

The Pharmaceutical Industry in Ireland - Innovation and the IP Framework

For the Irish Pharmaceutical Healthcare Association

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02 August 2018 | Final Report



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02 August 2018

The Pharmaceutical Industry in Ireland - Innovation and the IP Framework

Dear Oliver

In accordance with the terms of our engagement agreement dated 11 June 2018, we have assisted the Irish Pharmaceutical Healthcare Association ('IPHA' or the 'Association') in a study of the pharmaceutical industry in Ireland in the context of innovation and the IP framework (the 'Purpose'). Our role is to provide you with our analysis and findings. We have not performed any management functions or made any management decisions.

Limitations of scope

We have not, except to such extent as you have requested and we have agreed to in writing, sought to verify the accuracy of the data, information and explanations provided by yourselves, and you are solely responsible for this data, information and explanations. We have therefore relied on the information provided by you to be accurate and complete in all material respects. This report has been provided to you for the above Purpose only and should not be used or relied upon for any other purpose, nor should it be disclosed to, or discussed with, any other party without our prior consent in writing.

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We appreciate the opportunity to have provided EY's Advisory services to the Association.

Should you have any queries or comments regarding this report or if we may be of any further assistance, please do not hesitate to contact me on +353 1 221 2611.

Yours sincerely

Simon MacAllister
Partner



Dashboard

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Executive summary



1 Executive summary

This study examines the pharmaceutical industry and the IP framework relating to pharmaceutical products using a number of approaches.

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Introduction to this report

This study has been commissioned by the Irish Pharmaceutical Healthcare Association (IPHA) in the context of the European IP framework, and proposals to reduce the protections afforded to medicines researched within Europe. This report highlights the industry's commercial significance and its contribution to Irish society. It is designed to be of assistance to policymakers in examining the industry's contribution to Ireland's continued economic and social development.

Approach and methodology

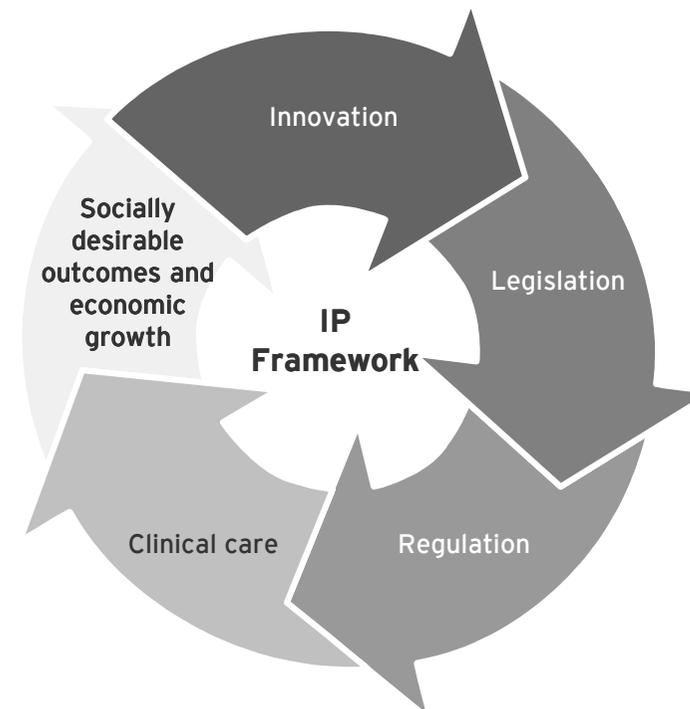
The analysis in this study has been undertaken using the following approaches:

- ▶ **Literature review:** Relevant publications from a wide range of entities were consulted, including Government bodies, industry groups such as the IPHA and the European Federation of Pharmaceutical Industries and Associations (EFPIA), and European legislative and regulatory bodies.
- ▶ **Stakeholder engagements:** Consultations were carried out with stakeholders including the Irish Patent Office, law firms, and other relevant bodies.
- ▶ **Quantitative indicators:** Relevant data was collected from a number of sources, including the Irish Patent Office, the European Medicines Agency, and Eurostat.
- ▶ **Comparators:** Four comparator countries to Ireland are highlighted: France, Germany, Sweden and the UK. Whilst these are larger countries in economic and population terms, the industry in Ireland makes a contribution of comparable magnitude to the industries in these countries.

The aim of this multi-faceted approach was to produce a rounded analysis of the relationship between innovation, a strong IP framework, and economic outputs and social outcomes.

Pharmaceutical products and IP

This report highlights the evolution of pharmaceutical products, from the research and development stage through to the consumer. At various stages along the value chain a range of IP-related factors impact innovation, access, outcomes, and returns on investment.





1 Executive summary

IP frameworks play a role throughout the evolution of a medicine, from the manufacturer to the patient.

1 Executive Summary

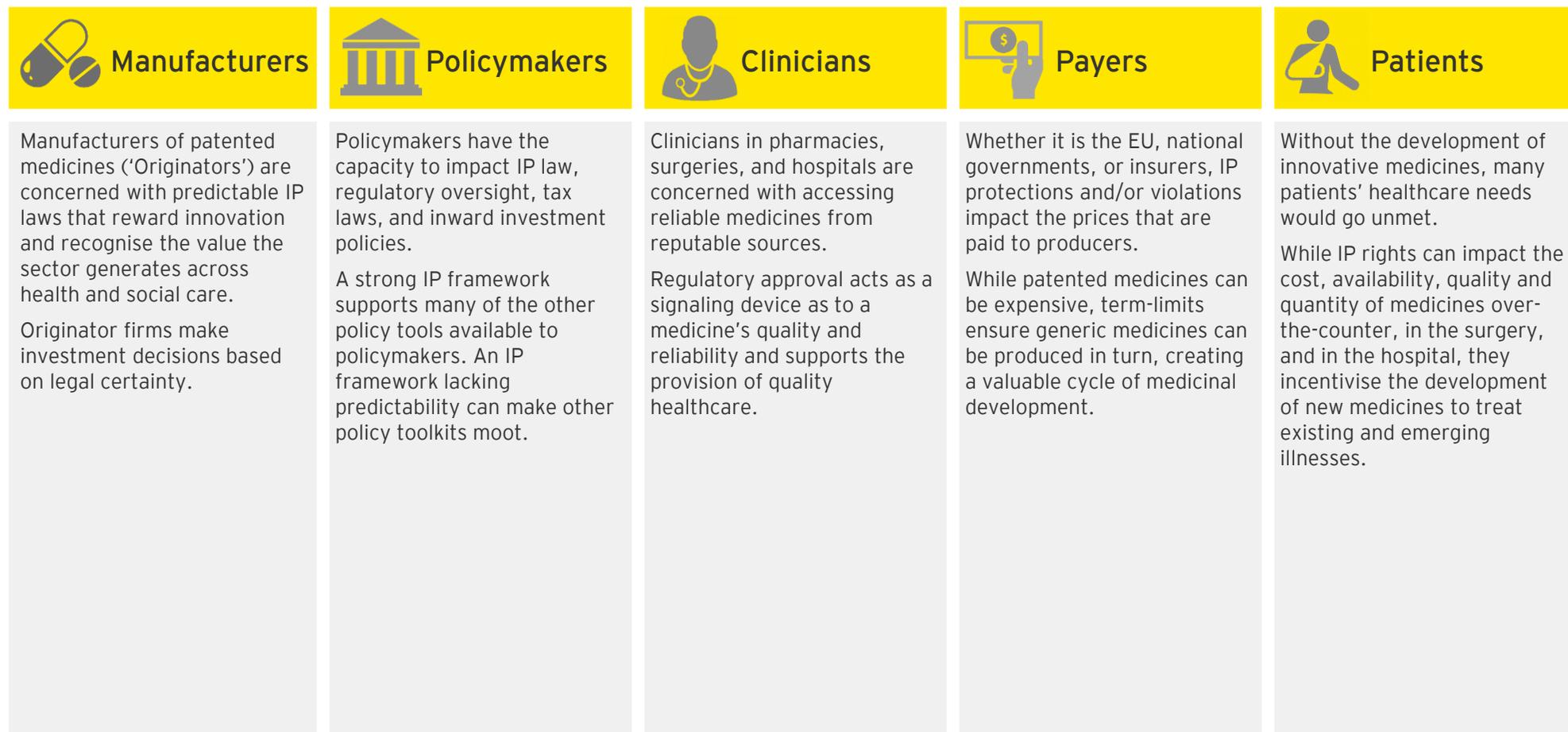
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Stakeholders in pharmaceutical industry

Pharmaceutical products move through the healthcare system from the factory to the patient, driven by innovation and IP.





1 Executive summary

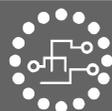
This study identifies a range of key findings relating to the industry and innovation, IP and economic and social outcomes.

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Investing in Innovation

- ▶ Intellectual property frameworks have economic rationales: to incentivise innovation, reward investment, and to secure a supply of quality medicines.
- ▶ About two-thirds of Europe's economic growth over the past two decades has been driven by innovation, according to the European Commission.
- ▶ The industry in Europe invests over €34bn per annum in costly and time-consuming research and development (R&D) activities, with the aim of identifying new medicines to treat a wide range of illnesses.
- ▶ In 2016, pharmaceutical companies in Europe invested 15% of net sales in research and development - nearly 33% more than was invested by the software industry. The pharmaceutical industry accounts for one in five euros invested in research and development in Europe.
- ▶ The industry undertakes R&D into a wide range of diseases and illnesses. One to two of every 10,000 substances synthesised in laboratories passes all stages of development needed to become a marketable medicine and it can cost more than €2 billion to bring one new medicine to market.



The IP Framework

- ▶ The IP framework in Ireland is underpinned by treaties, EU rules and regulations, and Irish institutions - patent protection is afforded to original discoveries for a period of 20 years.
- ▶ Supplementary Protection Certificates (SPCs) grant protection for a maximum of 5 additional years following expiry of the initial patent, to account for any delays in approval by regulators.
- ▶ The European Commission has put forward a number of proposals for reforms to the existing IP framework, with the intent of spurring economic activity. The proposed SPC 'manufacturing waiver' would allow generics manufacturers to produce patented medicines for export and sale outside the EU during the period covered by the SPC.
- ▶ If implemented, this proposal could afford generics manufacturers an effective competitive advantage viz-a-viz innovative firms in the period during the SPC and following its expiration, as these firms could produce medicines that innovators produce - in the same period - without having to invest in innovative research and development.
- ▶ Proposals to restrict the effects of the SPC waiver include limitations around export to countries where there is no intellectual property protection or where it has expired.



Ireland as a Global Player

- ▶ Over 30,000 people are directly employed in the industry in Ireland, in plants and labs in communities across the country, and in over 120 multinational and indigenous firms.
- ▶ Exports of pharmaceutical and chemical products from Ireland amounted to €68bn in 2017, 150% greater than in 2007 and contributing €50bn to Ireland's trade balance.
- ▶ Ireland's industrial policy has enabled the country to attract investments of scale across many sectors, including pharmaceuticals. This, in turn, creates high-quality, well-paid jobs, and spurs the development in Ireland of new therapies for diseases and conditions.
- ▶ All recent trends around job creation and export show that Ireland continues to attract a strong share of international investments in the discovery and manufacture of innovative medicines.



1 Executive summary

This study identifies a range of key findings relating to the industry and innovation, IP and economic and social outcomes.

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Tangible Outcomes

- ▶ Research shows that innovation by the industry results in the development of medicines that can improve human health and well-being, including workforce participation and labour force productivity.
- ▶ The National Cancer Strategy aims to place Ireland in the top quartile of European countries for cancer survival in the next decade - as about 73% of survival gains in cancer are attributable to new medicines, the industry's continued innovation in this area will be vital.
- ▶ The development of statins has revolutionised the treatment of cardiovascular disease - in a single decade in Ireland, the incidence of cardiovascular disease dropped by 28%.
- ▶ The introduction of anti-retroviral medicines in the mid-1990s transformed HIV from a terminal disease to a chronic illness, while Hepatitis C has virtually been cured by new medicines.
- ▶ The realisation of positive health and social outcomes is influenced by the accessibility of medicines - research shows that medicines approved by the EMA reach Irish patients later than patients in most of western Europe.



Risks to Growth

- ▶ Demographic changes, longevity, and more complex illness are leading to an increase in demand for new and original medicines, while also adding complexity to the approaches to treatment.
- ▶ Consumers are becoming increasingly more aware of pharmaceutical products and healthcare innovations, and are demanding innovative approaches in the delivery of healthcare.
- ▶ The withdrawal of the UK from the EU could present threats to the supply chain of pharmaceutical production in Ireland, dependent upon the final outcome of these negotiations.
- ▶ Reforms to the existing IP framework could mean fewer innovative medicines will be researched and developed, and could negatively impact the number and quality of jobs created by innovative firms.



Opportunities

- ▶ The industry has the capacity and desire to continue to innovate to research and develop the medicines that treat patients on a daily basis.
- ▶ It is adapting to changing demands for medicines by investing in precision medicines, digitalisation, and connected care - supporting the entire healthcare service from the lab to the patient.
- ▶ Already the industry cooperates with a range of public bodies across Europe on research - there are opportunities to deepen these engagements, so as to foster innovation and discovery.

2

Investing in Innovation





2 Investing in Innovation

The global pharmaceutical industry is growing and in Europe it makes a strong contribution to the economy, research, and employment.

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The pharmaceutical industry globally and in Europe

The pharmaceutical industry is of major importance to the European economy and to European society, contributing to exports, employment, and the Exchequer across the Member States. The research-based pharmaceutical industry can play a critical role in securing growth in Europe and ensuring future competitiveness in an advancing global economy.

- ▶ By 2021, the global pharmaceutical industry is projected to reach a value of US\$1.5 trillion, at a CAGR of 4%-7%.¹
- ▶ The United States will remain the largest market followed by Japan. 'Pharmerging' markets such as China, India, Brazil, Russia will grow at 6-9% per annum.
- ▶ The market value of the EU5, comprising France, Germany, Italy, Spain, and the UK, will reach between US\$170bn and US\$200bn by 2021.
- ▶ In 2016, the industry invested an estimated €35bn in R&D in Europe.²
- ▶ Across Europe, direct employment in the industry amounts to 745,000 in addition to employment indirectly, upstream and downstream.

€250bn
Total pharmaceutical
production in Europe in 2016

€35bn
R&D expenditure by the
pharmaceutical industry in
Europe per annum



22%
European share of global sales
of new medicines (2011-2016)

745,000
Direct employment in the
industry in 2016

Source: EFPIA; NB: 'Europe' includes Norway and Switzerland



2 Investing in Innovation

Ireland is successful at attracting firms that invest in manufacturing facilities, and has a public policy to increase innovation domestically.

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Innovation and investment in Ireland

The market for innovation and research is global - international cooperation in research and innovation plays an important role in the development and sustainability of a world-class innovation and research system. As a small, open economy, Ireland relies on external demand and international markets for sustainable and continued growth. At the same time, Ireland is central to developments in the pharmaceutical industry, attracting a considered number of research-oriented multinational firms:³

- ▶ 10 of the world's top 10 pharma companies have operations here
- ▶ 8th largest producer and the 5th largest exporter of pharmaceuticals globally
- ▶ 120 pharmaceutical companies have bases here
- ▶ 40 pharma and biopharma plants are FDA approved
- ▶ Strong clusters of firms in Dublin and Cork, and emerging areas around Sligo, Waterford and Mayo.

Competitor investment locations

While Ireland's successes are well-recognised internationally, both the industry and the Irish government recognise a number of key competitor locations:

- ▶ Puerto Rico - manufacturing
- ▶ Singapore - manufacturing and R&D
- ▶ Massachusetts- clinical trial management
- ▶ Netherlands - R&D
- ▶ Belgium - manufacturing.

Innovation 2020

Innovation 2020, the Government's policy on developing innovation in Ireland, outlines a range of objectives for a greater level of innovation to be fostered:

- ▶ Support research across all disciplines
- ▶ Increase public and private investment in R & D
- ▶ Enhance the impact of research and innovation
- ▶ Ensure that education drives innovation
- ▶ Focus research and innovation activity on social and economic development
- ▶ Protect and transfer knowledge between public and private bodies
- ▶ Become a Global Innovation Leader.

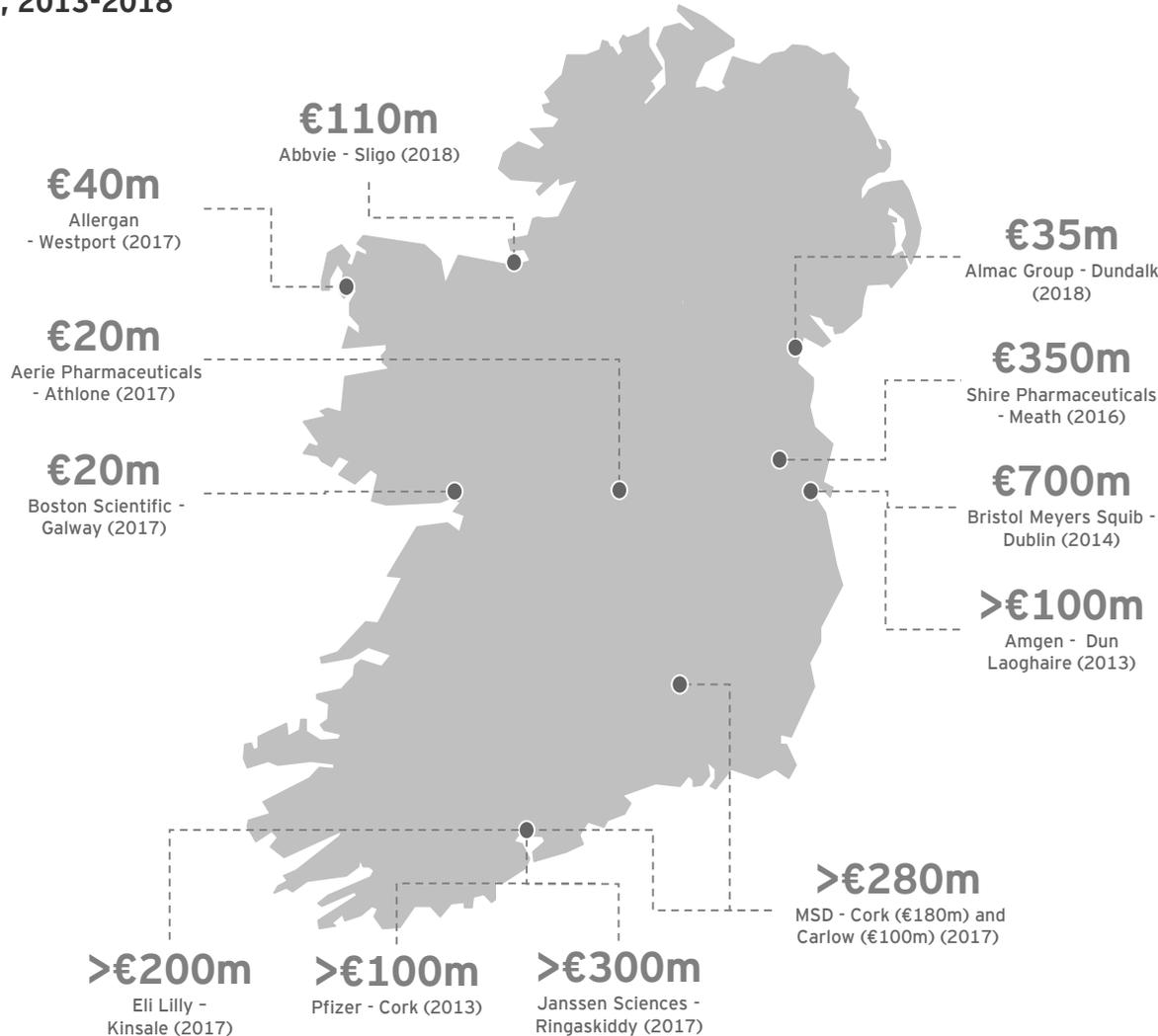
Committing to these objectives and monitoring success could secure a greater share of investment in innovation by both public and private entities, and would signal Ireland's commitment to dynamic research.

2 Investing in Innovation

There has been a significant number of investments made in manufacturing facilities in Ireland by multinational life sciences firms over recent years.

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Investments in Manufacturing and R&D Facilities in Ireland by Multinational Life Sciences Firms, 2013-2018



Investment in facilities

The industry invests in new and retrofit facilities across research and manufacturing throughout the country.

Stakeholders from the industry and public bodies emphasise that firms invest in plants and people in Ireland in the knowledge that these investments are backed up by a predictable legal and regulatory framework, and a policy environment that acknowledges the value of innovation.

Over the period 2008 to 2018, investments in new facilities has amounted to approximately €10bn while the number of biotechnology manufacturing sites has increased from 2 in 2003 to 20 in 2018.⁴

Source: IDA; years relate to year of announcement



2 Investing in Innovation

Ireland compares well in terms of attracting foreign funding for R&D and for the number of patent applications granted to firms based here.

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Investment in R & D in Ireland

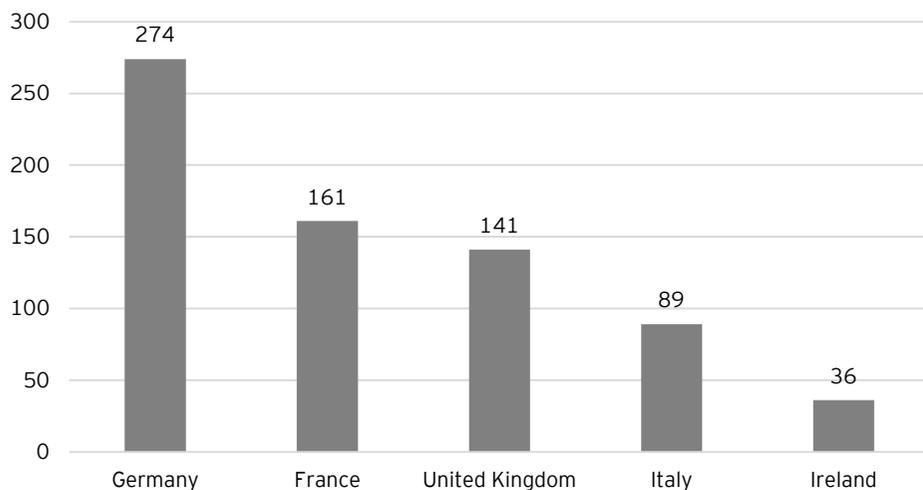
The role of pharmaceutical firms in Ireland’s economic success over the past number of decades has been immense. It is an Irish success story, and one dependent on our talent, stable public policy and legislative framework, and EU integration. Over the period 2011-2013, patent-intensive industries accounted for an average of 23.2% of GDP in Ireland - the highest share amongst all Member States and well above the EU’s 15.2%.⁵

Irish-based pharmaceutical firms are active in applying for, and being granted, patents on a domestic and European level. In 2017, 51 applications were made to the European Patent Office and 36 patents were granted.⁶ The number granted has been increasing over recent years, from 14 in 2013, and reflects the growing level of investment in research and development here.

The data also shows that while Ireland ranks well relative to other major producers of pharmaceutical products in Europe in terms of the number of patents filed, R&D investment in Ireland is more likely to be sourced from abroad than in many other western European countries, at 23%.⁷ This highlights Ireland’s success at attracting international funding for innovative research.

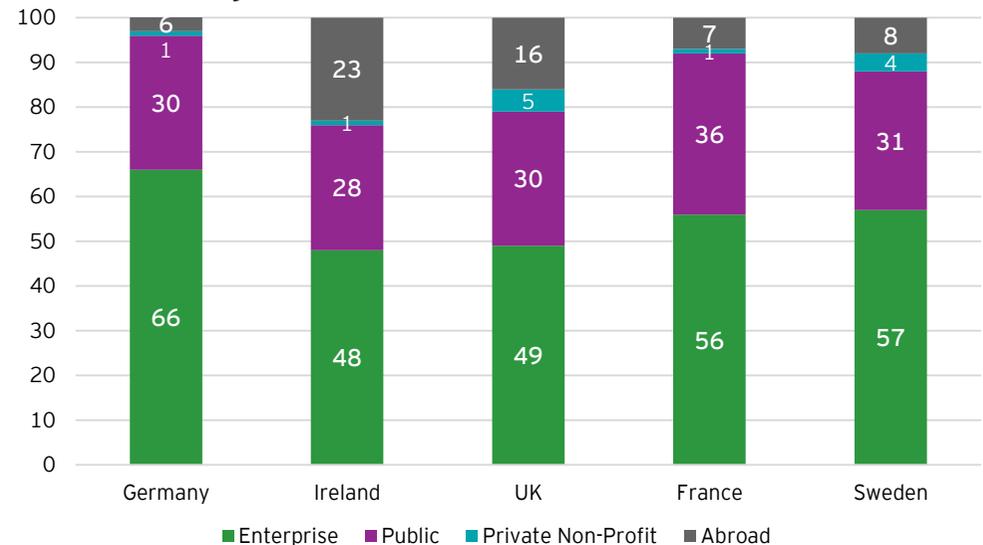
Related to this, the American Chamber of Commerce in its 2018 IP Index, which ranks countries’ IP rights frameworks for their ability to encourage and protect innovation, ranked Ireland 6th of 50 countries, and 4th in the area of patent rights specifically.⁸

Pharma patents filed at the EPO by firms based in selected countries (2017)



Source: European Patent Office

Sources of funding for R&D activities (2016)



Source: Eurostat

3

The Rationale for IP



3 The rationale for IP

IP frameworks encourage innovation in an industry in which research and development can be time-consuming and very often unsuccessful.

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The economics of IP

1. Encourage Innovation

- Reward risk
- Secure supply and access

Encourage innovation

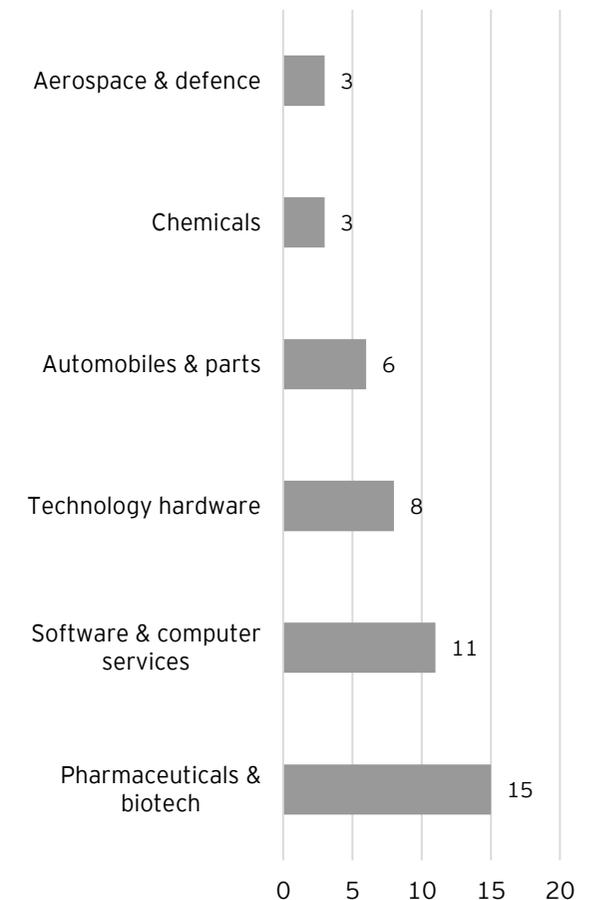
A number of market failures are directly linked to investment decisions in R&D. High risks, sunk costs, market uncertainty, lack of full appropriability of results, or unavailability of funding, can all result in underinvestment in R&D below what is socially desirable.

To maximise the spillovers that the creation and innovation generates, IP rights can be a pivotal driver. *Research shows that the stronger the IP framework the greater the incentive to invest in R&D and hence the rate of innovation (Nordhaus, 1969).*

Pharmaceutical incentives have been proven to turn science into medicine, identifying solutions to patients' unmet needs. Improved health outcomes can be the outcome: avoiding illness, slowing disease progression, improving patients' lives and reducing overall costs for healthcare systems.

The pharmaceutical and biotechnology industries invest considerable sums in R&D. In 2016 the industry invested 15% of net sales in R&D activities, nearly 33% more than was invested by the software industry in R&D.⁹ Hence, relative to other industries, the level of this investment in R&D is significant, especially in light of the fact that a return on investment is often achieved only after a lag of many years.

Global Investment in R&D (% of net sales, 2016)



Source: European Commission



3 The rationale for IP

IP frameworks reward risks of investment, in an industry in which the cost of research has been shown to be increasing over recent decades.

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The economics of IP

1. Encourage Innovation
- 2. Reward risk**
3. Secure supply and access

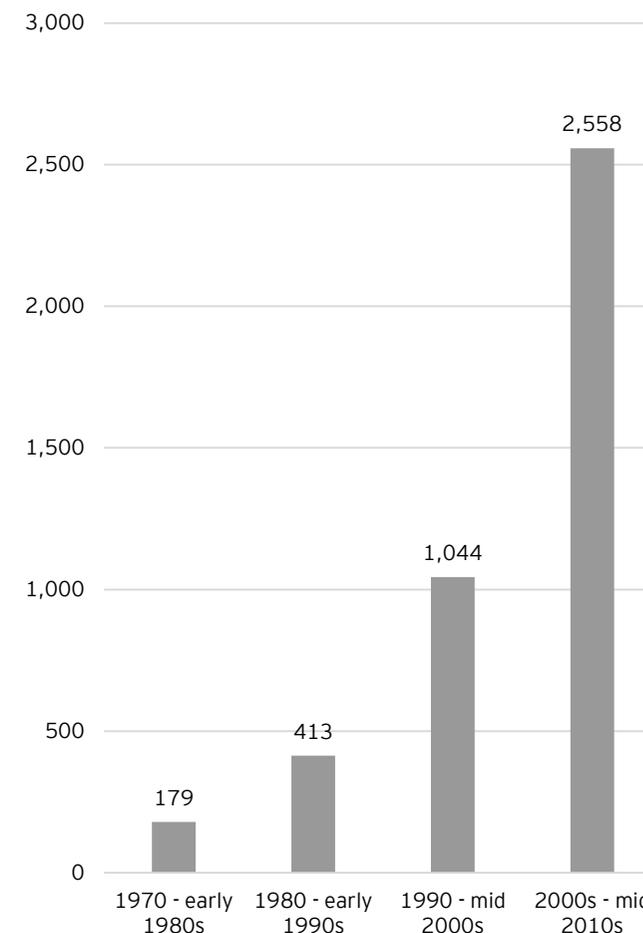
Reward risk

Pharmaceutical R&D is a complex, resource-intensive, and long-term process, with no guarantee of success. This is borne out in practice, through the various stages of the life cycle of a medicine.

- ▶ One to two of every 10,000 substances synthesised in laboratories will successfully pass all stages of development required to become a marketable medicine.¹⁰
- ▶ Research undertaken at the Tufts Centre for the Study of Drug Development shows that, over the past number of decades, the cost of bringing a medicine through the various stages of development has risen significantly, and now stands at 13 times what it stood in the 1970s.¹¹
- ▶ The overall likelihood of approval from the first clinical trial phase (Phase I) was 9.6% between 2006 and 2015, and 11.9% for all outside the field of oncology.¹²
- ▶ 12-13 years will elapse between the time of the first synthesis of the new active substance to the time the product reaches the market.¹³

Hence, for every active ingredient developed, only a small number make it from the research stage, in the lab, to marketability, on the shelf. IP rights reflect a rewards-based approach to risks of investment. They ensure that the certainty of patents can provide confidence that investments will not be exposed to unfair competition by manufacturers that did not bear these risks.

Cost of researching and developing a medicinal product (2013, \$m)



Source: DiMasi, Grabowski, Hansen (2016); inflation-adjusted



3 The rationale for IP

IP frameworks can ensure that there is a pipeline of medicines in development, supporting supply across healthcare systems.

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The economics of IP

1. Encourage Innovation
2. Reward risk
- 3. Secure supply and access**

Secure supply and access

Pharmaceutical incentives and rewards can spur the research and development of drugs that would be otherwise prohibitively costly or commercially non-viable. Firms researching and developing new active medicines are afforded the certainty they require to invest in the long, complex, costly and risky process.

At any one time up to 7,000 medicines across a wide range of classes of drugs are in development globally.¹⁴ Hence the industry is working to deliver new and improved treatments to patients who need them, despite the high level of risk in doing so.

In 2017 there were 35 new substances authorized by the European Medicines Agency.¹⁵ The medicines approved in 2017 represent a significant improvement in their therapeutic areas, and address illnesses across cancer care, infections, endocrinology, immunology, neurology.

Case Study: Medicines for children

Advances in medicines authorisations are essential to advancing public health as they bring new opportunities to treat certain diseases.

2017 marked the tenth anniversary of the EU Paediatric Regulation, which aims to stimulate the development of high quality, safe and effective medicines for children. Relevant medicines approved in 2017 include:¹⁶

- ▶ *Alkindi* for the treatment of hormonal disorders
- ▶ *Brineura*, for the treatment of rare brain diseases
- ▶ *Crysvita*, for the treatment of bone diseases
- ▶ *Spinraza*, for the treatment of spinal disease.

Innovation by the industry ensures that there is a pipeline of medicines being developed to support the lives and recovery of ill children - a valuable undertaking for all of society.

3 The rationale for IP

The process of bringing a medicine from discovery to marketability takes several years, and involves a number stages of regulatory oversight.

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The Research and Development and Authorisation Process

Medicines prescribed in Ireland and abroad go through lengthy regulatory and approvals processes, overseen by the Irish Health Products Regulatory Authority (HPRA), the European Medicines Agency (EMA) and, for exports to the US, the Food and Drug Administration (FDA).

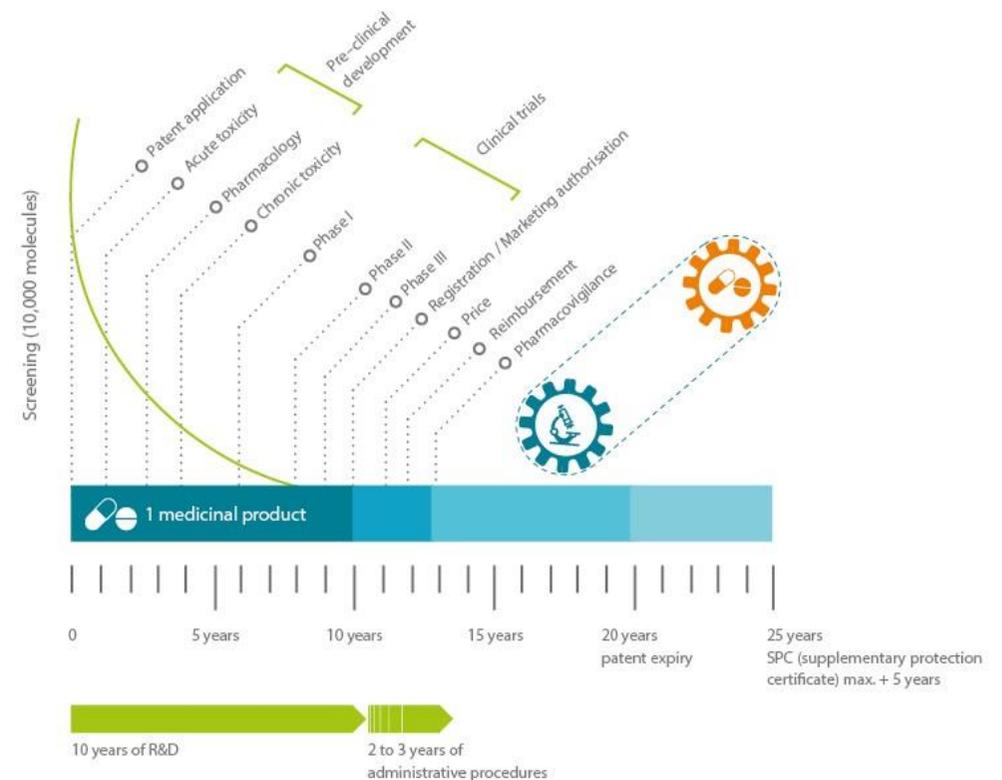
- ▶ **Discovery:** Researchers discover new drugs through new insights into a disease process, tests of molecular compounds, existing treatments that have unanticipated effects, and the application of new technologies.
- ▶ **Development:** Once researchers identify a compound for development, experiments are conducted to identify its effectiveness and benefits.
- ▶ **Pre-clinical:** any potential side effects of medicines are tested in living organisms, and in test tubes.
- ▶ **Clinical Trials:** studies/trial done in people to understand the real-life effects of medicines on the patient population:
 - ▶ Phase I: 20 to 100 participants, over a number of months.
 - ▶ Phase II: several hundred participants, over a period of up to 2 years.
 - ▶ Phase III: up to 3,000 participants with conditions, for up to 4 years.

Approval, authorisation and marketability

The industry engages closely with the HPRA, the Department of Health, and the Health Information and Quality Authority (HIQA) to ensure that clinical trials meet the highest standards.

Medicines that pass clinical trials are submitted by manufacturers for approval by regulatory bodies, including the HPRA. Thereafter the medicine can be marketed to patients and administered and dispensed by clinicians and pharmacists.

The road to marketability for medicines



Source: EFPIA

4

European Framework





4 European Framework

The European IP framework includes a range of legal protections for pharmaceutical medicines, of which patent law is a central pillar.

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The legislative framework

IP rights have legal, economic, and socio-political origins and rationales. The European IP framework is set out in treaties (European Patent Convention), regulations and directives, and administered by the EPO. Pharmaceutical medicines are protected across:

- ▶ Patent law, for new discoveries of medicines
- ▶ Design law, for shapes and designs
- ▶ Trademark law, for branding
- ▶ Data protection law, for some clinical trial data
- ▶ Market protections, to prevent copying.

Although there is a relatively uniform IP ecosystem across the EU, the framework can have varying impacts on innovation across countries, depending on:

- ▶ Institutions
- ▶ Market size
- ▶ The courts system.

Protection periods and SPCs

The standard period of protection for pharmaceutical medicine is 20 years from the filing of the application. Delays between filing and the point at which the medicines can be marketed to patients reduce the '*effective period of protection*' - the actual number of years for which pharmaceutical products are protected.

A Supplementary Protection Certificate (SPC) extends patent protection for medicinal products by up to 5 years, to account for delays in the early years when bringing the product from patented status to marketability.

Manufacturers can apply for an SPC for patented medicine in the Member State in which they are located. Manufacturers take account of SPC rights to secure an extension of their market exclusivity in order to recoup the costs of investments in research and development.

Balancing protection

Governments place limits on IP rights through a range of policy instruments:

- ▶ Establishing price regulations
- ▶ Purchasing medicines in bulk on behalf of all residents
- ▶ Issuing a compulsory license to another producer.

Governments across Europe and beyond utilise these approaches to mitigate some of the economic gains that patent rights confer.

IP rights are not absolute guarantors of returns, but rather provide greater certainty around investment decisions.



4 European Framework

The SPC framework is well regarded by the industry, while the Commission is proposing a manufacturing waiver for generics manufacturers.

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Trends in the SPC process

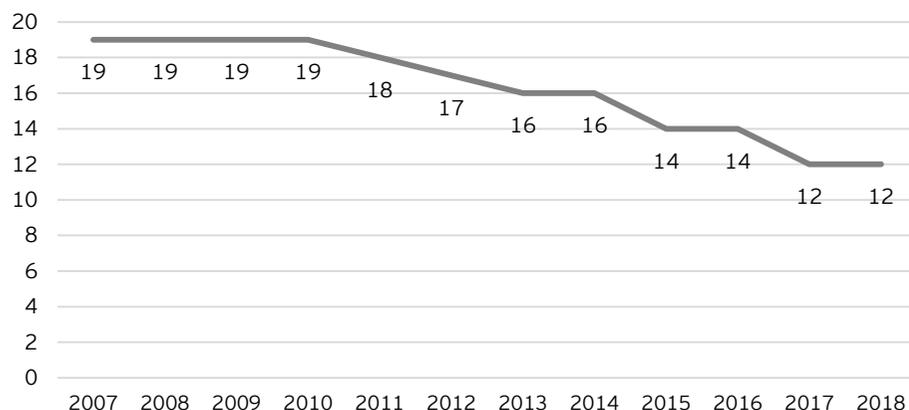
Between 1993 and 2013 the number of annual SPC applications submitted to the EPO tripled, reflective of the increasing levels of regulatory requirements that delay approval of medicines for use in clinics and hospitals.¹⁷

Data from the EPO shows that patented medicines are being granted SPC status earlier in their lifetimes:

- ▶ In 2007 an average of 19 years had elapsed between granting of a patent and granting of an SPC.
- ▶ In 2017 this period had fallen to 13 years (see graph).

This trend toward earlier granting of SPCs by definition indicates that originators are applying for SPC status earlier in a drug's lifespan. This decision to file earlier could suggest that innovative firms desire to attain a greater degree of certainty about future returns.

Years between granting of patent and granting of SPC



Source: Irish Patent Office

The EC's export waiver proposal

EU-based manufacturers of generic medicines are currently precluded from manufacturing generic copies of patented medicines for any purpose.

In October 2015, the European Commission (EC) outlined policy initiatives to adapt the single market with the stated purpose of spurring economic growth, creating jobs, and reducing administrative burdens.¹⁸

Following on from the 2015 policies, in May 2018 the College of Commissioners put forward a legislative proposal to amend the regulation on SPCs for medicinal products.¹⁹

Under the proposal, *manufacturers of generic medicines would be permitted to manufacture patented medicines for export to non-EU markets where SPC protection has expired or does not exist* (manufacturing waiver).

The Commission estimates that the SPC manufacturing waiver would yield at least €1bn per year in net additional export sales in the EU pharmaceutical sector, creating up to 25,000 extra high-skilled jobs over 10 years.²⁰



4 European Framework

The Commission commissioned two external reviews on the economic effects of the SPC proposal

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Analysis of the SPC waiver proposal

External reviews

The European Commission commissioned two external reports on the SPC waiver proposal, in order to understand its likely market effects.

Charles River Associates (CRA) studied the economic impact of a range of policy scenarios on the industry, and estimated that, relative to the base case, the manufacturing waiver could result in net additional sales for the EU-based pharmaceutical industry of €208m to €416m by 2025.²¹

Copenhagen Economics' (CE) report on the SPC utilised empirical evidence and noted that:²²

- ▶ Almost half of all medicinal products obtain an SPC in at least one EU Member State
- ▶ Since 1996 the average effective protection period afforded to originator medicine has declined by from 15 years to 13 years
- ▶ A longer effective protection period encourages research and development into medicinal products
- ▶ Medicines are more likely to be launched in larger and wealthier Member States than in smaller and less wealthy Member States.

Challenging the EC's assumptions

The EC proposal assumes gains for the European generics industry and is based on assumptions that:

- ▶ There will be a market in third countries for generic products produced by manufacturers in Europe
- ▶ Protection in the third country has already expired
- ▶ Generic producers in third countries are not already the preferred partners of the national health authorities.

Where SPC protection exists in both Europe and the third country, the waiver may not afford European producers a competitive advantage in third countries, if third countries weaken patent and/or SPC protection in their own jurisdiction, to support indigenous producers.

Ways to safeguard innovation

To safeguard innovation, the industry, via IPHA, has outlined a number of policy tools that could be included in the waiver proposal:

- ▶ Limit the waiver's applicability to export to non-EU markets where protection does not exist or has expired
- ▶ Exclude any re-importation to, and commercialisation in, EU markets
- ▶ Relate the waiver to all manufacturing acts that are strictly necessary for the export of the SPC-waived product
- ▶ Exclude pending SPC applications
- ▶ SPC owners can be notified at the same as the competent authority
- ▶ Extend the notification period and enable SPC-holders to seek judicial remedy
- ▶ Notification should mention both targeted export markets and the quantities of product to be exported.

5

The Industry in Ireland





5 The Industry in Ireland

The industry is embedded in communities throughout Ireland, supporting employment and exports and contributing to the Exchequer.

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The industry is an Irish success story

Ireland's industrial model

Ireland has an international reputation in pharmaceutical research and development, based mainly on process development and manufacturing, and built on a strong industrial model, as identified via consultations with the industry.²³ Key characteristics of the Ireland industrial model include:

- ▶ Evolution - openness to globalisation, policies to foster in enterprise and talent
- ▶ Global Footprint - Ireland matches strong FDI with strong outward investment and export markets
- ▶ Full Business Lifecycle - R&D, production, sales, marketing, logistics, and finance all take place here
- ▶ World class - globally competitive in terms of talent, research, and a collaborative culture
- ▶ Global Hub - top international companies converge to locate their headquarters here
- ▶ Cluster - a dynamic ecosystem involving multinationals and SMEs partnering with higher education institutions.

There is a strong collaboration in the research field between the industry and State supported research centres, where this is supported by Science Foundation Ireland, IDA Ireland, Enterprise Ireland and the Higher Education Authority (HEA).

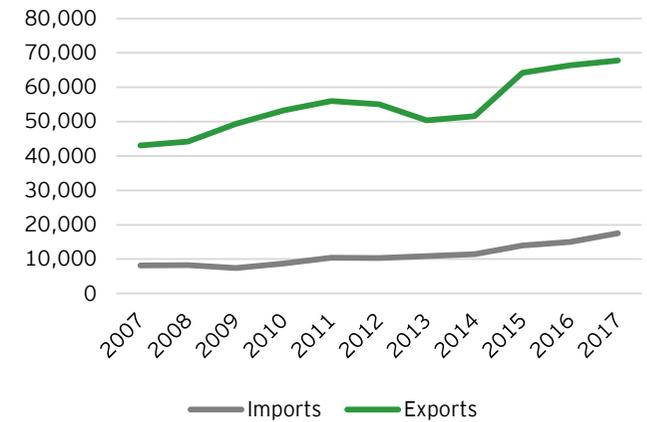
Contribution to exports

Pharmaceutical products are a key source of exports for the Irish economy. When considered together with chemical products - many products produced by the pharmaceutical industry fall into this category - total exports reached €68bn in 2017, while imports reached over €17bn, generating a trade surplus of over €50bn.

In comparative terms, Ireland is a hugely successful exporter of pharmaceutical products (defined narrowly). Ireland's exports of €35bn in 2017 were 50% those of Germany's, and greater than those of the UK. Through investments in R&D and manufacturing, Ireland has become the United States' single largest foreign source of pharmaceutical imports.²⁴

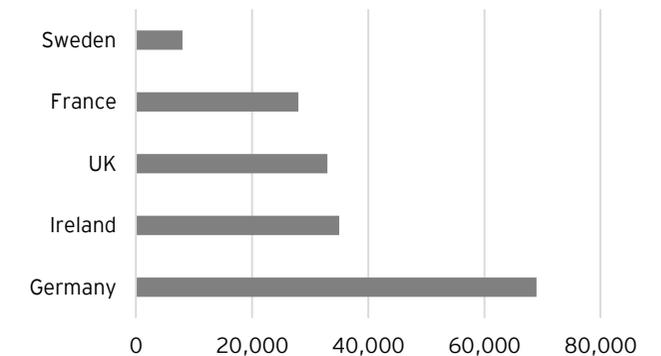
The industry's exports are produced by the country's clusters of firms, who have made significant investments in their Irish operations and whose representatives identify Ireland and Europe's IP framework as a draw.²⁵

Imports and exports of pharmaceutical and chemical products, 2007-2017 (€m)



Source: CSO

Value of exports of pharmaceutical products in selected countries (2016, €m)



Source: EFPIA; Note: Ireland refers to 2017 data



5 The Industry in Ireland

Employment in the industry in Ireland is significant, especially when measured against larger European economies, and is growing.

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Innovation supports livelihoods

The pharmaceutical industry makes a strong contribution to employment in Ireland. As of mid-2018, over 30,000 people are directly employed in the sector,²⁶ with around 35 companies comprising 85% of employment.²⁷

In comparative terms, the numbers employed in the industry in Ireland are very significant. Despite a population 18 times larger than Ireland's, employment in the pharmaceutical industry in Germany is less than 4.5 times that in Ireland.

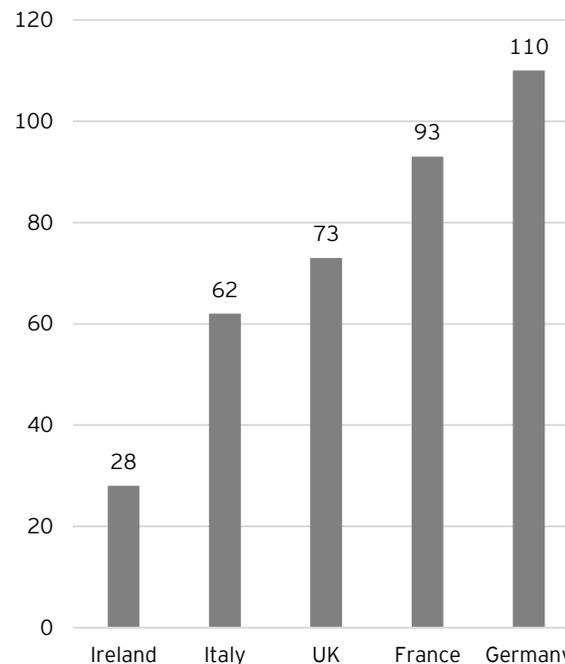
In 2016 an EPO and EC report noted that:²⁸

- ▶ Between 2011 and 2013, the rate of jobs growth by non-EU firms in IPR-intensive industries in Ireland was 22%, ranking Ireland first across the EU
- ▶ 53.6% of jobs created in patent-intensive industries in Ireland are attributable to foreign companies, placing Ireland third of all EU Member States.

Outside of job creation, innovation also supports productivity. An EC study has shown that, over the period 2000 to 2013, research and investment accounted for 30% of productivity growth in Ireland, whereas the average across the EU15 was 10%.²⁹

The rate productivity growth in Ireland that can be linked to research and investment was amongst the highest in Europe, highlighting the valuable contribution that innovation has made in increasing labour productivity here.

Employment in the pharmaceutical industry (2016, 000s)



Source: Eurostat

A pipeline of skills

In 2016, the Expert Group on Future Skills Needs reported that over 8,000 jobs would be created in the biopharma industry over the period 2016-2021.³⁰ Achievement of this target will be supported by IDA investment in the National Institute for Bioprocessing and Training (NIBRT), which upskills workers for new life sciences and biopharma developments.

For value to continue to be created by the industry in Ireland, a pipeline of skilled workers is vital. *The Expert Group on Future Skills Needs* identified a number of key actions to foster the talent of workforce, including:

- ▶ Increase scale of Graduate Entry Development Programmes
- ▶ Develop a Biopharma Apprenticeship Scheme
- ▶ Engage with the Regional Skills Fora to highlight skills requirements in the industry.



5 The Industry in Ireland

The ability to achieve positive health outcomes is influenced by the accessibility of medicines in healthcare systems and to patients.

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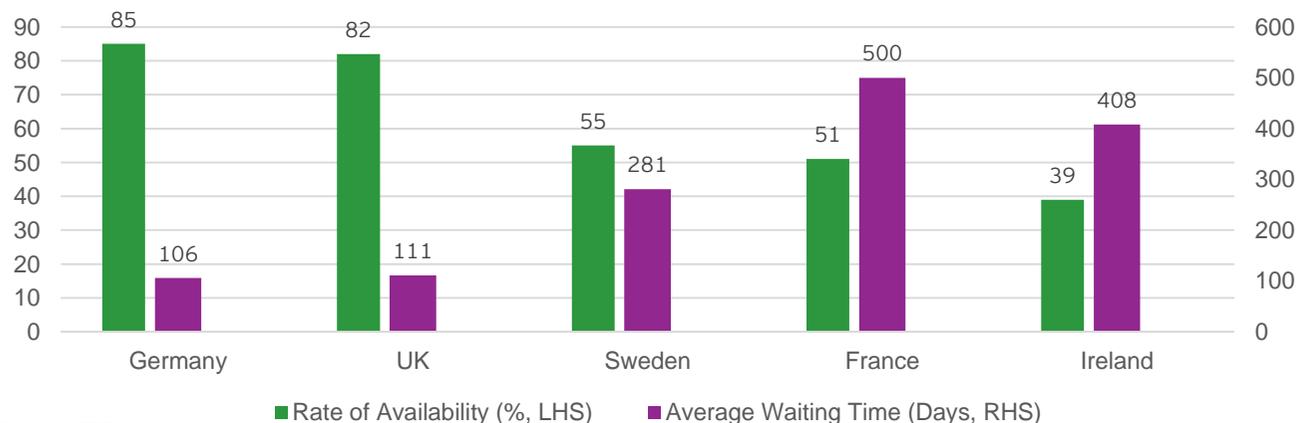
Access to new medicines in Ireland

The degree to which pharmaceutical products lead to positive health and social outcomes for populations is impacted by the prevalence of these medicines in healthcare systems. Whilst a considerable amount of activity is undertaken by the industry in Ireland, international evidence shows that Ireland is falling behind its European counterparts in terms of access to medicines, as highlighted by EFPIA's 2017 Market Access Delays Analysis.³¹

Below, 'rate of availability' refers to the share of all medicines authorised in Europe that are available to patients in the respective countries through reimbursement; 'average waiting time' refers to the number of days elapsing from the date of EU marketing authorisation to the day of completion of post-marketing authorisation administrative processes.

- ▶ Ireland compares poorly in relation to the availability of medicines to patients, ranking 18th of 26 countries in Europe. 39% of EMA-approved medicines are available to patients in Ireland, compared to 85% and 82% in Germany and the UK respectively, which rank 1st and 2nd.
- ▶ Relative to other countries, the period of time between authorisation and patients' access to medicines is long in Ireland, at 408 days on average, placing Ireland 14th of 26 countries, and considerably behind Germany at 106 days and the UK at 111 days, which rank 1st and 2nd respectively.

Availability of medicines and market access delays in selected countries



Source: EFPIA

Reimbursement Policy

The industry, through IPHA, works with the Government to reduce the cost of medicines to the Exchequer through the Pricing and Supply Agreement, whose goal is "that Ireland remains at the forefront of its European peers in terms of early access to these new medicines in an affordable manner and within available resources". The agreement therefore expressly connects Ireland's reimbursement policy with access to innovative medicines.

Improving Access

The industry, through IPHA, is keen to work with Government and political partners to improve the process for sustainably funding innovative new medicines and making them available efficiently for Irish patients.

IPHA is developing proposals for policymakers for how, together, it can tackle system shortcomings so that Ireland is competitive with European peer countries on access to innovative medicines for patients.



5 The Industry in Ireland

Brexit represents uncertainty to the Irish economy and to the pharmaceutical industry, especially for supply chains.

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The implications of Brexit

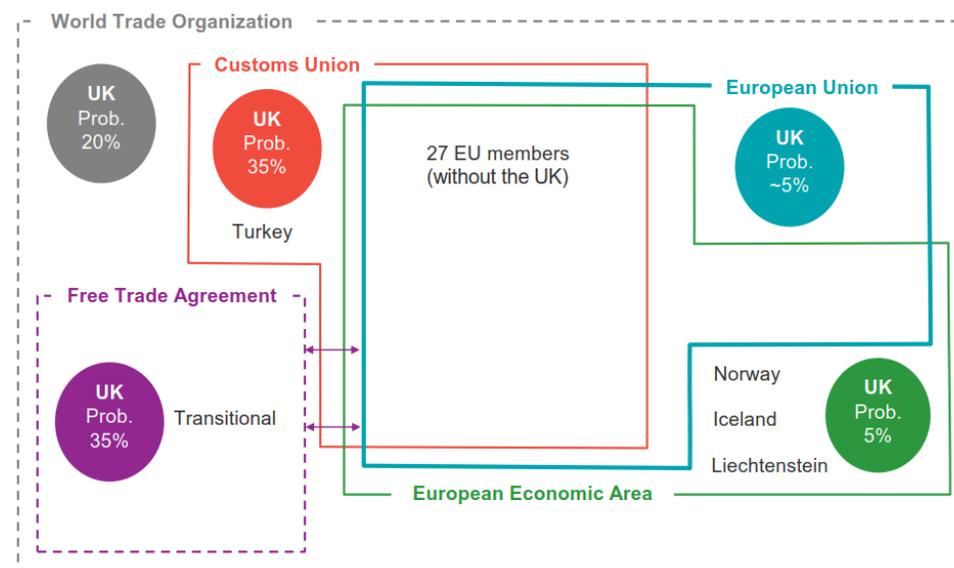
Continuing uncertainty surrounding Brexit has required adaptability by the industry in Ireland and in Europe. The industry is particularly concerned around disruption to supply chains, impacts on regulation, exports, and cross border research funding.

- ▶ **Supply Chain** - Many firms in the industry are taking ongoing measures to reorganise their supply chain in order to ensure compliance to coming regulatory changes, such as by the strategic placement of regulatory personnel (QPs) in Member States and other operational and contingency planning.
- ▶ **Testing and Labelling** - Ireland is at the end of the European supply chain, with many medicines currently originating from, or transiting through, the UK. As all medicines manufactured in a non-EU country must be retested upon importation into the EU, medicines prescribed in Ireland could face additional regulatory burdens. As 60% of medicines have joint Ireland/UK labelling at present,³² the industry is adapting its supply chain to account for this challenge.
- ▶ **Exports and Imports** - While WTO tariffs on pharmaceutical products are low and in many places are not applied, transactions between Ireland, the EU, and the UK will need to be considered from both a customs duty and import VAT perspective, adding complexity to the supply chain.
- ▶ **The IP Framework** - Upon withdrawing from the EU, the UK could face a policy choice as to whether it would like to weaken or strengthen IP rights in the post-Brexit landscape. If the UK moves to offer stronger protections to producers than those provided by the EU under the status quo or under the proposed reforms, this could disadvantage Ireland if the UK becomes a more competitive location in which to undertake research.

The industry is hopeful that the recently published *White Paper* is capable of dealing with all scenarios that might arise over the coming years. Brexit will pose a challenge to growth in the absence of regulatory alignment and/or mutual regulatory agreement. While the impact of customs may not be significant, the impact of regulatory divergence could be more significant.

Brexit outcome probabilities estimated by EY show that, as of July 2018, the likelihood of the UK remaining in the customs union and the likelihood the UK and the EU agreement a free trade agreement are each estimated at 35%.

EY's estimated Brexit outcome probabilities - July 2018



Source: EY, July 2018

6

Trends and Outcomes





6 Trends and Outcomes

There are a number of market-based developments emerging across the industry, to which the industry is adapting in turn.

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Market trends and industry responsiveness

Economic growth, market trends, regulation and oversight, regulatory change, and more informed consumers all contribute to a dynamic industry. To ensure that new discoveries are made as existing illnesses and diseases become more complex, the industry invests in research and development.

Scientific progress, data generation, augmented intelligence and a more empowered patient are all driving changes in the delivery of healthcare to a personalised experience with health outcomes as the core metric.

At the same time, the costs of innovation and access to patients remain amongst the industry's more significant challenges. These trends affect the capital strategy of every link in the life sciences value chain, from R&D and product supply to product launch and patient-centric operating models.

In-Market Changes

Economic growth: Slower growth in developed markets and faster growth in pharmerging markets impacts the nature of demand for medicine and the price paid by national authorities, especially in economic downturns.

Rationalisation: Globally pharmaceutical firms are rationalising operations, outsourcing functions such as R&D and sales, and embracing technology to operate more efficiently.

Non-Market Changes

Regulation: The industry is subject to tight regulation with numerous government policies influencing the manufacturing, pricing, and marketing of the industry's products. Heightened compliance requirements place additional budgetary constraints on operations.

Patent expiration: As key medicines currently in use go off patent, an increasing number of diseases are being treated with generics and biosimilars.

Super consumers: The cost of producing medicines requires high prices at the counter, while increasingly better-informed consumers at the same time demand lower prices, creating a mismatch in supply and demand.

Responding to Change

Digitalisation and Disruption: The role of disruptive players and new technologies is increasing, across big data, smartphone apps, social media, and sensors and monitors. New entrants from non-traditional industries, often not driven by profit, are competing with traditional pharmaceutical firms, and the industry is evolving in turn, engaging with patients in a more direct way.

Personalised healthcare: The merging of increasing computational power with the human genome/DNA and artificial intelligence will change the delivery of healthcare to personalised medicine, preventative medicines and a customised healthcare experience.



6 Trends and Outcomes

There is a tangible connection between medical advances and broader societal well-being, including longevity and labour force productivity.

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Social impacts of medicines

Successful new medicines have a significant positive influence on global health, prosperity, and economic productivity by saving lives, increasing lifespans, reducing suffering, preventing surgeries and shortening hospital stays.

Drug therapy is now an integral part of nearly every facet of healthcare, and new breakthroughs - supported by strong IP rights - promise to revolutionise the treatment of many diseases. The industry thus creates significant value across society.

Labour force productivity

In 2015, 910,000 and 810,000 work days were lost to illness and injury in Ireland respectively,³³ while Ibec estimates that absenteeism costs Irish businesses approximately €1.5bn per annum.³⁴ Medicines produced by the industry provide treatment to people on a daily basis. The existing IP framework ensures that there is a tangible link between investment in innovation and a more productive workforce.

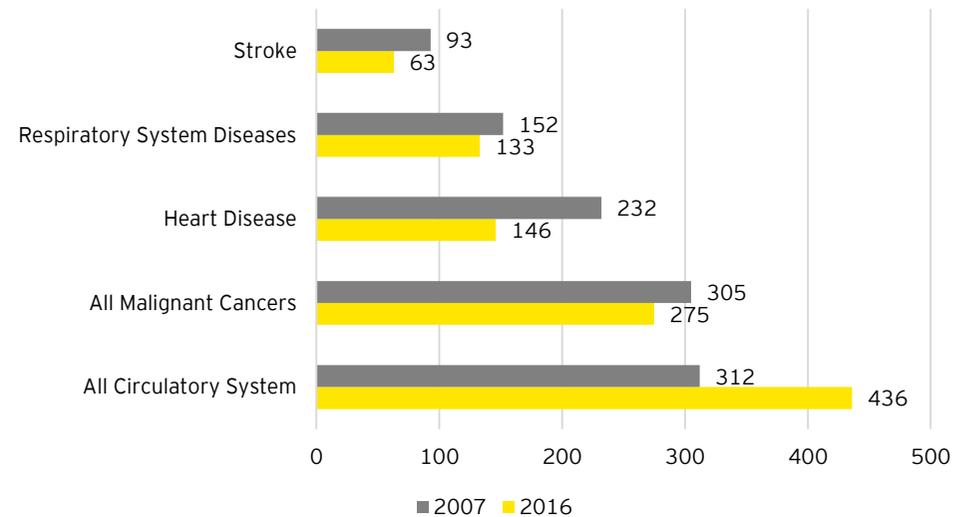
Research has shown that drugs and medicines can improve workforce participation and labour productivity. In particular, drugs that tackle cancer have been shown to result in many positive spillovers into the broader society and economy. In France 82% of women diagnosed with breast cancer return to work within 11 months,³⁵ and in the Netherlands 83% of working individuals diagnosed with head and neck cancer return to work, and most often within 6 months after treatment.³⁶

Longevity

Over recent decades, there have been significant improvements in health outcomes in Ireland as general health improved and medicines became more effective. The rate of death due to a range of different illnesses has been falling - strokes, respiratory system diseases, and heart diseases - and has led to increased longevity. In particular, the introduction of statins in the mid-1990s has had a significant impact on mortality rates from circulatory system diseases in Ireland, which fell by 28% between 2007 and 2016.³⁷

Between 2005 and 2015 the life expectancy of males at birth increased from 76.7 years to 79.6 and for females at birth from 81.4 years to 83.4 years.³⁸ Internationally, a study of 30 OECD countries over the period 2000-2009 showed improvements in life expectancy at birth of 1.74 years, of which 73% (1.27 years) was accounted for by innovative medicines, once other factors are taken into account.³⁹

Causes of death in Ireland, 2007 and 2016 (rates per 100,000)



Source: Department of Health, Health in Ireland: Key Trends 2017



6 Trends and Outcomes

By 2050, almost 25% of the Irish population could be aged over 66, resulting in increased and more complex medical needs.

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Changing demand will impact innovation

The ability of the industry to support positive health outcomes for society can be a factor in the nature of demands faced by producers and the healthcare sector more broadly. Challenges facing the industry include demographic changes, unpredictable economic growth, patent expiration, and reforms to legal systems and product regulation. These play a role in every link in the pharmaceutical value chain, from R&D and product supply to product launch and patient-centric operating models.

In most established markets, ageing population and lifestyles are leading to an increased incidence of chronic diseases which require long-term management. This will occur while the world's population will reach 9 billion by 2050, of which 2 billion will be aged 60 years and older, up from 900 million in 2015.⁴⁰

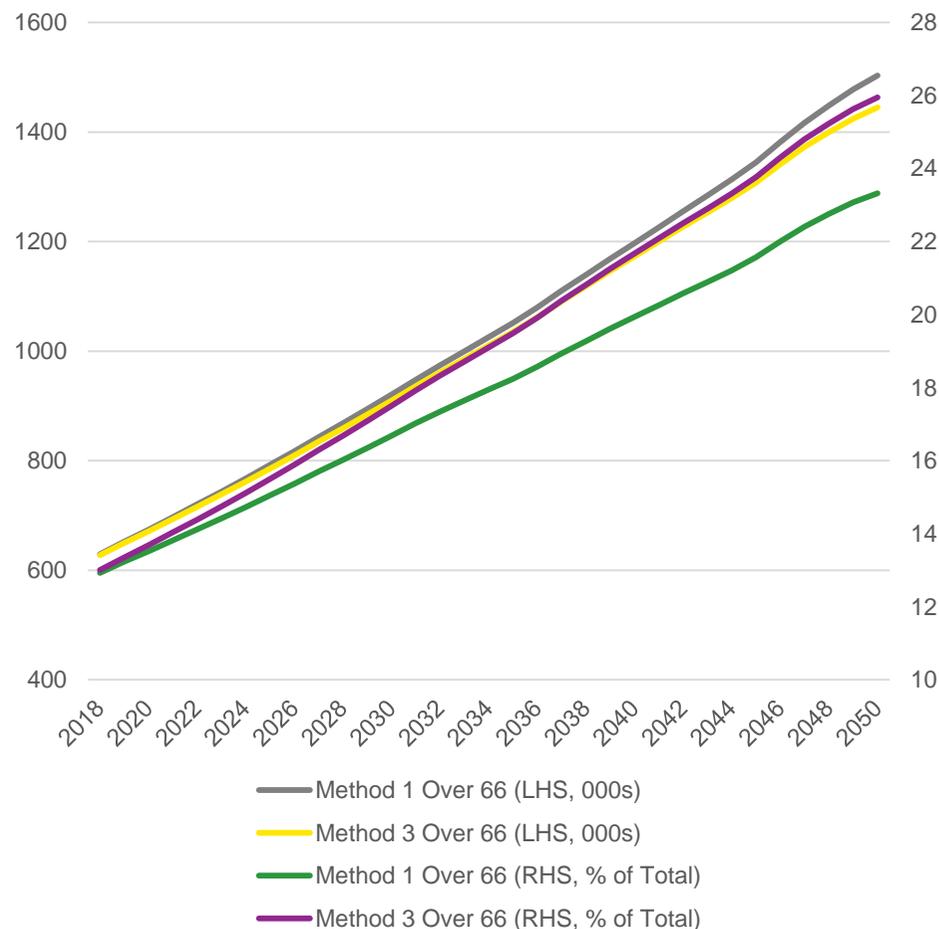
Related to this, the prevalence of non-communicable diseases, such as cancer and cardiovascular, metabolic, and respiratory diseases - currently estimated to lead to 38 million mortalities globally per annum - is increasing worldwide.⁴¹

Key developments in Ireland's population over the coming years will impact demand for healthcare here:

- ▶ The share of the population aged over 66 will increase from 12% in 2018 to 17% in 2030 and to at least 24% by 2050⁴²
- ▶ The ESRI projects that demand for medicines prescribed under State schemes will rise by between 34% and 38% by 2030, relative to 2015.⁴³

An increasing number of people accessing healthcare and treatment, particularly the elderly, will require innovation from the industry if the needs of this changing population are to be met. A strong IP framework can ensure that the industry is in a position to respond to emerging heterogeneous demographic developments.

Projected population of Ireland aged 66 and over (2018-2050)



Source: CSO Population Projections; Note: CSO methodologies - method 1 assumes a high birth rate going forward, method 3 assumes a low birth rate going forward; method 2 excluded.



6 Trends and Outcomes

The industry in Ireland and in Europe works closely with governments to foster innovation and to deliver high quality healthcare.

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Cooperation between the industry and public bodies

The industry and public bodies cooperate on a range of projects together, across cost containment and research and development activities. A strong IP framework can act as a conduit through which public co-investments support delivery of medicines to the final stage. Reforms to the existing IP framework could have a downside impact of the industry's strength at a time when industry groups are engaging with governments to reduce the cost of medicines to national health systems and engaging in numerous cooperative projects. Public bodies can continue to work with the industry on cooperative research ventures, as these foster innovation and result in positive spillovers.

Pricing Agreements

In recent years, cost containment has become an important issue in healthcare policy. Across Europe, governments and the pharmaceutical industry are developing pricing agreements that balance access to medicines with support for innovation.

The 2016 agreement between the Department of Health and IPHA increased the number of countries considered as part of the HSE's external reference pricing process from 9 to 14, which was designed to reduce the cost of medicines paid by the State to manufacturers and to facilitate timely access to new medicines.

The industry is supporting public bodies in implementing the agreement, which is projected to lead to saving of over €785m over its lifetime.⁴⁴

Public-Private Research

The industry and public bodies cooperate on a range of research projects both across Europe and in Ireland:

- ▶ Under Horizon 2020 - €3.3bn of public-private investment is being invested in pharmaceutical innovation over the period 2014 to 2024 through Horizon 2020 and EFPIA members⁴⁵
- ▶ EIT Health - a pan-European consortium public and private entities - is promoting and supporting innovation around healthy ageing⁴⁶
- ▶ BioInnovate - an Irish Government medical technology training programme - connects clinicians with industry and academia.⁴⁷

Meeting Unmet Needs

The industry recognises the role it can play in supporting healthcare systems to meet the unmet needs of patients and is working with partners across Europe on a number of innovative projects:

- ▶ The NEWMEDS project has created the largest known database of studies on schizophrenia in the world⁴⁸
- ▶ The New Drugs for Bad Bugs Programme is supporting research to tackle the growing threat of anti-microbial resistance⁴⁹
- ▶ The SFI Research Centre APC Microbiome Ireland - which funds gastro-intestinal health research - involves clinicians engaging with firms that support for over 7,000 jobs.⁵⁰

7

Key Messages





7 Key Messages

This report identifies several key messages that highlight the industry's commitment to innovation and its economic and social footprint in Ireland.

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1 Context

IP Rights

IP rights have an important and clear economic rationale: to encourage innovation, to reward risk, and to secure a supply of medicines across the healthcare system. Academic and industry research is supportive of these rationales, and research shows that stronger IP rights spur a greater degree of innovation.

IP Framework

Patent law affords protection to new medical discoveries for 20 years initially and for an additional 5 years if an extension, in the form of an SPC, is granted to take account of the delay in regulatory processes, which can be lengthy and challenging.

Reform Proposals

The European Commission is proposing to permit manufacturers of generic medicines to manufacture patented medicines covered by an SPC for export to non-EU countries where an SPC is not in place. Such a reform would represent a departure from the EU's existing IP framework.

2 Innovation

Investment

Throughout Europe, the industry invests considerable sums in research and development - over €35 billion in 2017. Globally, R & D investment account for circa. 15% of the industry's net sales, greater than the share invested by many other comparable industries - software, hardware, automobiles, etc.

Risks of Investment

The industry invests in innovation against a backdrop of considerable risk: drugs developed in the lab rarely make it to marketability, and even medicines that reach clinical trial stage very often do not pass that stage. The industry continue to invest in new discoveries despite these risks.

Funding Sources

Investment in R & D in Ireland is sourced from the public and private sectors, but relative to other countries Ireland is highly successful at attracting funding for R & D activities from abroad - at 23% of all funding for these activities, this is the highest rate amongst all Member States.

3 The Industry in Ireland

Export Success

The industry in Ireland makes a considerable contribution to the Irish economy - exporting products valued at almost €70 billion - and through taxation and capital investments. It is embedded in cities and towns throughout the country, from where innovative medicines are exported across the globe.

Livelihoods

Over 30,000 people are directly employed by the industry, throughout Ireland. There is a pipeline of skills available, with new graduates entering the workforce and adding to the industry's output. Between 2016 and 2021 it is estimated that the industry will create 8,000 new jobs.

Cooperation

In Ireland, the industry has engaged with government to reduce the cost of medicines, while across Europe cooperation in research, through Horizon 2020, amounts to several hundred million euro per annum. Through these ventures, firms and public bodies advance the healthcare agenda while meeting patient needs.

4 Measuring Success

Health Outcomes

Pharmaceutical products can improve health, lengthen lifespans and increase productivity. Research shows that there is a tangible link between innovation in the lab and health in the home, especially around survival rates for cancer patients, increase longevity, and the treating of influenza on a daily basis.

Access to Medicines

Comparatively, patients in Ireland are provided with access to medicines later than patients in many other EU countries, a factor of government reimbursement policies - the industry is keen to improve access and works with government to achieve this.

Changing Demand

The world's - and Ireland's - population is ageing and illnesses are becoming more complex. This requires adaptability by the industry, which it is embracing through innovation, by investing in R&D, new technologies, and new platforms.

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68482.pptx. Produced by BSC (Ireland). 07/18. ED none.

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