

Our position

EU Intellectual Property rules and incentives: When good policy is as important as good science

The US business perspective



AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled more than €2 trillion in 2016, directly supports more than 4.5 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

Contents

- Executive summary..... 3
- Introduction..... 4
- 1. The European Intellectual Property Framework promotes competitiveness and innovation 5
- 2. Sending the right signals to investors..... 7
- 3. The role of different IPR and incentives: providing needed certainty and stimulating innovation across the EU economy 9
- Conclusion 10
- 4. Annex..... 11
- 4.1. Patents..... 11
- 4.2. Supplementary protection certificates (SPC)..... 12
- 4.3. Additional incentive frameworks for pharmaceutical products to protect innovators and meet specific public health needs 13
- 4.3.1. Regulatory data protection..... 13
- 4.3.2. Paediatric rewards and market exclusivity for Orphan Medicinal Products 14

Executive summary

The European Commission's review of pharmaceutical incentives takes place in a context of controversy and debate on the sustainability of healthcare systems and pharmaceutical prices. These discussions are important and the American Chamber of Commerce to the EU (AmCham EU) is willing to be a constructive partner. However, we do not believe that a review of the EU Intellectual Property (IP) incentives framework is an effective means to manage the sustainability of healthcare systems across the EU and respond to patients' individual needs.

IP incentives exist to stimulate innovation, science and research. They are a strength to the European economy across all sectors, particularly for high-risk investments in essential research areas. The cornerstone of the knowledge-based economy, they are key to maintaining the attractiveness of the EU as an investment location in a globalised world.

AmCham EU calls on the EU to strengthen the existing IP incentives framework in order to promote an innovation-friendly environment in the EU to the benefit of European patients and the research and development (R&D) companies that serve their health needs.

Reducing the scope or duration of IP incentives, particularly for sectors that depend the most on such mechanisms, risks jeopardising the EU's industrial competitiveness and growth. The EU faces global competition to attract the best brains and the smartest capital. The temptation to move backwards on IP incentives will send a very negative signal to US and global investors as to the prospects of the European R&D sector, particularly for the biotechnology industry and start-ups.

Faced with the future burden of Europe's ageing population, continued efforts to sustain and improve the existing incentive framework for pharmaceutical R&D is crucial for the development of future innovative therapies in areas of great demand.

AmCham EU calls on EU policymakers to take this into account when performing the IP incentives review for the pharmaceutical sector.

Introduction

Intellectual property rights (IPR) and other incentives are key to driving investment in innovation across the European economy. In the case of the biopharmaceutical sector, R&D efforts bring direct benefits to patients and help address public health challenges. Innovation enables people to live longer, healthier and more productive lives.

As the Commission reviews the impact of these incentives, it is critical to find ways to safeguard and foster investment in pharmaceutical research. The life sciences industry contributes significantly to Europe's economic and social prosperity. Therefore a conducive regulatory framework strengthens industrial competitiveness and growth in the EU.

This paper illustrates how IPR and other incentives foster investment in innovation in all sectors of the European economy. It also explains the role and scope of each incentive available to pharmaceutical companies, including patents, supplementary protection certificates (SPC), regulatory data protection (RDP) as well as paediatric and orphan incentives and rewards.

1. The European Intellectual Property Framework promotes competitiveness and innovation

A strong and predictable IP and exclusivity-based incentives framework is key to the attractiveness of Europe as an investment location. Such frameworks are essential for IP intensive-industries such as the life sciences sector to continue supporting the competitiveness and growth of the EU economy¹.

AmCham EU brings together some of the most R&D-intensive sectors, which invest widely across Europe and rely on this strong and predictable IP framework. Aggregate US investment in Europe totalled more than €2 trillion in 2016, and generates billions of euros annually in income, trade and R&D.

Currently, the EU suffers from an investment deficit compared to other regions of the world, such as the US². In a report from 2016, the Commission states that *'the EU needs to put in place better incentives and conditions for businesses to innovate'*³ as it notably lags behind the US and South Korea in important framework conditions such as product market regulation, barriers to entrepreneurship, ease of doing business or intellectual property right protection. Weakening the European IP incentives framework for pharmaceutical companies would do the opposite and jeopardise efforts to close the gap with other economies in the world, as well as the future growth of the EU economy.

¹ 'Setting EU priorities, 2014-19 - The ten points of Jean-Claude Juncker's political guidelines', 15 July 2014.

² 'European Union R&D Scoreboard 2016, The 2016 EU Industrial R&D Investment Scoreboard', European Commission, <http://iri.jrc.ec.europa.eu/>

³ 'Science, Research and Innovation Performance of the EU. A contribution to the Open Innovation Open Science Open to the World Agenda', 2016, http://www.ewivlaanderen.be/sites/default/files/science_research_and_innovations_performance_of_the_eu.pdf

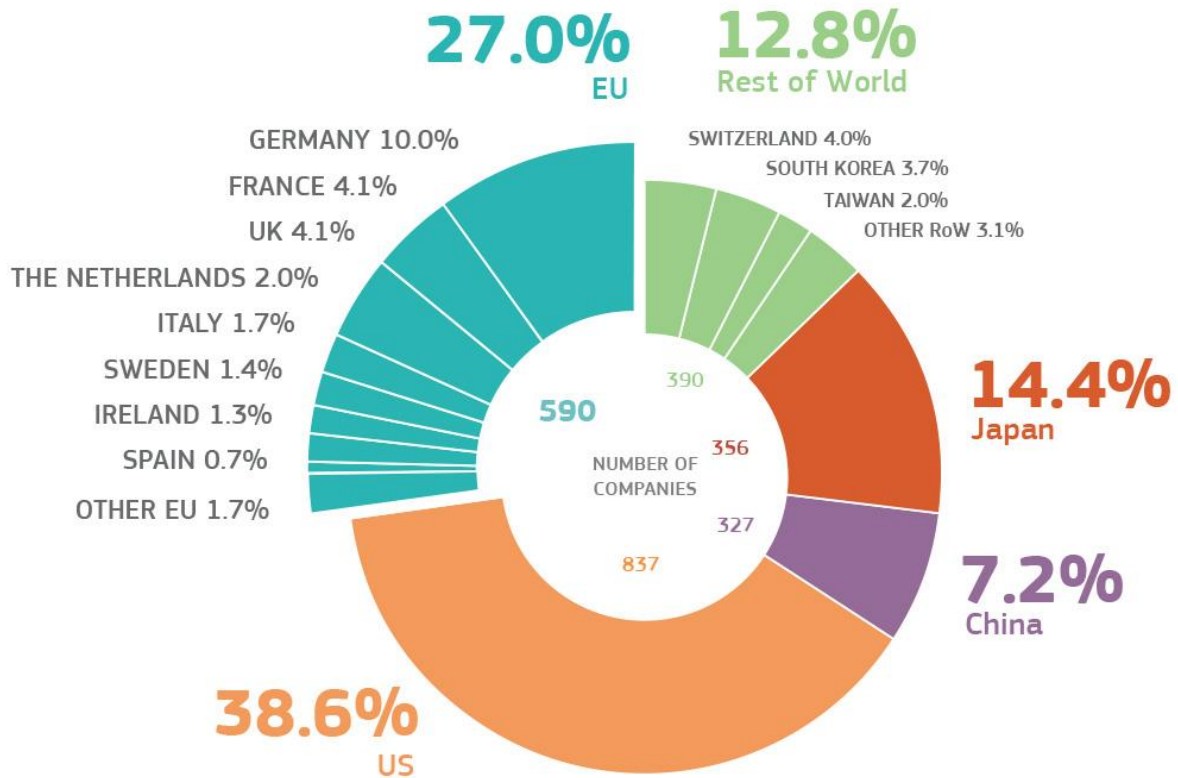


FIGURE 1.1 – R&D INVESTMENT BY THE TOP 2500 COMPANIES, BY MAIN WORLD REGION (% OF TOTAL €696.0BN)
 Source: The 2016 EU Industrial R&D Investment Scoreboard. European Commission, JRC/DG RTD.

Where markets are open and intellectual property is protected and enforced, innovators can rely on the predictability and certainty they need to collaborate with partners, compete successfully and accelerate the launch of new products. For the biopharmaceutical industry, this is essential for the development of new and innovative medicines. The opposite can be seen where countries do not have a strong incentive regime. Some governments, including India and Indonesia, have issued compulsory licenses that allow local companies to make, use, sell or import particular patented medicines without the consent of the patent holder. The level of investment in R&D, even after taking into account other factors, is considerably lower.

- 38% of the 82 million jobs in Europe are directly and indirectly attributable to IP-intensive industries.
- IP-intensive industries account for 42% of EU’s GDP and represent approximately 90% of EU’s trade with the rest of the world⁴.
- Over 2 million jobs are supported by the biopharmaceutical sector in the EU which makes a significant and positive contribution to the EU trade balance with 75 billion trade surplus in pharmaceuticals in 2013.
- Within the first decade from the implementation of the Orphan Medicinal Products (OMP) Regulation – i.e. after 2000 – there was a 30% increase in new biotech companies across Europe⁵. Moreover, nearly all of these companies have their R&D activities and staff located in the EU⁶.

⁴ EUIPO, ‘Intellectual Property Rights-intensive industries and economic performance in the EU’, October 2016.

⁵ Genetic and Rare Disorders Organisation, ‘Importance of Research on Rare Diseases and Orphan Drugs’, 2009.

⁶ OHE, ‘Assessment of the impact of Orphan Medicinal Products (OMPs) on the European economy and society’, 2010.

As an example, in the pharmaceutical sector, bringing innovative and better medicines and treatment options to patients that are safe and efficient, typically takes ten to twelve years of high-risk investments. It is the foundation on which new and better cures and treatments are made available to patients who need them. They enable patients across Europe to live longer, healthier and more productive lives.

- Two out of three people diagnosed with cancer now live at least five years, and approximately 83% of survival gains in cancer are attributable to new treatments⁷.
- HIV has been transformed from a death sentence to a manageable disease: there has been an 85% drop in the number of deaths since its peak in Europe and the US [Source: WHO Mortality Database].
- Since the introduction of the Orphan Regulation, the number of EU approved orphan drugs has gone up from eight in 2000 before the Regulation, to about 133 treatments today⁸.

It is also important to emphasise that IP incentives not only support innovation but also competition, and pave the way for low-cost generic medicines when exclusivity rights expire.

2. Sending the right signals to investors

Investment in R&D is sustained through funds from capital markets and the revenue generated from the innovation stemming from these investments. The pharmaceutical and biotechnology sector is one of the largest investors in R&D in Europe. According to the EU Scoreboard report on R&D investment in 2016, it invested more than €120 billion. The sector ranks first in terms of R&D intensity (total investment in R&D as a percentage of sales) in 2016⁹.

A substantial part of R&D funding, notably for young companies with limited or no commercial portfolio, comes from investors through private equity, venture capital and public listings. For the biopharmaceutical sector in particular, investment derives to a significant extent from large institutional investors, including pension and insurance funds that are expected to provide returns on investment for their clients, who are often regular citizens or even patients themselves. Therefore, political statements are extremely important as they act as a signal for investors' capacity to generate returns on investment.

⁷ Sun et al., 'The determinants of recent gains cancer survival: an analysis of the surveillance, epidemiology, and end results (SEER) database', *Journal of Clinical Oncology*, 2008.

⁸ Orphanet *Journal of Rare Diseases*, 2017, <https://doi.org/10.1186/s13023-017-0617-1>

⁹ European Union R&D Scoreboard, 'The 2016 EU Industrial R&D Investment Scoreboard', 2016, European Commission, <http://iri.jrc.ec.europa.eu/>

SECTOR	GLOBAL R&D INTENSITY (%)	EU	USA	JAPAN	CHINA
Pharmaceuticals & Biotechnology	15.0	13.8	18.7	11.8	2.7
Software & Computer Services	10.6	10.2	14.7	1.9	10.2
Technology Hardware & Equip.	8.4	15.1	9.3	5.2	6.7
Leisure Goods	5.9	2.7	5.8	5.9	5.1
Electronic & Electrical Equipment	4.7	5.3	4.2	4.5	4.3
Automobiles & Parts	4.3	5.4	4.1	4.0	2.4
Aerospace & Defence	4.3	5.4	3.1	1.4	3.1
Health Care Equipment & Services	3.6	5.1	2.8	8.0	7.8
Industrial Engineering	3.2	3.1	3.3	3.0	3.8
Chemicals	2.9	2.2	3.6	3.9	2.0
General Industrials	2.8	4.8	3.1	3.0	2.2
Top 11 Industries	6.0	6.3	7.6	4.3	4.5
Other Industries	1.1	1.0	1.5	1.1	1.2
All Industries	3.8	3.2	5.8	3.3	2.5

TABLE 3.2 - RANKING OF THE TOP 11 INDUSTRIAL SECTORS BY OVERALL R&D INTENSITY IN THE 2016 SCOREBOARD

Source: The 2016 EU Industrial R&D Investment Scoreboard, European Commission, JRC/DG RTD

When R&D programmes are successful, they generate revenue that must both provide a return on their investment (including investment in failed development of products) and finance future development programmes. Investment only takes place if there is a positive risk-return balance, in a competitive environment where many different sectors vie to attract R&D funding from investors. When prospects of return are uncertain or nonexistent for a given sector, investment risk being diverted towards other sectors of the economy or towards other geographical areas that are perceived as less risky and provide more certainty on financial returns.

As an example, in the pharmaceutical sector, the risk of investment is high in terms of failure rates. The average cost of developing a new medicine is considered to be around €2.2 billion (before tax)¹⁰. Less than 1% of molecules that are patented make it to clinical trials and only 10% of those that are tested in trials ever get approved¹¹. For Alzheimer's disease, from 1995 to 2014, the industry invested in 1 120 unique molecules in their pipelines, but only four were developed into approved medicines.

Public policies and exclusivity-based incentives are a way for policy-makers to provide a certain degree of certainty with respect to returns on investment, channeling private investments towards areas they consider as public priorities. Providing certainty on the likelihood and duration of IPR or period of exclusivity provided to

¹⁰ Tufts Center for the Study of Drug Development, 2014

¹¹ Soerjomataram et al., 'Global burden of cancer in 2008: a systematic analysis of disability-adjusted life-years in 12 world regions', Lancet, 2012, 24;380(9856):1840-50

companies to protect their inventions, as well as on the price levels of the resulting innovation, acts as a signal and helps reduce the risk of investments.

Reducing the period of IP incentives in the pharmaceutical sector would affect the potential revenues in case of success, while the inherent risk of R&D and failure would remain the same. In addition, it would put the life sciences industry at a competitive disadvantage compared to other IP and R&D intensive sectors. It would simply deter investment in life sciences companies.

Finally, we do not believe that a review of the EU IP incentives framework is an effective means to manage the sustainability of healthcare systems across the EU and respond to patients' needs. Authorities must review the functioning of their healthcare systems, the allocated healthcare/pharmaceutical budgets, and look at concrete ways to implement differential pricing approaches and innovative pricing and payment models.

3. The role of different IPR and incentives: providing needed certainty and stimulating innovation across the EU economy

Recognising the inherent risk and amount of capital investment required for innovation in all R&D intensive sectors of the European economy, the EU has laid down a system of IPR and incentives playing different and complementary roles.

The European incentives framework for the biopharmaceutical sector comprises several components: patents, Supplementary Protection Certificates (SPC), regulatory data protection (RDP), paediatric and Orphan Medicinal Products (OMP). They aim to address the complex range of medical needs. All are time-limited, but vary in the coverage and degree of protection they provide, for example whether they are indication-specific and/or apply to the whole product, or whether they allow for competition under certain circumstances. These work together to provide a coherent and complementary set of incentives:

- Balancing the need to reward innovation with the need to foster competition;
- Allowing for innovation while not extending exclusivity in perpetuity;
- Protecting the innovators investment while allowing generic providers to prepare for market entry;
- Providing incentives or rewards where required, e.g. additional rewards to encourage companies to develop medicines for children to combat insufficient research

In annex can be found a full description of the role and scope of the different IP incentives available to biopharmaceutical companies in Europe.

Conclusion

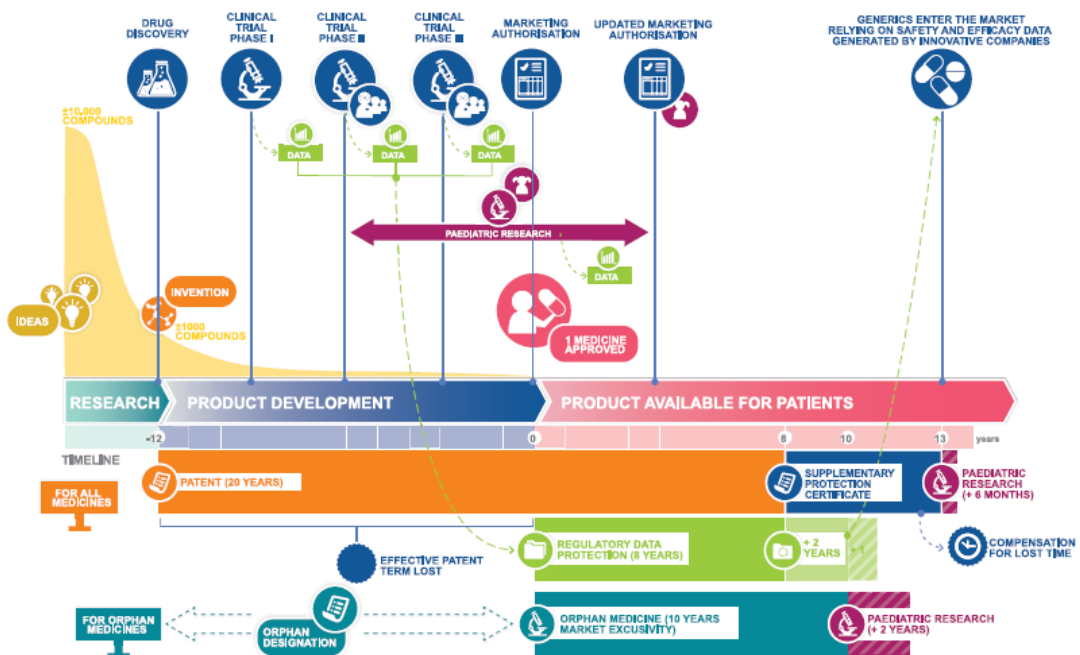
IP protection and incentives are essential to driving investment in innovation across all sectors of the European economy, particularly for high-risk investments in essential research areas. AmCham EU strongly recommends that the EU preserve the range of existing IPR and incentives available to the companies developing these products, allowing them the certainty and protection required to bring them successfully to the market and meet the needs of citizens and patients. Reducing these rights and incentives would not only put these needs at risk, but would also risk jeopardising the EU's industrial competitiveness and future growth. EU policymakers should take this into account during the ongoing review of available rights and incentives.

4. Annex

In this section we present the different IPR and incentives existing for all/several economic sectors (patents and SPCs) and specifically for the pharmaceutical sector (RDP, paediatric and orphan rewards).

All the incentives described below are time limited and intended to encourage and balance the needs of competition with those of incentivising innovation.

EUROPEAN PHARMACEUTICAL INCENTIVES FRAMEWORK



Source: EFPIA

4.1. Patents

Patents apply to all sectors of the European economy and reward an inventor by providing a limited period of time, generally twenty years from patent application. During this timeframe, the inventor may exclude others from copying their invention in exchange for the inventor teaching others how to make and use it.

Patents protect any invention that is novel, has industrial applicability and involves an inventive step, regardless of whether the invention is a molecule, a machine, a formulation, a process, a method of use, etc. The scope of protection conferred by a patent is limited to the claims for which the patent is granted.

As an example, in the case of pharmaceuticals, when new formulations of the same molecule (e.g. one that permits a new route of administration that may be more convenient for patients) are claimed in a later patent,

the patent will only apply to the new formulation, while the old one is subject to generic competition once its related patent has expired. Although they are not specific to pharmaceuticals, patents are particularly relevant to medicines, as medicines take a lot of time and effort to develop but require relatively little effort to replicate.

Patents are more than just a monopoly to incentivise innovation – they constitute a social contract between the innovator and society. They promote knowledge sharing by requiring the details of the patented invention to be placed in the public domain in return for the exclusive right to exploit the invention. In the absence of this exchange, inventors might protect the details of new inventions through secrecy. The disclosure requirements of the patent system are based on the idea that ‘scientific and technical openness benefits the progress of society more than do confidentiality and secrecy’¹². This contributes to defining a space for innovator competition by triggering research in specific areas of interest. Other companies may decide to further build on discoveries and bring further innovations to the market.

The knowledge-sharing effect of patents increase R&D efficiency at societal level. Patents reduce the duplication of research efforts.

They can also facilitate innovation spill-overs. Researchers are encouraged and able to build on existing inventions and find ways to improve upon it (incremental innovation). Access to patented inventions may also facilitate research that would not otherwise be possible. For example, access to a patented research tool may enable vital research into the causes of a genetic disorder and lead to the creation of a genetic test or treatment. This research may not have occurred if the tool had remained secret. The cumulative nature of genetic research makes knowledge-sharing particularly important.

In addition to the knowledge and innovation spill-overs, the economic benefits related to the exploitation of the knowledge will be extended to all economic operators at the expiration of the patent. In other words, while the reward for innovation is temporary, the benefits for society are everlasting.

4.2. Supplementary protection certificates (SPC)

SPC have been established to compensate for the loss of effective patent protection due to the length of the development and regulatory approval processes, notably in the pharmaceutical and agrochemical sectors.

Most inventors are able to begin exploiting their patent rights as soon as they file their patent application. However, in the pharmaceutical sector, inventors file patent applications years before the related medicine reaches patients. It takes on average ten to twelve years for pharmaceutical companies to complete the full clinical development required before a new drug can be approved for marketing. Plant protection products are subject to similar compulsory and lengthy testing periods prior to obtaining regulatory market approval following patent application. This greatly diminishes the effective duration of the exclusivity right of patents for those inventions. This is why the SPC has been established for these products.

The SPC provides for a supplementary protection period of up to five years to a maximum total term of fifteen years from marketing authorisation (an additional six months may be available from paediatric medical incentives) in order to compensate for the loss of effective patent protection.

¹² J Goldstein and E Golod, ‘Human Gene Patents’ 77 *Academic Medicine* 1315, 1315, 2002.

4.3. Additional incentive frameworks for pharmaceutical products to protect innovators and meet specific public health needs

Recognising the specificity of the R&D and marketing authorisation for medicines and the public health need for further research into paediatric and orphan medicines, the EU has developed additional incentives frameworks specific to the pharmaceutical sector.

The range of pharmaceutical incentives is designed to protect and incentivise biopharmaceutical R&D in different ways. For example, RDP (see 4.3.1 below) and patents protect different aspects of a marketed medicine and operate and run independently of one another. They work together in a complementary, non-duplicative manner to optimise the incentives available to encourage the development of new medicines.

The period of patent protection and other incentives is already limited, and after expiration, medicinal products lose their exclusivity, allowing generics/biosimilars to enter the market.

Additional incentives specific to the pharmaceutical sector are presented in this section.

4.3.1. Regulatory data protection

The process of bringing a medicine to market is highly regulated, and manufacturers need to undergo a marketing authorisation procedure. This requires them to generate, analyse and submit a comprehensive set of data on the quality, safety and efficacy of the new drug. RDP protects company data on quality, safety and efficacy from unfair commercial use.

Designing and conducting necessary studies and analysing the data generated requires substantial effort and investment. In an effort to compensate innovator companies for that investment, the EU regulatory framework provides for a period of eight years of RDP, starting on the day of marketing authorisation, followed by two years of marketing exclusivity. During the period of regulatory data protection, generic/biosimilar companies cannot rely on pre-clinical and clinical data generated by the innovator company to apply for a generic marketing authorisation. During the subsequent two years of market protection, generic/biosimilar manufacturers cannot market the product but can rely on the regulatory data package for registration.

To encourage companies to further develop their existing molecules in new indications, the EU framework provides for the possibility to address patients' needs and extend the market protection by one year.

Regulatory data protection and patents are nevertheless complementary: if only RDP were available, companies would be incentivised to work in secrecy, fearing that a competitor could copy their work and race to be first on the market. Such secrecy would slow the rate of and diminish the quality of innovation. Alternatively, without RDP and associated market exclusivity, there would be no incentive to invest in the development of products with no or limited patent protection (for example, where patents expire prior to or shortly after approval).

4.3.2. Paediatric rewards and market exclusivity for Orphan Medicinal Products

Paediatric and orphan incentives have been established in order to fill certain gaps in the incentives framework and reward different contributions to healthcare.

The EU Paediatric Regulation provides for a six-month extension of the SPC of a drug under patent (SPC) protection or a two-year extension of orphan exclusivity, when the manufacturer effectively complies with the requirements to conduct a Paediatric Investigational Plan (PIP). In view of the challenges and costs associated with the development of paediatric medicines, this reward was established to encourage companies to invest in paediatric development. This incentive has increasingly become a requirement for regulatory authorities.

Market exclusivity for Orphan Medicinal Products (OMPs) provides for a period of ten years during which no copy or 'similar' product (same molecular structure, same Mechanism of Action (MoA), same indication) can receive market authorisation in that indication, providing companies with the prospect of generating return on their investment in a rare disease indication.

Orphan market exclusivity addresses the market failure existing in therapeutic areas affecting a very small patient population. This incentive fosters investment in disease areas where there would otherwise be limited commercial interest, while also encouraging the development of products with no or limited patent or RDP (for example, where patents or RDP expire prior to or shortly after approval).

When OMPs that already benefit from market exclusivity are developed in a new indication, they are required to conduct clinical trials and provide robust evidence on safety and efficacy in that specific indication and prove the significant benefit required to obtain an orphan designation, which ultimately justifies the new period of ten-year orphan market exclusivity that manufacturers benefit from for that specific indication only.