

Economic and societal footprint of the pharmaceutical industry in Europe

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Foreword from EFPIA



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I firmly believe that building a strong European economy, a cohesive European society and a healthy population are inextricably linked. It is one of the things that makes our sector unique. As an industry we invest a greater percentage of revenue in research and development than any other sector, we are an integral part of Europe's economic landscape and most importantly, our medicines transform the lives of patients and the way we manage our healthcare.

To help inform policy and shape industrial strategy, EFPIA commissioned PwC to conduct an analysis of the economic and societal impact of the pharmaceutical industry in Europe. PwC's analysis shows the impact on patients' lives across a selection of diseases. In addition, it indicates that, in 2016, 2.5 million jobs were supported by the pharmaceutical sector, with the average Gross Value Added per employee significantly higher than that of other key R&D sectors at €156,000. The activities of pharmaceutical companies directly contributed nearly €100 billion to EU economies, with an additional €106 billion provided through the supply chain and employee spending.

The race to attract life-science research, development and manufacturing and investment is a global endeavour. The number of new medicine approvals in the US is outstripping approvals in the EU and

the gap is continuing to grow, all in the context of increasing competition from China and the Far East.

What does this mean for Europe? As a recent report¹ from the European Political Strategy Centre stated: "Particular attention needs to be paid to areas:

- a. where Europe possesses or is developing a competitive advantage,
- b. chooses to prioritise and invest public resources, given their importance in addressing societal challenges,
- c. sees as vital to its strategic autonomy."

Given its dual role as a driver of economic growth and significant positive impact on public health, the research-based pharmaceutical industry is one of the industries of critical strategic importance that Europe can benefit from by fostering and supporting innovation, in particular by offering a predictable regulatory environment and incentives model.

The report underlines the economic and societal contribution of the innovative pharmaceutical industry to the European economy. From employment to investment, research to new treatments, as an industry, we won't rest in creating a healthier future for Europe.

¹ 'EU Industrial Policy After Siemens-Alstom', European Political Strategy Centre, European Commission, 18 March 2019.

Foreword from PwC



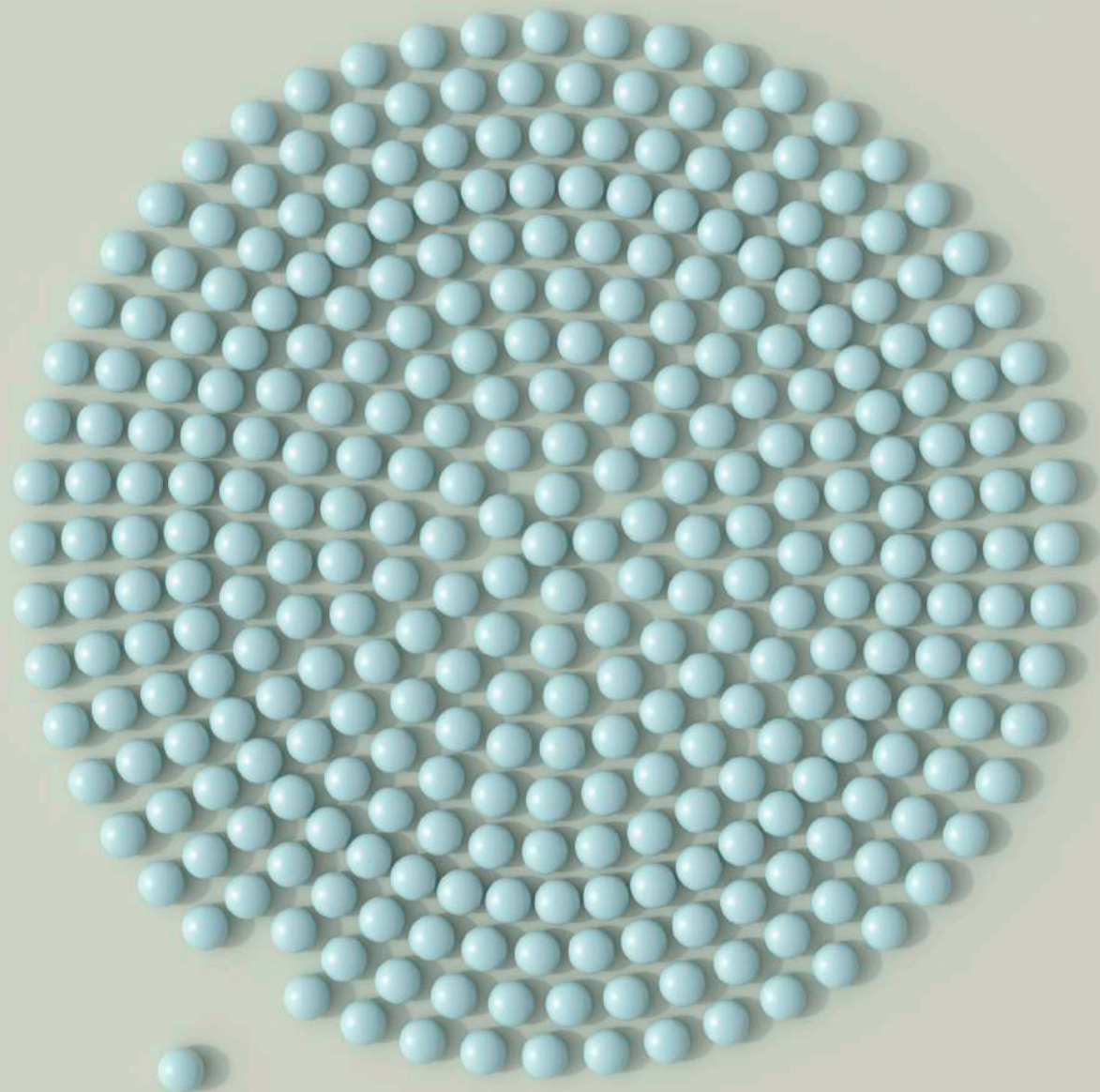
Jo Pisani
Partner, PwC UK

We are pleased to support EFPIA on this important piece of work and we thank the companies and industry bodies who have contributed and helped make this work possible.

The pharmaceutical industry has delivered substantial value to the health of European Union (EU) citizens over decades and delivered significant economic value through the research, manufacturing and commercialisation activities that are conducted in Europe. Continued research and the application of new technologies mean that treatments and cures for many more diseases are within grasp. However, with many EU health economies having to manage the increasing health costs of an ageing population and an increase in chronic diseases

there has been continued scrutiny on the affordability of medicines, and in particular, the need for intellectual property incentives to stimulate research and commercialisation of new therapies.

This debate should consider the benefits of innovative medicine as well as costs. We hope that our research is valuable in driving productive dialogue and further informs the debate by assessing the overall contribution of the industry to economic prosperity and employment, the health and societal benefits of innovations in specific areas of medicine, and by reviewing the importance of incentive mechanisms in driving continued R&D and commercialisation.



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Abbreviations

ART	Antiretroviral therapy
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
EU	European Union
GDP	Gross Domestic Product
GTAP	Global Trade Analysis Project
GVA	Gross Value Added
HAART	Highly Active Antiretroviral Therapy
HER2+	Human Epidermal growth factor Receptor 2-positive
HLY	Healthy Life Year
HR+	Hormone Receptor-positive
IP	Intellectual Property
QALY	Quality Adjusted Life Year
R&D	Research & Development
SME	Small and Medium sized Enterprise
STEM	Science, Technology, Engineering and Mathematics
STR	Single Tablet Regimen
TA	Therapeutic Area
WHO	World Health Organization

Executive summary

We have shown that the whole of the pharmaceutical industry across the EU in 2016 contributed to...

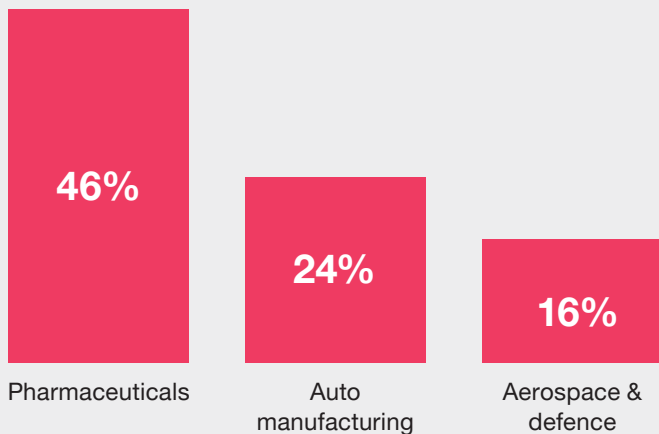
€206 billion

in Gross Value Added and...

 **2.5 million**
jobs

46% of people employed directly by the industry are women

Share of female employees



Medicines benefit millions of people on a daily basis. In just a subset of medicines within HIV (HAART) and breast cancer (HER2+, HR+) we saw that...

Over 650,000

people in the EU were treated with these medicines between 2007–2017, who are estimated to have gained around...



 **2 million**
healthy life years, leading to around...

€27 billion

In productivity gains for EU economies, and approximately...



 **€13 billion** in
healthcare cost savings due to avoided complications



The value of the pharmaceutical industry to both patients and society is often lost in the public debate surrounding medicine prices. This analysis seeks to highlight the broader value that the research-based industry delivers to the wider European community.

The pharmaceutical industry is a major contributor to the European economy. We estimate that in total, it contributed €206 billion in Gross Value Added (GVA) and 2.5 million jobs in 2016, equivalent to 1.4% of the EU's combined GDP and 0.9% of the region's employment¹. The largest contributions are made in Germany, the United Kingdom and France. As well as supporting a significant number of jobs, the industry has been making strides in areas of representation and gender equality and compares favourably with other key industries. In 2016, 46% of the pharmaceutical industry's workforce were women.

However, the benefits brought by pharmaceutical innovation are not just economic. The industry improves the lives of millions of Europeans through its contributions to public healthcare and wider societal benefits. In order to illustrate some of these benefits, we investigated two therapeutic areas – breast cancer and HIV – as case studies, measuring the impact of a selection of medicines in each case study.

The advent of targeted breast cancer treatments designed to treat specific genotypes have resulted in an estimated gain of over one million healthy life years in Europe for patients treated with selected medicines between 2007 and 2017, and have delivered a wider impact on both patients' family members and the broader breast cancer population.

Prior to the advent of highly active antiretroviral therapy (HAART), an HIV diagnosis was almost a death sentence. The development of HAART therapy has turned HIV into a treatable disease, and this is evidenced in the increases in healthy life years and increases in productivity it has brought to the European HIV population. For patients treated between 2007 and 2017, the HAART therapies we looked at are estimated to lead to a gain of 800,000 healthy life years and €22 billion of productivity. Outside of the quantifiable gains in healthy life years and productivity, these innovations have the potential to reduce both health inequalities and HIV transmission rates.

It is worth noting that the benefits quantified in our analysis represent only a fraction of the overall health and societal contribution of the pharmaceutical industry in Europe. Our analysis focused only on specific medicines within two therapeutic areas. New, more effective drug therapies improve the psychosocial health of patients, family members and the

community, which our analysis has not quantified. We also have not accounted for the effect of improved health on increases in informal employment, such as domestic work, childcare, and family caretaking, the imputed value of such is estimated at 20 to 40% of EU GDP². Moreover, the medicines have a ripple effect in that all of them have helped pave the way for further innovations across different medical disciplines.

The current EU incentives model, which includes Supplementary Protection Certificates, Regulatory Data Protection, Orphan Market Exclusivity and Paediatric Rewards, is fundamental to ensuring a strong pharmaceutical industry in Europe. It has helped to generate investment in areas with previously unmet needs and fostered a thriving industry that makes a significant contribution to the European economy and society. A survey of 18 EFPIA corporate members reinforces the importance of these incentives. Respondents indicated that, within the current incentives environment, they have increased investment in the EU over the past three years. Members indicated that intellectual property (IP) incentives and faster market access are the leading factors influencing R&D investment decisions, and that dismantling the current incentive model would have a negative impact on their R&D and Commercial operations in Europe. Drastically changing the incentives model therefore risks damaging the pharmaceutical industry's ability to deliver value in Europe.

¹ GVA captures the gross economic contribution that a sector makes to the economy, in terms of the value that its activities add to overall economic output. GVA is broadly equivalent to GDP but it excludes some indirect taxes. It is commonly used to measure the value of a company or sector of the economy for whom it is difficult to attribute certain taxes.

² Giannelli et al. (2012). GDP and the value of family caretaking: how much does Europe care?

Introduction

The value of the pharmaceutical industry to both patients and society is often lost in the public debate surrounding medicine prices

In the past 20 years, the pharmaceutical industry has pioneered research into a vast range of life-saving medicines. Research into small molecule medicines and vaccines has paved the way for new treatments in a number of key areas, affecting millions of lives, including precision medicines, biologics, cell and gene therapies, siRNA and digital therapeutics.

These innovations have allowed us to tackle complex diseases far more effectively and with greater precision than ever before. Yet these breakthroughs are expensive: accounting for the cost of failed drugs, the average cost of bringing a new drug to market is now estimated to be over \$2bn.³

Medicine prices are set through negotiation with governments based on the value they deliver to patients and health systems. Unlike other parts of the healthcare system, they are subject to rigorous value assessments before being reimbursed. Yet these value assessments can overlook the direct and indirect benefits of pharmaceutical innovation, both in the field of medicine and to the wider patient population, their careers, the community, and the economy.

A better understanding of the broader value that the industry delivers can contribute to more holistic dialogue and decision-making

To better understand the direct and indirect contribution of the pharmaceutical industry in Europe, EFPIA commissioned PwC to conduct a study focussed on three key areas:

- The economic impact of the industry;
- The health and societal impacts of the industry; and
- The enabling environment for continued investment in innovation.

³ DiMasi et al. (2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. Tufts Center for the Study of Drug Development, Tufts University, United States.



Methodology

For the economic analysis, we estimated the economic contribution of the pharmaceutical industry, defined here as the pharmaceutical and life science companies developing and distributing medicines and vaccines⁴, in the EU.

The analysis examines how the industry contributes to the economy through Gross Value Added (GVA) and employment. GVA captures the gross economic contribution that a sector makes to the economy, in terms of the value that its activities add to overall economic output.⁵ Employment captures the number of people who are directly employed in a given sector, who have a contract of employment and receive compensation in the form of salaries.

In addition to the direct economic contribution of the industry, we used input-output analysis to estimate the industry's broader economic contribution through its supply chain and employee spending. The total contribution of the industry is made up of direct, indirect and induced effects, which we define as follows:

Direct economic impact

Consists of the economic value that the sector created directly and the number of people that organisations within the sector employ.

Indirect economic impact

Consists of the impact of the sector's expenditure on suppliers (for example, by purchasing raw materials) and suppliers' expenditure through subsequent tiers of the supply chain.

Induced economic impact

Consists of the impact of employees of both the pharmaceuticals sector and its supply chain spending their wages.

For the health and societal impact case studies, we investigated two therapeutic areas: breast cancer and HIV. These were chosen because they cover different disease profiles, including non-communicable and communicable, acute and chronic diseases, and affect people of different ages and socioeconomic backgrounds.

For the two therapeutic areas, we focused on a subset of medicines that represent important innovations in their field and address previously unmet patient needs. To assess their impact, we followed a bottom-up process to estimate the aggregate health, productivity and cost impact of these medicines for patients treated from 2007 to 2017. By estimating the incremental gain in healthy life years⁶, working days and the change in net health care costs compared with standards of care prior to the introduction of the medicines, we were able to come up with a picture of the benefits these medicines have

brought to society. The case study approach covers only a fraction of the impacts of medicines, and is intended to provide illustrative examples of health and societal benefits rather than be a comprehensive analysis across the pharmaceutical industry.

To understand the importance of the current EU incentives model, which includes Supplementary Protection Certificates, Regulatory Data Protection, Orphan Market Exclusivity and Paediatric Rewards, we surveyed EFPIA corporate members. The survey sought to determine how the current incentives model affects their Europe based R&D, commercial and manufacturing operations and what dismantling this incentives structure might mean for them.

For more detail on the methodology, please refer to the Technical Report.

⁴ We have defined the pharmaceutical industry as using NACE code C21 (Manufacture of basic pharmaceutical products and pharmaceutical preparations). NACE codes are a Europe-wide standard classification for businesses, which allow us to conduct analysis across countries consistently.

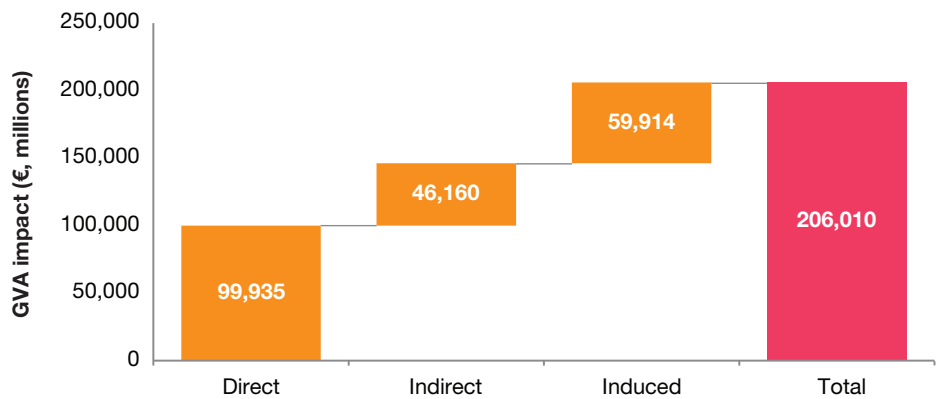
⁵ GVA is a similar measure to GDP, but GDP includes some additional indirect taxes which are difficult to attribute to individual sectors. The formula to calculate GVA is: Direct GVA = Operating Profits + Depreciation + Amortisation + Direct employee costs.

⁶ In this report, the term 'healthy life year' is used as the plain English equivalent of the technical term: Quality-Adjusted Life Year (QALYs). One healthy life year is therefore the same as one QALY and is equal to 1 year of life in perfect health. Or, for example, 2 years living with a severe illness which reduces quality of life by 0.5. The QALY is a widely used health outcome measure which reflects both the length and quality of life lived. QALYs are measured in terms of the person's ability to carry out the activities of daily life, as well as freedom from pain and mental disturbance. (NICE).

Economic impact

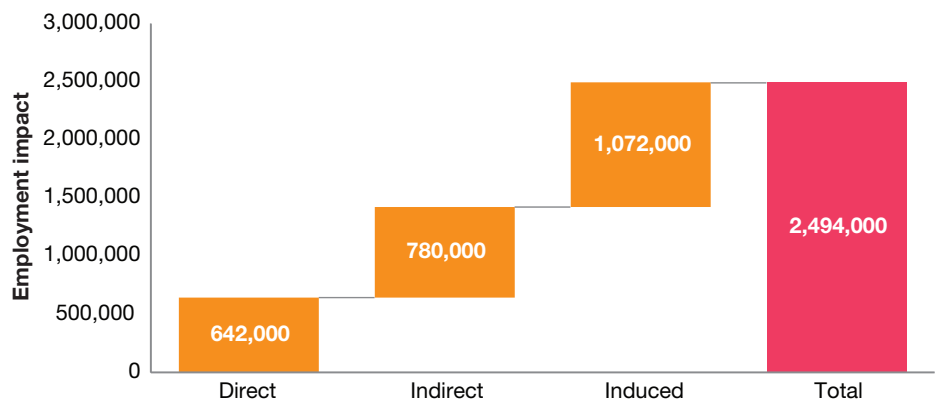
The pharmaceutical industry is a major contributor to the EU economy. We estimate that in total, it contributed €206 billion in GVA and 2.5 million jobs in 2016, equivalent to 1.4% of the region's combined GDP and 0.9% of employment.

Figure 1: GVA contribution of the pharmaceutical industry in the EU, 2016



Source: PwC analysis

Figure 2: Employment contribution of the pharmaceutical industry in the EU, 2016



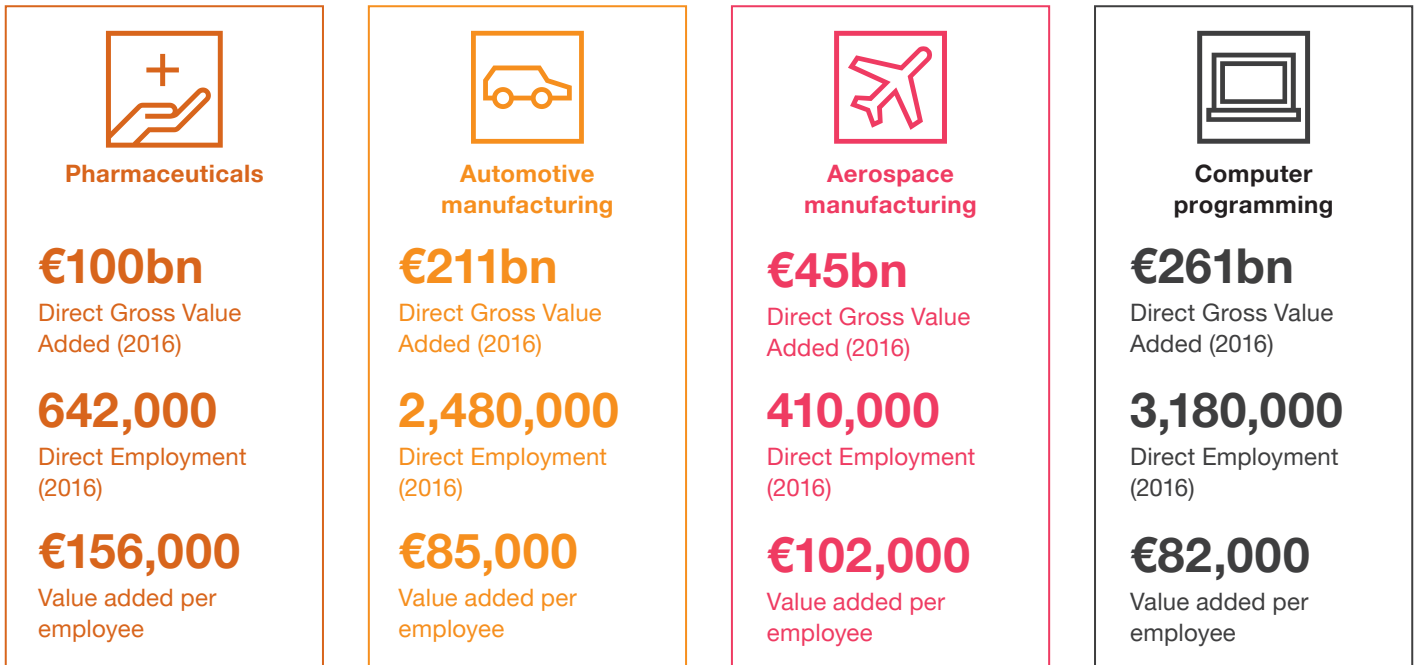
Source: PwC analysis

The pharmaceutical industry directly employs a large number of highly-skilled staff, who each make a significant contribution to the economy.

The pharmaceutical industry directly contributes an average of €156,000 of GVA for every employee. This figure is significantly higher than the region's average of €59,000, and it is also higher than other industries. For example, the GVA per employee in the car manufacturing industry is €85,000.

The benefits of the pharmaceutical industry's productivity extend beyond the industry itself: it helps to raise living standards, keep wages high and increases tax revenues for government.

Figure 3: Economic contribution of the pharmaceutical industry versus other key industries



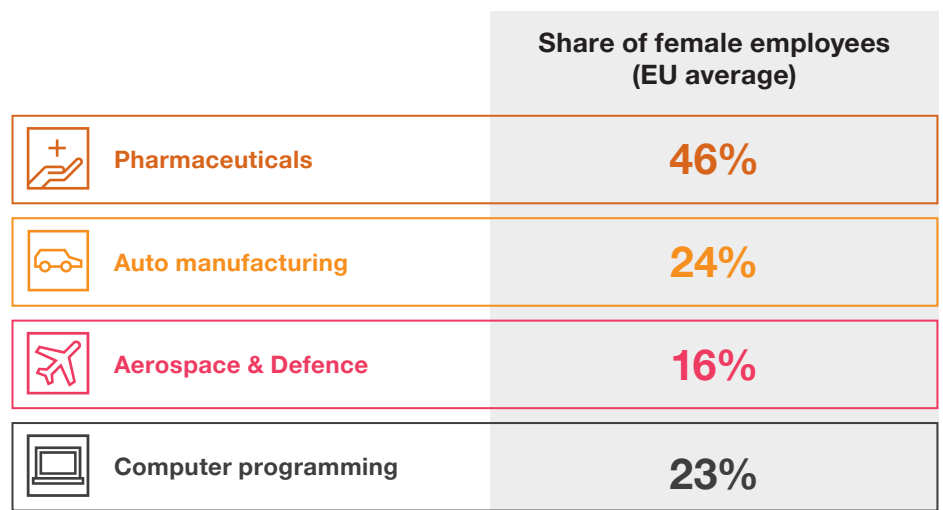
Source: PwC analysis

Breaking down GVA by country shows that the pharmaceutical industry offers the largest contribution to GVA in Germany and the United Kingdom, with these countries accounting for 33% of the total GVA created by the industry in the entire region. The GVA contribution is concentrated in these countries as they are home to many large pharmaceutical companies, who employ a large number of staff in high productivity roles. Jobs supported by the industry are also concentrated in these countries along with France. Germany, France and the United Kingdom account for nearly half (49%) the total jobs supported by the industry in the region. For more detail on country-specific results, see Technical Report.

The pharmaceutical industry’s workforce is more gender balanced than other key industries

The pharmaceutical industry has been making strides in areas of representation and gender equality. In 2016, 46% of the pharmaceutical industry’s workforce across the EU were women. This compares favourably against, for example, the gender distribution of the 18 million scientists and engineers in the EU who are women (41%), and the distribution of scientists and engineers in high and medium-technology manufacturing who are women (just 17%).⁷

Figure 4: Percentage of female employees in the pharmaceutical industry versus other key industries



Source: PwC analysis

⁷ Eurostat (2019). Women in science & technology

The Orphan Regulation has helped to address an unmet need in the pharmaceutical industry, whilst also encouraging the growth of small and medium sized enterprises (SMEs)

Orphan diseases affect circa 30 million people in the EU, with more than half of newly diagnosed cases occurring in children, a third of whom will die before they are five years old. Despite this, fewer than 15% of orphan diseases benefit from what the European Medicines Authority describes as ‘even minimal amounts of scientific knowledge’, and 95% of the 7,000 known rare diseases have no approved therapies.

The EU Orphan Regulation, adopted in December 1999, provides 10 years of market exclusivity to medicines for orphan diseases⁸, alongside protocol assistance, reduced fees for regulatory activities, and additional incentives for SMEs, defined by the EMA as enterprises with fewer than 250 employees and either an annual turnover of not more than €50 million or an annual balance-sheet

total of not more than €43 million. Since its adoption, the number of orphan medicines in the EU has risen significantly, from only 8 products prior to 2000, to 164 today⁹. The medicines treat a wide variety of diseases, however, there has been a clear focus on orphan cancer medicines, which account for more than 40% of orphan medicines with market access, and medicines targeting illnesses with a particularly low prevalence (below 3 in 10,000).

The number of medicines granted orphan designation by the European Commission has risen year on year, suggesting a greater number of higher quality applications. This goes hand in hand with the rising number of scientific publications on rare diseases, which are providing companies with the knowledge they need to develop effective orphan medicines.

SMEs contribute significantly to the orphan medicines market, indeed, more than half the medicines that have so far received orphan designation were developed by SMEs.

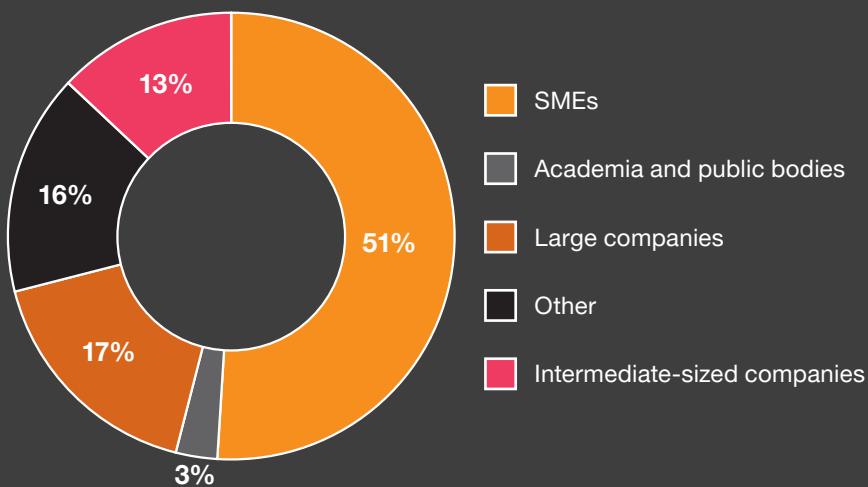
Ronny’s story

When Ronny was diagnosed with neuroendocrine tumours, he did what people do in movies and asked how long he had to live. When the oncologist said: ‘months, years...’, Ronny switched off. But he did remember the oncologist adding: ‘But with the right treatment you could live a lot longer.’ Fortunately, Ronny had access to the right treatment at the right time. He is now living a reasonable quality of life, participating in activities such as bicycle rides with his wife. He thinks he’ll even be able to live to see some of his grandchildren graduate from school.

⁸ According to the Orphan Regulation requirements, an orphan disease cannot have a prevalence higher than 5 in 10,000

⁹ EMA (2018) Annual report on the use of the special contribution for orphan medicinal products. Available online here: https://www.ema.europa.eu/en/documents/report/annual-report-use-special-contribution-orphan-medicinal-products-2018_en.pdf

Figure 5: Types of organisations with orphan designations in development from 2002 to 2012

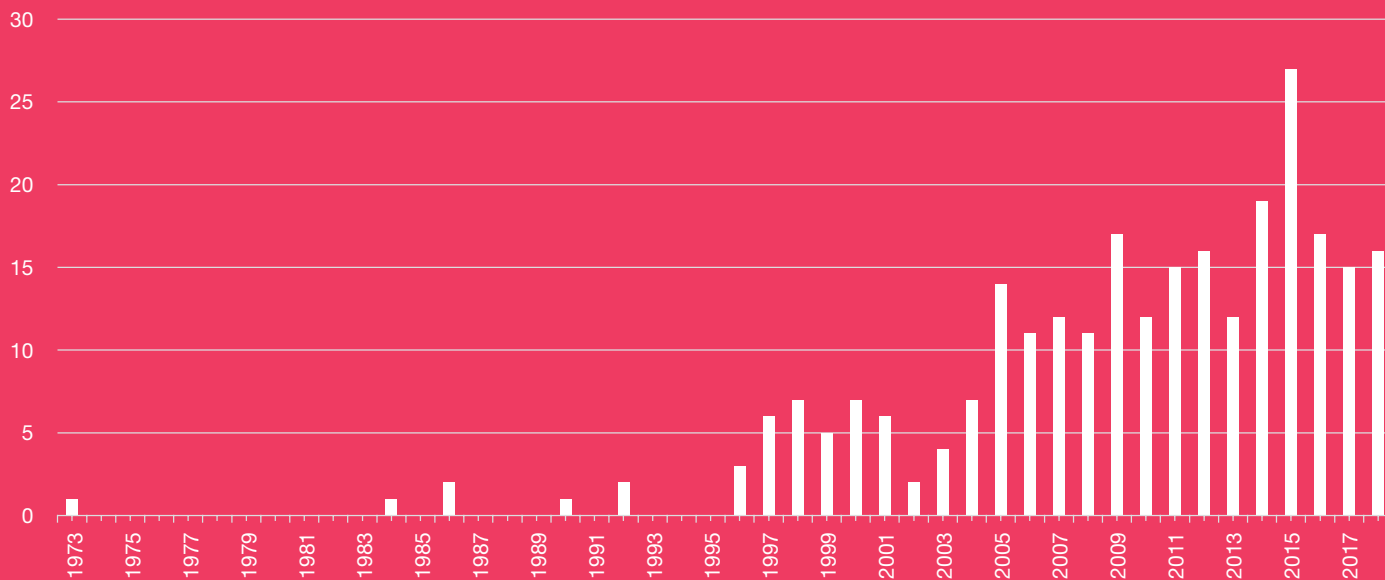


Source: Charles River Associates (2017)



The number of orphan-focused SMEs has risen since the adoption of the Regulation: of the 276 SMEs focusing on orphan medicines that currently exist, 90% were incorporated after 2000.

Figure 6: Number of SMEs focusing on orphan medicines



Source: European Medicines Agency SME Register



Alongside benefits provided by the Regulation exclusively to SMEs, SMEs developing orphan medicines can benefit from attracting early investment. Venture capitalists investing in orphan medicine start-ups typically do so on average one year before they would in a non-orphan medicine equivalent.¹⁰ Benefits aside, the orphan medicines market is suited to SMEs, as it offers a wide breadth of niche areas that require bespoke research, creating an environment with less direct competition.

¹⁰ Charles River Associates (2017). An evaluation of the economic and societal impact of the orphan medicine regulation

Health and societal impact

The benefits brought by pharmaceutical innovation are not just economic. It improves the lives of millions of Europeans through its contributions to healthcare and wider societal benefits. The following case studies illustrate some of these benefits.

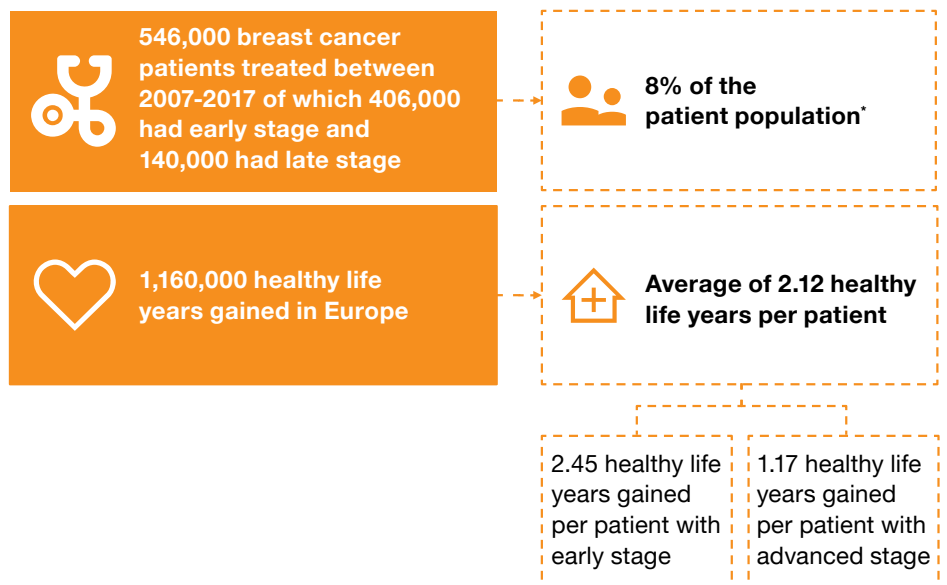
Breast cancer

Before 2005, many patients with aggressive or advanced breast cancer had very low chances of survival¹¹ and were limited in their treatment options. Drug resistance¹² in these cancers meant that patients were forced to undergo gruelling and in some cases ineffective chemotherapy courses.¹³ For certain metastatic breast cancer patients, for example, average life expectancy after diagnosis was 20 months, with patients responding to chemotherapy for an average of just six months.¹⁴

Innovation in medicines has helped to address this previously unmet need. In our case study, we consider patients with early and advanced HER2+¹⁵ and advanced HR+ breast cancer.

Pharmaceutical innovations since 2005 have led to an improved prognosis for these patients. The subset of medicines¹⁶ we investigated for both the HER2+ and HR+ forms of the disease represent a pipeline of treatment innovation, in that they capture both the first treatment forms and their subsequent evolutions.

We estimate that between 2007 and 2017, over 500,000 breast cancer patients received these targeted treatments, resulting in a gain of nearly 1.2 million healthy life years.



* With only 4% of patients with advanced breast cancer eligible for HER2+ treatment, and 10% of patients with early stage cancer eligible for HER2+ treatment, this is a significant proportion of the eligible population.

¹¹ Slamon et al. (2001). Use of Chemotherapy plus a Monoclonal Antibody against HER2 for Metastatic Breast Cancer That Overexpresses HER2.

¹² Moiseenko et al. (2017). Resistance mechanisms to drug therapy in breast cancer and other solid tumors: An opinion.

¹³ Sledge et al. (2014). Past, Present, and Future Challenges in Breast Cancer Treatment.

¹⁴ Slamon et al. (2001). Use of Chemotherapy plus a Monoclonal Antibody against HER2 for Metastatic Breast Cancer That Overexpresses HER2.

¹⁵ HER2+ breast cancer is a breast cancer that tests positive for a protein called human epidermal growth factor receptor 2 (HER2), which promotes the growth of cancer cells. Approximately 20% of breast cancer cases are HER2+ breast cancer.

¹⁶ See Technical Report for list of medicines considered in the study.

Through more effective treatment these medicines have also reduced days lost to illness thus creating additional economic benefits. We estimate that the new treatments create productivity gains of €9,700 per patient, or €5.3bn in total, which is equivalent to about 3.5% of the total economic cost for breast cancer care in Europe.¹⁷

Outside of the quantifiable gains in healthy life years and productivity, these innovations deliver a wider impact on both patients' family members and the broader breast cancer population. The health and societal impact presented here will likely be much greater than that captured by our analysis. This is owing to the disproportionate contribution of women, more specifically mothers, to the economy in terms of unpaid work. Globally, women spend up to ten times more time on unpaid work than men,¹⁸ and as breast cancer largely affects women, the impact of improved breast cancer treatment on unpaid work is significant.

Improved treatments have also helped to alleviate the burden placed on primary caregivers and patients' immediate family members. It has been reported that among breast cancer caregivers, 30% suffered from depression and almost 80% of employed caregivers missed work.¹⁹

Furthermore, the patent lifecycle of these medicines opens the way for new entrants, such as biosimilars or improved versions through life cycle management, resulting in a healthy competitive ecosystem. These new entrants are typically offered at a lower price, thereby

allowing increased access to a similar standard of care. For example, in Europe, four trastuzumab biosimilars have recently come to market,²⁰ indicating a drive from pharmaceutical companies to continue innovating and delivering impact.

Finally, the medical benefits of these new treatments are not limited to HER2+ and HR+ breast cancer treatment: they paved the way for antibody-targeted treatment across many different cancer types.

Suzanne's story

When Suzanne Leempoels found out at the end of her early breast cancer treatment that she had metastasis in her lungs, the first thought that crossed her mind was that she wanted to live to one day meet her grandchildren. Fortunately, her oncologist opted for curative treatment, and five years later, her cancer is inactive.

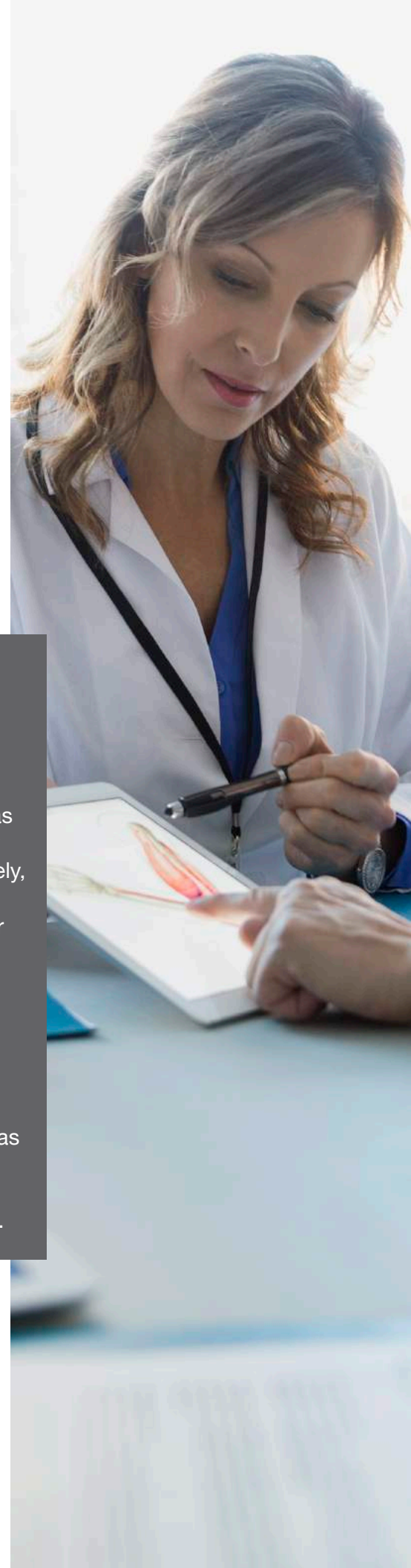
Suzanne now campaigns for awareness on behalf of other metastatic cancer patients. In particular, she wants to highlight that cancer is more than just a medical problem; it affects all areas of life, from work and financial security, to patients' emotional condition and sense of self-worth.

¹⁷ Luengo-Fernandez et al. (2013). Economic burden of cancer across the European Union: a population-based cost analysis.

¹⁸ Promundo (2019). State of the World's Fathers: unlocking the power of men's care.

¹⁹ Grunfeld, E. (2004). Family caregiver burden: results of a longitudinal study of breast cancer patients and their principal caregivers.

²⁰ Generics and Biosimilars Initiative (2018). Biosimilars of trastuzumab.



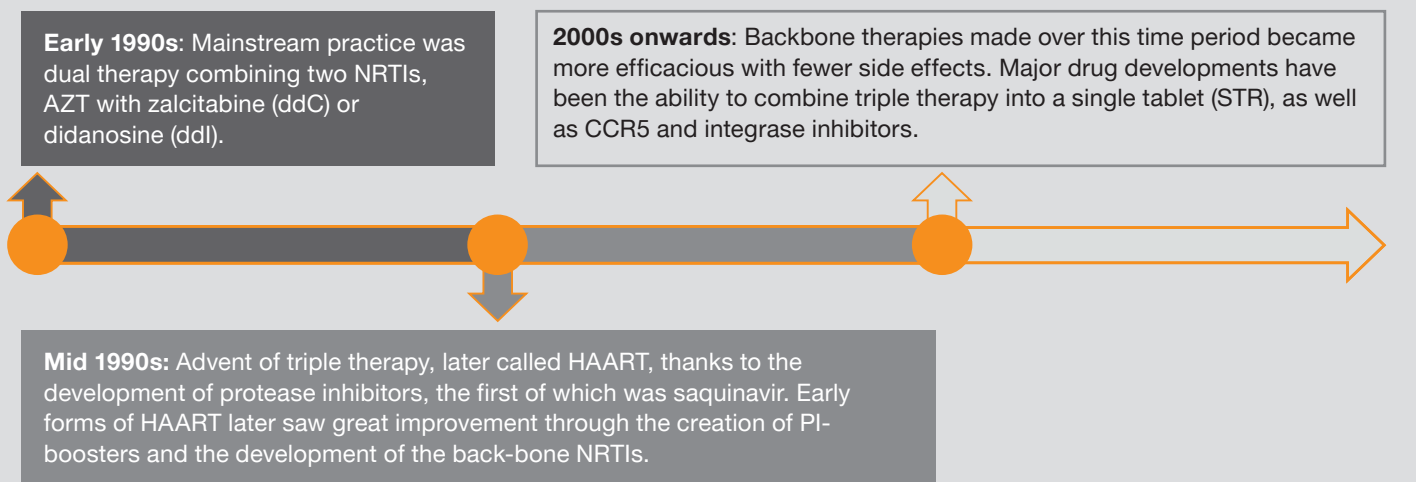
HIV

Prior to the advent of highly active antiretroviral therapy (HAART), an HIV diagnosis was considered by many to be a death sentence. In the early 1990s, HIV patients were treated with dual NRTI therapy (AZT with zalcitabine or didanosine) which had limited success in lowering viral load and was accompanied by severe side effects, including nausea,

vomiting, anaemia, neutropenia, myopathy, pancreatitis, and peripheral neuropathy,²¹ as well as a high chance of developing AIDS. The low tolerability of these side effects contributed to poor adherence.

The advent of HAART, which saw the introduction of protease inhibitors and the development of backbone NRTIs, in the mid-1990s marked a breakthrough for patients. These backbone therapies became more efficacious with fewer side effects over time. Our analysis looks at the health and societal benefits that HAART has brought.

Timeline of HIV treatment development



The development of HAART has turned HIV into a treatable, chronic disease. These new drugs tackle the potency of the virus with no further risk to the patient. In doing so, they have overcome the single biggest challenge facing HIV drug development.

There are now more than 30 HIV drugs available, of which there are 13 fixed dose combinations that are called single tablet regimens (STR). Continued investment in the research and development of new anti retrovirals, including within STRs, has resulted in the development of new combinations that

have better tolerability and thus improve the quality of life for people living with HIV. The development of STRs has also enabled greater medication adherence within the HIV community, which has had a significant positive impact on viral suppression in HIV patients.

Looking at a subset of STRs introduced in the last decade²², we can see the difference these treatments have made to patients' lives and to society at large. We estimate that HAART gives the average HIV patient an extension of 9 years in life expectancy (approximately 7.4 healthy life years) compared to

treatment pre mid-1990s²³, bringing life expectancy for people with HIV on anti-retroviral treatment and responding to treatment in line with the general population²⁴, meaning patients can expect to live full lives. In total, for patients treated between 2007 and 2017, we estimate a gain of 775,000 healthy life years. This increase in health extends their ability to work and contribute to society, resulting in an estimated €207,000 in productivity gains on average per patient over their lifetime.

²¹ Darbyshire et al. (2000). Zidovudine (AZT) versus AZT plus didanosine (ddl) versus AZT plus zalcitabine (ddC) in HIV infected adults.

²² See Technical Report for medicines included in analysis.

²³ See Technical Report for details on methodology

²⁴ NHS UK. What is the life expectancy for someone with HIV?



105,000 HIV patients were treated between 2007-2017



8% of the patient population*



775,000 HLYs gained in Europe



Average of 7.4 HLYs per patient

* The medicines we have analysed are single tablet therapies. Many people are treated with multi tablet regimens with the same active ingredients.

By reducing patients' risk of developing AIDS and other HIV-related complications, HAART has also alleviated pressure on healthcare systems. We estimate that, compared to treatment in the early 1990s, treating someone with HIV using HAART could result in net savings to the healthcare system of €11,000 per patient over their lifetime²⁵. This suggests that despite the high cost of new HIV medicines, they deliver value for money in the long-term.

In addition to the quantifiable gains in healthy life years and productivity, these innovations have the potential to reduce both health inequalities and HIV transmission rates. HIV is most prevalent among vulnerable groups and especially among those of lower socioeconomic status. Treatment outcomes for these groups tend to be worse, due to a combination of factors including failure to diagnose HIV early enough, late initiation of antiretroviral therapy (ART)²⁶ and poor adherence to ART. These

failures in treatment make the possibility of virologic rebound high among patients in these groups.²⁷ Through better adherence and improved viral suppression, access to STRs would disproportionately benefit less privileged socioeconomic groups.

Moreover, HAART has had a major impact on HIV transmission rates. A recent study found that due to the reduction in virologic load, patients on HAART treatment presented no transmission risk to their partners²⁸. Reducing the transmission risk could further significantly lower the prevalence of HIV across Europe and in turn, reduce the healthcare burden of HIV and HIV related illnesses. Furthermore, studies are now evaluating the use of such medicines as pre-exposure prophylaxis (i.e. taken to prevent HIV infection by those who do not have HIV but are at substantial risk of getting it), which have proven successful in lowering HIV transmission in America.

Patrick's story

Patrick Reyntiens was diagnosed as HIV-positive in 1985. At the time, the disease was close to a death sentence. The great breakthrough came in 1996, with the introduction of 'AIDS Cocktails' (early HAART). Initially, Patrick was on 20 – 30 pills a day and he felt sicker on the medication than from the virus itself. These days, however, Patrick takes only five pills a day. Many patients only need to take one. Patrick's quality of life has improved enormously and he uses his time to raise awareness of HIV. He's hopeful treatment will continue to improve and that one day there might even be a cure.

²⁵ This could range from net savings of €40,000 to net cost of €31,000 depending on assumptions applied. See Technical Report for further information.

²⁶ Lodi, S. (2014). Delayed HIV diagnosis and initiation of antiretroviral therapy.

²⁷ Burch et al. (2016). Socioeconomic status and treatment outcomes for individuals with HIV on antiretroviral treatment in the UK: cross-sectional and longitudinal analyses.

²⁸ European Centre for Disease Prevention and Control. (2018). The benefits of HIV treatment: undetectable means you do not pass on the virus.

Role of IP incentives

For the industry to continue to deliver such value to the European community, it is essential that the legal and regulatory environment encourages innovation and fosters growth. This kind of environment has been enabled in the EU through the introduction of several initiatives, including IP incentives, which have encouraged the development of innovative medicines. To help understand the importance of the current incentives model, and the potential effects of dismantling it, we undertook a survey of 18 EFPIA corporate members.

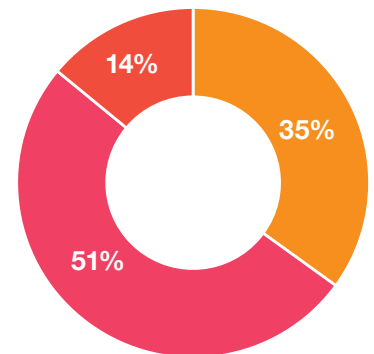
The IP incentives considered in the survey are the Supplementary Protection Certificates (SPCs), Regulatory Data Protection, Orphan Market Exclusivity, and Paediatric Rewards, among others. Research and development of new medicines can be a long, complex, risky – and ultimately expensive – process. These incentives are designed to encourage continued innovation by offering additional protection for medicines that make it to market.

Within the current environment, over 80% of respondents reported that they have increased or maintained current levels of investment, which is consistent with reported figures²⁹ from the pharmaceutical industry. Research and Development (R&D) and Commercial are the segments of the value chain that have benefited most from this trend as a result of maturing pipelines, incremental investments in existing facilities and capabilities, new product launches and partnership-led R&D approaches.

²⁹ Informa UK (2017) Pharma R&D Annual Review 2017.

Figure 7: Percentage of respondents reporting a change in European footprint in the last three years

Change in European footprint
% of respondents reporting a change in the last 3 years



■ Increase ■ No change ■ Decrease

Source: Results of PwC survey of EFPIA corporate members

“

We made multi-million € investments focused on modernising existing R&D facilities, ramping up R&D activities, and enhancing R&D capabilities

Respondent to PwC survey

EFPIA members indicated that IP incentives and quicker market access are the leading factors influencing R&D investment decisions. IP incentives were consistently ranked by the respondents in the top three factors influencing investment decisions.

Figure 8: Market factors in order of importance in terms of deciding which countries to invest

		Overall rank
	IP incentives	1
	Accelerated approval/early access schemes	2
	Skills and wage costs of labour	3
	Size of economy and potential for growth	4
	Macro-economic/political issues (e.g. inflation, political uncertainty)	5
	Attractiveness to conduct clinical trials	6
	Tax rates	7
	Infrastructure and transport	8

Source: Results of PwC survey of EFPIA corporate members

According to EFPIA members, dismantling the current incentives model would have a negative impact on pharmaceutical companies' EU research-based investment activity. Respondents indicated that phasing out current incentives in Europe would have a material negative effect on their European operations, with over half indicating that this scenario would lead to a reduction in their R&D and Commercial footprints of more than 25%. Organisations choosing to reduce their footprint in Europe would seek opportunities to increase investment in regions where their IP is better protected and innovation more actively rewarded. This finding is consistent with previous studies^{30, 31} which show that weaker intellectual property regimes limit the willingness of companies to invest in R&D.

“ Investments have been increased by more than 10% per year over the last 3 years to launch new products, continue increasing our investments in our existing portfolio, support the creation of new affiliates, and reinforce our expertise and global organisation, particularly in terms of R&D

Respondent to PwC survey

³⁰ NERA Economic Consulting (2007). Key Factors in Attracting Internationally Mobile Investments by the Research Based Pharmaceutical Industry.

³¹ Porter, M. (2000). Location, Competition, and Economic Development: Local Clusters in a Global Economy.

Conclusion

Our research provides evidence of the significant economic contribution that the pharmaceutical industry makes to economic prosperity and employment in the EU. We estimate that in 2016, it generated over €206 billion in GVA (including indirect and induced effects) and employed over 2.5 million people across the EU.

This study also highlights the valuable health and societal benefits of pharmaceutical innovations in specific areas of medicine. We estimate that for over 650,000 HIV and breast cancer patients treated between 2007 and 2017, the subset of medicines analysed resulted in gains of nearly 2 million healthy life years and €27 billion in terms of productivity. It is worth noting this only quantifies a fraction of the overall health and societal contribution of the pharmaceutical industry. Aside from addressing only two therapeutic areas, we have not touched on the ways in which new, more effective drug therapies improve the psychosocial health of patients, family members and the community, and our productivity calculations do not account for increases in informal employment, such as domestic work, childcare, and family caretaking. The imputed value of such unpaid work has been estimated at 20 to 40% of the EU GDP³². Even the impact of the medicines analysed here are likely to be greater than stated, given that all of them have helped pave the way for further innovations across different medical disciplines.

The results of our survey of pharmaceutical companies indicate that the current incentives model is important to ensuring a strong industry in Europe. It has helped to generate investment in areas with previously unmet needs and fostered a thriving industry that makes a significant contribution to the European economy and society. Drastically changing the incentives model risks damaging the pharmaceutical industry's ability to deliver value in Europe.

There is an ongoing debate about the affordability of medicines and the need for the current level of IP incentives – justifiably so given the numerous competing objectives of government. However this debate should consider benefits as well as costs, and the pharmaceutical industry has contributed to many significant advances over recent decades. For example, cancer death rates have fallen by 20% over the last 20 years³³, and close to 30 diseases are preventable by vaccination, preventing between 2 to 3 million deaths globally per year³⁴. By providing better understanding of the direct and indirect contribution of the pharmaceutical industry in Europe, we hope that our research will prove valuable by further informing the debate and facilitating productive dialogue.

³² Giannelli et al. (2012). GDP and the value of family caretaking: how much does Europe care?

³³ Jönsson et al. (2016). The cost and burden of cancer in the European Union 1995–2014.

³⁴ World Health Organization. (2018). 10 facts on immunization.



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