

# BRINGING HEALTH AND GROWTH TO IRELAND

How the pharmaceutical industry helps patients, the health service and the economy



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# Introduction



The Irish Pharmaceutical Healthcare Association (IPHA) represents international pharmaceutical companies that actively engage in the research, development, manufacture and delivery of new, innovative medicines that improve people's health and well-being and extend their lives.



Healthcare is expensive and the cost of providing it continues to rise every year as treatments and technologies improve. Because of this, everyone has an opinion on healthcare – its cost, its accessibility, its regulation and its availability.

The debate on healthcare can only be constructive if the underlying facts and figures are presented. This booklet sets out to explain the role of innovative medicines and vaccines in the Irish health services and the value that they bring to Irish patients. It explains how the appropriate use of innovative medicines not only improves health outcomes but also brings significant other social and economic benefits. It outlines the complex and lengthy process of medicines development and production, what this costs and how medicines are priced. It also details the broader economic contribution of the pharmaceutical industry in Ireland and its relationship with healthcare professionals.

The information presented here underlines the case for continuing support for one of our most successful industries – an industry that improves the lives of all our people and adds value to our economy.

# 1

## Innovative medicines transform people's lives

Advances in medical care including the use of innovative medicines and vaccines have played a crucial part in the huge improvements seen in the health outcomes of the Irish population, with consequent increases in life expectancy. However, with increased life expectancy comes new challenges; the growing prevalence of chronic conditions and degenerative diseases mean that more people with some form of medical disability or illness are living longer. The proper use of medicines and vaccines can have a significant impact on health outcomes in many conditions and can improve health system efficiency, thereby reducing total healthcare costs and productivity losses in the workplace due to disability and illness.

- Innovative medicines and vaccines change people's lives and impact positively on society by improving survival rates and facilitating the better management of chronic illnesses, eliminating or reducing the burden of disease and increasing life expectancy.
- People are living longer and more productive lives than ever before. This is due to many factors such as health system access, higher standards of living, better education, advances in medical care and technologies and significantly, innovation in medicines<sup>1</sup> (see **fig. 1**).
- Cutting edge medicines and vaccines have virtually wiped out diseases such as diphtheria, smallpox and polio<sup>2</sup>. In February 2014, the World Health Organisation officially declared India polio free following the success of an extensive eradication programme.

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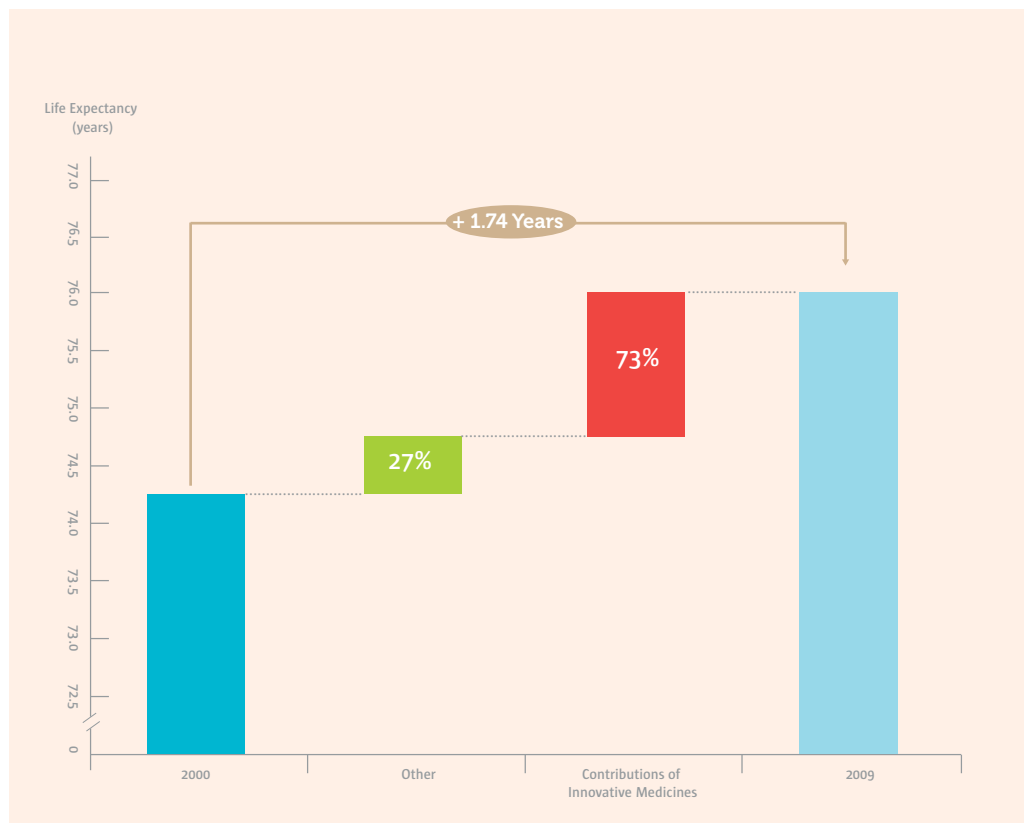
<sup>1</sup> Lichtenberg, F Pharmaceutical Innovation and Longevity Growth in 30 Developing and High income Countries 2000-2009 NBER Working Paper 18235, National Bureau of Economic Research (2012)

<sup>2</sup> WHO: Vaccines-preventable diseases monitoring system (2009)

- People with conditions such as diabetes, rheumatoid arthritis and HIV are able to live fuller lives as a result of new medicines<sup>3</sup>. This is perhaps most dramatically illustrated by HIV, where the introduction of the first anti-retroviral treatments (ART) in 1995 followed by further innovative medicines in subsequent years, has seen a huge drop in the death rate from AIDS (see **fig. 2**). A 20 year old HIV-positive patient on treatment can now expect to live into their early 70s, a life expectancy approaching that of the general population<sup>4</sup>.
- Over the past decade alone, innovative medicines are estimated to have accounted for over 73% of the health gains achieved across 30 OECD countries including Ireland<sup>5</sup>.

**Figure 1: Contribution of innovative medicines to increase in life expectancy (2004-2009)**

Source: EFPIA 2013 Lichtenberg, F: Pharmaceutical Innovation and longevity growth in 30 developing OECD and high-income countries. 2000 - 2009 (2012)



<sup>3</sup> PhRMA: New Medicines. New Hope (Sept 2012)

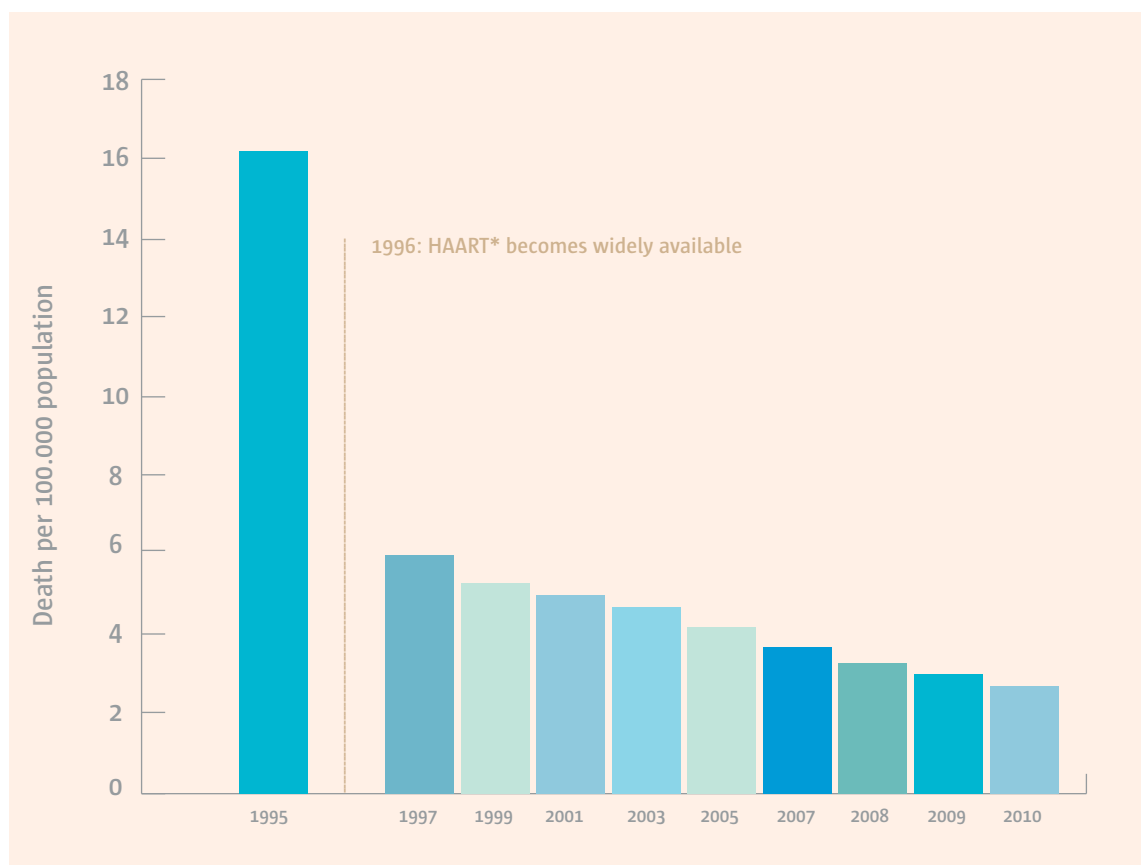
<sup>4</sup> Samji H et al. Closing the Gap: Increases in Life Expectancy amongst Treated HIV-Positive Individuals in the United States and Canada. PLoS ONE 2013; 8(12):e81355

<sup>5</sup> EFPIA: 2013

- Recent data<sup>6</sup> shows that long-term cancer survival rates in Ireland have improved significantly in the last decade – from 42% in the period 1994 -1999 to 60% in 2005-2009 in men and from 52% to 62% over the same period in women due in part to innovative medicines. The rate of decline from coronary heart disease between 1990 and 2011 was 59%, largely as a result of cholesterol-lowering medicines<sup>7</sup>.

Life expectancy continues to improve today - and medicines usage has made a major contribution

**Figure 2** Deaths from HIV/AIDS by year  
Source: IFPMA Facts and Figures 2012



\*HAART: Highly Active Antiretroviral Therapy

<sup>6</sup> National Cancer Registry Ireland: Cancer in Ireland 2013; available at <http://www.ncri.ie/publications/statistical-reports/cancer-ireland-2013-annual-report-national-cancer-registry> (accessed March 2014)

<sup>7</sup> OECD: Health at a Glance 2013

# 2

## The lifecycle of a medicine – finding the right balance

The lifecycle of a medicine follows a distinct pattern from costly, high risk up-front investment, through a short period of value creation to the delivery of efficiencies and savings at the end of the patent life:

- Innovation – the initial period of research and development is capital intensive, lengthy and highly risky as the vast majority of molecules will fall at this hurdle.
- Value creation – during this phase the molecule benefits from patent protection thus allowing the manufacturer to recoup its research and development costs.
- Efficiency – once the patent expires on a medicine, a generic copy can be produced relatively cheaply, leading to competition in the market place. The price of the medicine may drop sharply at this point.
- The lifecycle for innovative medicines and vaccines is undergoing large challenges due to delays in products reaching the market, restrictions in access, downward pricing pressures at all stages and a growing focus on promoting generic usage post-patent expiry (see **fig. 3**).
- The success of the innovative pharmaceutical industry depends on governments adopting a balanced approach across the lifecycle. Key to this is permitting timely reimbursement of new medicines at a fair and reasonable price whilst at the same time, harvesting efficiency savings through the development of a well-functioning generics market where the savings accrue to the State or individual patients.

In Ireland, once a generic copy of a medicine becomes available on the market, the price of the branded product falls to

**70%**

of its original price to wholesaler.

Twelve months later, the price drops further to

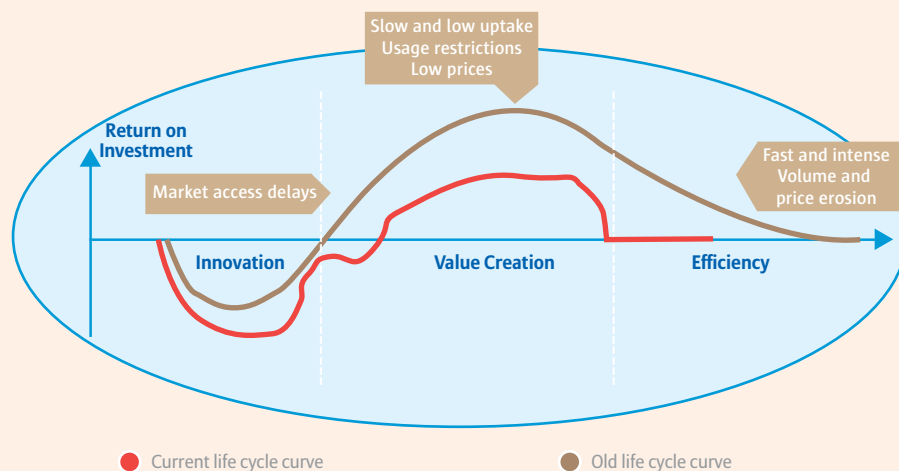
**50%**

of the original price.

- In Ireland, once a generic copy of a medicine becomes available on the market, the price of the branded product falls to 70% of its original price to wholesaler. Twelve months later, the price drops further to 50% of the original price.
- New legislation introduced in 2013<sup>8</sup> provides for further significant price reductions for groups of off-patent molecules which are deemed 'interchangeable' by the Health Products Regulatory Authority (formerly the Irish Medicines Board) through a system of reference pricing and pharmacist substitution.

**Figure 3: The changing lifecycle curve of innovative medicines**

Source: Delivering value to the UK: The Contribution of the pharmaceutical industry to patients, the NHS and the economy, ABPI 2014



<sup>8</sup> Health (Pricing and Supply of Medical Goods) Act, 2013 (No. 14 of 2013))



# 3

## Medicine pricing in Ireland – a partnership approach provides value

A well-functioning healthcare system is an important element of modern societies and a sound pharmaceutical policy is a fundamental prerequisite for health systems to perform at the required level. Health systems are complex mechanisms through which products, services and care are delivered to patients. Their success requires joint effort and collaboration amongst all the key stakeholders. For its part, the research-based pharmaceutical industry plays an essential role in the supply of innovative medicines and support to the overall healthcare structure.

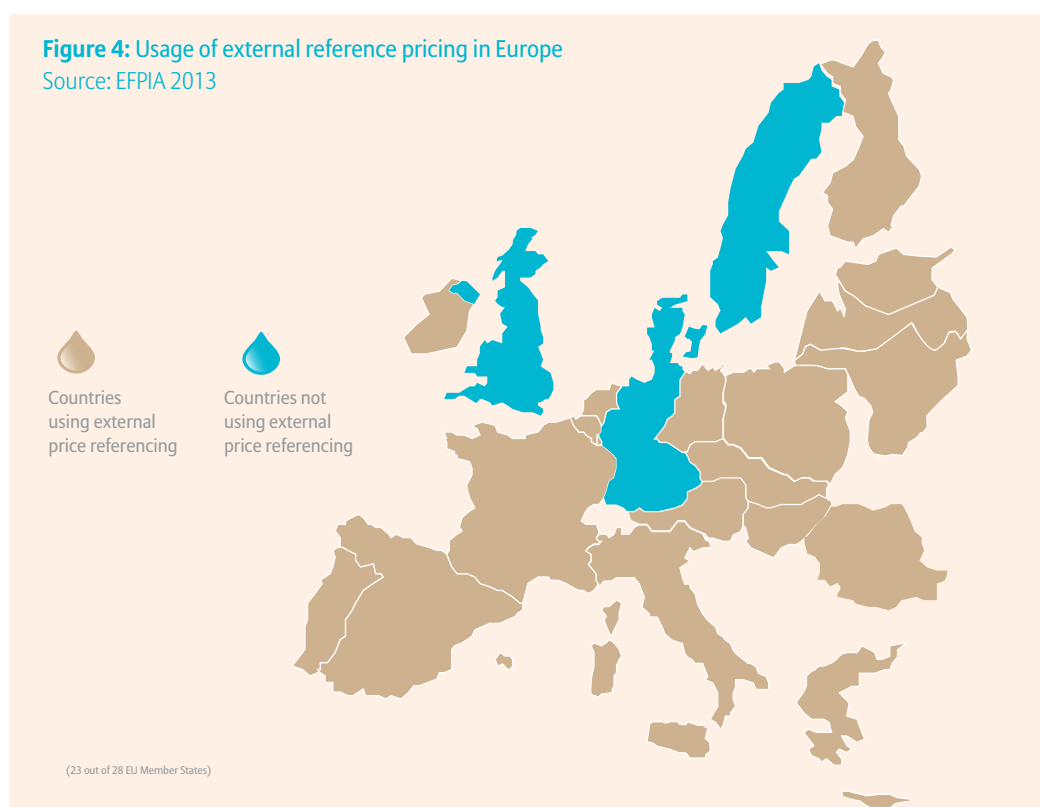
- Medicine pricing is a highly complex issue and a balance must be struck between the State's need for value for money and industry's need to have a fair return on its investment. The right balance can be achieved through a sound partnership approach with Government.
- For many years, the State and the IPHA have entered into a series of framework agreements which determine the terms and conditions under which medicines are supplied to the Irish health service.
- These formal arrangements between the industry and the State have resulted in a stable, predictable market where patients have timely access to the full range of cutting edge medicines regardless of their ability to pay.

- International reference pricing is widely used for medicines in Europe including Ireland.

The latest framework agreement (October 2012)<sup>9</sup> ensures that new medicines in Ireland are priced at the average of a 'basket' of nine European countries whose healthcare systems, prescribing patterns and pharmaceutical markets and population are comparable. Geographic proximity is also taken into consideration.

**Figure 4: Usage of external reference pricing in Europe**

Source: EFPIA 2013



This structured and transparent process ensures that the prices of on-patent products are in line with the average prices of the basket of nine countries to which Ireland is linked (Austria, Belgium, Denmark, Finland, France, Germany, Netherlands, Spain and the UK).

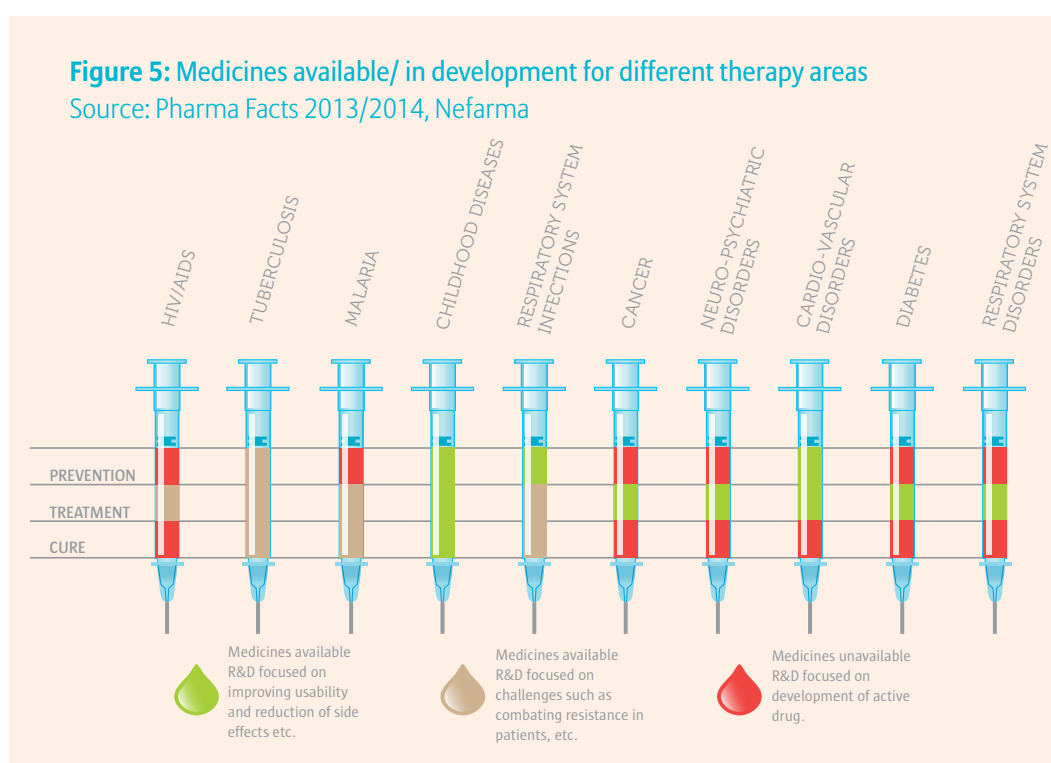
The Irish price index is in line with the index in the other basket countries; which demonstrates that the Irish international reference pricing model is effective in calculating fair prices for on-patent medicines in the Irish market, which are neither too high nor too low and serve to ensure continuity of supply of products for Irish patients.

<sup>9</sup> Framework Agreement between the Irish Pharmaceutical Healthcare Association and the Department of Health and HSE on the Supply Terms, Conditions and Prices of Medicines (October 2012)

# 4

## Investing in pharmaceutical innovation yields high returns for society

The raison d'être of the pharmaceutical industry is to improve patients' lives. To do that, we research and develop new medicines and vaccines. This is a lengthy, risky and highly regulated endeavour. The private sector has produced nearly all the medicines and vaccines on the market today. **Fig. 5** shows how much has been achieved in many areas but it also illustrates how important it is to continue the search for innovative medicines.

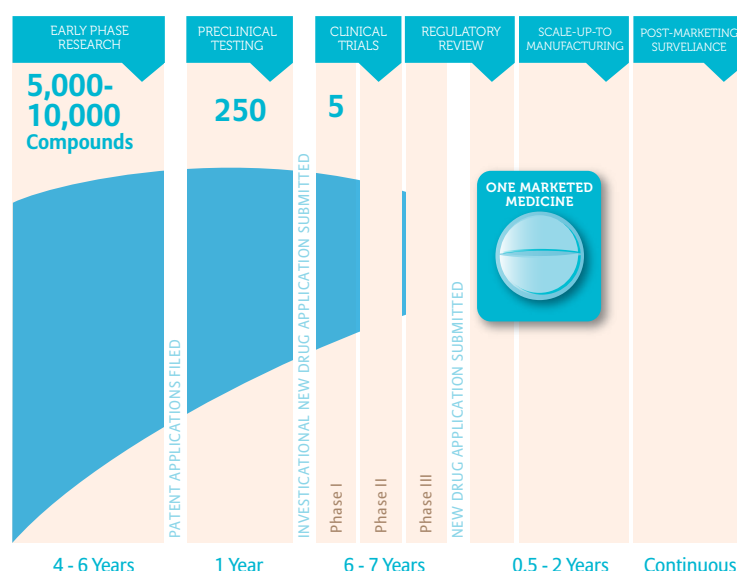


- The cost of developing a new medicine is almost €1.4 billion and the process takes 12 years on average.<sup>10</sup> Typically a patent is registered immediately upon the discovery of a potential compound. Although the patent lasts for 20 years, the effective period for return on investment can be as short as 8 years as all molecules must undergo extensive clinical trials and regulatory and reimbursement approval processes prior to their launch.

<sup>10</sup> ABPI: Time to Flourish – Inside Innovation: the Medicine Development Process (2012)

- Pharmaceutical innovation can be marked by high failure rates. On average, only one or two of every 10,000 promising molecules will satisfy the extensive testing and regulatory requirements and make it all the way to the pharmacist's dispensary for use by patients (see **fig. 6**).

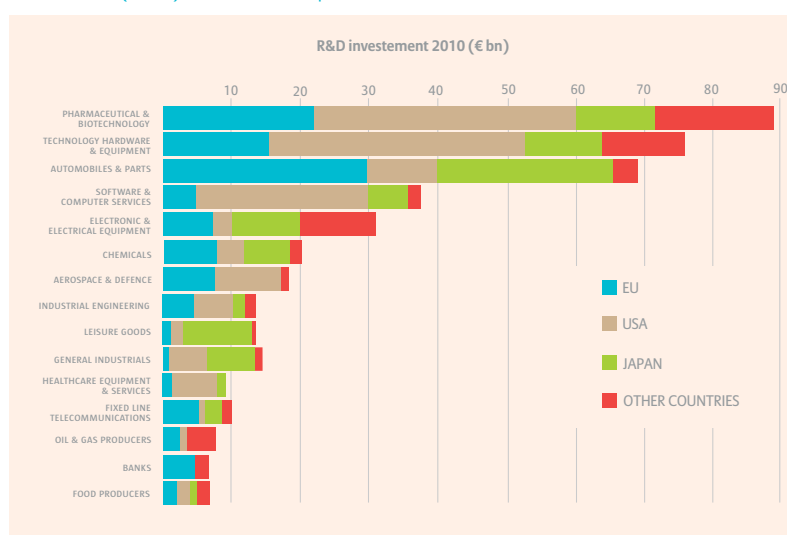
**Figure 6: The research and development process. IFPMA Facts and Figures 2012**



- The pharmaceutical industry has consistently invested more than any other industrial sector in innovation, even in times of economic turmoil and financial crisis as experienced in recent years. The annual spend on research and development by the pharmaceutical industry is 5 times greater than that of the aerospace and defence industries, 4.5 times that of the chemicals industry and 2.5 times that of the software and computer services industry (see **fig 7**).

**Figure 7: R&D investments by sector in 2010.**

Source: The 2011 EU industrial R&D Investment Scoreboard. Joint Research Centre (2011). Brussels: European Commission



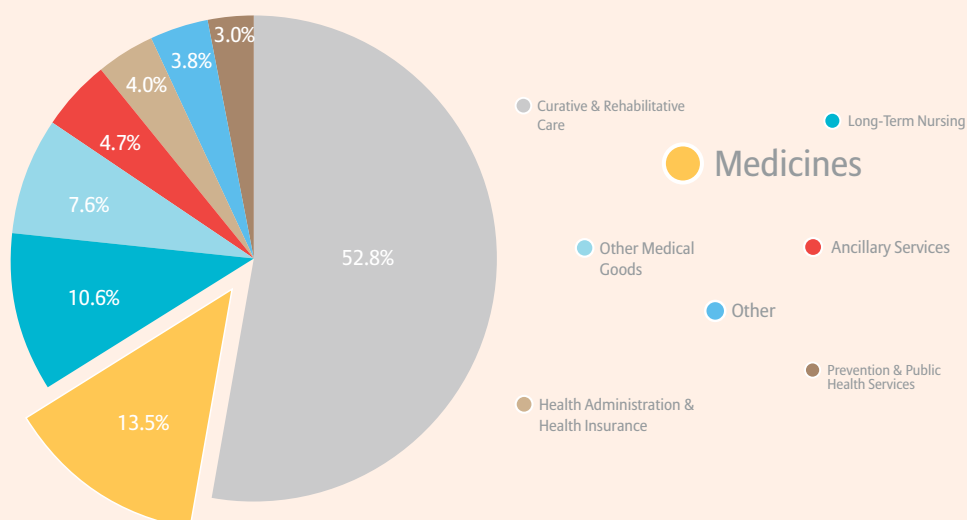
# 5

## Spending on medicines contributes to efficiencies and savings

- Less than 13%<sup>11</sup> of the health budget in Ireland is spent on medicines. Overall medicines across Europe represent less than 15% of total expenditure although variances exist between disease areas (see **fig. 8**).
- Since 2007, the pharmaceutical industry in Ireland has helped the HSE to secure savings of at least €800 million in its medicines bill. Average price reductions of 30% per item reimbursed under the various State community drugs schemes have been achieved, with the average cost per item of medicine now running at 2001/2002 levels<sup>12</sup>.
- As a greater proportion of the population lives longer, there is an increase in the number of people living with chronic illnesses. Early and appropriate use of medicines and vaccines can help avoid far more costly interventions, such as surgical treatments and hospital stays, thereby creating additional capacity throughout the health system and savings in health budgets<sup>13</sup>.

**Figure 8: Analysis of spend on medicines and other healthcare costs in Europe**

Source: EFPIA 2013



<sup>11</sup> IPHA estimate based on IMS, HSE and Department of Health statistics

<sup>12</sup> Dáil Éireann Official Report – 23rd January 2014. Written answer (no. 238) by Minister of State for Primary Care Alex White, T.D.

<sup>13</sup> EFPIA: 2013

- Keeping the population healthy and productive is a critical priority and medicines have played and can continue to play a part in this. According to IBEC, there is 11 million days lost every year to absenteeism in Ireland. This costs employers €1.5 billion per annum<sup>14</sup>. The appropriate use of medicines can help ease this burden, as patients can manage their illnesses and remain at work, thereby also avoiding a dependence on social welfare.
- Medical and surgical advances including the use of medicines also allow more patients in Ireland to be treated as day cases, where previously an expensive hospital overnight stay might have been required. This has contributed to the number of day cases in Ireland rising from 390,000 in 2002 to over 900,000 in 2012, saving valuable resources and preventing more than half a million unnecessary hospital stays a year<sup>15</sup>.

**Figure 8(ii): Analysis of spend on medicines and other healthcare costs in Europe**

Source: EFPIA 2013

COST FACTOR	COPD†	DIABETES	CHRONIC HEART FAILURE	ALZHEIMER'S	PROSTATE CANCER
CARE	21%	8%	6%	9%	34%
HOSPITALISATION	30%	22%	64%	11%	31%
INDIRECT COST	22%	35%	18%	76%	N/A
OTHER COST	14%	20%	6%	1%	2%
MEDICATION	<b>14%</b>	<b>15%</b>	<b>5%</b>	<b>3%</b>	<b>34%</b>

† Chronic Obstructive Pulmonary Disease

<sup>14</sup> IBEC: Employee Absenteeism Study (2011)

<sup>15</sup> Department of Health: Health in Ireland: Key Trends (2013)

# 6

## The pharmaceutical industry in Ireland – one of our greatest successes

The value provided by the pharmaceutical industry in Ireland extends beyond the delivery of life enhancing and life saving medicines. Successive Irish governments have for many decades, attracted foreign investment in high value added industries such as pharmaceuticals to Ireland. Today the pharmaceutical industry is one of the biggest employers in the State, generating high quality jobs for graduates and contributing heavily to our export driven recovery and a positive balance of trade in pharmaceuticals. Ireland's economic recovery and future prosperity depends on fostering strong, robust and thriving export industries.

*"The pharmaceutical and biopharma industries play a vital role in our economy. Eight of the top 10 pharmaceutical companies in the world have Irish facilities, and the country is one of the premier global locations for pharmaceutical and chemical product manufacture. Ireland also has 7 of the top 10 global biopharmaceutical companies with strategically important operations here. Building on this success and creating jobs is what this Government is about."*

*An Taoiseach, Enda Kenny TD<sup>16</sup>*

- For a country of its size, Ireland has a particularly vibrant pharmaceutical sector, employing over 25,000 people directly, and as many more working in services supporting the industry<sup>17</sup>.
- Over 50% of those employed in the pharmaceutical sector have a third level qualification, with over 25% of PhD researchers working in the industry<sup>18</sup>.

<sup>16</sup> Speech by the Taoiseach Mr Enda Kenny TD, Alexion Pharmaceutical's Investment/Jobs Announcement April 3rd 2014

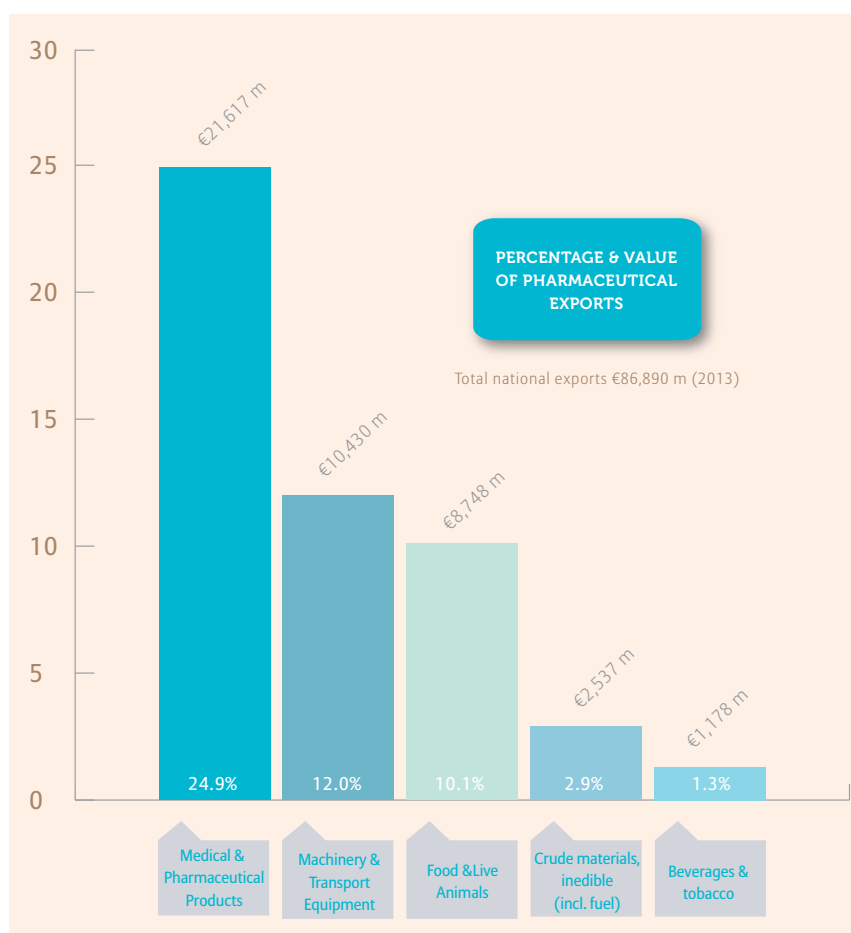
<sup>17</sup> <http://www.enterprise-ireland.com/en/Source-a-Product-or-Service-from-Ireland/Sector-and-Company-Directories/Pharmaceutical-Sector-Profile.pdf> (accessed March 2014)

<sup>18</sup> PharmaChemical Ireland: Ireland – the Location of Choice for Scientific Investment (2011)

- Between 2011 and 2013 over €1.7 billion has been invested in the sector in Ireland leading to the creation of an additional 1,500 jobs<sup>19</sup>.
- Eight of the top 10 pharmaceutical companies in the world have a presence in Ireland, producing 5 of the top 20 global blockbuster medicines<sup>20</sup>.
- Irish exports are dominated by pharmaceuticals and Ireland is now the largest net exporter of pharmaceuticals in the EU<sup>21</sup>.
- As a member of the EU, Ireland is well positioned to take advantage of a strong projected growth in demand for healthcare and pharmaceuticals, particularly from emerging markets where it is forecasted that 70% of the global increase in medicines usage will come from between 2011 and 2016<sup>22</sup>.

**Figure 9: Exports by sector from Ireland 2013**

Source: CSO, Goods Exports and Imports, Feb 2014



<sup>19</sup> 'Irish pharmachem industry fights to maintain its global position,' Matt Moran, 12th December 2013 (available at <http://www.engineersjournal.ie/irish-pharmachem-industry-fights-to-maintain-its-global-position/> - accessed March 2014)

<sup>20</sup> <http://www.idaireland.com/business-in-ireland/life-sciences-pharmaceuti/> (accessed March 2014)

<sup>21</sup> EFPIA: The Pharmaceutical Industry in Figures – key data (2013)

<sup>22</sup> EFPIA: 2013



# 7

## Working with healthcare professionals for better patient outcomes

The pharmaceutical industry and healthcare professionals work together on clinical trials and share information about new medicines and patients' responses to treatments, including side effects, in order to generate insights that all parties can use to improve patient outcomes. In the interests of patients and continuing pharmaceutical innovation, this close collaboration between the pharmaceutical industry and healthcare professionals is absolutely vital.

- Healthcare professionals need to stay informed about current and new medicines to provide patients with the best possible care and treatment options. Industry support for medical education, expert-led forums and speakers meetings enables healthcare professionals to meet their ongoing information needs.
- To help ensure that they are able to make the best treatment recommendations to their patients, the pharmaceutical industry provides doctors with the latest information about its medicines and vaccines. The industry also helps set up discussions, meetings and conferences about diseases and treatments for healthcare professionals so they can share their knowledge and experience.
- Healthcare professionals provide the pharmaceutical industry with information on how to improve its medicines: They do this through providing feedback about how medicines work in real-world patient settings.

The industry facilitates the attendance of healthcare professionals at independent (third party organised) national and international medical education meetings by providing sponsorship towards registration fees, travel, accommodation and meals, giving them the opportunity to hear about ground-breaking new research and practice developments in their fields first hand.

As an integral part of the medicines development process, companies occasionally pay fees for consultancy services to healthcare professionals who act as investigators in clinical trials, speak at educational meetings or provide advisory or training services. So long as there is a legitimate need for the service and the healthcare professional is selected because of their suitability to provide it, it is appropriate to fairly compensate them for their time and expertise.

Collaborations and partnerships between the innovative pharmaceutical industry and healthcare professionals are subject to stringent legislation<sup>23</sup>. IPHA further regulates these relationships through a robust Code of Practice<sup>24</sup>.

Compliance with all provisions of the Code is a condition of membership of the Association.

The Code is continually evolving to ensure that it reflects the highest standards of ethics and transparency and from 2016 IPHA member companies will publish details of how healthcare professionals and organisations work together with the industry to develop innovative medicines, advance research and improve patient health.

This will include details of specific interactions such as research and medical grants; attendance at international scientific meetings and patient education initiatives.

<sup>23</sup> Medicinal Products (Control of Advertising) Regulations 2007 (S.I. No. 541 of 2007)

<sup>24</sup> IPHA Code of Practice for the Pharmaceutical Industry





[www.ipha.ie](http://www.ipha.ie)

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