The economic and societal footprint of the pharmaceutical industry in Europe

Presentation by PwC UK
27 June 2019

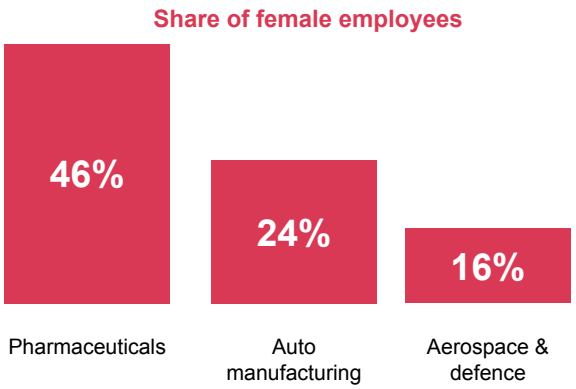
Pharmaceutical companies have created a thriving industry that makes an economic and societal contribution to the EU

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



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

Setting the scene

Highlighting the broader value that the industry delivers can contribute to more holistic dialogue and decision-making

- With **greater pressure on government finances**, the **public debate** has frequently turned on the **high prices** of new medicines
- This debate **ignores the direct and indirect benefits** that the industry brings to both the field of medicine and the wider patient population, all whilst overlooking the wider societal impact the industry has on economies
- To **highlight the broader value the sector delivers within the EU**, we have sought to demonstrate the economic, health and societal impact of the industry in Europe using several approaches. We consider:

The economic impact of the industry

The health and societal impact of the industry through the case studies on select therapeutic areas

The value pharmaceutical companies place on incentives, specifically IP incentives

Our analysis consists of three main components: economic, health & societal, and role of IP incentives

	Purpose	Methodology	Outputs
Economic	Demonstrate the scale of the Pharmaceutical industry in the EU-28	PwC input-output multiplier model	Direct, indirect and induced GVA and employment
Health & societal	Demonstrate the value of selected medicines through health and productivity gains	Incremental changes in health outcome, costs, and absenteeism from literature	Incremental changes in healthy life years, productivity and costs
Role of IP incentives	Understand the relevance and importance of IP incentives	Survey of EFPIA corporate members	Relative importance of IP incentives compared to other market factors

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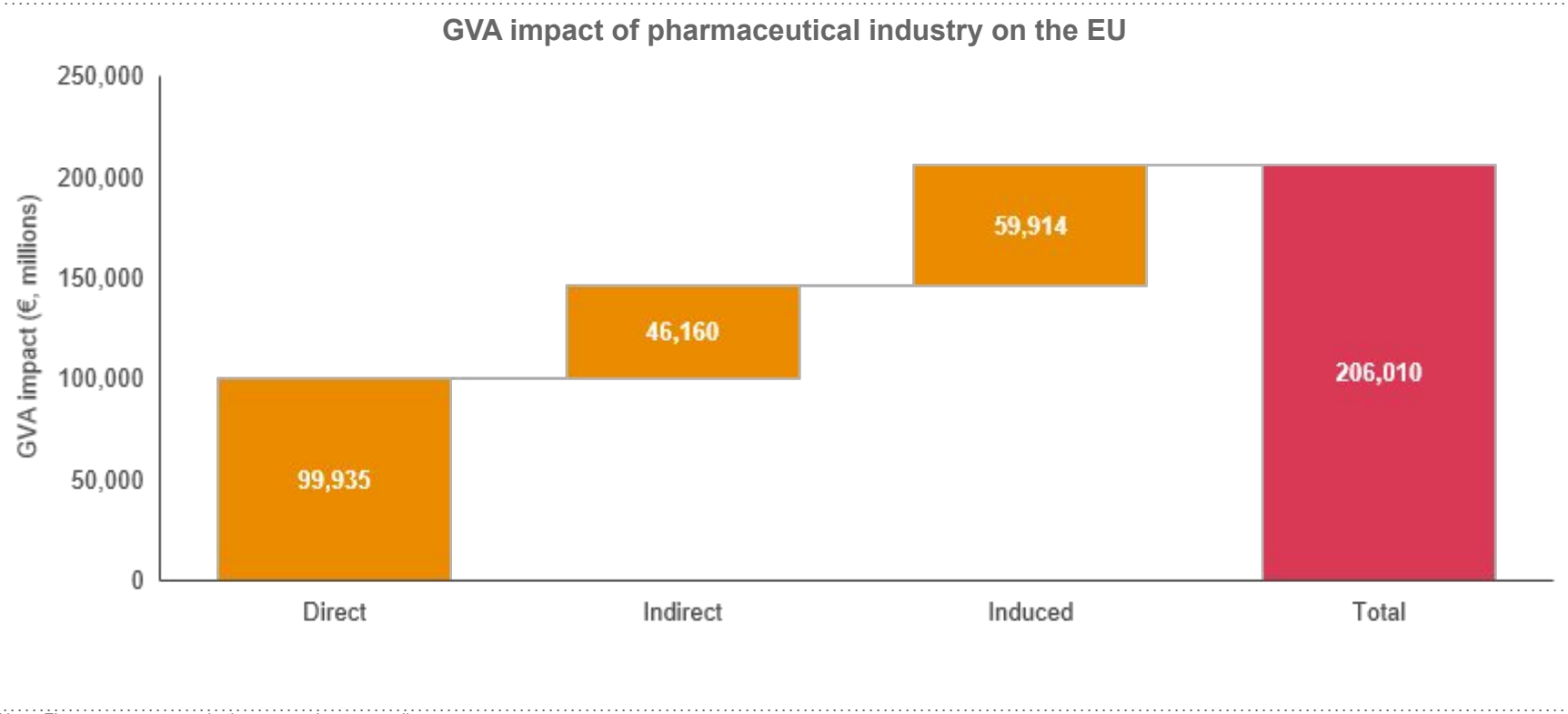
Economic impact assessment

The pharmaceutical industry supports a total of 1.4% of the EU's GDP

- The pharmaceutical industry contributed a total of €206 billion in GVA to the EU's economy in 2016.
- The industry directly contributes 0.7% of the region's GDP, while its total contribution is equivalent to 1.4% of the region's GDP.



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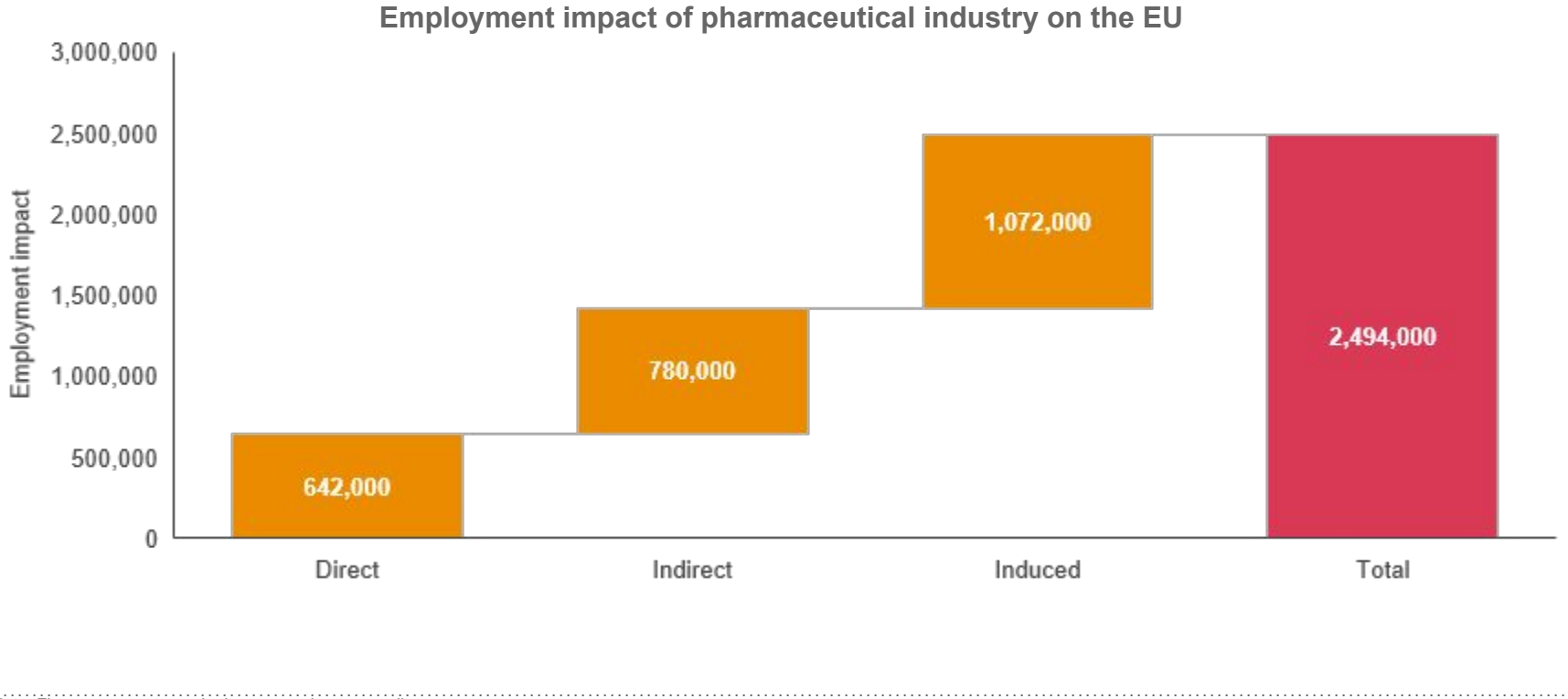
The pharmaceutical industry supported nearly 2.5 million jobs across the EU

- The pharmaceutical industry contributed nearly 2.5 million jobs to the EU in 2016, many of which are high skilled and highly productive.
- The jobs supported directly by the pharmaceutical industry account for approximately 0.2% of the region's employment, while its total contribution is equivalent to 0.9% of the region's employment.



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The pharmaceutical industry is highly productive, and has a higher GVA per worker than other key industries

Pharmaceuticals

€100bn
Direct Gross Value Added (2016)

642,000
Direct Employment (2016)

€156,000
Value added per employee

Automotive manufacturing

€211bn
Direct Gross Value Added (2016)

2,480,000
Direct Employment (2016)

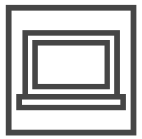
€85,000
Value added per employee

Aerospace manufacturing

€45bn
Direct Gross Value Added (2016)

410,000
Direct Employment (2016)[1]

€102,000
Value added per employee



Computer programming

€261bn
Direct Gross Value Added (2016)

3,180,000
Direct Employment (2016)[1]

€82,000
Value added per employee

1. Eurostat do not publish a figure for 2016. We have estimated aerospace employment for 2016 using the GVA growth rate, as 2016 data is not available.
Source: Eurostat, PwC analysis. Note we have selected comparator industries which are important to the economy, high value, and with a significant international presence. Our analysis suggests that the pharmaceutical industry (defined by NACE code C21) has one of the highest rates of productivity of any industry.

The pharmaceutical industry has a higher proportion of females in its workforce than many other key industries

	Share of female employees (EU average)
Pharmaceuticals	46%
Auto manufacturing	24%
Aerospace & Defence	16%
Computer programming	23%

Source: Eurostat, PwC analysis. Note for the Aerospace and & Defence industry, we have used the 'Other transport manufacturing' industry to calculate share of female employees due to data availability.

Impact of the Orphan Regulation

Orphan diseases affect 30 million people in the EU and treatment options are limited or non-existent

To qualify for orphan designation in the EU, the prevalence of the condition cannot be more than 5 in 10,000.

More than half of newly diagnosed cases are in children, 1 in 3 of which will die before their 5th birthday

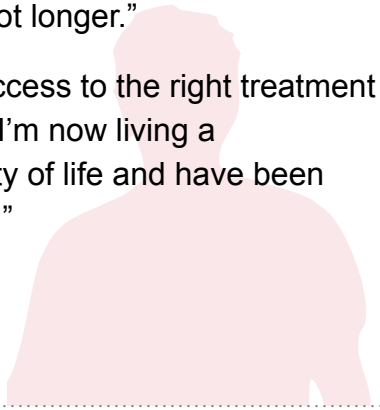
Fewer than 15% of orphan diseases benefit from even minimal amounts of scientific knowledge

95% of rare diseases have no approved therapies

Ronny, diagnosed with neuroendocrine tumors, a type of orphan cancer

"I did what people do in movies and asked how long I had to live. And the oncologist said: "months, years…" And I kind of switched off after that. But what he did say after that was: "But with the right treatment you could live a lot longer."

Because I had access to the right treatment at the right time, I'm now living a reasonable quality of life and have been able to do things."

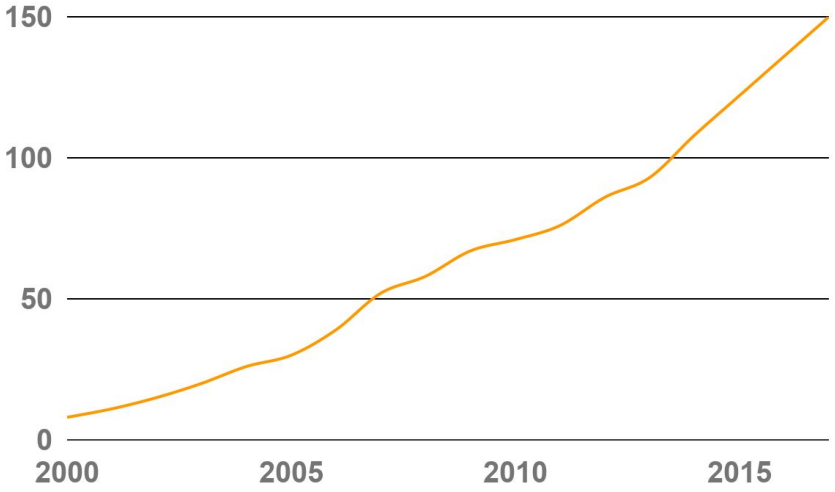


Sources: European Medicines Agency, EvaluatePharma Orphan Drug Report 2015/2018.

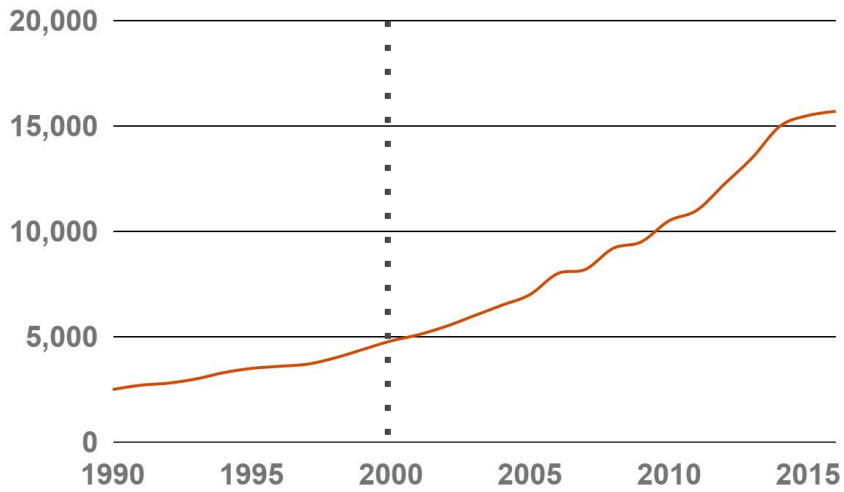
Since the adoption of the Orphan Regulation in late 1999, the number of orphan medicines in the EU has risen steadily

Prior to 2000, only 8 products had been authorised to treat rare diseases in the EU. Now there are over 150.

Cumulative number of authorised orphan medicines in the EU



Worldwide number of scientific publications on rare diseases



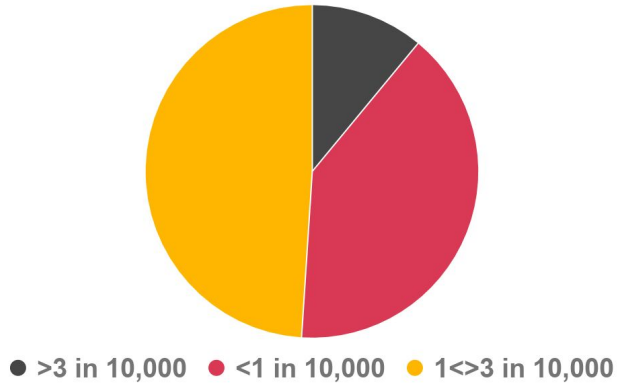
The number of medicines granted orphan designation by the European Commission has risen year on year - this suggests a greater number of higher quality applications

The benefits have also been seen in research and development - the number of scientific publications on rare diseases has risen at a faster rate since 2000

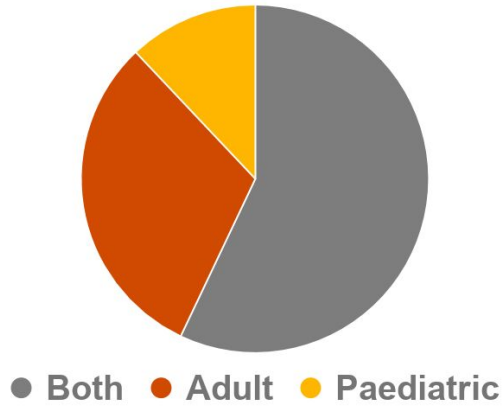
Sources: European Medicines Agency, EvaluatePharma Orphan Drug Report 2015/2018, PubMed.

Existing orphan medicines treat a wide variety of indications, with many focusing on orphan cancers

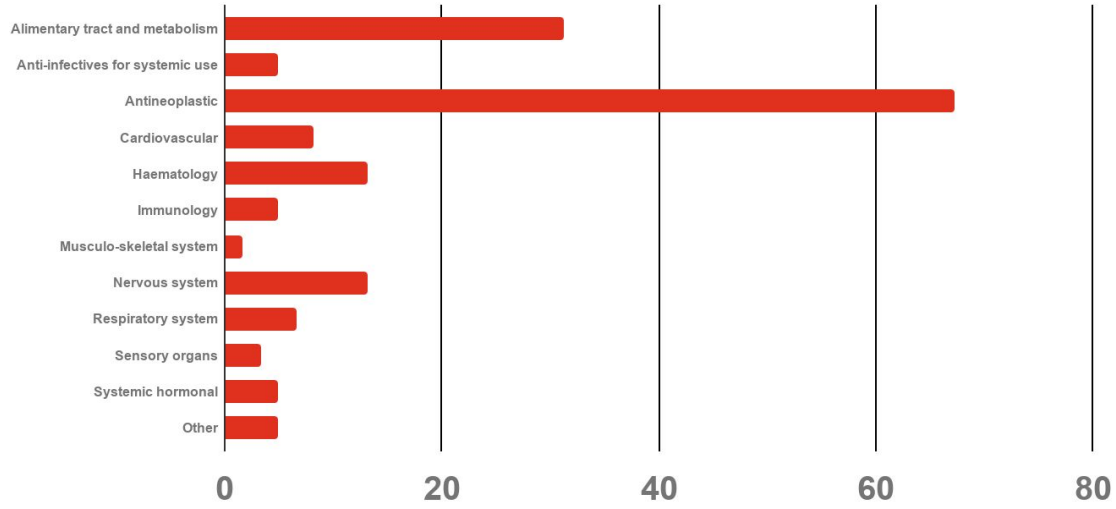
Prevalence of designated orphan conditions from 2000 to 2018



Intended patient group for orphan designations from 2000 to 2018



Number orphan medicines with marketing authorisations by therapeutic area



- **The majority of orphan designations from 2000 to 2018 were designed for conditions affecting less than 3 in 10,000 people**
- **Orphan cancer medicines account for over 40% of all orphan medicines**

Source: European Medicines Agency

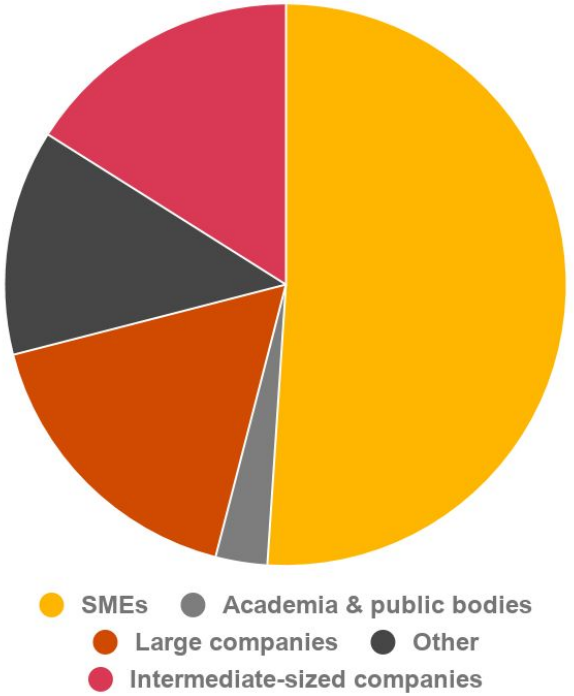
The Orphan Regulation has added benefits for SMEs not available to larger companies

SMEs* benefit from reduced fees for key services, including scientific advice, pre- and post-authorisation procedures, and applications for marketing authorisations

In 2015, protocol assistance for orphan drugs developed by SMEs represented 44% of all protocol assistance procedures

More than half the medicines receiving orphan designation are developed by SMEs

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

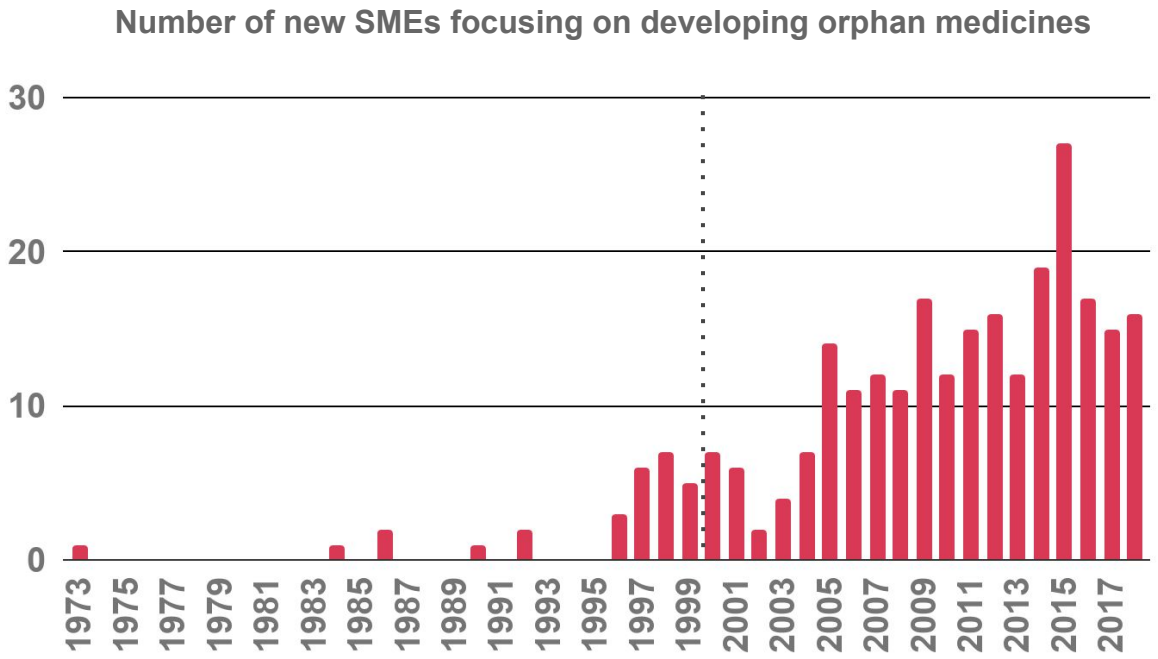


*SMEs are defined as enterprises with fewer than 250 employees and either an annual turnover of not more than €50 million or an annual balance-sheet total of not more than €43 million.

Sources: European Medicines Agency 'Report on the 10th anniversary of the SME initiative', 2016
Morel. T 'Regulatory watch: the orphan drug pipeline in Europe', 2016
CRA Report: 'An evaluation of the economic and societal impact of the orphan medicine regulation',2017

Since the Orphan Regulation was introduced, there has been a significant rise in orphan-focused SMEs

- One potential **attraction of orphan medicines to SMEs** is the opportunity to **attract early investment**
- **Venture capitalists investing** in orphan medicine startups typically do so **on average one year before** they would in a non-orphan medicine equivalent (CRA, 2017)



There has been a notable increase in the number of SMEs developing orphan medicines since 2000. The 248 SMEs started since the introduction of the Orphan Regulation employ over 8,700 people.

Sources: European Medicines Agency SME Register, CRA Report: 'An evaluation of the economic and societal impact of the orphan medicine regulation' - 2017

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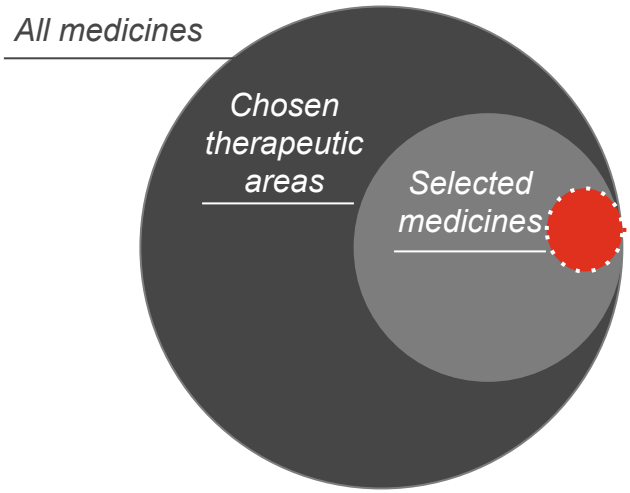
Health & societal impact

The pharmaceutical industry provides major health and societal benefits to the lives of millions of Europeans

Our analysis intends to quantify and bring some of these benefits to life by focusing on two therapeutic areas. These only represent a fraction of the total benefits of medicines.



For the selected medicines, we estimated ...

- Number of patients treated between 2007 - 2017 using data from IQVIA
- Healthy life years gains* using data from reimbursement submissions and academic literature
- Productivity gains in terms of GDP from reduced absenteeism as a result of improved health
- Net change in medicine and treatment costs

*'Healthy life years' is used as the plain english equivalent of the technical term: Quality-Adjusted Life Years (QALYs). Healthy life years, productivity and change in healthcare costs were estimated relative to a comparator standard of care

Our selected therapeutic areas cover different disease profiles

Within the therapeutic areas, we selected a subset of medicines that represent an innovation in their field of medicine that addressed a previously unmet patient need.

Therapeutic area	Breast cancer	HIV
Category of drug	Adjuvant HER2+ and HR+ therapies	Highly active antiretroviral therapy (HAART)
Specific medicines	• trastuzumab • pertuzumab • trastuzumab emtansine • ribociclib • palbociclib • lapatinib	• emtricitabine/eilpivirine/tenofovir disoproxil • elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (as fumarate) • dolutegravir/abacavir/ lamivudine • efavirenz/ emtricitabine/tenofovir disoproxil (as fumarate)
Standard of care comparator	Typically chemotherapy, tumour resection and radiotherapy (where possible)	Dual NRTI therapy without protease inhibitors

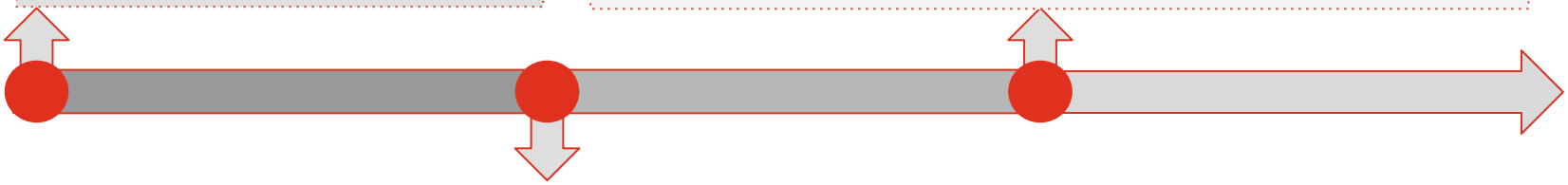
HIV

Thanks to pharmaceutical innovation, HIV has transformed from a death sentence to a treatable, chronic disease

Timeline of HIV treatment development

Early 1990s: Mainstream practice was dual therapy combining two NRTIs, AZT with zalcitabine (ddC) or didanosine (ddI).

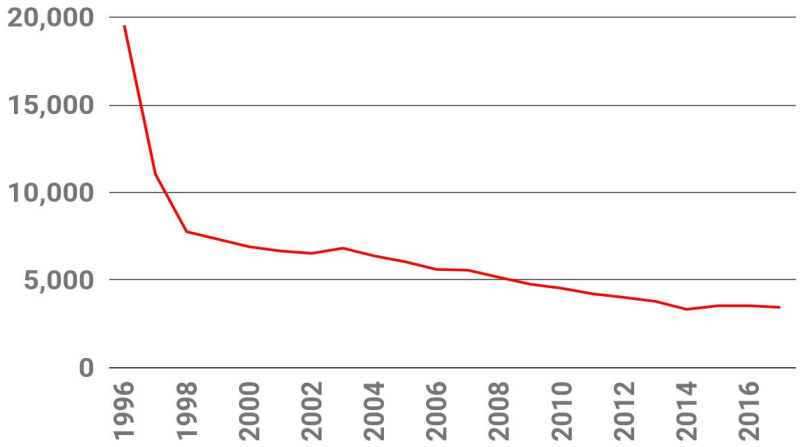
2000s onwards: Backbone therapies made over this time period became more efficacious with fewer side effects. Major drug developments have been the ability to combine triple therapy into a single tablet (STR), as well as CCR5 and integrase inhibitors.



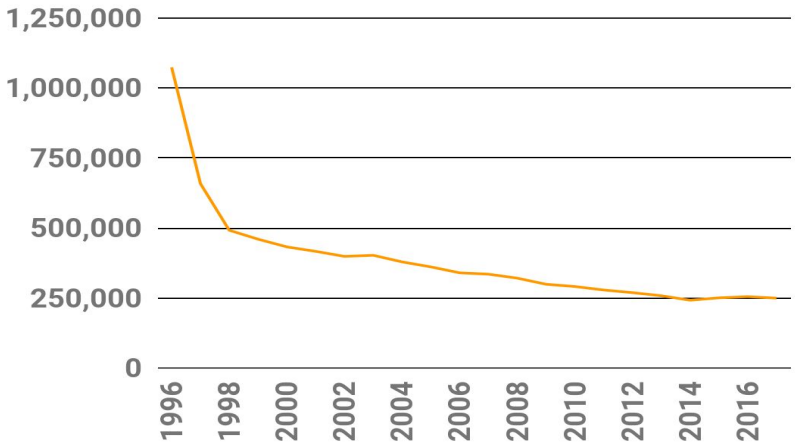
Mid 1990s: Advent of triple therapy, later called HAART, thanks to the development of protease inhibitors, the first of which was saquinavir. Early forms of HAART later saw great improvement through the creation of PI-boosters and the development of the back-bone NRTIs.

Thanks to pharmaceutical innovation, HIV has transformed from a death sentence to a treatable, chronic disease

HIV/AIDS-related deaths*



Burden of disease (in DALYs) for HIV/AIDS**



Patrick's story: Living with HIV evolved so quickly

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. Patients felt sicker on the medication than from the virus itself. These days, Patrick takes only five pills. Many patients only have to take one. Patrick's quality of life has improved enormously. He takes time to raise awareness of HIV. He's hopeful treatment will continue to improve and there might even be a cure one day.

*Source: Our World in Data - statistics included for Western Europe 1996 - 2017
**Source: Global Health Data Exchange - statistics included for European Union 1996 - 2017

The advent of HAART therapies have resulted in the gain of nearly 800,000 HLYs in Europe

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

Thanks to an increase in working days, average productivity gains per patient were around €200,000

Increase in productivity per patient expected to result in gains of €22 billion

Over 6 years of potential productivity gained per patient

Our assessment relative to dual NRTI therapy reveals a net cost reduction over a 30 year time horizon

Increased cost of medicines is significantly offset by reduced treatment costs

There could be a net saving in healthcare of around €11,000 per patient

These innovations have potential further impact in terms of inequalities in health and on HIV transmission rates

Health inequality

- HIV infection is higher in more vulnerable groups of society, particularly those from a lower socioeconomic background.
- Gains in HIV treatment could thus **disproportionately benefit a lower socioeconomic group**.

Transmission rates

- HAART could have a wider impact on HIV transmission rates in Europe through lowering virologic load to undetectable levels and through their use as post-exposure prophylaxis.
- At undetectable levels, risk of transmission can be considered negligible.
- Reduced transmission could **lower overall HIV prevalence** and therefore lessen its health burden in the European population.

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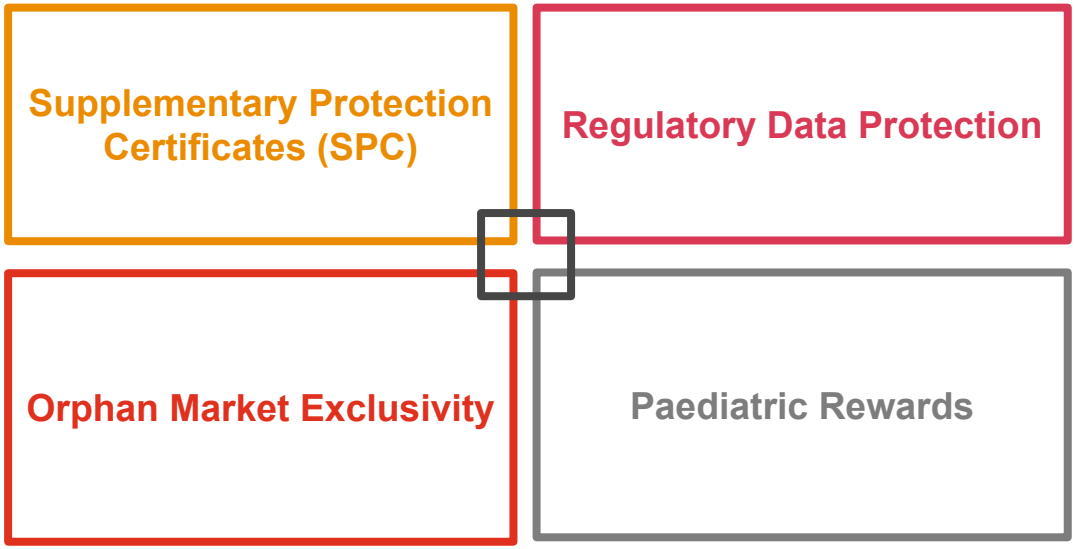
Role of IP incentives

A survey of EFPIA corporate members provides insight into the importance of the European incentives model

- Research and development of new medicines can be a long, complex, risky and ultimately expensive (at around $2bn to bring a drug to market) process
- The European incentives model is designed to encourage continued innovation by providing additional protection to medicines (that make it to market) from competition
- 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

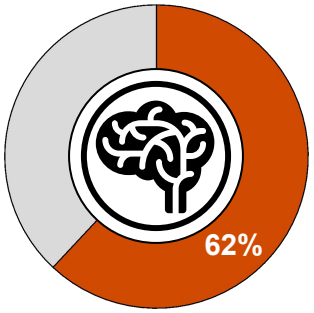
Incentives explored in the survey



Companies indicated incentives and quicker market access are the leading factors influencing R&D investment decisions

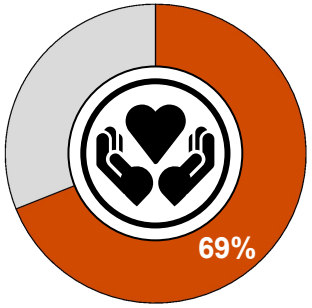
	Overall Rank
IP Incentives	1
Accelerated approval / early access schemes	2
Skills and wage costs of labour	3
Size of economy and potential for growth	4
Macro-economic / political issues (e.g. inflation, political uncertainty)	5
Attractiveness to conduct clinical trials	6
Tax rates	7
Infrastructure and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

Ranking in Top 3 (%)



IP Incentives

Important across the value chain, crucial in influencing R&D and Commercial investment decisions.



Accelerated approval / early access schemes

Important factor in influencing R&D and Commercial investment decisions, less so for Manufacturing.

Dismantling the current incentive model would have a negative impact on pharmaceutical companies' R&D activity

Scenario

Existing IP incentives are phased out in Europe over a period of 4-5 years. Other factors remain the same, including funding for medicines and market access / reimbursement hurdles for innovative medicines.

Over half of respondents suggest this would lead to a **reduction** in their R&D and Commercial footprints **of over 25%**

Conclusions

Incentives are important to ensuring the pharmaceutical industry continue to deliver broader value to the EU

The current incentives model is important to ensuring continued R&D investment by the pharmaceutical industry in Europe

Innovation has brought health benefits to patients with previously unmet needs and fostered a thriving industry that significantly contributes to European GDP and jobs

The benefits go beyond what we have quantified: improved psychosocial health of patients and carers, contribute to the informal economy, and stimulate innovation across different medical disciplines

Thank you

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