



DRIVING EUROPE'S HEALTH AND GROWTH

A Call for an Industrial Strategy for
Europe; including Health – one of
Europe's key strategic sectors

September 2019

As the President elect of the European Commission outlined in her *Agenda for Europe*, it is critical to create "a sustainable Europe (...) that opens up opportunities, innovates, creates jobs and offers a competitive edge to its industries"¹.

The pharmaceutical industry alone employs over 765,000 people in Europe, contributing over €105 billion to the balance of trade and invests an estimated €36.5 billion in research and development across Europe. Beyond the significant economic impact, the industry invests more of its revenue than any other sector in research and development, an investment that focuses on improving the health of citizens across Europe and beyond.

As an industry, we support initiatives that promote Europe's smart regulation, driving investment and innovating in the region, enabling us to meet the needs of patients, healthcare systems and society as a whole. We want to see Europe leading global pharmaceutical discovery and development, and delivering the treatments that patients need.

In order to sustain and develop the research-based European pharmaceutical industry's significant contribution to the European economy, particularly in the context of increasing competition from other global economies, we believe the EU needs a new, invigorated industrial policy strategy. An initiative supported by EU leaders at their meeting in March 2019² and confirmed by the Competitiveness Council in May 2019³.

As reported in the European Political Strategy Centre's paper 'EU Industrial Policy After Siemens-Alstom', "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"⁴.

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. There is enormous potential that Europe can realise by fostering and supporting innovation, in particular by offering a predictable regulatory environment and incentives model. 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 spending⁵.

The pharmaceutical industry can play a central part in the competitiveness of Europe, given its key role in addressing a number of Europe's societal challenges, the investment in Europe's research and development eco-system, and its potential to leverage some of Europe's key strengths and facilitate access to new treatments for patient across Europe. A new EU industrial policy strategy can help unlock this enormous potential through:

- **Maintaining a world-class system for the approval of medicines**
- **Better innovation policies to enable Europe to lead in R&D**
- **A digital Europe to help support patients in their healthcare journey**
- **A smart trade agenda that supports EU competitiveness and access**
- **Policies to preserve the environment**



MAINTAINING A WORLD-CLASS SYSTEM FOR THE APPROVAL OF MEDICINES

A solid regulatory environment for pharmaceuticals means safe and effective medicines, and increased access for patients. Such system should be adaptable to evolving science and technology, and accelerate regulatory and Health Technology Assessment (HTA) review, while supporting the review of value of medicines across all stakeholders. In addition, it promotes the functioning of the internal market, by encouraging innovation.

We call on the European institutions to ensure a competitive, world-class regulatory system that embraces advances in science technology and medicines, accelerating access to innovative healthcare solutions and optimized patient outcomes.



BETTER INNOVATION POLICIES TO ENABLE EUROPE TO LEAD IN R&D

Innovators consider many factors, including the robustness of Intellectual Property (IP) protection, when deciding where to invest. In fact, IP makes it possible for companies to sustain investments in risky, costly and lengthy R&D. Europe has greatly benefited from the introduction of robust IP incentives, that have allowed the pharmaceutical industry to transform the lives of patients, improved health outcomes and contributed to a thriving economy.

At the same time, Europe is facing increasing competition not only from the US and China, but also from rapidly-growing economies such as Brazil and India. Unless Europe acts to remain one of the best places in the world for pharmaceutical R&D, the geographical balance of the pharmaceutical market is likely to shift gradually towards other economies.

We call on the European institutions to robustly analyse the full IP eco-system and ensure that any future IP-related decisions promote sustainable innovation, create opportunities for jobs and growth and retain Europe's competitive advantage in the global economy, including in the pharmaceutical sector.



A DIGITAL EUROPE TO HELP SUPPORT PATIENTS IN THEIR HEALTHCARE JOURNEY

There are a number of fundamental prerequisites for allowing new technologies to deliver the full potential of benefits for society: the creation of platforms to optimise the availability of health data from various sources, and a clear and coherent EU framework for public and private stakeholders, to enable increased access to and availability of data for research purposes. These should be based on criteria such as interoperability, connectivity and safety, with a clear data governance model at EU level, alongside the development of analytical tools necessary to manage large volumes of data. The EU has a critical role to play to continue and further build on public-private collaborations in this field, as well as initiatives regarding strategic value chains such as Smart Health⁶. These collaborations can have a critical impact on the speed and accuracy with which data can be analysed and used.

We call on the European institutions to set up a European Health Data Space that encourages the use of digital tools (e.g. artificial intelligence, machine learning and mHealth). This would enable Europe to become a center of excellence in medical research and manufacturing.



A SMART TRADE AGENDA THAT SUPPORTS EU COMPETITIVENESS AND ACCESS

Through an ambitious trade policy, the EU can support its pharmaceutical innovation and EU competitiveness by ensuring that Intellectual Property (IP) rights are protected and enforced around the world. Furthermore, by removing trade barriers, easing customs procedures and rules of origin, and improving regulatory standards in third countries via regulatory approximation, the EU can ensure better and faster access for patients to innovative medicines manufactured in Europe, especially when also the focus on FTA implementation is increased. It is also of utmost importance for the EU to maintain a strong and as close as possible relationship with the UK, including in the regulatory field and for scientific cooperation. This includes minimising any medicines supply or regulatory issues as a consequence of Brexit.

We call on the European institutions to advance Europe's smart trade agenda to promote the quality of standards and investment, as well as actively use trade policy to promote Europe's regulatory and IP frameworks globally.



POLICIES TO PRESERVE THE ENVIRONMENT

One of the unintended and inevitable results of delivering life-changing medicines to patients is that our products can find their way into the environment. Pharmaceuticals can enter the environment at all stages of a product's life cycle. We are committed to playing a role in addressing the concerns and to actively engage in minimising the impact of pharma activities on the environment. We believe that only a balanced and collaborative approach will allow us to meaningfully increase our mutual knowledge and understanding about how to minimise any potential impact, issue or concern that pharmaceuticals in the environment might pose. One concrete example is the joint campaign by healthcare stakeholders to raise awareness on how to appropriately dispose of unused or expired medicines in Europe⁷.

In addition, the Eco-Pharmaco-Stewardship (EPS) initiative has been developed. It considers the entire life-cycle of the medicine and addresses the roles and responsibilities of all parties involved, including public services, the pharmaceuticals industry, environmental experts, doctors, pharmacists, and patients⁸. Furthermore, we continue to monitor the issue of environmental impacts from the production of antibiotics and have initiated several health-based commitments as well as working, directly or via our member companies, through the AMR Industry Alliance⁹ to manage potential risks. The industry is also committed to improving our emission and carbon footprint, and is part of relevant initiatives: the Science Based Targets Initiative¹⁰, the Greenhouse Gas Protocol¹¹ and Carbon Disclosure Project¹².

We call on the European institutions to make the most of EU funding instruments to further encourage research to assess the impact on pharmaceuticals in the environment, through Public Private Partnerships, as well as research programs such as Horizon Europe.

THE PHARMACEUTICAL INDUSTRY IN EUROPE



€35 billion
invested in R&D across
Europe in 2018



€93.3 billion
trade surplus in 2018



760,000
people employed



46%
female employees

7,000
medicines in
development

1,813

CANCERS

599

CARDIOVASCULAR
DISORDERS

475

DIABETES

159

HIV
AIDS

1,120

IMMUNOLOGICAL
DISORDERS

1,256

INFECTIOUS
DISEASES

511

MENTAL HEALTH
DISORDERS

1,329

NEUROLOGICAL
DISORDERS



84
medicines
recommended
for approval
by EMA in 2018



Of these, **42**
are new active
substances



4,000
clinical trials are
authorised each year
in the EEA
approximately

EFPIA (The European Federation of Pharmaceutical Industries and Associations) represents the research-based pharmaceutical industry operating in Europe.

Founded in 1978, its members comprise 36 national pharmaceutical industry associations and 39 leading pharmaceutical companies undertaking research, development and manufacturing of medicinal products in Europe for human use.

EFPIA aims to create an environment that enables its members to innovate, discover, develop and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy. EFPIA's vision is for a healthier future for Europe. A future based on prevention, innovation, access to new treatments and better outcomes for patients.

1 <https://www.efpia.eu/media/25628/eps-a-holistic-environmental-risk-management-program.pdf> <https://www.europarl.europa.eu/resources/library/media/20190716RES57231/20190716RES57231.pdf>

2 <https://www.consilium.europa.eu/media/38789/22-euco-final-conclusions-en.pdf>

3 An EU Industrial Policy Strategy: a Vision for 2030', <https://www.consilium.europa.eu/media/39507/st09706-en19.pdf>

4 European Political Strategy Centre, EU Industrial Policy After Siemens-Alstom. Finding a new balance between openness and protection, p. 16, https://ec.europa.eu/epsc/sites/epsc/files/epsc_industrial-policy.pdf

5 Economic and societal footprint of the pharmaceutical industry in Europe, PwC, June 2019

6 <https://s3platform.jrc.ec.europa.eu/-/european-commission-announces-the-key-strategic-value-chains?nheritRedirect=true>

7 www.medsdisposal.eu

8 <https://www.efpia.eu/media/25628/eps-a-holistic-environmental-risk-management-program.pdf>

9 <https://www.amrindustryalliance.org/>

10 <https://sciencebasedtargets.org/>

11 <https://ghgprotocol.org/>

12 <https://www.cdp.net/en>