efpia

European Federation of Pharmaceutical Industries and Associations

EU Industrial and Pharmaceutical Strategy:

An Opportunity to Drive Europe's Health and Growth






FOREWORD

As President of EFPIA and CEO of a European headquartered innovative pharmaceutical company, I am delighted that the new mandate of the European Commission is developing a renewed Industrial Strategy for Europe and has recognised the strategic importance of a vibrant life sciences sector to Europe's health and economic growth.

I am deeply convinced that no one can solve the Healthcare challenges alone. This applies equally to an Industrial Strategy that enables Europe to compete with other regions. As a company, UCB is based in Europe but operates globally. It means making decisions on locating research, development and manufacturing resources based on the research and policy environment in which we operate, wherever that may be.

How can we work together to have the next Google or Tesla coming out of our European Labs?

How can we connect all Europe has to offer to enable our best Researchers from across Companies and our Universities to develop the solutions for the world of tomorrow?

How can we create a policy environment not only to be an engine room for all those innovations but also to ensure they reach European citizens?

Europe has many strengths on which to build if we can work together to create an environment that fosters innovation, supports sustainable access to new medicines and builds a research infrastructure designed to deliver the next generation of new treatments. EFPIA is committed to working with the EU institutions and Member States to achieve that goal.

Jean-Christophe Tellier
President, EFPIA
CEO, UCB

INTRODUCTION

When I qualified from university as a biotechnologist it was an exciting time to be in life sciences in Europe, the region was at the forefront of ground-breaking medical innovation. Today, just 25 years on, 47% of global new treatments are of US origin and more and more new treatments are being approved first in emerging markets such as China. This compares to just 25% emanating from Europe (2014-2018)[1]. It represents a complete reversal of the medical innovation landscape since I graduated.

In parallel, Europe's share of global R&D investment is falling. Over the past twenty years, the region's research and development base has gradually eroded, with new leading-edge technology research units being transferred out of Europe, mainly to the United States over the past years and more recently to China. Until 1990, Europe led the world in pharmaceutical R&D and innovation, and it has steadily lost ground so that by 1997, for the first time, the US industry overtook its European counterpart in terms of the total amount of R&D expenditure. Between 1990 and 2017, R&D investment in Europe grew 4.5 times, while in the US it increased more than 8 times.[2]

The reasons behind this 25-year downward trend in Europe can be attributed to a number of factors and what is crystal clear is that unless the Commission acts now, the trend will continue and even accelerate in the context of fierce global competition for life science investment.

Therefore, as an industry, we look forward to the publication of the Commission's Industrial Strategy and the roadmap for the upcoming Pharmaceutical Strategy. Both bring the future of Europe's life sciences sector into sharp focus and both represent a unique opportunity to work together to reestablish Europe's global leadership in medical innovation while ensuring access to new treatments and technologies today. This was the call in Commission President von der Leyen's letter to Commissioner Kyriakides and we hope for an open and constructive dialogue to find shared and concrete solutions to address issues of supply, access and availability of new medicines for patients as well as to create the conditions in which Europe can re-establish itself as a world industrial leader in bringing transformative treatments to patients.

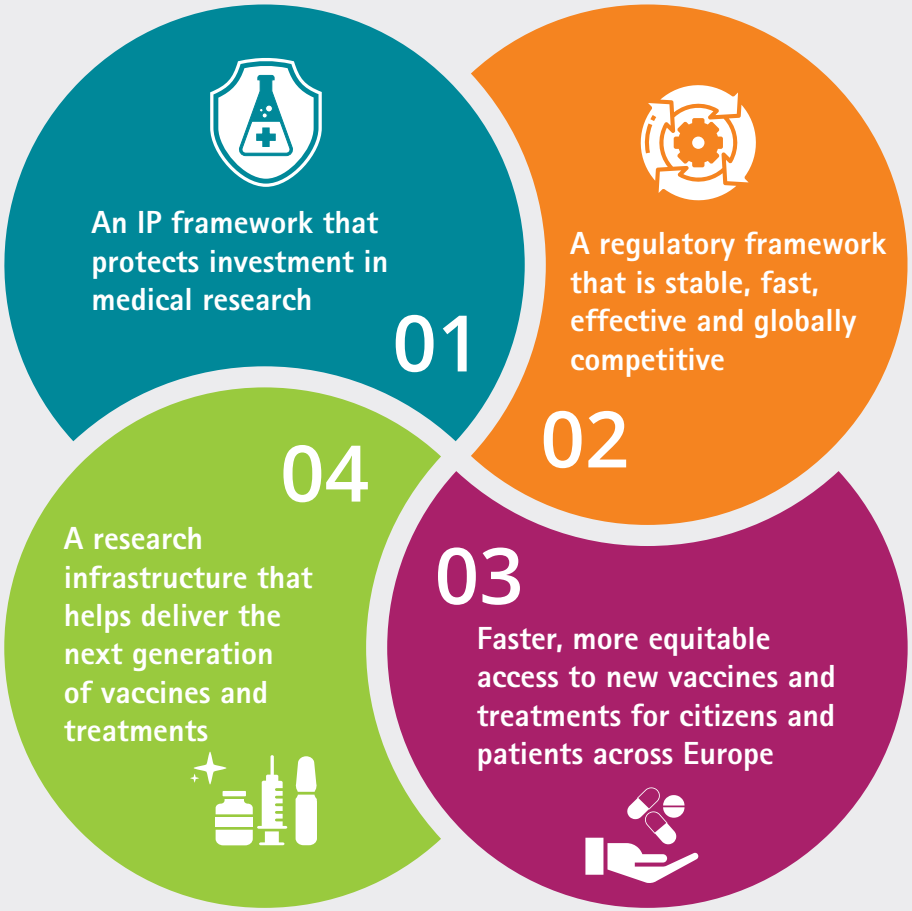
To start that dialogue very concretely, throughout this document we have outlined steps we believe that Europe can and should take and we look forward to engaging with all stakeholders in the coming months to realise our region's potential for the benefit of today and tomorrow's patients. The time is now.

Nathalie Moll
Director General
EFPIA

[1] Pharmaprojects & SCRIP, March 2019
[2] EFPIA member associations & PhRMA, yearly publications 1990-2019

Recommendations for inclusion in Europe's renewed Industrial Strategy

Despite the 25-year haemorrhaging of research and development activity to the US and China, the industry still invested an estimated €36,500 million in R&D in Europe in 2018. It directly employs some 765,000 people in the region and according to a report released by PwC in June 2019 supports around 2.7 million jobs across the EU. The same report highlighted that the activities of pharmaceutical companies contributed over €127 billion directly to the EU economy, with an additional €140 billion provided through the supply chain and employee spending[3]. In addition, Europe has a long history of vaccine manufacturing, and benefits from a strong industrial infrastructure with 76% of the major innovative global vaccine manufacturers production in Europe. We believe Europe has the core capabilities to build on this base if we include the following proposals in a renewed industrial strategy for Europe:



[3] https://www.efpia.eu/media/412939/efpia-economic-societal-footprint-industry-final-report-250619.pdf

An IP framework that protects investment in medical research can be achieved by:

- Maintaining and developing Europe's world-class IP system by promoting strong IP protection, incentives and reward mechanisms for R&D in particular for orphan and paediatric medicines.
- Ensuring that the overall EU IP/ incentives framework remains globally competitive in order to attract investment into the development of future innovation for the benefit of patients.
- Identifying and implementing new incentives in areas of unmet medical need. For example, in the fight against AMR.
- Identifying appropriate incentives to ensure sustainable investment in new scientific developments such as Advanced Therapy Medicinal Products and personalized medicines.
- Increasing harmonisation in the area of Supplementary Protection Certification (SPC) and patent systems to increase certainty for all stakeholders.
- Implementing a smart trade strategy that promotes this world-class IP system and reward for R&D globally.

Faster, more equitable access to new vaccines and treatments for citizens and patients across Europe can be achieved by:

- Creating a High-Level Forum on Better Access to Health Innovation to develop multi-stakeholder solutions to introducing new technologies into health systems and reduce the time patients in Europe wait for access to new treatments. The Forum would serve to jointly identify, analyse and address the reasons why patients do not get access to treatments or endure significant delays, then co-create solutions.
- Improving understanding and intelligence regarding the root causes and drivers of shortages and implementing appropriate monitoring mechanisms involving all supply chain actors.
- Developing and implementing novel pricing and payment approaches to address the needs of patients, health systems and governments. These include combination-based pricing, indication-based pricing, outcomes-based payments, over-time payments and subscription payments.
- Evolving HTA to ensure effective harmonisation of clinical data requirements and removal of duplicative assessments.
- Promoting disease prevention, including sustainable vaccination programmes that embrace innovation.

A regulatory framework that is stable, fast, effective and globally competitive can be achieved by:

- Utilising Real World Data (RWD) and Real World Evidence (RWE) in regulatory decision-making.
- Embracing innovative clinical trial approaches and the development of the associated IT infrastructure.
- Creating a dynamic regulatory assessment process allowing for a more flexible EU regulatory pathway. This would include an iterative process for seeking early advice on data sets intended to be included in the marketing authorisation application, as they are generated and continued evidence review (utilisation of scientific advice/dialogue).
- Introducing a clear assessment pathway for drug/device combination products, including a streamlined pathway for a biomarker validation.
- Modernising the variation framework (Delegated EU Regulation 1234/2008) to ensure its full alignment with risk-based principles and tools; that it embraces innovation by being adapted to future developments; enables efficiency gains for both regulators and industry by focusing on changes with significant impact; and paves the way to international alignment across variation systems.
- Promoting global regulatory convergence through the EU's trade policy and active participation in global forums such as ICH and PIC/S.

A research infrastructure that helps deliver the next generation of treatments and vaccines can be achieved by:

- Ensuring parity with the US and China in life science IP incentives to remain an attractive location for R&D investment and industrial development.
- Building an operational European Health Data Space with clear rules of engagement for private and public parties.
- Developing clinical trials networks and sites, biobanks and data banks of appropriate quality to support the generation of data suitable for regulatory purposes.
- Delivering Public Private Collaboration mechanisms to balance health imperatives and scientific advances with translational drive and solid industrial processes which will accelerate bringing health solutions to patients.

An industry integral to Europe's Future

The innovative pharmaceutical industry is an industry of critical strategic importance to Europe. There are many ways the industry can contribute to Europe's Industrial Strategy, its economic, social and healthcare future.

Driving better health in Europe[4]

- Deaths from cancer have fallen by 21% since the 1990s. Now two out of three patients diagnosed with cancer live beyond 5 years.
- 95% of the 15 million Europeans living with Hepatitis C can now be cured with a 12 week course of medicines.
- Since the 1990s HIV has been turned from a death sentence to a manageable disease.
- Europe hosts 76% of the major innovative global vaccine manufacturers production.
- Immunization currently prevents between 2,000,000 – 3,000,000 deaths every year. Immunization is one of the most successful and cost-effective public health interventions.
- A new generation of gene therapies are transforming the lives of patients living with rare disease, cancer and other diseases.

A digital Europe to help support patients in their digital journey

The pharmaceutical industry strategic aim in the digital health space is to support the transformation of European healthcare for the benefit of patients and that digital evolution enables a move towards outcomes data-driven healthcare systems, ensuring the continued competitiveness of Europe.

EFPIA is involved in several Innovative Medicines Initiative (IMI) projects aimed at harnessing the power of digital health to improve patients' outcomes.

- **Big Data for Better Outcomes** (BD4BO) supports the evolution towards outcomes-focused and sustainable healthcare systems, by exploiting the opportunities offered by big and deep data sources.
- **The European Health Data & Evidence Network** (EHDEN) will harmonise 100 million health records across multiple data sources such as hospitals and primary care networks and develop a 21st century ecosystem for real world health research in Europe.
- **Remote Assessment of Disease and Relapse – Central Nervous System** (RADAR-CNS) is a research programme which is developing new ways of monitoring major depressive disorder, epilepsy, and multiple sclerosis using wearable devices and smartphone technology.

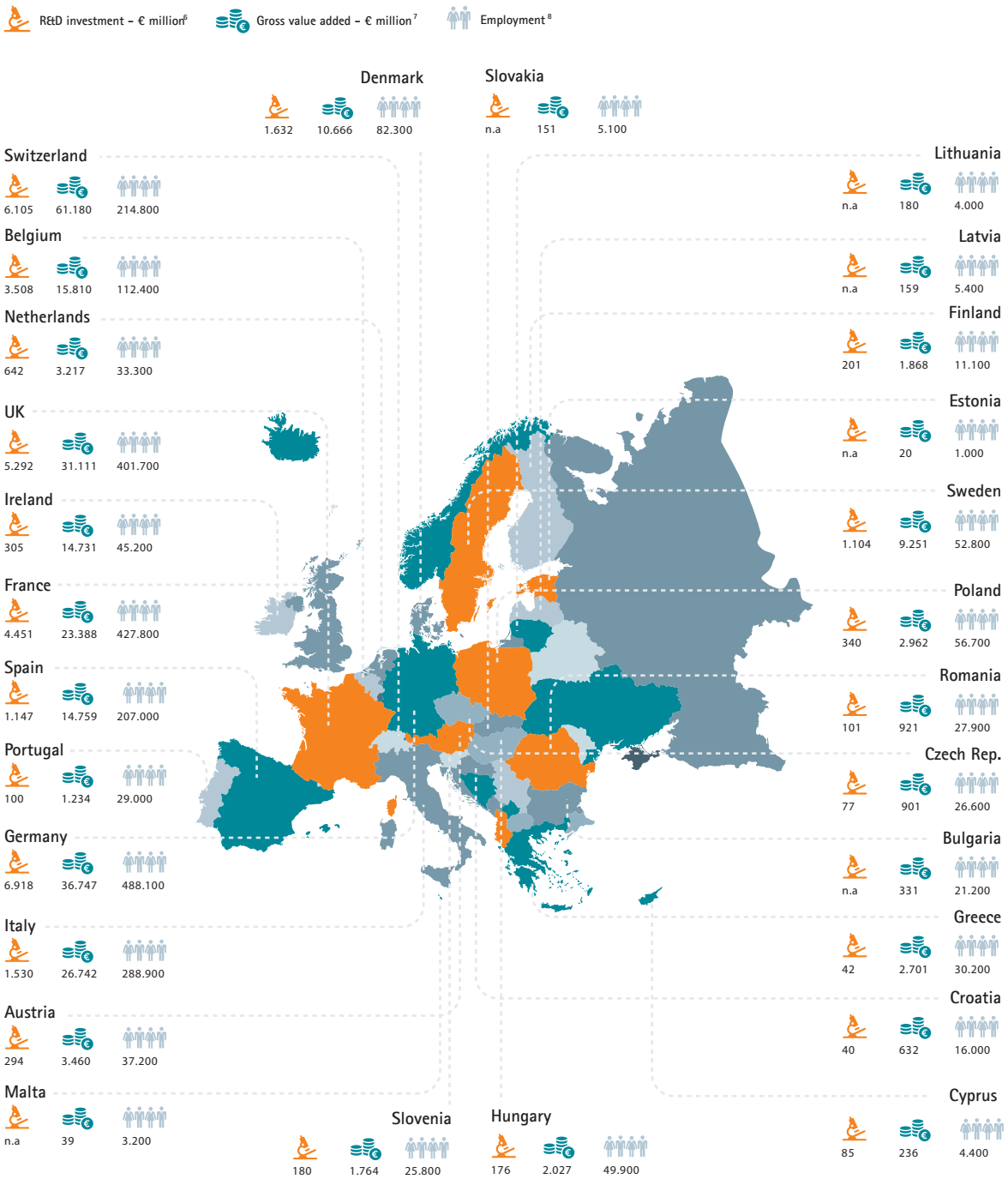
Driving economic growth and trade[5]

- As an industry we employ 2.7 million people (directly and indirectly), create a gross value added of €206 billion and consist of both large companies as well as SMEs.
- The innovative pharmaceutical industry is also the most R&D intensive industry in the EU with R&D costs constituting 15% of total net sales (and with over €35 billion in investments in the EU). This makes the industry one of the largest drivers for innovation on the European continent.
- The pharmaceutical industry's trade surplus amounted to €102 billion for the EU in 2018 (the largest of all industrial sectors), strongly embedded in pharmaceutical global value chains.
- Our industry contributes to values that Europe finds important as a way of life. For example, the sector has the highest share of female employment of all industrial sectors, with 46% of people employed directly by the industry being women; has a strong and important SME contingent in its value chains; and creates not only many but also high-quality jobs with the highest safety-at-work standards.

Policies to preserve the environment

- The pharmaceutical industry is committed to making a positive impact on the lives of patients while operating sustainably.
- Our industry encourages appropriate use of a risk based approach to environmental challenges and undertakes initiatives to promote greater environmental responsibility by supporting the principles in the UN Global Compact regarding climate, the United Nations' Sustainable Development Goal 13, the Paris Climate Accord approved at COP21, and the adoption of a global framework (based on COP21) to address CO2e challenges.
- IMI's CHEM21 project dealt with the sustainability of drug manufacturing processes, aiming to reduce the industry's carbon footprint and environmental footprint.
- To proactively engage in environmental considerations, together with other industry sectors, EFPIA has developed the Eco-Pharmaco Stewardship Initiative. The initiative strives to protect patient access to medicines while appropriately considering environmental aspects and considers the entire life-cycle of the medicine.

[4] https://efpia.eu/about-us/annual-reports/
[5] https://www.efpia.eu/media/412939/efpia-economic-societal-footprint-industry-final-report-250619.pdf



[6] https://www.efpia.eu/media/413006/the-pharmaceutical-industry-in-figures.pdf

[7,8] https://www.efpia.eu/media/412939/efpia-economic-societal-footprint-industry-final-report-250619.pdf

efpia
European Federation of Pharmaceutical Industries and Associations

@EFPIA
www.efpia.eu