FORUM OF INTERNATIONAL
RESEARCH & DEVELOPMENT
PHARMACEUTICAL COMPANIES, EIG

# (IN)SIGHT INTO PHARMACY

# ABOUT THE FORUM

The Forum of International Research and Development Pharmaceutical Companies, EIG (Forum) is the representative of the innovative pharmaceutical industry in Slovenia.
We bring together 21 innovative pharmaceutical companies with a common mission: #WeWontRest in developing innovative medicinal products, vaccines and therapies that play a key role in the management of diseases and improving the quality of life of patients around the world.

The Forum operates as a non-government, non-profit, non-political and independent economic interest group that acts as a trustworthy partner in the field of medicines, health and healthcare in Slovenian society. We actively strive for better information and greater awareness of decision makers, patients and the general public on these complex, yet extremely important issues for individuals and society as a whole.

## Mission and vision

The Forum actively contributes to a sustainable and high quality health system that provides patients with timely access to innovative therapeutic solutions. As the representative of the innovative pharmaceutical industry, the Forum is a recognised and reliable partner in society's efforts towards finding the best solutions in healthcare.

# THE PHARMACEUTICAL INDUSTRY IN SLOVENIA

The pharmaceutical industry employs about 10,000 people in Slovenia. Recent studies in certain countries show that the research-based pharmaceutical industry supports about four times as many direct than indirect jobs.[1]

Pharmaceutical companies invest about **180 million Euros** into research and development in Slovenia.[1]

*Source:*
*1. EFPIA The Pharmaceutical Industry in Figures, Key Data 2021, data for 2019*

# PHARMACEUTICAL INDUSTRY IN THE EU

In Europe the pharmaceutical industry employs 765,000 people and supports about 2.7 million jobs. Annual investments in research and development amount to about 36.5 million Euros. Activities of pharmaceutical companies directly contribute over 100 billion Euros into the EU economy, with a further 106 billion Euros contributed through the supply chain and employee consumption.

Europe has lost its position as the leader in medical innovation. Currently no more than 25 % of new medicines are coming from Europe (data for 2014–2018)[1]. However, the EU27 account for over 60 % of the global medicinal product export, so a major share of the global population depends on Europe for medicines.[2]

Over 80 % of all vaccines are produced in Europe and the EU is also the best location to perform clinical trials.[3]


An encouraging environment for research and development is very important in order to provide the best possible conditions for patients throughout Europe, as well as to maintain the competitive edge of the European economy. The severe human and economic burden of the covid-19 pandemic has shown us more than ever the importance of discovery, development and access to innovative diagnostic procedures, medicines, vaccines and other health technologies in order to effectively respond to global health threats and address unmet medical needs in Europe.

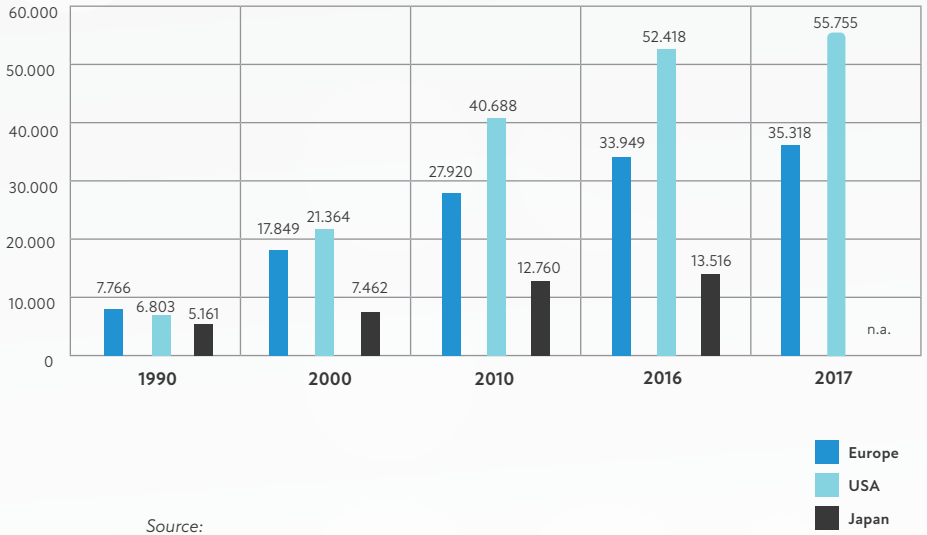
Stakeholders should pursue measures to allow the EU to maintain its position as the world's largest exporter of pharmaceutical goods. Europe needs a strong global trade strategy (multilateral and bilateral) to improve its access to third markets, as well as a strong research and development infrastructure within the EU to support the development of innovative medicines with high added value.

*Sources:*
*1. Pharmaprojects & SCRIP, March 2019*
*2. World Health Organisation, 2019*
*3. EFPIA Manifesto*

# RESEARCH AND DEVELOPMENT

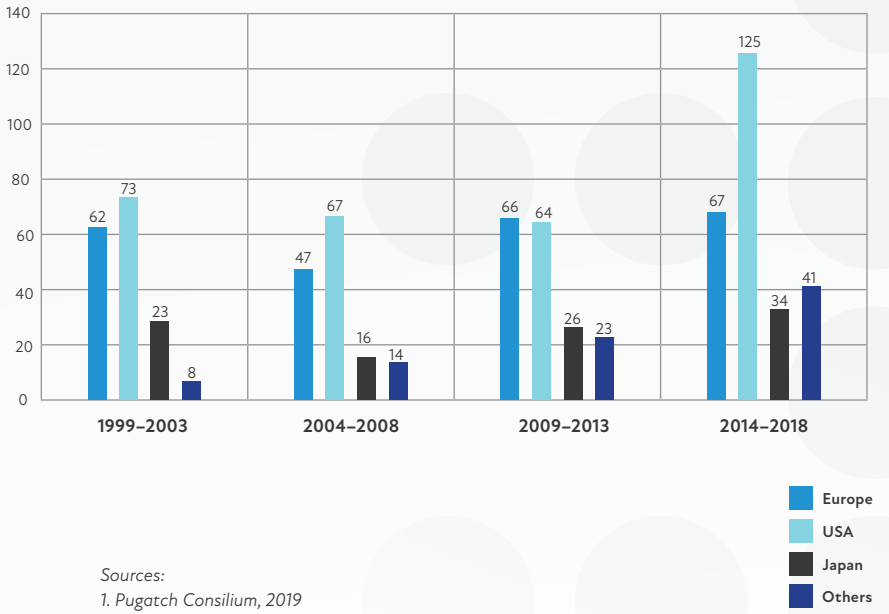
Research and development brings patients the discovery of new and innovative medicines to address their diseases and this can only be achieved through a concerted effort of all partners in healthcare. Patients also need access to all currently available treatment options. We therefore need to foster and promote research and development of new treatment options, particularly in areas where no treatment currently exists. Fostering the research and development of orphan medicines is a good example of how the industrial strategy of the EU can focus R&D into fulfilling unmet needs of patients while also strengthening the European economy. In 2000 the European Union adopted the Regulation on orphan medicinal products to accelerate the development of new medicines for patients who previously had no treatment options. Since the adoption of the Regulation the number of approved medicines for rare diseases grew from 8 to the current 164[1,2].

**Pharmaceutical R&D expendture in Europe, USA and Japan (million of national currency units), 1990–2017**




*Source:*
*1. Pugatch Consilium, 2019*

**Number of new chemical or biological entities (1999–2018)[3]**

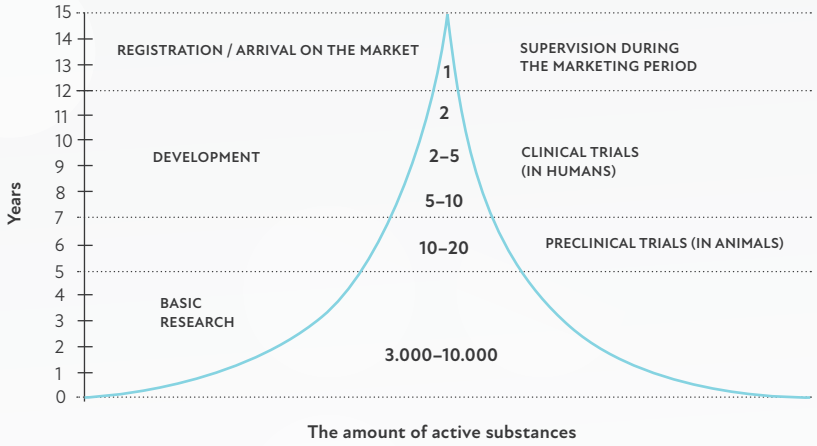



*Sources:*
*1. Pugatch Consilium, 2019*
*2. European Medicinal Agency, 2020*
*3. SCRIP – EFPIA calculations (according to nacionality of mother company)*

# RESEARCH AND DEVELOPMENT

Research and development of new medicines carry a high degree of risk since only a small fraction of all potential new chemical entities successfully pass all stages of development. Pharmaceutical companies' study between 3,000 and 10,000 substances in the initial phases of development and only one usually passes through the entire process.

## Discovery and development on new chemical entity (NCE)




*Source: PhRMA analysis data, updated in accordance with data from the Tufts Center for the Study of Drug Development (CSDD) database.*

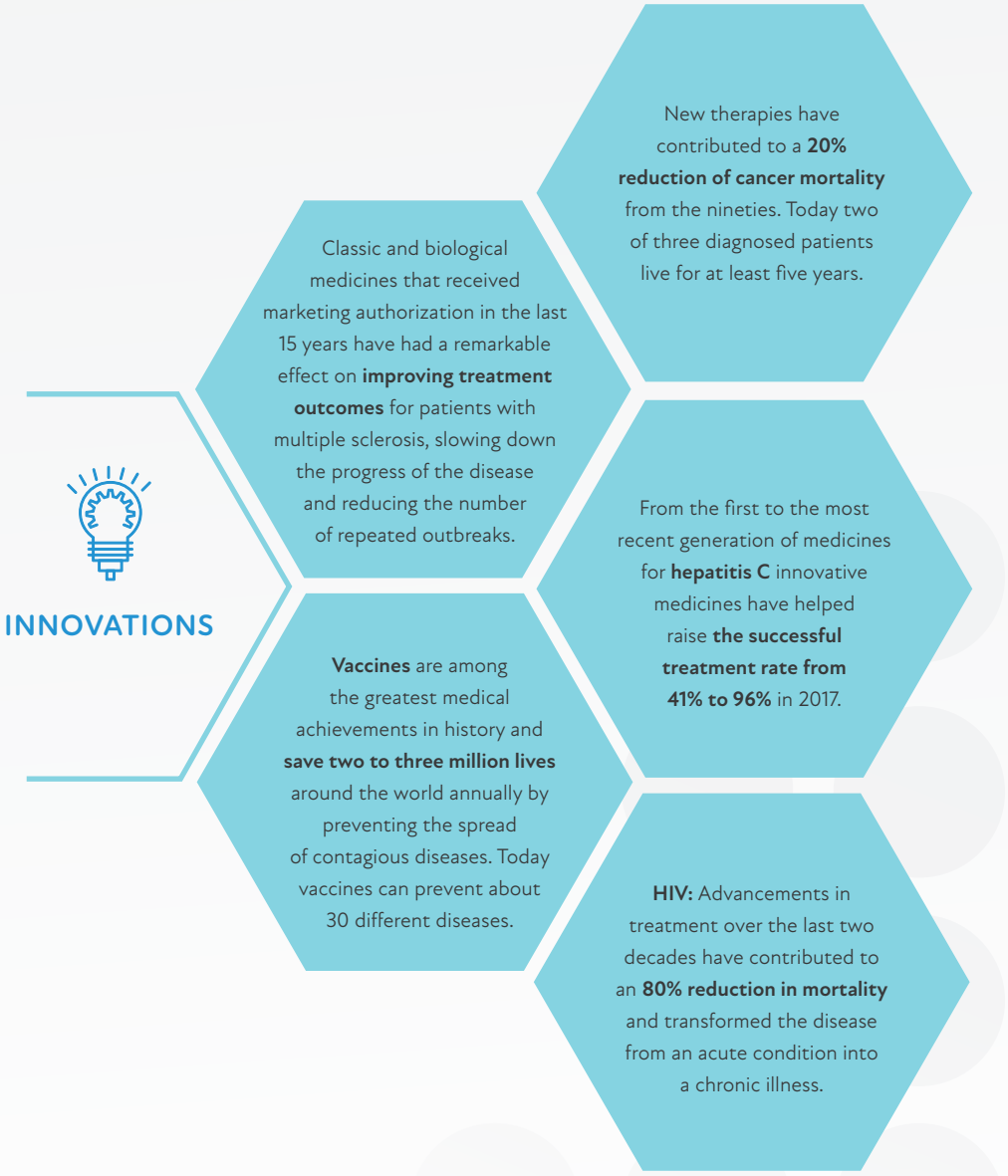
➜ Pharmaceutical companies include on average **3,000 to 10,000 active substances** in basic research for a new medicine.

➜ Throughtout **the entire research and development process**, **1 active substance** is penetrated until the registration phase and then the arrival on the market.

# VALUE OF INNOVATION

Innovative medicines and innovative (digital) health solutions deliver savings in many areas, including hospitalization and physician time.

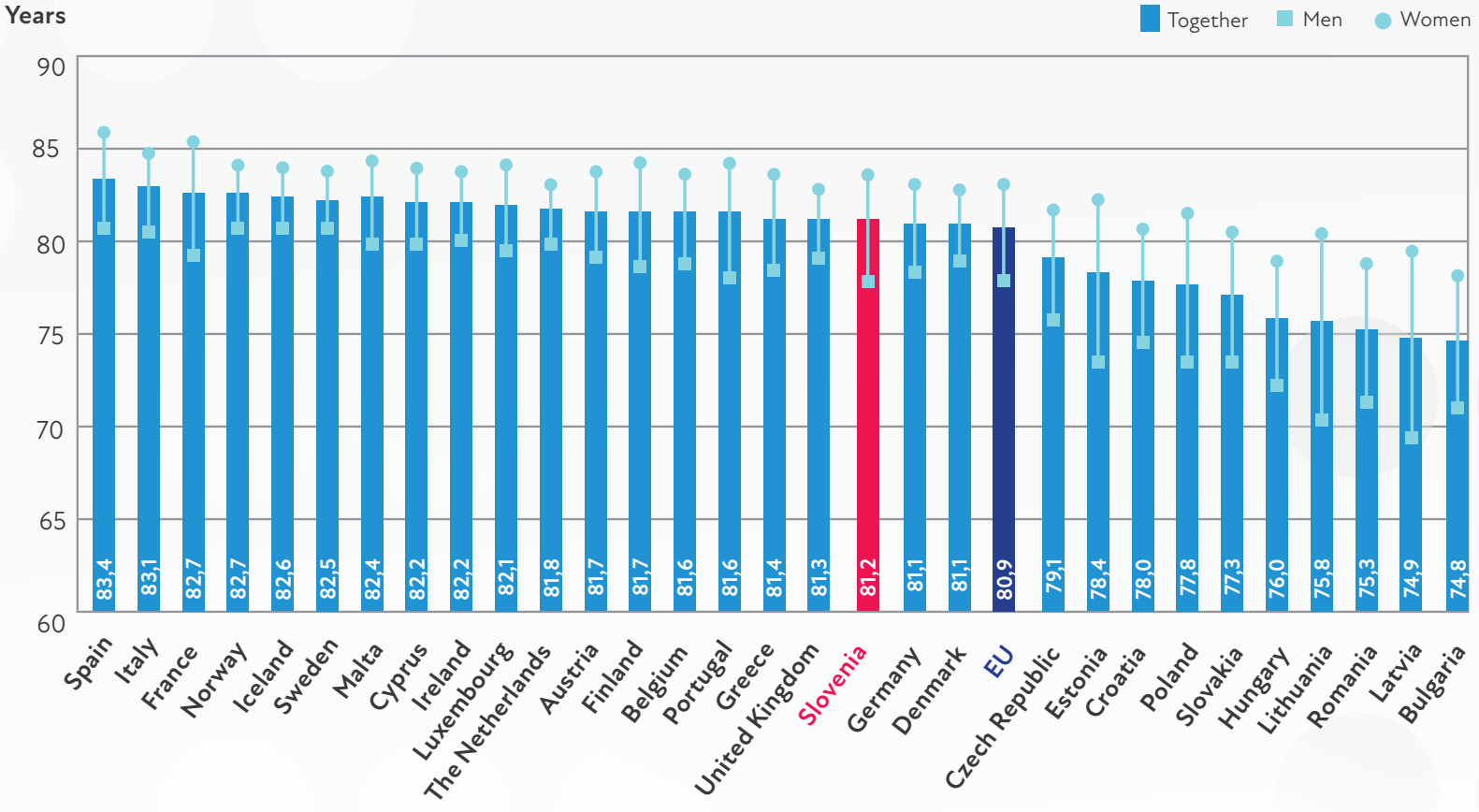
Innovations have a positive effect on economic growth and are a fundamental driving force behind improvements in health and longevity.




*Sources:*
*1. The National Multiple Sclerosis Society. "The MS Disease-modifying Medications: General Information." Washington, DC: National Multiple Sclerosis Society, April 2013. Available at www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/12-3-7_DiseaseModifyingDrugs.pdf.*
*2. C. Augustyn, B. Walker, and T.F. Goss. "Recognizing the Value of Innovation in the Treatment of Rheumatoid Arthritis." Boston, MA: Boston Healthcare Associates, March 2013. Available at www.phrma.org/sites/default/files/1888/rawhitepaperfinal2.pdf.*
*3. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics. "Health, United States, 2010: With Special Feature on Death and Dying, table 35." Hyattsville, MD: HHS, 2011. Available at www.cdc.gov/nchs/data/hus/hus10.pdf#045 (accessed February 2014)*
*4. American Cancer Society. "Cancer Treatment and Survivorship Facts & Figures 2012-2013." Atlanta, GA: American Cancer Society, 2012.*

# HEALTHCARE INNOVATIONS HAVE A MAJOR IMPACT ON LIFE EXPECTANCY AND LONGEVITY

Between the years 2000 and 2017 life expectancy at birth in Slovenia increased with five years (from 76.2 to 81.2 years). This is one of the greatest extensions in the EU in this period.




**Gender gap:**
Slovenia 5.8 years
EU: 5.2 years

*Source: State of Health in the EU, Slovenia Health profile in 2019, data refers to year 2017.*

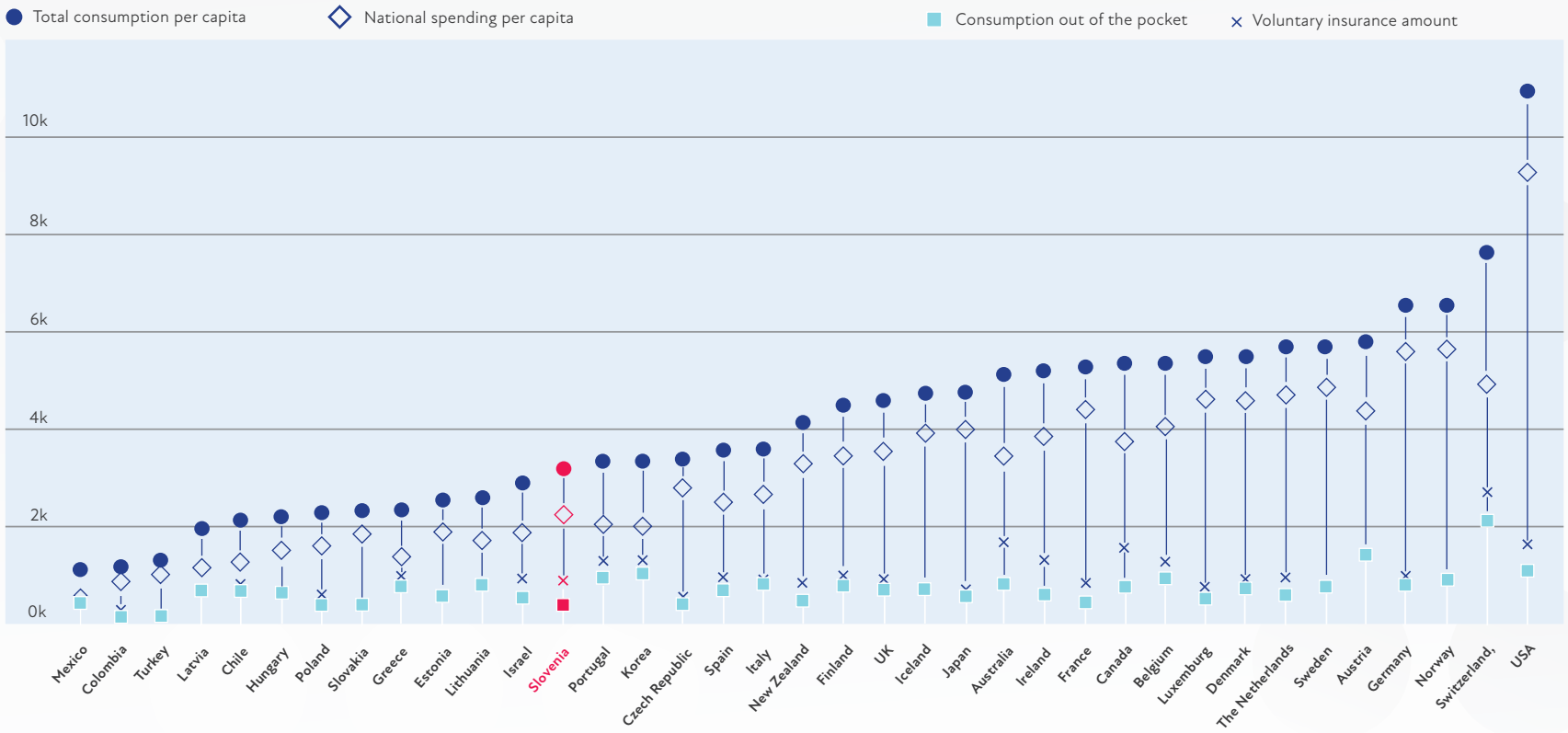
# UNMET MEDICAL NEEDS

In 2017, 3,5 % of the population reported unmet needs in the field of healthcare due to finance, remoteness and waiting period issues. This is almost double the EU average, which stands at 1.7 %. The main reason for unmet medical needs were long waiting periods.[1]

Slovenia devotes a substantially lower share of its GDP to healthcare than many Western European countries. The share is also lower than the OECD average. Slovenia spends less on healthcare per capita than the OECD average.

According to latest OECD data for 2019, OECD countries spend an average of 4,224 USD per capita on population health (by purchasing power parity). On average, Slovenia spends less, 3,224 USD per capita (by purchasing power parity). At current EUR prices this amounts to 1,904 EUR, whereby 1,367 EUR is financed from public funds, 22 EUR comes from other private sources (e.g. occupational medicine), 256 EUR comes from voluntary insurance (additional, supplementary) and an average of 259 EUR is paid by individuals.

Unmet medical needs must be addressed from different perspectives: increased investments into the healthcare system, conducive environment to focus research and investments, mode and digitisation of the healthcare system, financial support for different segments (HR, infrastructure, etc.).



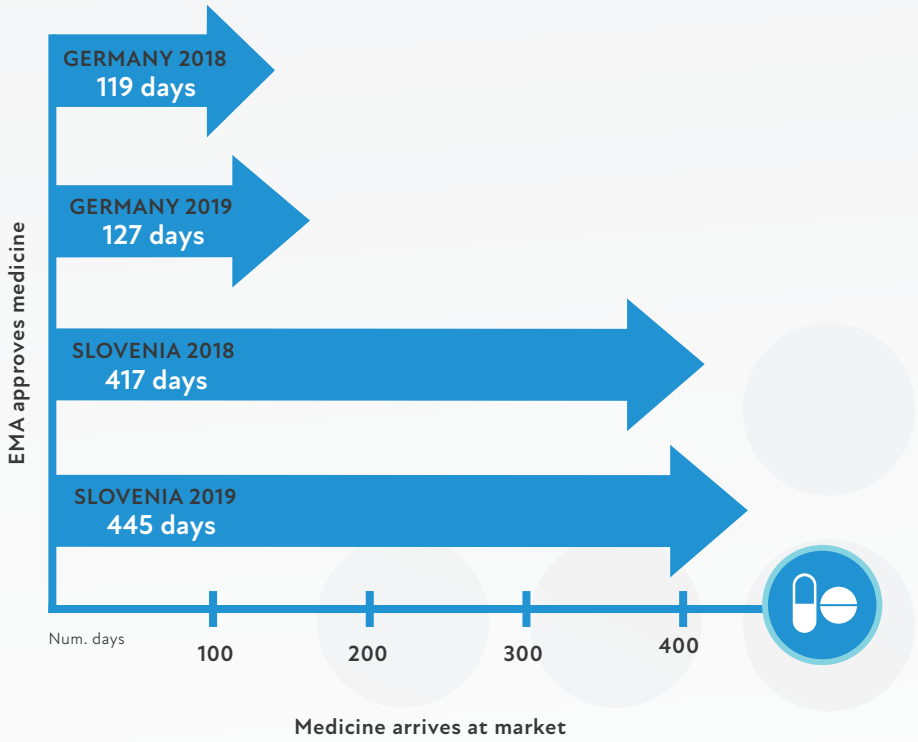

*Sources:*
*Data in USD by purchasing power parity*
*Note: Data in the chart uses USD by purchasing power parity*

# ACCESS TO MEDICINE

Patient access to new medicines varies greatly throughout Europe. Availability is best in Northern and Western Europe and worst in Southern and Eastern Europe countries. Average delays between marketing authorization and actual patient access in Europe can vary by a factor greater than six. Patients in Northern and Western Europe can access new medicine in 100–350 days after approval of the European Medicines Agency (EMA), while patients in Southern and Eastern Europe need to wait as long as 600–850 days.

Addressing the issues of equal access is exceptionally important to reduce the burden of disease for patients across Europe.

Rapid access to medicine, technologies, diagnostics and all the programs necessary for comprehensive treatment of patients are extremely important for reducing the burden of disease and providing faster and more effective treatment.




*Source:*
*1. EFPIA Patients W.A.I.T. Indicator 2019 Survey*

*Source:*
*EFPIA Patients W.A.I.T. Indicator 2019 Survey*

# SUSTAINABLE HEALTH SYSTEM

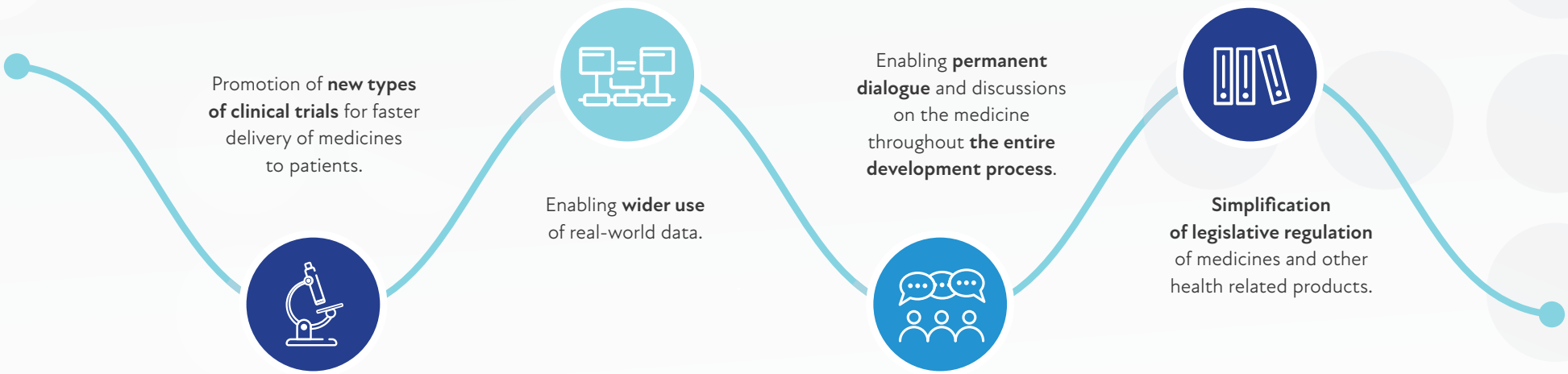
The primary concern for patients is the assurance of universal access to quality treatment and medicine, therapy and vaccines immediately after EMA approval. This requires a sustainable system that promotes innovative solutions such as digitisation of health, remote patient monitoring (telehealth and telemedicine) and advanced analytics (digitisation of data and registries) focused on achieving the best treatment outcome for everyone.

Members of the Forum in Slovenia are working to achieve collaboration of all stakeholders in the health system – from decision makers through practitioners to patient associations. Optimal solutions for a sustainable health system can only be found through common efforts.

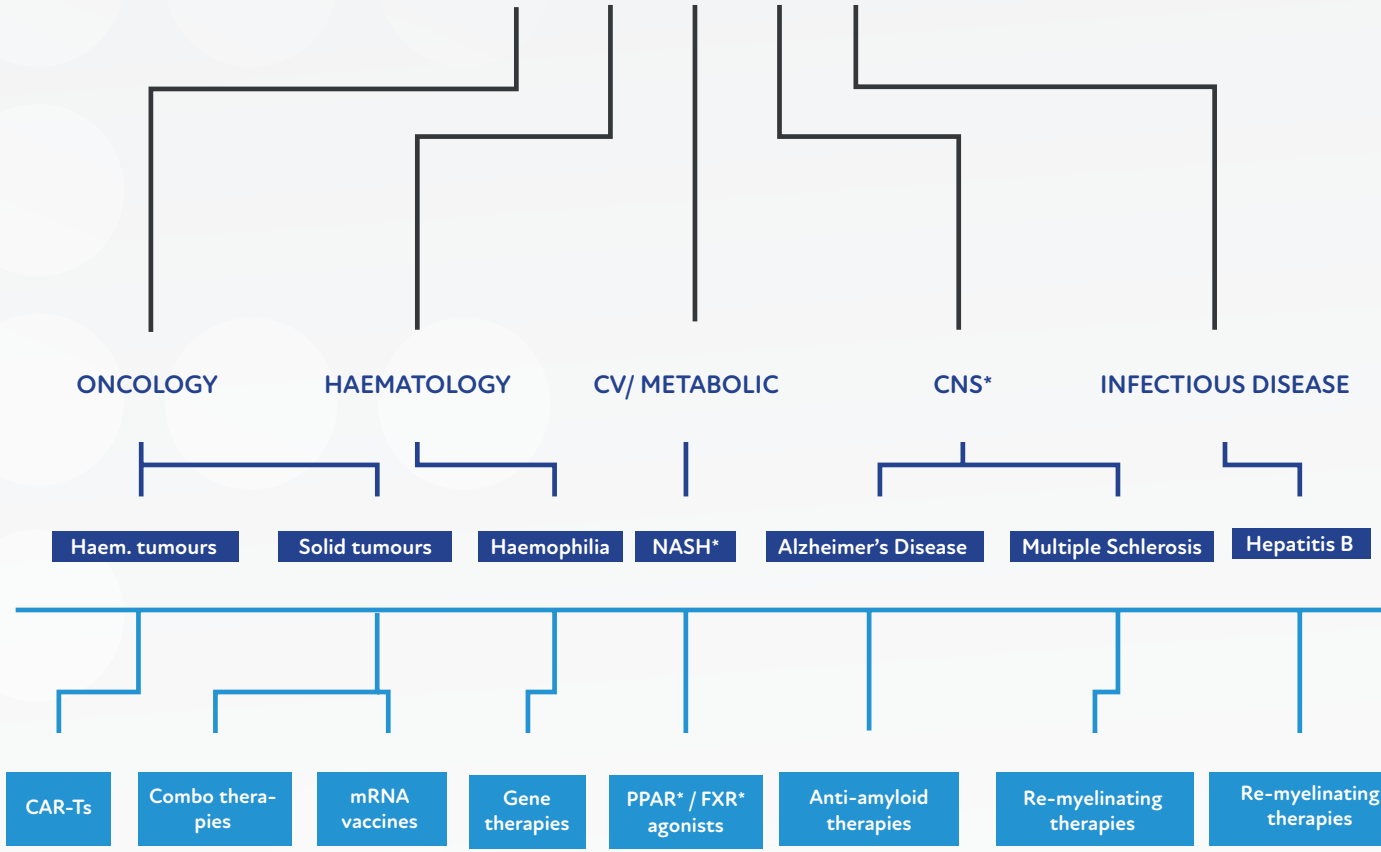
# #WeWontRest

Assuring access to new medicine today and in the future is a common goal and responsibility that requires the cooperation of all partners in healthcare: regulators, governments, policymakers, payers, and, of course, patients. Stakeholders must work together to find solutions for a sustainable and resilient healthcare system. Appropriate sources of financing must be found to maintain fast and permanent access to medicine.

We believe that it is now time for a new round of talks in European institutions about accepting the proposal of the EU health coalition and establishing a European health forum to improve access to health innovations. A European health forum would bring together all stakeholders in the search for solutions for access to new medicine and technology today and in the future and would contribute to the development of sustainable healthcare systems in a globally competitive Europe. Only through such discussion can we identify and develop an appropriate response to challenges facing our healthcare systems.



# THE PIPELINE REVIEW




While past innovation has improved health, Europe still faces significant unmet need in some **diseases**.

Over the next 5-10 years, we see nine major innovations that will address this unmet need and bring benefits to patients and society.[1]

**Valuing and rewarding innovation**

**Adapting regulatory pathways**

**New financing models**

**Integrated care**

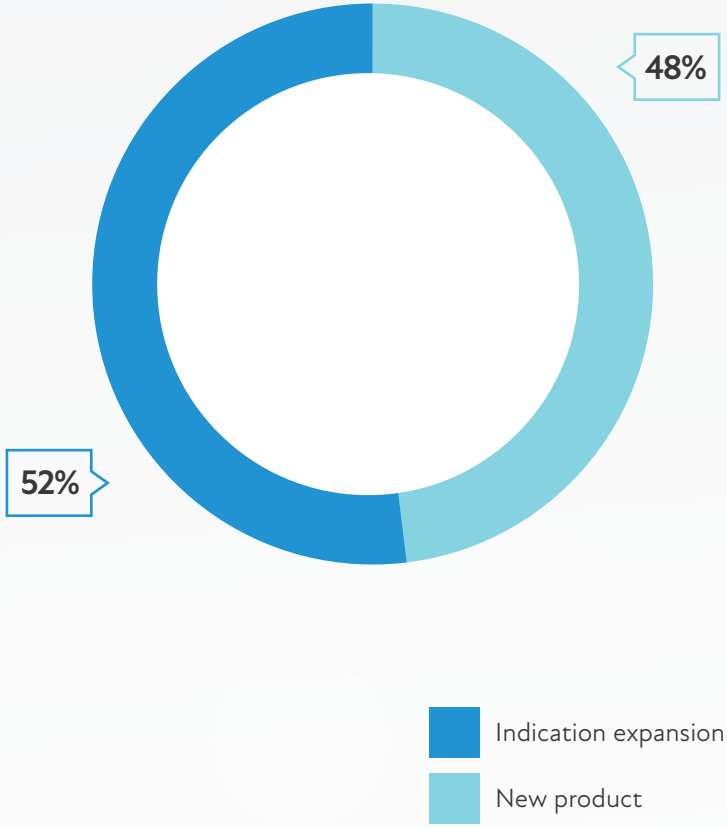
**Real world data**

However, European health systems must **prepare and reform** to **provide rapid and effective access** to these innovations.[1]

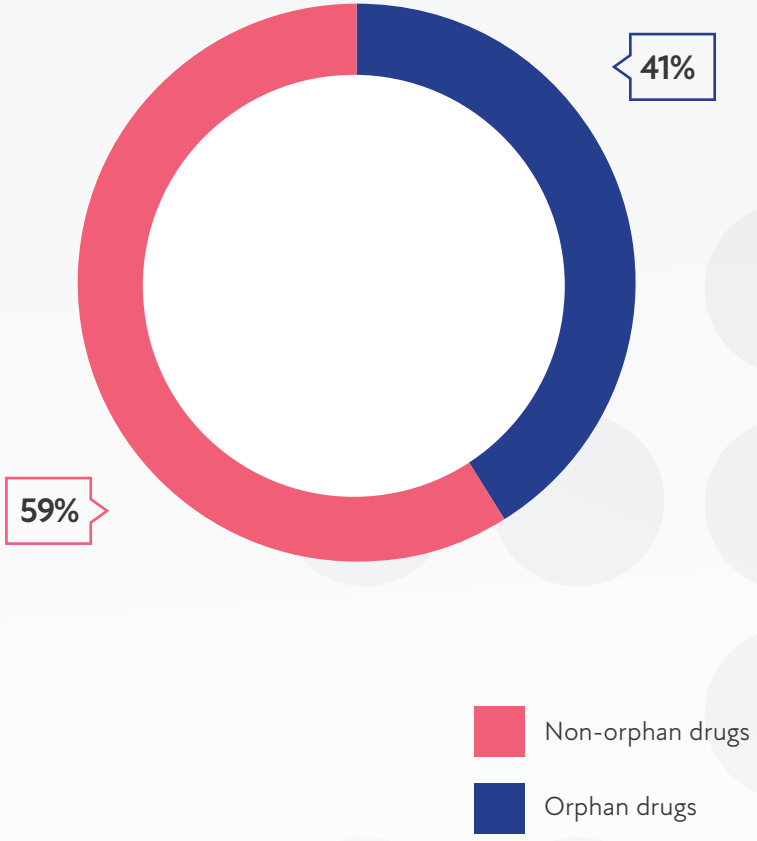
**CNS: central nervous system*
**NASH: non-alcoholic steatohepatitis*
**PPAR: Peroxisome proliferator-activated receptors*
**FXR: Farnesoid X receptors*

*Source:*
*1. IQVIA/EFPIA Pipeline Review 2021*

# ALMOST HALF OF THE PIPELINE ARE NEW SUBSTANCES, MANY RESEARCHES ARE DEDICATED TO ORPHAN DRUGS




*Source:*
*1. IQVIA/EFPIA Pipeline Review 2021*




*Source:*
*1. IQVIA/EFPIA Pipeline Review 2021*

# THE WAY FORWARD – HOW CAN HEALTHCARE SYSTEMS PREPARE?

To provide rapid, effective, fair, equitable and sustainable patient access to new medicines, healthcare systems can prepare in five areas:

**Adapting regulatory pathways**

**Developing new ways of valuing and rewarding innovation**

**Creating new financing models**

**Evolving the way services are delivered to reflect new approaches to treatment**

**Enabling real world data to be captured and used to enable innovative care**

*Source:*
*1. IQVIA/EFPIA Pipeline Review 2021*

# STAKEHOLDER COLLABORATION ACROSS HEALTHCARE AND INDUSTRY WILL BE REQUIRED

**Addressing considerations together will allow patients to benefit from innovation now and in the future:**

➔ Increased quality of life, better health outcome and more treatment options.

➔ Provide new ways to improve access to innovative therapies, as well as a framework for how to set proactive healthcare agendas.

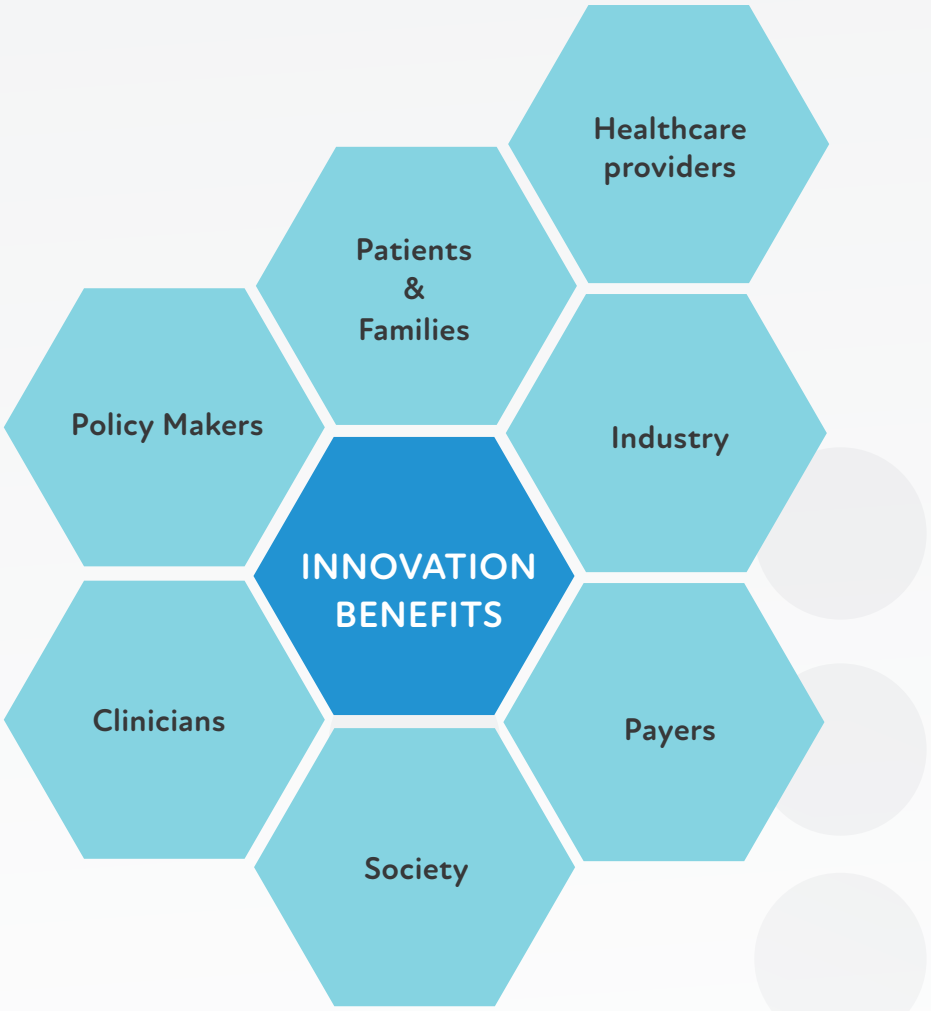
➔ Provide more effective treatment options to provide patients the best treatment for their individual needs.

➔ More effective use of resources.

➔ Incentive to invest in high risk innovation for diseases with a high unmet need.

➔ Costs avoided by reduction in future procedures/long term treatment and better disease management.

➔ Productive people, reduced welfare costs.




*Source:*
*1. IQVIA/EFPIA Pipeline Review 2021*

**Forum of International Research and Development Pharmaceutical Companies, EIG**

*Dunajska 159, 1000 Ljubljana*
*www.farmaforum.si/en*

*May, 2021*