimistic; it's just a little frustrating at the moment.

View from the National Association Committees



Leonardo Vingiani – Director Assobiotech – Italy

EY: How does the Italian Biotechnology Association encourage the development of the biotechnology industry within Italy?

Vingiani: Our focus as an association is to show society, and the institutions, the opportunities biotech provides to create jobs and value. Just 10 years ago, Italy was well behind all the big European countries, and some of the smaller ones. Our culture didn't understand how life sciences and biotech could help not only to improve quality of life, but also to create jobs, and competitiveness. Things have changed over the last decade because a healthy scientific environment and some very capable entrepreneurs have demonstrated the value of biotech.

EY: What are the most important challenges for biotech in Italy?

Vingiani: Financial. We have a tax policy for startups but the real problem is that it doesn't help medium-sized companies. We think the tax policy for biotech in the UK, for example, could be a good example for Italy. But we're only just recovering from the financial crisis of 2008, and it's difficult to create a special tax environment for biotech. However, society, opinion leaders, and politicians understand that biotech is a key to change and a way of creating value for our country, so things will change in time.

Biotech, especially life sciences, could be a big opportunity for investors to make a lot of money. Nevertheless, it's not so simple to invest in something that has such a long-term return and where there is a lot of risk. I think we don't have enough incentives for investors in Italy, and this is a problem for our companies.

EY: Italy has a great track record in industrial sectors and in health; where do you think the biotech winners will come from?

Vingiani: We've created a lot of value in life sciences in terms of jobs and turnover, but also in terms of quality of life. Italy has an increasing sector in the "white" industrial biotech, with some big worldwide players. Industrial biotech presents the opportunity to change the methods of production – becoming more environmentally friendly – and everyone is well aware of the importance of biotech for the health sector in creating new diagnostic and new medicines, so people see the technology's societal value. Unfortunately, that's not the case for "green" agricultural biotech, which is still associated with genetic modification; Italy is one of the most highly opposed countries in the world to GMOs.

I think that if we want to have Europe as a leader in more environmentally-friendly production, we have to cooperate at the European level to create the conditions for growth for this industry, and public procurement has a key role in creating a strong white biotech industry in Europe.

EY: A healthy biotech industry should attract great talent and entrepreneurs; are you seeing this in Italy at the moment?

Vingiani: The most promising factor for the biotech industry in Italy is human capital. In the past, we haven't had enough professionals to enable companies to create value through research but the

Government has helped considerably by creating incentives to attract very skilled people from abroad.

EY: Would a change to regulations make things easier for biotech in Italy?

Vingiani: If you think that for a new drug to be marketed in Italy, you need one year just to obtain national clearance following EU authorization, and then another six to 12 months to get it into the hospitals, you understand the problems of regulation. And it's similar in other countries. Europe could help significantly, by creating improved regulatory conditions, minimizing time for authorization of new medicines and time to market.



Nic Alexakis, CEO, Swiss Biotech Association, Switzerland

The Swiss Biotech Association represents 230 companies in Switzerland. It has links to policymakers and supports knowledge and technology transfer. We help with financing questions for biotech and have a support mechanism for education and professional development.

EY: How have the challenges for biotech changed over the last three or four years, and looking ahead to the future?

Alexakis: After the financial crisis, biotechnology started to be questioned by investors. It took 10 or more years before investors could see a return on investment. Now it's changing again; last year the biotech stocks were very successful and over-performed in a few cases. We're either all good or all bad; risky but rewarding! Finance is a challenge; venture capitalists are even more prudent than they were before the crisis. So we've had quite a bit of work to convince the finance sector and also the policymakers which are influencing the framework conditions.

Another issue is in the proof of concept funding stage. If you look at the value chain of a startup, you get first funds of family, friends and so on. Then there are a couple of awards that can be won and result in publicity and/or additional funds. But it needs more than that. My plea is that a company or a startup will only be successful in the investor market when they can show improved proof of concept results. That is a key driver for investors to gain confidence in the science and subsequently to fund the venture. Switzerland should improve this process.





EY: How do you see biotech competing with other sectors at the startup level in Switzerland?

Alexakis: I think it's improved a lot; the startup industry came publicly alive in the last three or four years, mainly through a few fine public and private initiatives which showcased success. ICT obviously does well and is well understood by the public, whereas the benefits from biotechnology can be a more difficult to understand. We try to work with the medtech sector – medical devices are “showable” and Switzerland has a very strong medtech industry that goes back about 150 years, so there's a certain economic pride. Biotechnology is still very young.

EY: Switzerland has a very successful pharmaceutical and medtech sector; how supportive are those industries of biotech?

Alexakis: Pharma relies to a certain extent on the small biotechs in terms of new innovation, and pharma is widely respected as an economic contributor, so this is a complementary game. Where we do have an issue is that the chemical companies, or those companies that use more industrial biotechnology solutions, are less good at communicating that they use biotechnology in their products; conveying the message to the household that the washing powder is reducing water consumption and temperatures, ergo energy consumption, thanks to biotech would be an excellent way of making people aware that biotechnology in general is cool.

EY: Where do you see the sort of specific opportunities and challenges for a Swiss company?

Alexakis: In the industrial sector, we're trying to push forward a national research proposal whereby a group of university institutes work together with industrial companies to find potential solutions that biotech could offer by replacing perhaps some chemical processes.

In the medical sector, there is huge potential. Orphan drugs are being widely debated and could potentially be a really big thing going forward. I think an interface between medtech and biotech is highly likely; in Switzerland, we have these two good industry foundations. In terms of neuro – scientists, we've always excelled and have some very good companies and institutions developing strongly and fast; Alzheimer's and Parkinson's diseases are the main drivers, and I think that's a potential field of successful activity.

The regulatory arena is a real issue. Not just in Switzerland, but everywhere. Unless politicians start to understand that you can't regulate everything, Europe will lose out globally. Everybody agrees that, if at all possible, you don't need animal testing, but by law you have to do these things. There are difficult contradictions to overcome.



Isabel Garcia, Secretary General, ASEBIO, Spain

What is the focus of the Spanish Biotech Association to encourage the biotechnology industry in your country? Can you describe the landscape in the biotech sector in Spain?

How does Europe support country-specific strategies? Do you think your country is generally supportive of the biotechnology industry?

ASEBIO, part of EuropaBio, is the Spanish Bioindustry Association with currently 261 partners, and a private, non-profit organization funded by memberships. The majority of our members are private biotech companies although universities, research institutions, and other public entities belong to ASEBIO. In this sense, ASEBIO promotes the development of the biotech industry in Spain and brings together all the players related to the industry that carry directly or indirectly activities related to biotechnology in order to improve the collaboration networks.

ASEBIO works for a political, regulatory, financial and social environment that allows the development of enterprises employing science and technology to create value for life. In fact, many of the positive steps

that have been launched to support biotechnology in Spain would never have occurred without the work that has been done from ASEBIO in the last decade and our partners, who also benefit from these measures, have actively participated in their design, contributing therefore to build their own future.

Over the past years, Spain has witnessed consolidation of its biotechnology sector as a consequence of the growth in the number of companies and the overall turnover, as well as of internationalization processes. Particularly since 2008, when the Central Government support for the sector started to act as a catalyst in attracting the interest of foreign investors. Nevertheless, there has traditionally been a lack of political recognition for the role played by biotechnology in the transformation of the economy and society, as well as a lack of a clear strategy with regards to economic support for the sector, with financing being subject to immediate rather than long-term factors. For example, a funding gap present in Spain is at “the proof of concept” stage. There are companies that have been successful in their initial stages but later find themselves in a difficult situation not being able to grow and go further. This is especially true for SMEs, and the Spanish biotechnology sector consists mainly of SMEs.

This is why decisions such as regulating innovative public purchasing; the creation of the Law of Support for the Entrepreneur and internationalization, which includes tax incentives for investors and companies; the redesigning of different programs,

such as INNVIERTE and Plan Profarma (that includes developments that favor the biotech sector) are all contributing factors toward creating an attractive and competitive environment for a sector that is on the rise in Spain, particularly from the perspective of project financing. And of course, Horizon 2020 and the ERDF fund, which now have a greater focus on innovation, open up the range of options for the creation of cooperative consortiums which Spanish companies have so much experience with.

Do you think European biotechnology has enough resources at its disposal to compete internationally, in developing as well as in developed markets?

Is enough being done to create incentives for European biotech startups? What sorts of incentives are most beneficial? How can governments best contribute? What about the private sector and multinational corporations?

The biotechnology sector promises a brighter future for Europe and the world. But for this to happen, the industry requires sound policy decisions that support innovation and risk-taking as well as a public that is well informed about how biotech is creating a healthier, greener, more productive and more sustainable economy.

Today, Europe has adequate resources and a powerful industry, but of course, it's never enough and we could work on intensifying activities associated with improving the financial environment, tax incentives and explore new opportunities.

The biotech sector needs a stable regulatory framework, without constant price cuts in the pharmaceutical field, which allows companies to undertake long-term business plans, requiring large sums to allocate investments. Biotechnology markets need more attention both from the public agenda as well as from the economic one. We also feel that private and public investment in biotechnology companies should be encouraged.

Regarding private sector and multinational corporations, there are large biotechnology companies that have decided to come to Spain to build a research center or a production plant, as is the case with Celgene, which established the Celgene Institute for Translational Research Europe (CITRE) in Seville in 2010, and the transfer to Spain of part of Pfizer's production in animal health. The fusion of the Belgian company TiGenix with the Spanish company Cellerix has also caught the interest of foreign investors since its very inception.

In Spain, ASEBIO continues working on these and other opportunities such as the negotiation of public debt accumulated by the sector, the launch of a roadmap for education and training of professionals in the new employment niches created by the bioeconomy and areas of special interest in the biotech sector.

In addition, we will continue working on internationalization, which remains one of our highest priorities. Last year was the first edition of an event we organized called Biolatam held in Bogotá, Colombia. The

event welcomed over 700 attendees from 29 countries and around 900 business development meetings were registered. Up to six countries from around Latin America showed interest in hosting the event in 2015. Also, the Spanish Parliament has adopted 2014 as the Year of Biotechnology in Spain and we will be holding our annual Biospain 2014 event in Santiago de Compostela between September 24 and 26.

Is there enough understanding at a general level of the benefits of medical biotechnology? If not, what could be done to improve it?

No other industry is better placed to enhance quality of life and respond to society's "Grand Challenges" of tackling an ageing and ever increasing population, health care choice and affordability and also resource efficiency, food security, climate change and energy shortages.

From new drugs that address our medical needs and fight epidemics and rare diseases, to industrial processes that use renewable feedstock instead of crude oil to lower the impact on the environment and crops that are able to grow in harsh climatic conditions and ensure safe and affordable food, biotech can and will pay economic, social and environmental dividends.

All of these bold technologies, and those that are still in the pipeline, will bring a new bioeconomy. For this to happen, an effort in communication and dissemination of science and the benefits from biotechnology by different stakeholders is necessary.

What are the biggest obstacles to the ongoing growth of the European medical biotechnology industry (eg., cost pressure, talent shortages, lack of investment money, inconsistent or over-stringent regulations)? What can be done to overcome them?

There are many factors that may prevent the development and growth of the industry. The sector demands a transparent clear framework for action, where patented drugs are protected and identify barriers to equal access throughout the system and as a generator of innovation fosters growth.

In terms of access to funding, the sector should be able to benefit from a strong financial ecosystem consisting of analysts, banks, and investors specialized in biotechnology in order to get know-how and resources available to the companies, accompanied by large pharmaceutical companies as well as universities. Increasing the liquidity in the market could

make it easier for venture capital funds to exit their portfolio companies; this would make the biotechnology sector more attractive to investors.

We are members of EuropaBio, and as such ASEBIO agrees with many of EuropaBio's demands in this area, such as:

- ▶ There is a need for common solutions to improve the cost effectiveness and sustainability of health systems that go beyond simple and sometimes short-sighted cost cutting exercises of national health budgets.
- ▶ There is a need for cooperation between EU countries about health systems to provide information and knowledge on efficient ways of investing in health.
- ▶ There is a need for the implementation of an effective pharmacovigilance system to ensure patient safety and recognize recent efforts that have been made to ensure greater fairness, proportionality and transparency in some aspects of the proposals for the mechanism of fees to be paid to EMA for these pharmacovigilance activities. However,

the industry is concerned about the increasing financial burden of regulatory costs incurred since the adoption of the pharmacovigilance package in 2010 especially in light of the annual saving for pharmaceutical industry.

Industry supports the political agreement on the draft Clinical Trials Regulation reached at the end of 2013, thus paving the way for the adoption of the Regulation by the co-legislators, the European Parliament and the Council, in 2014. The Clinical Trials Regulation, however, must reflect a balanced approach with regard to competitive assessment timelines and the disclosure of clinical trial data. We believe that the compromised text is not ambitious enough to meet the objective of securing timely patient access to innovative treatments and improving the attractiveness of Europe in terms of clinical research, and thus contributing to the growth objective of the Europe 2020 Strategy.

Funding – debt-financing on a steep rise

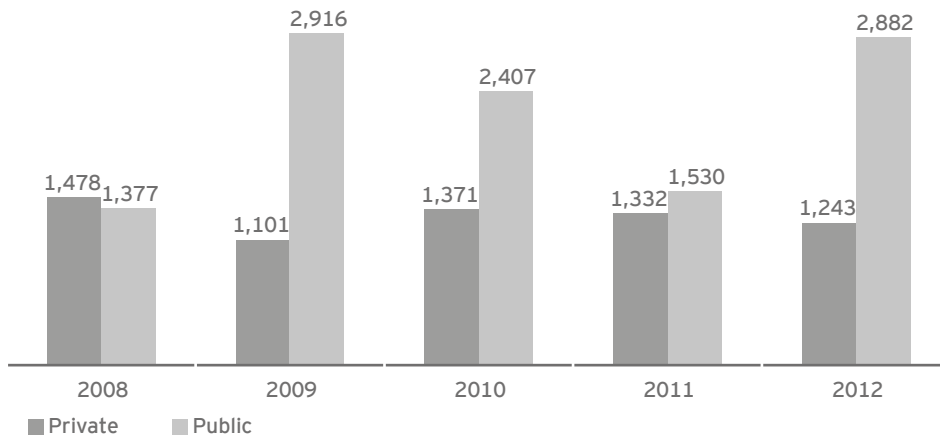
In Europe, although capital raised grew by 44% (y-o-y) to €4.2b in 2012 as compared to a decline of 23% (y-o-y) in 2011, it was entirely driven by debt financing, which increased by 392%. Four European companies contributed to debt financing in excess of €150m, including Elan Corp. (€600m) and Jazz Pharmaceuticals (€575m).

In the four years preceding the financial crisis of 2008, the average IPO capital raised per year was €831m. In the four

years since the crisis, the comparable number stands at just €111m. Over the last two years, the average has fallen even further, to €41m. There were only three IPOs in Europe in 2012, raising a total of €40m. This was a decline even from the weak performance in 2011, when eight IPOs raised a total of €43m.

In Europe, the majority of funding is innovation capital. Overall fluctuating trend in capital raised has been driven by commercial leaders, as innovation capital for R&D at smaller companies has been almost consistent since the financial crisis.

Figure 1: Capital raised by European health care biotech – based on ownership type (in US\$m)



Note: OANDA has been used for currency conversion for the years 2008 and 2009

Source: EY and company financial statement data (taken from *Beyond Borders* report 2010-2013)

Figure 2: Capital raised by European biotech – based on transaction type (in US\$m)



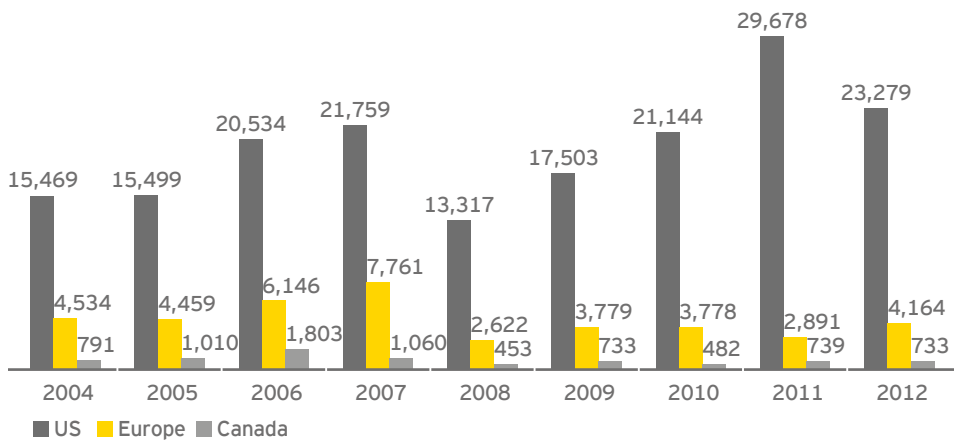
Note: Numbers may appear inconsistent because of rounding. Convertible debt instruments are included in "debt."
 Source: EY, BioCentury, Capital IQ and VentureSource (taken from *Beyond Borders* report 2013)

The European biotech industry mirrors the financing situation prevalent in all established biotech centers, i.e., large debt transactions by a few commercial leaders and a challenging funding environment for most R&D-phase companies. In the US, biotechnology companies raised US\$23.3b in 2012, the second-highest total over the past decade, after 2011, when the industry raised US\$29.7b. Debt-financing was the prime driver for this growth in both years. However, debt raised declined from US\$19.8b in 2011 to US\$11.8b in 2012. Continuing the previous trend, Amgen (which raised US\$5b) and Gilead (US\$2.2b) were responsible for the majority of debt

raised in 2012. On the other hand, non-debt financing increased by 16% y-o-y in 2012 as a result of an increase in follow-on and other offerings.

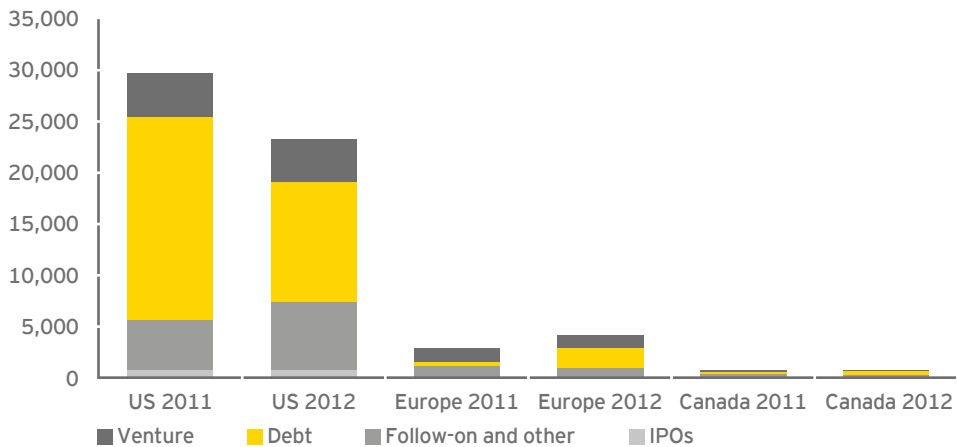
Similar to the US and European industry funding, Canadian biotech experienced large contributions from debt financing, which increased more than 100% (y-o-y) in 2012. For Canada, for the fifth consecutive year, there were no IPOs, and venture funding was down by 60%. The Canadian industry witnessed a decline of almost half in average amount of capital raised since the financial crisis, similar to the European trend.

Figure 3: Geographic comparison – capital raised (in US\$m)



Note: Numbers may appear inconsistent because of rounding. Convertible debt instruments are included in "debt."
 Source: EY, BioCentury, Capital IQ and VentureSource (taken from *Beyond Borders* report 2013)

Figure 4: Geographic comparison – Capital raised by transaction type (in US\$m)



Note: Numbers may appear inconsistent because of rounding. Convertible debt instruments are included in "debt."
 Source: EY, BioCentury, Capital IQ and VentureSource (taken from *Beyond Borders* report 2013)

Deals – pharma involvement prominent in both M&A and strategic alliances

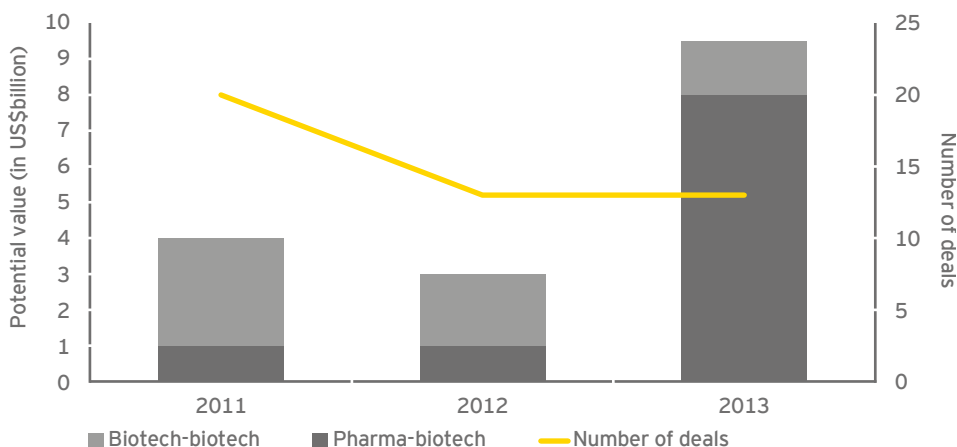
The European biotech industry was more active in strategic alliances (46 in number) as against M&A activity (13) in 2012. Regarding M&As, the deal volume in 2012 was the lowest since 2006 and has remained flat for the year 2013. Following the trend of declining number of deals, the deal value also declined by 28% (y-o-y) to US\$2.9b in 2012. However, in 2013 the M&A value increased significantly to US\$9.6b, buoyed by the acquisition of Elan Corp by Perrigo for US\$6.5b. This reflects a trend of increase in pharma-biotech deals in Europe, which has helped balance out the skewed distribution of biotech-biotech deals that accounted for about 75% of all M&As in 2011. Other major deals during the year included acquisition of Gentium by Jazz Pharmaceuticals for about US\$1b to gain access to its lead product; acquisition

of Spirogen by MedImmune for US\$440m to build on its oncology platform; and acquisition of Okairos by GSK for US\$324m to expand its vaccine business.

For the US, there was a decline in the M&A deal value in 2013 to US\$14b versus US\$23.8b in 2012; however, the total deal volume remained almost consistent in 2013. The industry witnessed only one deal (acquisition of Onyx Pharma by Amgen, worth US\$9.7b) of over US\$2b in 2013 as compared to four in 2012. In Australia, there were four M&A deals in 2013, worth US\$10m. Of these, three were biotech-biotech deals and one was pharma-biotech. For Canada, there were nine M&A deals in 2013 worth US\$950m and of these, six were pharma-biotech deals and the remaining were biotech-biotech.

Big pharma, represented by AstraZeneca, Bristol-Myers Squibb and Amgen, has been involved in multiple acquisitions during the last two years.

Figure 5: M&A by European biotech



Note: Chart excludes transactions where deal terms were not publicly disclosed.

Source: EY, Capital IQ, ThomsonONE, MedTRACK and company news (taken from *Beyond Borders* report 2013)

Table 1: Top 10 M&A deals for 2012 and 2013

Company	Country	Acquired or merged company	Country	Total potential value (€m)	Year
Amgen Inc	US	Onyx Pharmaceuticals Inc	US	9,123	2013
Perrigo Co	US	Elan Corp Plc	Ireland	6,535	2013
Bristol-Myers Squibb	US	Amylin Pharmaceuticals	US	5,300	2012
Hologic	US	Gen-Probe	US	3,800	2012
GlaxoSmithKline	UK	Human Genome Sciences	US	3,600	2012
Bristol-Myers Squibb	US	Inhibitex	US	2,500	2012
Celgene Corp	US	Acetylon Pharmaceuticals Inc	US	1,700	2013
AstraZeneca	UK	Ardea BioSciences	US	1,260	2012
Amgen	US	Micromet	US	1,160	2012
AstraZeneca Plc	UK	Pearl Therapeutics Inc	US	1,150	2013

Note: "Total potential value" includes upfront, milestone and other payments from publicly available sources.

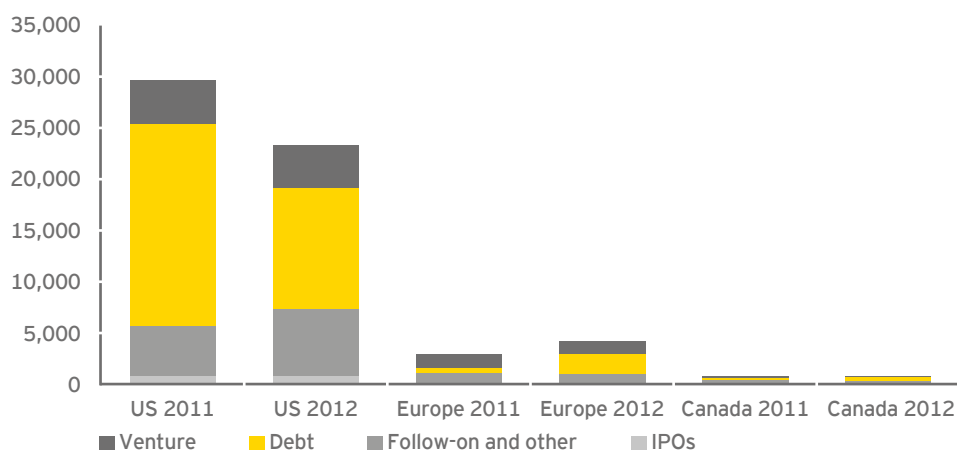
Source: EY, Capital IQ, ThomsonONE, MedTRACK and company news (taken from *Beyond Borders* report 2013)

In terms of strategic alliances based on bio bucks, Europe witnessed a rebound in 2012 with value reaching US\$11.1b from approximately US\$8b in 2011. However, the number of strategic alliances fell to 46, the lowest since 2006. This European trend is in contrast to the scenario in the US, where biobucks value of alliances fell and number of deals remained flat. In both the US and Europe, the pharmaceutical sector is dominant over the biotech sector when it comes to forming strategic alliances with biotech companies.

For strategic alliances based on upfront payments, the European biotech industry almost touched the US upfront payment value of US\$1.3b in 2012. This can be attributed to a steep decline of 19% (y-o-y)

in US upfront payments and a stark rise of 135% (y-o-y) in European upfront payments to US\$1.1b. Dominance of big pharma players is even more striking in upfront payments than biobucks, with biotech-biotech deals accounting for only 3% of total upfront payments in 2012. This increased interest of pharma in biotech assets is mainly to compensate for patent cliff and slower growth in emerging markets.

Figure 6: Geographic comparison – strategic alliances based on biobucks



Note: Chart shows potential value, including upfront and milestone payments for alliances where deal terms are publicly disclosed.

Source: EY, ThomsonONE, MedTRACK and company news (taken from *Beyond Borders* report 2013)

Table 2: Alliances with big upfront payments, 2012

Company	Country	Partner	Country	Upfront payments (US€m)
GlaxoSmithKline*	UK	Basilea Pharmaceutica	Switzerland	231
Abbott	US	Galapagos	Belgium	150
Merck & Co	US	AiCuris	Germany	141
Johnson & Johnson	US	Genmab	Denmark	135
Merck & Co	US	Endocyte	US	120
Valeant	Canada	QLT	Canada	113
Abbott	US	Action Pharma	Denmark	110
The Medicines Company	US	Bristol-Myers Squibb	US	105
Novartis	Switzerland	ThromboGenics	Belgium	96
Celgene	US	Epizyme	US	90
Boehringer Ingelheim	Germany	Forma Therapeutics	US	65
Forest Laboratories	US	Adamas Pharmaceuticals	US	65
Allergan	US	Molecular Partners	Switzerland	63
Vidara Therapeutics*	US	InterMune	US	55
AstraZeneca	UK	Amgen	US	50

Note: *Company acquired an asset from the “partner.”

Source: EY, ThomsonONE, MedTRACK and company news (taken from *Beyond Borders* report 2013)

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Glossary of terms

Accounting period

The period of time used to determine a company's or organization's taxable profit for corporation tax. The period normally matches an organization's financial year.

Bioeconomy Strategy

A strategy adopted by the Commission in 2012 to shift the European economy toward greater and more sustainable use of renewable resources. It outlines a coherent, cross-sectoral and interdisciplinary approach to the issue. The goal is a more innovative and low-emissions economy, reconciling demands for sustainable agriculture and fisheries, food security and the sustainable use of renewable biological resources for industrial purposes, while ensuring biodiversity and environmental protection.

Capital allowances

Enable a company to deduct (write-off) the cost of capital assets, such as machinery, computers, equipment or vehicles, against taxable profits for corporation tax, instead of deducting the full cost of the item as an expense from taxable profits in the year it was acquired. A portion of that cost is deducted over a period of years.

Carry on business

A company or organization that is active.

Chargeable gain

If a company or organization is liable for corporation tax, capital gains tax is not due separately on capital gains (in contrast to individuals, self-employed, sole traders or partners in partnerships). Instead, tax on chargeable gains is paid as part of corporation tax profits.

Clinical phase

Refers to the stage of the clinical trial process:

Phase 1 – the first phase of a clinical trial, which usually involves a low number of participants and has the purpose to determine the best method of delivery, best dosage and, most importantly, if the treatment is safe for humans.

Phase 2 – the second phase of a clinical trial which involves more participants than phase 1 and is carried out to determine if the treatment is effective on patients. It also provides additional safety data.

Phase 3 – the third phase of a clinical trial with the purpose of determining if the new treatment works better than the established treatment for the same disease or condition.

Common Agricultural Policy (CAP)

The EU Common Agricultural Policy is aimed at supporting farmers' incomes while also encouraging them to produce high-quality products demanded by the market and ensuring rural development in the most environmentally sustainable way. The CAP is due to be reformed by 2013 with the aim of making it a more effective policy to boost innovation, competitiveness and sustainable agriculture in rural areas.

Computation

The mathematics which shows how entries have been calculated from the figures in company accounts.

Corporation tax

A tax on the taxable profits of limited companies and some organizations, including charities, clubs, societies, associations, cooperatives and other unincorporated bodies.

Credit, tax

Tax credits reduce the amount of corporation tax paid by deducting an amount (the credit) directly from the amount of corporation tax payable. If there is no corporation tax to pay, sometimes there is a cash repayment.

Declaration

The section at the end of a company's tax return which an authorized person must read, sign and date to verify that the information is correct and complete.

Deduction

An amount deducted from taxable profit for corporation tax purposes. Tax authorities use deductions and reliefs to refer to various expenses, losses or allowances to be subtracted from profits before corporation tax is paid. This is in contrast to credits or other types of relief which are deducted directly from the amount of corporation tax payable.

Depreciating assets

Any fixed plant or machinery, not forming part of a building, or any asset that will have a life of 60 years or less in the UK from when it was acquired by a company or organization.

European Medicines Agency (EMA)

The European Medicines Agency is a decentralized agency of the European Union, located in London. The agency is responsible for the scientific evaluation of medicines developed by pharmaceutical companies for use in the European Union.

EU 2020 Initiative

Europe 2020 is the EU's growth strategy for the coming decade. Concretely, the Union has set five ambitious objectives – on employment, innovation, education, social inclusion and climate/energy – to be reached by 2020. Flagship initiatives are what underpin this strategy.

Genetically modified crops (GM crops)

Genetic modification of crops means that existing genes are modified or new genes included to give plant varieties desirable characteristics, such as resistance to certain pests or herbicides, or enhanced nutrient profiles.

Health Technology Assessment (HTA)

HTA is a research-based assessment of the medical, economic, social and ethical implications of the incremental value, diffusion and use of a medical technology in health care.

Horizon 2020

Horizon 2020 is the financial instrument implementing the Innovation Union, a Europe 2020 flagship initiative aimed at securing Europe's global competitiveness. Running from 2014 to 2020 with an €80b budget, the EU's new program for research and innovation is part of the drive to create new growth and jobs in Europe.

HTA authority

A national body tasked with carrying out health technology assessments (HTAs) for prospective new medical technologies (e.g., the UK's National Institute for Clinical Excellence or NICE).

Indication

The purpose for which a certain medical technology, such as a test, medication, procedure or surgery, is used and approved.

Intangible assets

Intangible assets include, subject to some exceptions, goodwill and intellectual property such as patents, trademarks, registered designs and copyright, together with licenses to exploit such assets and other intangible assets, such as agricultural and fishing quotas.

Market access

An opportunity for a company to enter a specific market to commercialize its products or services.

Marketing authorization application (MAA)

An application for authorization to place medicinal products on the market.

Orphan disease

A rare disease which affects a small percentage of the population.

Permanent establishment

A company that is not resident but carries on a trade from a fixed place of business (a permanent establishment) is liable for corporation tax on that activity.

Pivotal clinical trial

A trial which provides the significant evidence which enables the "cost-benefit" analysis of an authority charged with carrying out HTAs.

Pricing and reimbursement (P&R)

Pricing refers to the direct or indirect setting of pharmaceutical prices by Member States within the European Union. Reimbursement refers to the process of a state paying back (reimbursing) a patient the cost of a medicine approved for reimbursement. Systems differ between Member States with some reimbursing only to a point, while others do so fully.

Pre-clinical

The pre-clinical stage is the stage of product development when the substance has yet to be tested on humans.

Rates (of corporation tax)

There are two rates of corporation tax in the UK, depending on the company or organization's taxable profits: the lower rate – also known as the small profits rate, and the upper rate – known as the full rate or main rate. There is also a sliding scale between the lower and upper rates known as marginal relief.

Relief

An amount deducted from taxable profit for the purposes of corporation tax. The tax authorities use reliefs and deductions to refer to various expenses, losses or allowances subtracted from profits before the amount of corporation tax is calculated. This is in contrast to credits or other types of relief which are deducted directly from the amount of corporation tax payable.

Research and development (R&D)

In the context of commerce, "research and development" normally refers to future-oriented, longer-term activities in science or technology, using similar techniques to scientific research without predetermined outcomes and with broad forecasts of commercial yield.

Small and medium-sized enterprise (SME)

In the European Union, an SME is defined as a company with no more than 250 employees, annual turnover of €50m or less and a balance sheet not exceeding €43m.

Tax credit

Reduces the amount of corporation tax paid by deducting an amount (the credit) directly from the amount of corporation tax payable.

Tax liability

The amount of corporation tax owed.

Transfer pricing

Refers to the setting, analysis, documentation, and adjustment of charges made between related parties for goods, services or use of property.

Tax treaty network

Many countries have agreed with others in treaties to mitigate the effects of double taxation. The treaty may cover income tax, corporation tax, indirect tax or other taxes.

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