



# Pharmaceutical **POLICY PASSPORT**

Understanding pharmaceutical innovation  
to improve access to new treatments

**Special Edition** – EU Pharmaceutical Legislation Reform





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**MSD IS A LEADING BIOPHARMACEUTICAL COMPANY THAT FOCUSES ON CUTTING-EDGE RESEARCH TO SAVE AND IMPROVE LIVES GLOBALLY. OUR MISSION IS TO HARNESS THE POWER OF SCIENCE TO ADVANCE THE PREVENTION AND TREATMENT OF DISEASES IN HUMANS AND ANIMALS.**

**FOR MORE THAN 130 YEARS, WE HAVE BROUGHT HOPE THROUGH THE DEVELOPMENT OF IMPORTANT MEDICINES AND VACCINES. TODAY, WE ARE AT THE FOREFRONT OF RESEARCH TO DELIVER INNOVATIVE HEALTH SOLUTIONS THAT ADVANCE THE PREVENTION AND TREATMENT OF DISEASES IN PEOPLE AND ANIMALS.**

**TO LEARN MORE ABOUT MSD, PLEASE VISIT OUR WEBSITE AT [MSD.COM](https://www.msd.com)**

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## WHY A POLICY PASSPORT ?

At MSD, we believe that pharmaceutical innovation is the result of a sophisticated policy framework that supports science, healthcare, and industrial policy focused on building a knowledge economy.

EU institutions and national governments play a key role in the creation and sustainability of our research and innovation ecosystem. They do so by investing in fundamental science, financing healthcare, and providing incentives to attract private sector investment in pharmaceutical innovation. This web of public policies provides the conditions for pharmaceutical companies such as MSD to invest and develop innovative treatments that benefit patients and societies.

In 2021 alone, research-based pharmaceutical companies have invested an estimated €42,5 billion in R&D in Europe.<sup>1</sup>

As the EU is embarking on a comprehensive reform of its general pharmaceutical legislation, our Policy Passport is intended to provide policy makers and other stakeholders with a “roadmap” of the drivers and critical policies that support pharmaceutical innovation.

I want to thank my team at the MSD Brussels Policy Centre for producing this Policy Passport, with very special thanks to Boris Azaïs, Director Public Policy.

David Earnshaw,  
Associate Vice-President  
MSD Brussels Policy Centre

IN THE EU, WE HAVE THE  
SCIENCE, THE HEALTH SYSTEMS,  
AND THE PHARMACEUTICAL  
COMPANIES TO PROVIDE BETTER  
HEALTH TO OUR CITIZENS



1 EFPIA, [The Pharmaceutical Industry in Figures – Key Data 2023](#).



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### CONTACT

Brussels Policy Centre  
Rond-Point Schuman 6  
1040 Brussels

For questions or comments on the Policy Passport, please contact Boris Azaïs [here](#).

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Second edition,  
dated January 2024.



# THE SOCIETAL VALUE OF PHARMACEUTICAL INNOVATION

Pharmaceutical innovation is one of the driving forces behind the tremendous progress in life expectancy and better health we have experienced in the last 60 years.



After clean water and sanitation, the development of novel health technologies by pharmaceutical companies has been a key driver of healthier and longer lives.<sup>1</sup>

Antibiotics, vaccines, cardiovascular medicines, diabetes medicines, antiretrovirals against HIV/AIDS, hepatitis C cures, and breakthrough cancer medicines are some of the many treatments discovered by pharmaceutical companies that have helped us achieve significant progress in healthcare.

## BUT WHAT DRIVES PHARMACEUTICAL INNOVATION ?

How do we make the link between fundamental science and a medicine or vaccine that will deliver better health?

EU leaders are at the source of the legislation that supports the long pathway between a scientific discovery and the prescription filled for a patient at a pharmacy.

POLICY MAKERS PLAY  
A CRITICAL ROLE  
IN STRENGTHENING  
THE EU LEADERSHIP  
IN PHARMACEUTICAL  
INNOVATION



<sup>1</sup> Frank R. Lichtenberg, [The Impact of New Drug Launches on Longevity: Evidence from Longitudinal Disease-Level Data from 52 Countries, 1982–2001](#). International Journal of Health Care Finance and Economics, 2005.



# PHARMACEUTICAL INNOVATION POLICY



NAVIGATING A COMPLEX POLICY FRAMEWORK



# POLICY MAKERS ARE IN THE DRIVING SEAT

## THREE POLICY PILLARS



SCIENCE  
POLICY



HEALTHCARE  
POLICY



INDUSTRIAL  
POLICY

DRIVE



### Investment in Science

- Higher education
- Academic centres
- Bioclusters

### Investment in Healthcare

- Patient centered care
- Value-based pricing
- Rapid access

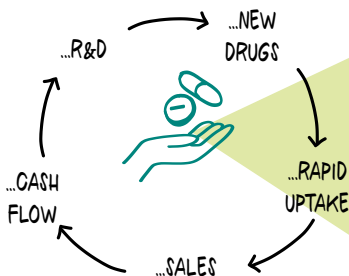
### Innovation-Friendly Policies

- Intellectual property
- Agile regulatory system
- Push/pull incentives

RESULTING IN

NEW TREATMENTS

POLICY OUTCOMES



- BETTER HEALTH
- SUSTAINABLE HEALTH SYSTEMS
- HIGHER PRODUCTIVITY
- ECONOMIC GROWTH AND JOBS





## REGAINING EU GLOBAL LEADERSHIP

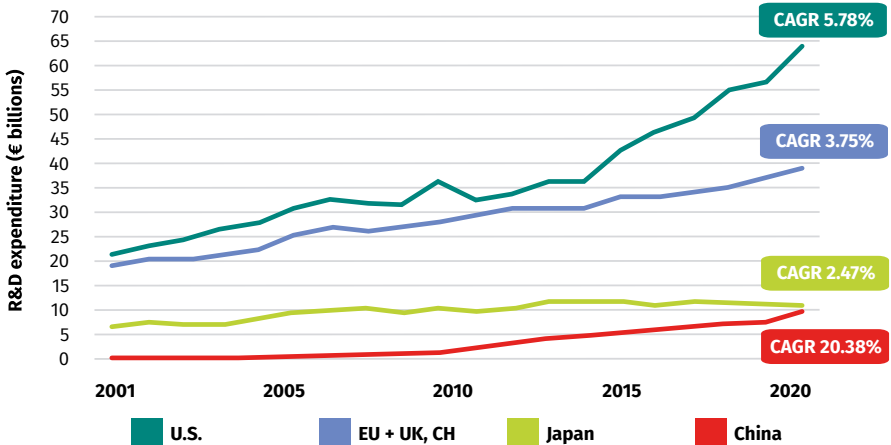
The research-based pharmaceutical industry is one of the leading high-tech sectors in Europe.<sup>1</sup> While it remains a leading source of new medicines and vaccines globally, Europe has been losing ground against its main competitors. Twenty years ago, the amount of investment made by pharmaceutical companies in R&D in the US and Europe differed by only €2 billion. By 2020, pharmaceutical companies' R&D investment in the US exceeded the amount spent in Europe by almost €25 billion.<sup>2</sup>

As a knowledge-based economy, Europe can regain its global leadership, provided that we continue to invest in science and in healthcare, and maintain a competitive incentive framework.

**INVESTING IN RESEARCH AND INNOVATION IS INCREASINGLY CRUCIAL FOR SHAPING A BETTER EUROPEAN FUTURE IN A RAPIDLY GLOBALISING WORLD, WHERE SUCCESS DEPENDS EVER MORE ON THE PRODUCTION AND CONVERSION OF KNOWLEDGE INTO INNOVATION.**

Pascal Lamy, [Investing in the European future we want](#), Report of the High Level Group on EU Research & Innovation Programmes, 2017.

### LOCATION OF PHARMACEUTICAL COMPANIES' R&D EXPENDITURE 2001-2020



\*CAGR (Compound Annual Growth Rate) is the average rate of growth across a number of years

Source: Charles River Associates, [Factors affecting the location of biopharmaceutical investments and implications for European policy priorities](#), Figure 1, November 2022.

1 EFPIA, [The Pharmaceutical Industry in Figures - Key Data 2023](#).

2 EFPIA, [Europe's share of global medicines R&D shrinks by a quarter in 20 years – as sector's declining trends continue](#), 7 November 2022.





## R&D IMPROVES LIVES

Since 1950, more than 1,800 new drugs have been approved.<sup>1</sup> This wave of innovation has played a key role in the steady increase in life expectancy.

In the last decades, innovative medicines are estimated to have contributed up to 73% of the increase in life expectancy at birth after accounting for other factors.<sup>2</sup>

Over decades, research-based pharmaceutical companies have developed innovative medicines and vaccines across a broad range of diseases representing most of the burden of disease (cardiovascular, cancer, HIV/AIDS, diabetes, etc.)

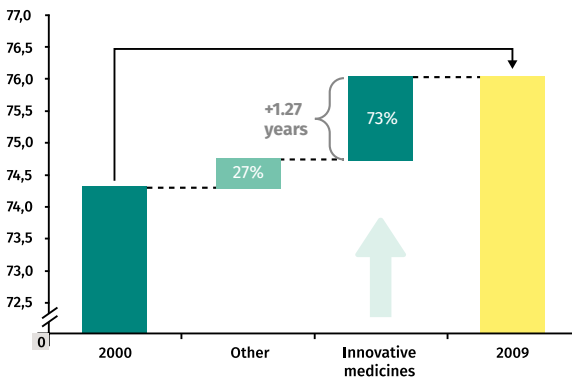
For example, the 5-year survival rate of metastatic skin cancer went from less than 5% to over 50% thanks to innovative treatments.<sup>3</sup>

Pharmaceutical innovation also brings additional health benefits by releasing other healthcare resources - e.g., HIV/AIDS treatments freeing up hospital wards, hepatitis C cures lowering the need for liver transplants or HPV vaccination preventing cervical cancer.

**LONGER LIFE THROUGH NEW MEDICAL INNOVATION IS THE LAST CENTURY'S GREATEST GIFT.**

Nobel Prize-winning economist Gary Becker.

### CONTRIBUTION OF INNOVATIVE MEDICINES TO INCREASE IN LIFE EXPECTANCY



*“Pharmaceutical innovation increased life expectancy by 1.27 years during 2000-2009.”*

Prof. Frank Lichtenberg

Source: Lichtenberg F, [Pharmaceutical innovation and longevity growth in 30 developing OECD and high-income countries 2000–2009](#), Health Policy & Technology, 2012.

- 1 Kinch et al., [An Overview of FDA-Approved New Molecular Entities \(NMEs\): 1827–2013](#), Drug Discovery Today, 2014. Updated with FDA CDER, New Drug Therapy Approvals 2022, January 2023.
- 2 See Frank Lichtenberg’s papers: (a) [The Impact of New Drug Launches on Longevity: Evidence from 52 Countries, 1982–2001](#), International Journal of Health Care Finance and Economics, 2005; (b) [Pharmaceutical innovation and longevity growth in 30 developing OECD and high-income countries 2000–2009](#), Health Policy & Technology, 2012; (c) [The effect of pharmaceutical innovation on longevity: Evidence from the US and 26 high-income countries](#), Economics & Human Biol., 2022.
- 3 European Society of Medical Oncology, [One in Two Patients with Metastatic Melanoma Alive after Five Years with Combination Immunotherapy](#), 28 Sep 2019.



# R&D PROMOTES GROWTH

**Over 2.5 million jobs are supported by the pharmaceutical sector in Europe both directly and indirectly.<sup>1,2</sup>**

In 2021, pharmaceutical companies invested an estimated €41.5 billion in R&D in Europe, making it the sector with the highest ratio of R&D investment to net sales in the EU – about 46% above the ICT sector, which ranks second.<sup>1</sup>

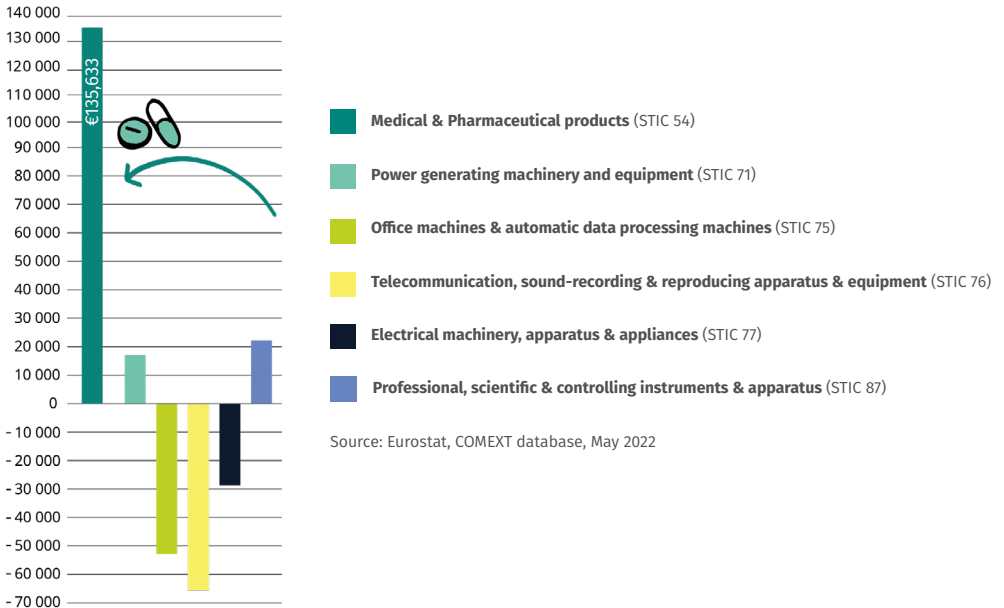
According to EUROSTAT, the pharmaceutical industry is the high-tech sector with the highest added value per employee, and contributed €136 billion to the EU trade surplus in 2021.<sup>2</sup>

**THE TRADE SURPLUS IN PHARMACEUTICAL AND MEDICINAL PRODUCTS GREW FROM €18 BILLION IN 2002 TO A RECORD HIGH OF €136 BILLION IN 2021.**

EUROSTAT, International trade in medicinal and pharmaceutical products, Data from March 2022.<sup>3</sup>

## EU-27 TRADE BALANCE – HIGH TECHNOLOGY SECTORS

€ Million – 2021



Source: Eurostat, COMEXT database, May 2022

1 PwC/EFPIA, Economic and societal footprint of the pharmaceutical industry in Europe, June 2019.  
 2 EFPIA, The Pharmaceutical Industry in Figures – Key Data 2022.  
 3 According to updated EUROSTAT data, “the EU’s trade surplus in medicinal and pharmaceutical products reached €175 billion in 2022.”

# THE SOURCE OF INNOVATION

*Over the course of 25 years,  
the field of viral hepatitis advanced  
from discovery of the virus to  
the beginning of the curative era  
for HCV infection.*

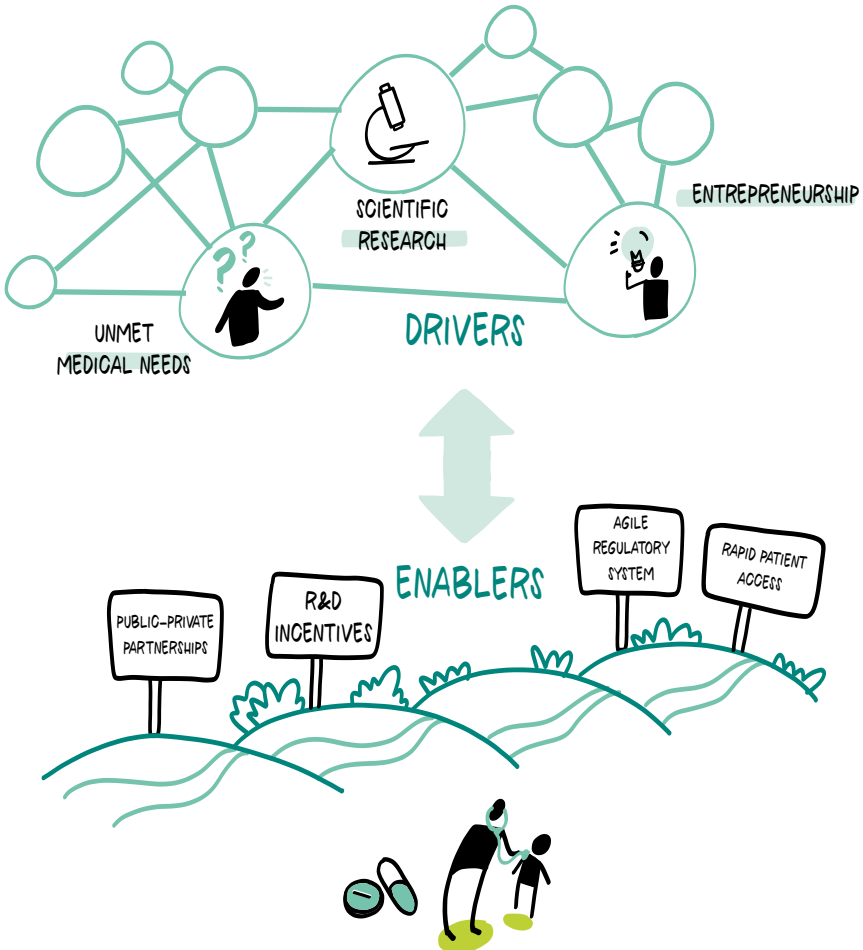
John Ward, Hepatitis C virus: [The 25-year journey  
from discovery to cure](#), *Hepatology*, August 2014.



# WHAT DRIVES PHARMACEUTICAL INNOVATION?

Pharmaceutical innovation is at the junction of **scientific advances**, **unmet medical needs**, and **entrepreneurship**.

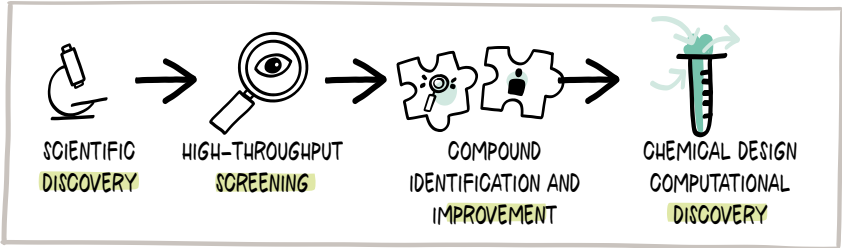
These drivers are shaped by governments through strong enablers, such as intellectual property rights (to secure capital to conduct R&D), and healthcare systems (to ensure uptake of new treatments). This policy mix allows companies to engage in high-risk and high-cost research and development activities.





# THE LONG ROAD FROM BENCH TO BEDSIDE

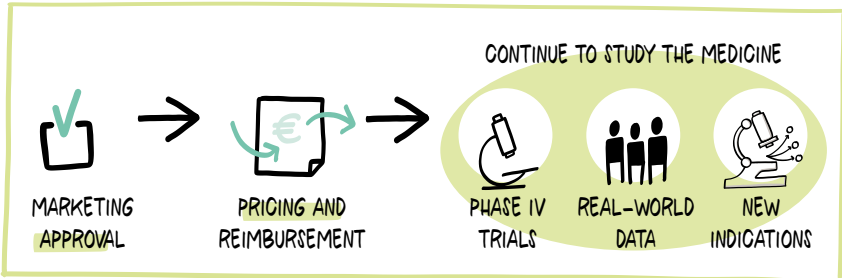
## RESEARCH



## DEVELOPMENT



## APPROVAL



## AND ALL THIS TAKES ON AVERAGE



**10-15 YEARS** AND COSTS ABOUT



**€2.13 BILLION**

USD 2.6b converted from USD at August 2023 rate

DiMasi J., Gabrowski H., Hansen R., *Innovation in the pharmaceutical industry: new estimates of R&D costs.* J Health Economics, 2016.



## FROM THEORY TO THERAPY

**From a scientific paper to a medicine that saves lives, public and private research laboratories play a complementary role in a series of increasingly expensive bets spanning several decades.<sup>1</sup>**

First comes the science. To develop a new treatment, we need to understand human biology and disease mechanisms. Once we have a working theory, we enter into the realm of applied research to translate scientific insights into new medicines. This is where scientific papers are put to the test - starting with trying to replicate their findings. The journey from hypothesis to a novel therapy requires major involvement of industry, as it possesses the expertise and resources unavailable in academia.<sup>2</sup>

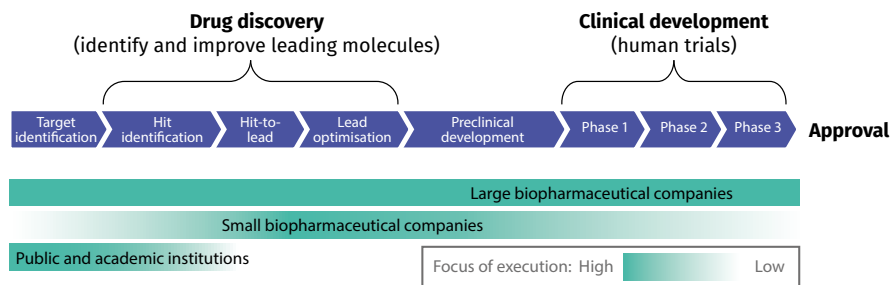
We can debate endlessly which is more important between basic and applied research. But when it comes to drug development, we need both. We will never treat people with a scientific paper, and we cannot look for a therapy without understanding the disease.

**OUR STUDY SHOWED THAT 23,230 NIH GRANTS MADE IN 2000 WERE LINKED TO 18 APPROVED MEDICINES BY 2020. TOTAL PRIVATE INVESTMENT FOR THE 18 APPROVED MEDICINES WAS US\$44.2 BILLION COMPARED TO US\$670 MILLION IN NIH FUNDING.**

Vital Transformation, [Who Develops Medicines? An Analysis of NIH Grants](#), May 2021.

Basic and applied research are complementary and also inform each other. Drug development operates at the frontier of our scientific knowledge. The repeated failures in the last decade of promising compounds against Alzheimer's disease have provided important insights in the amyloid hypothesis on which these R&D programmes were based.

PHARMA COMPANIES DO MOST OF THE RESEARCH TO TRANSLATE BASIC SCIENCE INTO NEW MEDICINES.<sup>2</sup>



Source: LEK, Rand Europe & SIRM, [The financial ecosystem of pharmaceutical R&D](#), February 2022.

<sup>1</sup> For an illustration, see Dolin E., [The tangled history of mRNA vaccines](#), Nature, 14 September 2021.

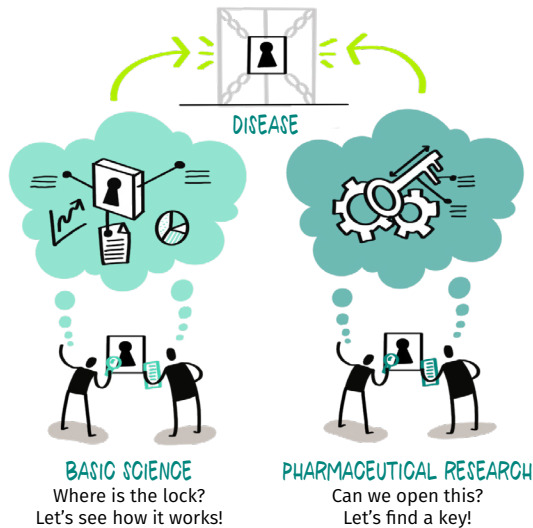
<sup>2</sup> Flier J., [Academia and industry: allocating credit for discovery and development of new therapies](#), Journal of Clinical Investigation, 20 May 2019.



# PUBLIC AND PRIVATE RESEARCH ARE COMPLEMENTARY

Let's use an analogy: if disease is like a closed door, basic research is focused on finding the lock that opens the door, and then describes how it works in scientific publications. Once we have a working theory, private sector starts searching for a key that could safely open the door, ie, a therapeutic that patients can use.

In practice, pharmaceutical companies also conduct basic research. They also assess if published research can be replicated to check if this is really “the lock that will open the door.” This is an important step before engaging in costly R&D, considering that “a majority of published findings could not be reproduced.”<sup>1</sup>



**FROM 2013 TO 2019, WE FOUND THAT BIOPHARMACEUTICAL R&D EXPENDITURE BY THE PRIVATE SECTOR ACROSS COUNTRIES IS ON AVERAGE 82% GREATER THAN PUBLIC SECTOR SPENDING.**

Charles River Associates, The Roles and Synergies of Public and Private Investment in European Medicines Research and Development, 2023 (publication pending).

For more on the role of public and private sector, please see Derek Lowe, [Where Drugs Come From: A Comprehensive Look](#), Science, May 2019, and Jeffrey S. Flier, [Academia and industry: allocating credit for discovery and development of new therapies](#), J Clin Invest., 2019.

<sup>1</sup> Kannt A., Wieland T., [Managing risks in drug discovery: reproducibility of published findings](#), Naunyn-Schmiedeberg's Arch Pharmacol, 2016.

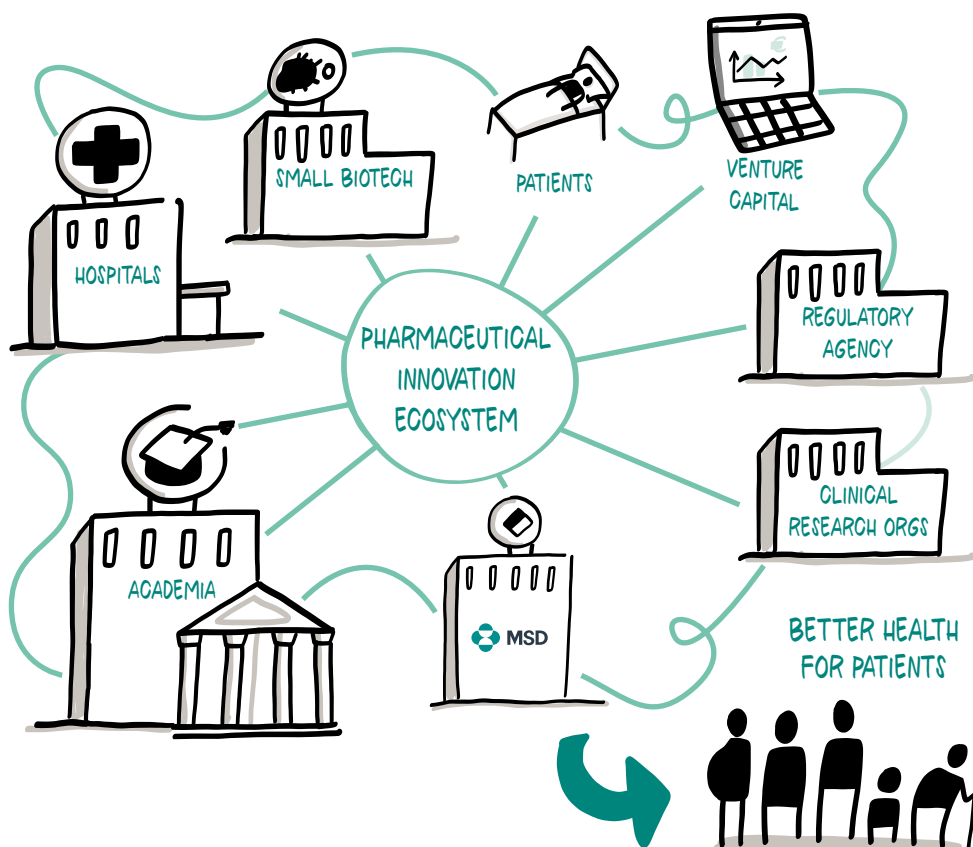


## IT TAKES A VILLAGE

**Pharmaceutical innovation takes place in a complex ecosystem with numerous actors from both public and private sectors.**

Through pro-innovation policies, the EU and national governments support the collective effort to turn science into new medicines. There is a long list of actors and stakeholders including health authorities, regulators, universities, industry labs, physicians, pharmacists, patients, hospitals, and many more.

**MANY ACTORS PARTICIPATE  
IN DRUG DEVELOPMENT**







## WE DON'T REST

**Over decades, pharmaceutical companies have relentlessly innovated to address unmet medical needs.**

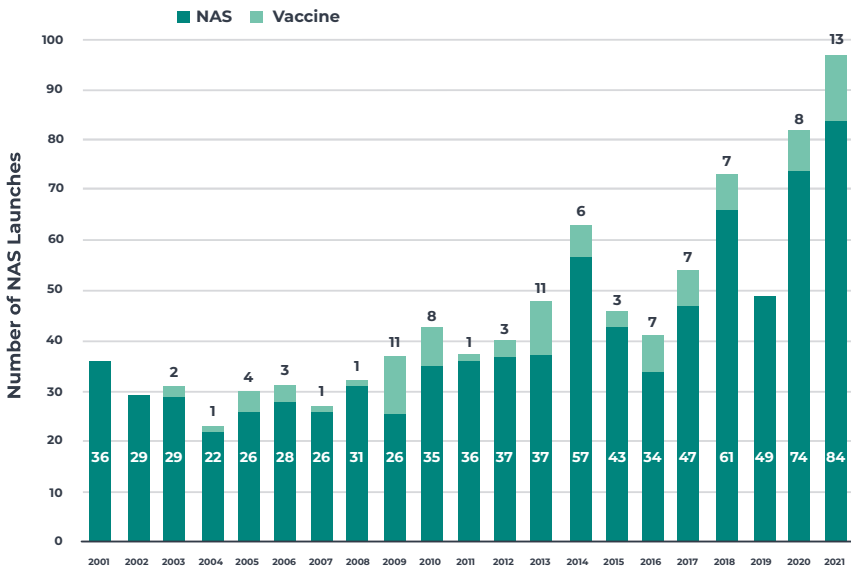
In 2021, pharmaceutical companies have launched globally a record number of 97 new active substances and vaccines. 'New active substance' refers to any new chemical or biological entity that had received no prior approval.

This was a record year, and historical figures show an average rate of 43 new treatments and vaccines launched every year since the start of the millennium.

This achievement is quite spectacular, since R&D costs have continued to rise during the last 15 years due to the increasing complexity of scientific challenges and increased regulatory requirements.<sup>1</sup>

### 944 INNOVATIVE MEDICINES AND VACCINES LAUNCHED SINCE 2001

Number of new active substances (NAS) and vaccines launched per year



Source: Pharmaproject®, [Pharma R&D Annual Review 2022 Supplement](#), February 2022.

<sup>1</sup> DiMasi J., Gabrowski H., Hansen R., [Innovation in the pharmaceutical industry: new estimates of R&D costs](#). J Health Economics, 2016.

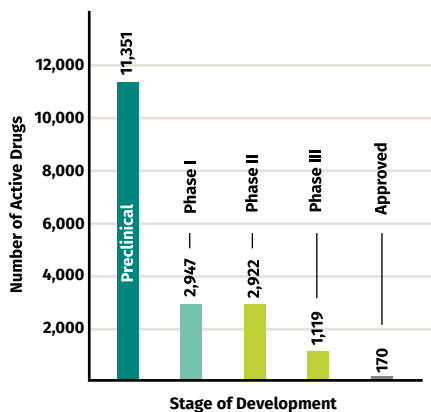


## A RISKY BUSINESS

**Drug development is a long and high-risk endeavour that requires significant capital investment. On average, the development of a new medicine takes 10 to 15 years and costs €2.13 billion.<sup>1</sup>**

To put this into perspective, it took almost 25 years between the discovery of the hepatitis C virus and the development of safe, tolerable, and once-daily treatments that deliver over 95% cure rates.<sup>2</sup>

### R&D PIPELINE BY PHASE IN 2022



Source: Citeline Pharma Intelligence, [Pharma R&D Annual Review 2022: Navigating the Landscape](#).

A defining feature of drug development is the significant failure rate. Even after years of discovery efforts (preclinical stage), only one out of ten drug candidates that gets tested in clinical trials (phases I to III) achieves marketing approval.<sup>3</sup> Failure rates can be as high as 95% in oncology<sup>3</sup> or 98% in Alzheimer's disease.<sup>4</sup>

Pharmaceutical R&D is indeed a risky business. Most R&D investments don't go into the few molecules that make it to the market, but on the many molecules that fail.<sup>5</sup>

**WE FOUND THAT APPROXIMATELY ONE IN TEN (10.4%, N = 5,820) OF ALL INDICATION DEVELOPMENT PATHS IN PHASE 1 WERE APPROVED BY FDA.**

Hay et al., [Clinical development success rates for investigational drugs](#), Nature Biotechnology, 2014.

1 DiMasi J., Gabrowski H., Hansen R., [Innovation in the pharmaceutical industry: new estimates of R&D costs](#). J Health Economics, 2016.

2 Burstow et al., [Hepatitis C treatment: where are we now?](#), Int J Gen Med., 2017.

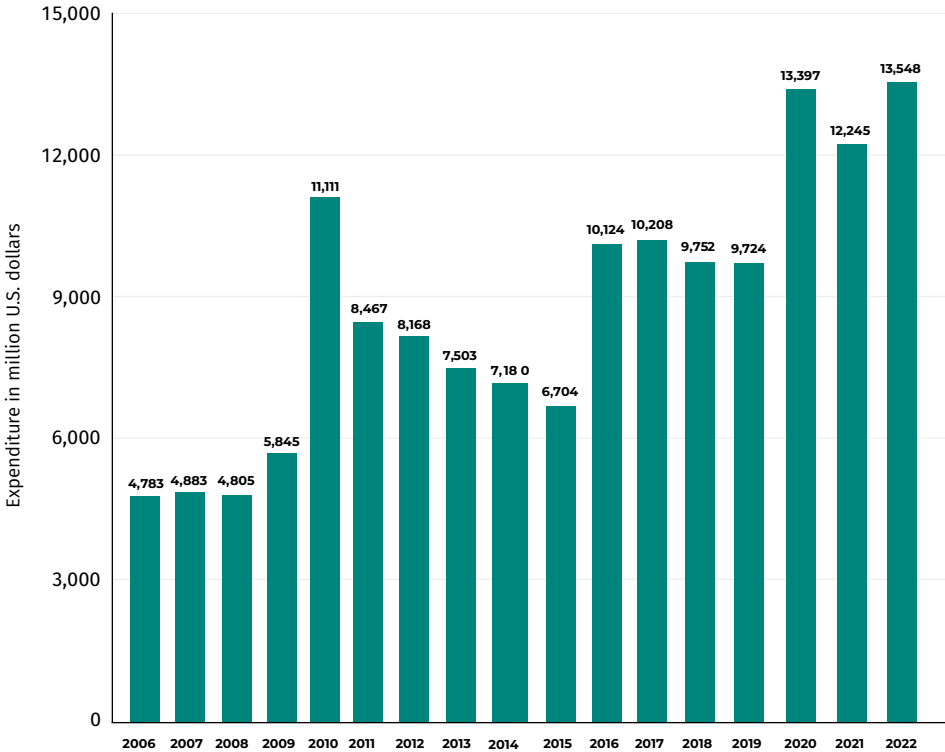
3 Mullard A., [Parsing clinical success rates](#), Nature Review Drug Discovery, 2016.

4 PhRMA, [Researching Alzheimer's Medicines - Setbacks and Stepping Stones](#), 3 June 2021.

5 Kannt A. and Wieland T., [Managing risks in drug discovery: reproducibility of published findings](#), Naunyn Schmiedebergs Arch Pharmacol, 2016.



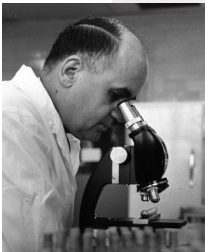
## MSD'S EXPENDITURE ON R&D FROM 2006 TO 2022



Source: [MSD's expenditure on research and development from 2006 to 2022](#), Statista, 8 March 2023. Data extracted from MSD Forms 10-K. 2010 numbers represent MSD/Schering-Plough merger.



### Did you know?



Dr Maurice Hilleman led MSD's Department of Virus and Cell Biology from 1957 to 1984. **Throughout his career, he helped develop more than 40 vaccines**, including against measles, mumps, hepatitis A and B, chickenpox, meningitis, and pneumonia. *"His outstanding scientific endeavours led to vaccines that saved millions of lives, extended human life expectancy, and improved the economies of numerous countries."*

Source: Tulchinsky TH., [Maurice Hilleman: Creator of Vaccines That Changed the World. Case Studies in Public Health](#). 2018.



# THE CRITICAL ROLE OF INCENTIVES

**Intellectual property rights enable innovative companies to raise capital and make the significant R&D investments required to develop new medicines.**

Fundamentally, when inventing a new treatment, pharmaceutical companies discover the properties of a chemical or biological product in humans and demonstrate that it can treat a disease at a particular dose. In that sense, a medicine encapsulates a large amount of scientific and medical knowledge.

This “knowledge-in-a-pill” is extremely expensive to develop, but at the same time easy to replicate once it has been discovered: patents are published, and clinical evidence is presented at conferences and in scientific papers.

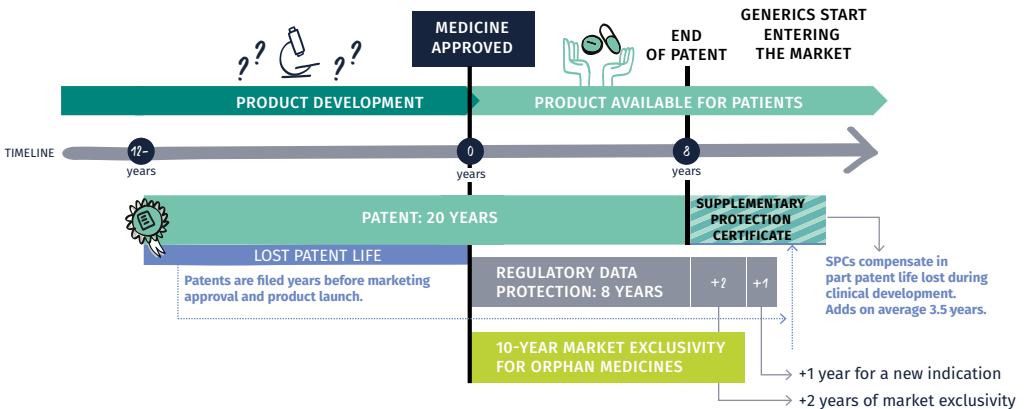
Intellectual property (IP) rights provide some degree of certainty to research-based companies that, for a limited period, they can benefit from their R&D investments.

Weakening incentives may marginally improve access – which in fact depends on many other factors beyond IP rights.<sup>1</sup> However, it will primarily disincentivise investments in drug development resulting in less innovation for patients. Nobody can access let alone afford a treatment that has not been invented.

## THE AVERAGE EFFECTIVE PROTECTION PERIOD HAS DECREASED BY ABOUT TWO YEARS FROM 15 TO 13 YEARS SINCE 1996

Copenhagen Economics, [Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe](#), May 2018.

## DIFFERENT TYPES OF INCENTIVES ARE REQUIRED TO DRIVE INNOVATION FOR DIFFERENT PATIENTS\*



\* Based on EU legislation before reform of general pharmaceutical legislation launched in 2023.

1 EFPIA, [The root cause of unavailability and delay to innovative medicines: Reducing the time before patients have access to innovative medicines](#), April 2022.



**Intellectual property is a key driver of medical innovation. Europe's incentive framework enables investment into tomorrow's treatments.<sup>1</sup>**

**PATENTS**

- 20-year exclusivity term
- Filed years before regulatory approval
- Publication of the invention 18 months after application

**Publication ensures that other inventors can benefit from state of the art and push their research further.**

**SUPPLEMENTARY PROTECTION CERTIFICATE**

- From 0 to 5 years
- Same exclusivity as patent + SPC capped at maximum 15 years after regulatory approval

**Average duration of SPCs is 3.5 years (Copenhagen Economics, 2018).**

**REGULATORY DATA PROTECTION**

- 8 years of data exclusivity (generic companies can't rely on clinical data for EMA approval) +2 years of market exclusivity (no generic on the market) +1 year if new indication is developed

**Protects investment to generate pre-clinical and clinical data required for regulatory approval.**

**ORPHAN DESIGNATION**

- 10-year market exclusivity linked to one specific orphan designation
- Incentivise companies to research and develop medicines for rare diseases

**Market exclusivity does not prevent similar products to be authorised if they prove significant benefit.**

**PAEDIATRIC EXTENSION**

- 6-month SPC extension or 2-year extension of orphan market exclusivity
- Requires companies to do clinical trials to test safety and efficacy of a medicine for children

**Completion of a Paediatric Investigation Plan is mandatory.**

## NO PATENTS NO MEDICINES, INCLUDING GENERICS

<sup>1</sup> EFPIA, [Intellectual Property](#). Accessed 30 August 20223.



## FUTURE-PROOFING DRUG APPROVAL

**The way regulatory authorities approach clinical evidence will either act as a brake or as an accelerator in our ability to bring new treatments to patients.**

Much of the focus of European policy makers has been on improving access for patients at the point of care. But this can only happen if innovative medicines are approved for marketing.

Regulatory approval processes need to be fit for purpose as science and technology evolve. This includes new ways to produce and collect clinical data, or being able to assess drug-device combinations, among others.

Despite recent convergence in approval times, the EU still lags behind other leading agencies. In 2020, the median approval time was 244 days in the US, 313 days in Japan, and 426 days in the EU.<sup>1</sup>

Europe should increase the resources of the European Medicines Agency and design a world-class regulatory system that embraces scientific and technological advances in order to accelerate patient access to innovative products.

### POLICY PRIORITIES TO RENEW EUROPE'S GLOBAL LEADERSHIP IN REGULATORY SCIENCE AND PRACTICES.

REAL WORLD  
DATA & EVIDENCE

DYNAMIC  
REGULATORY  
ASSESSMENT

DRUG-DEVICE  
COMBINATION  
& BIOMARKER  
VALIDATION

INNOVATIVE  
CLINICAL TRIAL  
APPROACHES

**THE PACE OF INNOVATION HAS ACCELERATED DRAMATICALLY IN RECENT YEARS AND REGULATORS NEED TO BE READY TO SUPPORT THE DEVELOPMENT OF INCREASINGLY COMPLEX MEDICINES THAT MORE AND MORE DELIVER HEALTHCARE SOLUTIONS BY CONVERGING DIFFERENT TECHNOLOGIES.**

European Medicines Agency, [Regulatory Science to 2025 – Strategic reflection](#), December 2018.

<sup>1</sup> Centre for Innovation in Regulatory Science, [New drug approvals in six major authorities 2011-2020: Focus on Facilitated Regulatory Pathways and Worksharing](#), 2021.



# AGILE REGULATORY PROCESS

## Learning from our response to the COVID-19 pandemic.

COVID-19 pushed regulators to work differently. Faced with a pandemic, they streamlined their review process by introducing rolling reviews thus saving valuable time. This was critical in ensuring the rapid approval and deployment of vaccines and therapeutics against COVID-19.<sup>1</sup>

The regulatory flexibilities introduced during the pandemic have value beyond COVID-19. Driven by digitalisation, innovations in regulatory process (eg, rolling reviews, flexible

Scientific Advice) “improved the process and outcomes measurably.”<sup>1</sup>

Taking stock of the lessons from COVID-19, the head of the European Medicines Agency has called for “a more agile and expertise-based system.”<sup>2</sup>

## THE REVISION OF THE EU'S PHARMACEUTICAL LEGISLATION OFFERS OPPORTUNITY TO LEVERAGE EXPERIENCE GAINED FROM COVID-19 FOR STREAMLINING REGULATORY PROCESSES.

EFPIA, [How Regulation Can Boost the EU Innovation?](#), 23 February 2023.



### GENERALISE ROLLING REVIEWS

to ensure seamless communication between companies and regulators

### TAILOR ASSESSMENT PROCESS TO EACH PRODUCT CHARACTERISTICS

by focusing questions on critical issues and involving appropriate experts

**IMPLEMENT ELECTRONIC PRODUCT INFORMATION** and common EU packs

**ALIGN VARIATION PROCEDURES WITH INTERNATIONAL STANDARDS** such as ICH Q12

**SHORTEN THE 67 DAYS IT TAKES** for the Commission to issue a marketing authorisation

1 Klein et al., [Regulatory Flexibilities and Guidances for Addressing the Challenges of COVID-19 in the EU: What Can We Learn from Company Experiences?](#) Ther Innov Regul Sci., March 2022.

2 Emer Cooke, Executive Director of the European Medicines Agency, [A future-proof EU regulatory framework – key challenges to be addressed](#), 7 February 2023.

# VALUE OF INNOVATION

*IMF sees cost of COVID pandemic rising beyond \$12.5 trillion estimate.*

Reuters, January 20, 2022





## ‘INNOVATION’ IS WHAT HELPS THE PATIENT

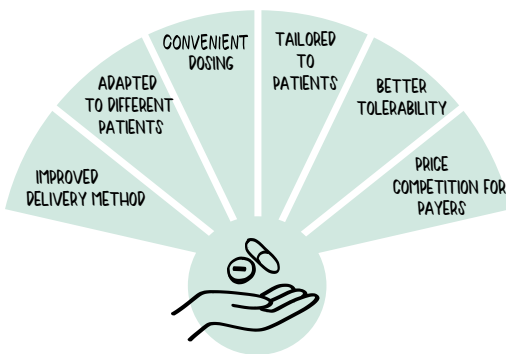
**Like science, technology progresses through incremental steps. Patients, doctors, and payers all benefit from these innovations through greater choice and competition across and within therapeutic classes.**

Everybody likes to talk about “major breakthroughs” when it comes to pharmaceutical innovation, and critics are quick to downplay “incremental innovation”, even talking about “me-too” drugs. But patients are different and don’t respond similarly to a treatment. Pharmaceutical innovation is about getting better products that help all patients, thus delivering effective patient-centred healthcare.

Patients, doctors and payers all benefit from improved treatments, be that in the form of improved drug regimens, less side effects, better tolerability, or ease of use, among others. The patients and their doctors who are helped by these novel treatments welcome such improvements.<sup>1</sup>

The innovation cycle is driven by competition. Companies race in parallel to develop innovative medicines. They strive to come first to market, but “first” is not necessarily “best”. Not all patients respond the same to a given treatment, and some clinical trials may take longer to complete. Over years of R&D and multiple waves of innovation, new treatments emerge supported by new clinical data and evidence, bringing greater choice for patients and prescribers, and greater competition for payers.

### INNOVATION IS IN THE EYE OF THE BEHOLDER



**IF I HAVE SEEN A LITTLE FURTHER IT IS BY STANDING ON THE SHOULDERS OF GIANTS.**

Isaac Newton, Letter to Robert Hooke, 1676.

Adapted from Globerman, S., Lybecker K., [The Benefits of Incremental Innovation: Focus on the Pharmaceutical Industry](#), Fraser Institute, 2014.

<sup>1</sup> Thomas Allvin, [On innovation, patient-centricity and added value](#), EFPIA, 18 Sept. 2019.



# PREVENTION IS BETTER THAN CURE

**According to the WHO, “Vaccines have saved more human lives than any other medical invention in history.”<sup>1</sup> More than 20 life-threatening diseases can now be prevented by vaccines. WHO estimates that immunisation prevents 3.5-5 million deaths every year.<sup>2</sup>**

Immunisation campaigns are one of the most cost-effective healthcare interventions. Vaccines protect individuals and the society as a whole, including those who cannot receive it because of age or existing medical conditions. Life-course vaccination also generates billions in savings by preventing the economic impact of lost productivity due to illness.

Global warming is creating more favourable conditions for mosquito-borne infectious diseases. This will call for surveillance and new preventative methods, including vaccines.

**VACCINES REMAIN OUR BEST TOOL TO KEEP EU CITIZENS SAFE AND PROTECT OUR NATIONAL HEALTHCARE SYSTEMS AND ECONOMIES.**

*Opening Remarks* by Commissioner Stella Kyriakides at the EPSCO Council, 9 Dec. 2022.

HPV vaccination in Sweden led to almost **90% reduction in cervical cancer** incidence.<sup>3</sup>

Measles vaccination **averted 56 million deaths** between 2000 and 2021.<sup>4</sup>

**VACCINATION IS AN INVESTMENT FOR LIFE**

Two-thirds of EU countries spend **less than 0,5%** of their health budget on immunisation.<sup>5</sup>

**€1 invested** in shingles, HPV, and pneumococcal vaccines **generates a return of €2.18.**<sup>5</sup>

1 WHO, [A brief history of vaccines](#).

2 WHO health topics, [Vaccines and Immunization](#). Accessed 14 May 2023.

3 Lei J, Ploner A, Elfström KM, et al., [HPV Vaccination and the Risk of Invasive Cervical Cancer](#). N Engl J Med., 2020.

4 WHO, [Fact sheet on measles](#), 20 March 2023. Accessed 16 May 2023

5 Faivre et al., [Immunization funding across 28 European countries](#), Expert Review of Vaccines, 2021.

6 Vaccines Europe, [Realising the full value of vaccination](#), 21 February 2022.



# BENDING THE CURVE OF CANCER

**Cancer care is changing fast thanks to strong political commitment at the EU level with Europe’s Beating Cancer Plan<sup>1</sup> and the launch of new treatments across more cancer types.<sup>2</sup>**

As our population is ageing, the number of cancer cases is expected to rise across Europe.<sup>3</sup> Cancer incidence increased by around 50% between 1995 and 2018 in Europe.<sup>3</sup> However, thanks to advances in screening, diagnostics, and medical treatment, the number of people dying of cancer increased much less than the number of people diagnosed with it.<sup>3</sup>

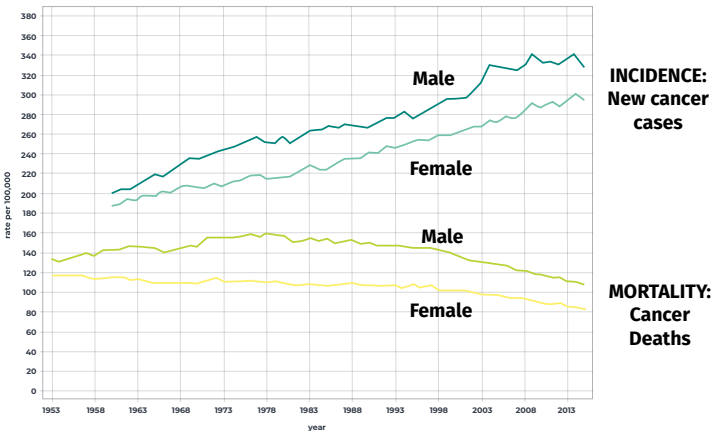
Despite increased spending on cancer medicines (driven by demographics and the ability to treat more tumour types), the overall cost of cancer care has remained stable over 20 years – representing 4-7% of total health expenditure across European countries.<sup>3</sup>

**IN EUROPE AS A WHOLE, THE SHARE OF EXPENDITURE SPENT ON CANCER IN 2018 WAS 6.2%, EQUIVALENT TO A PER-CAPITA SPENDING OF €195.**

Hofmarcher et al. IHE Comparator Report 2019.<sup>2</sup>

## BENDING THE CURVE OF CANCER

The impact of prevention, screening, diagnosis and treatment



Source: NORDCAN© Association of the Nordic Cancer Registries (04/11/2018)

- 1 [Europe’s Beating Cancer Plan: A new EU approach to prevention, treatment and care](#), 3 February 2021.
- 2 IQVIA Institute, [Global Oncology Trends 2023](#), May 2023.
- 3 Hofmarcher et al., [Comparator Report on Cancer in Europe 2019 – Disease Burden, Costs and Access to Medicines](#), Swedish Institute for Health Economics.



# OUR FIGHT AGAINST CANCER

**Oncology is now the leading therapy area in terms of R&D efforts. This is measured in number of clinical trials, share of R&D pipelines, or number of new cancer treatments being launched.**

In 2021, a record 35 oncology novel active substances were launched globally, bringing it to a total of 237 since 2003.<sup>1</sup> These medicines included significant clinical advances across a range of tumours.<sup>2</sup>

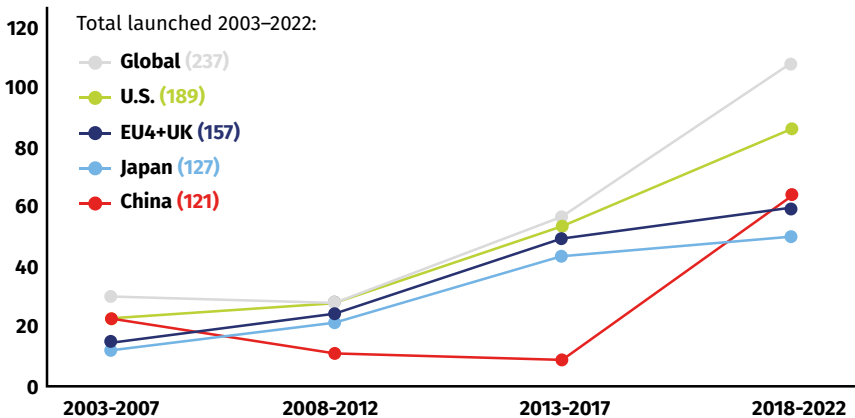
**CHINA-BASED COMPANIES ARE PLAYING AN INCREASING ROLE IN THE ONCOLOGY PIPELINE ACCOUNTING FOR 23% IN 2022, UP FROM ONLY 5% A DECADE AGO.**

IQVIA Institute, [Global Oncology Trends 2023](#).

The introduction of immunotherapy has led to marked improvements for patients with skin and lung cancer. For example, in only ten years, the 5-year metastatic skin cancer survival rate went from less than one patient in 20 to one patient in two.<sup>3</sup>

Hofmarcher et al. found that from 2005 to 2015, R&D investment in cancer research by the pharmaceutical industry grew much quicker than investments by public and private non-profit sources, “accounting for around three quarters of total funding.”<sup>2</sup>

## NUMBER OF ONCOLOGY NOVEL ACTIVE SUBSTANCES LAUNCHED GLOBALLY AND IN SELECTED COUNTRIES



Source: IQVIA Institute, [Global Oncology Trends 2023](#), April 2023.

1 IQVIA Institute, [Global Oncology Trends 2023](#).  
 2 Hofmarcher et al., [Comparator Report on Cancer in Europe 2019 – Disease Burden, Costs and Access to Medicines](#), Institute for Health Economics, October 2020.  
 3 ESMO, [One in Two Patients with Metastatic Melanoma Alive after Five Years with Combination Immunotherapy](#), 28 Sep 2019.



# ORPHAN MEDICINES FOR MILLIONS OF PATIENTS

**Orphan medicines address life-threatening or very serious conditions affecting no more than 5 in 10,000 people. Up to 36 million people in the EU live with a rare disease.<sup>1</sup>**

The introduction of new incentives, including a 10-year market exclusivity, through the Orphan Medicinal Products Regulation<sup>2</sup> in 2000 led to the development of more than 200 products serving the needs of millions of patients<sup>3</sup> with previously unavailable treatment options.<sup>5</sup>

Developing treatments for rare diseases is extremely challenging. There are thousands of rare diseases, most of which affect a very small number of patients – about 90% of rare

diseases affect about 12% of rare disease patients. The smaller the patient population the more difficult it is to conduct clinical trials. They require more hospital sites in more countries and take longer to enroll a sufficient number of patients to produce meaningful statistical evidence. In addition, scientific knowledge about many of these diseases is limited or even lacking.

There is still a high unmet medical need in rare diseases. It is thus critical that we continue to invest in basic science and incentivise R&D investments in rare diseases by maintaining a robust regulatory and incentives framework.<sup>4</sup>

## SINCE YEAR 2000<sup>4</sup>



**2,552 ORPHAN DESIGNATIONS**



**207 ORPHAN MEDICINES AUTHORISED**

**THE EU REGULATION ON ORPHAN MEDICINAL PRODUCTS CONTINUES TO BE A SUCCESS IN FULFILLING ITS PRIMARY PURPOSE - TO ATTRACT INVESTMENT TO THE DEVELOPMENT OF THERAPIES FOR LIFE-THREATENING OR DEBILITATING DISEASES FOR MILLIONS OF PEOPLE WHO TODAY HAVE EITHER NO TREATMENT AT ALL OR NO SATISFACTORY TREATMENT.**

EURORDIS Rare Disease Europe, [Breaking the Access Deadlock to Leave No One Behind](#), January 2018.

- 1 [European Commission Expert Group on Public Health, Rare diseases](#). Accessed 10 May 2023.
- 2 [Regulation \(EC\) No 141/2000 of 16 December 1999 on orphan medicinal products](#).
- 3 European Commission [Staff Working Document - Evaluation of Regulation \(EC\) No 141/2000](#), 11 August 2020, and [orphan medicinal products](#) webpage, accessed 26 September 2023.
- 4 European Medicines Agency, [Annual report on the use of the special contribution for orphan medicinal products](#), March 2022.
- 5 Charles River Associates, [An evaluation of the economic and societal impact of the orphan medicine regulation](#), November 2017.



## VALUE FOR MONEY

### Pharmaceutical innovation delivers outstanding value for money.

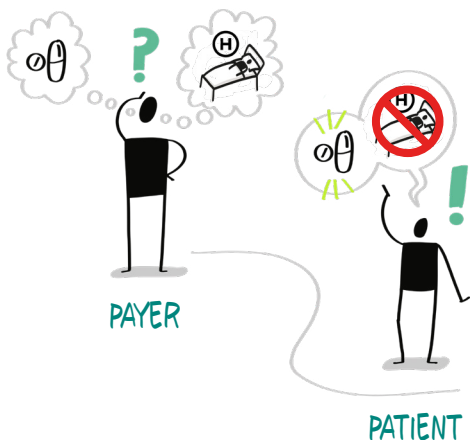
Many more people are alive today, living longer and have more productive lives thanks to new medicines and vaccines now available across a broad range of diseases. Among many examples, we can cite the 94% reduction in age-standardised death rates from HIV since 1991 in France; the 95% of the 15 million Europeans living with Hepatitis C who now can be cured; or the 27,000 cervical cancer cases and 12,000 deaths that can be prevented each year thanks to HPV vaccination.<sup>1</sup>

Medicines can also generate savings to health systems. First by reducing or delaying use of more expensive services (eg, hospitalisation, see page “Money Well Spent”). But also by simply being used as prescribed: the OECD estimates that non-adherence to treatment generates a loss of €125 billion in European countries.<sup>2</sup>

Beyond their value for patients and health systems, innovative medicines also deliver substantial social and economic benefits to our societies<sup>3</sup>. The global pharmaceutical industry directly contributed US\$532 billion of gross value added to the world’s GDP in 2017 – an amount equivalent to the GDP of the Netherlands.<sup>4</sup>

**MEDICINES HAVE DELIVERED TREMENDOUS PROGRESS IN RECENT DECADES. THEY HAVE IMPROVED SURVIVAL AND QUALITY OF LIFE FOR MANY PATIENTS AND CHANGED THE COURSE OF DISEASES SUCH AS HIV, CERTAIN CANCERS AND MORE RECENTLY, HEPATITIS C.**

OECD, Pharmaceutical Innovation and Access to Medicines, 2018.<sup>2</sup>



1 EFPIA, *Value of Medicines*, 2022.

2 OECD Health Policy Studies, *Pharmaceutical Innovation and Access to Medicines*, 2018.

3 Jenner A., *Pharma innovation – giving value for value received*, 2 April 2014.

4 Ostwald et al., *The Global Economic Impact of the Pharmaceutical Industry*, WifOR, September 2020.



# HEALTHY ANIMALS MAKE FOR HEALTHY PEOPLE

**Ensuring the health of animals is also vital to safeguarding the health of people.**

Healthy animals mean a sustainable food supply, protection for humans against diseases passed from animals, and longer, healthier lives for pets. That's why we are committed to the One Health approach.

Disease prevention promotes the health and well-being of both farm and companion animals and prevents suffering. Animal vaccines and other treatments such as parasiticides, not only maintain high standards of animal health and well-being,

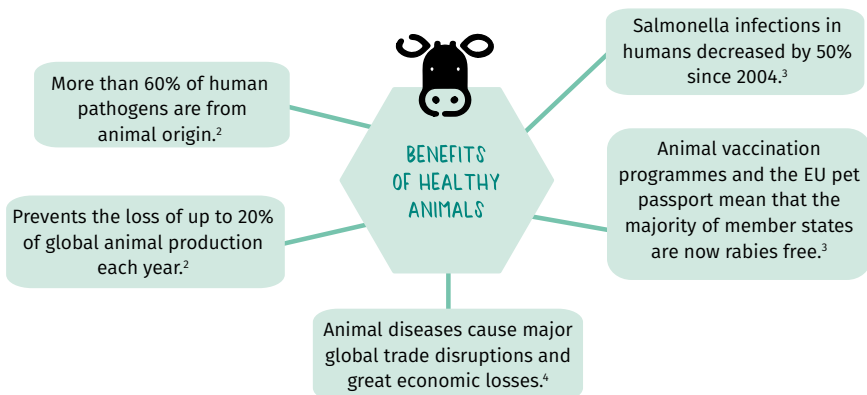
but they also help to protect consumers from harmful food-borne pathogens or zoonotic agents that can come from farm animals.

In addition to prevention and treatments, MSD provides data-driven solutions that empower farmers and veterinarians to safeguard animals' health and secure a healthy food supply.

**ANIMAL VACCINATION IS NEEDED TO KEEP ANIMALS HEALTHY. THIS IS AN IMPORTANT PART OF THE ONE HEALTH APPROACH. PREVENTION IS BETTER THAN CURE!**

Vytis Andriukaitis, European Commissioner for Public Health, 20 April 2018.<sup>1</sup>

## FROM FARM TO FORK ANIMAL HEALTH MATTERS FOR EVERYONE



<sup>1</sup> [https://twitter.com/V\\_Andriukaitis/status/987260364579594240](https://twitter.com/V_Andriukaitis/status/987260364579594240).

<sup>2</sup> Rahman et al., *Zoonotic Diseases: Etiology, Impact, and Control*, Microorganisms, 2020.

<sup>3</sup> *Animal Health Europe Manifesto*, 2019.

<sup>4</sup> Jonathan Rushton and Will Gilbert, *The economics of animal health: Direct and indirect costs of animal disease outbreaks*, WOA 84th general session, May 2016.

# HEALTH COSTS

*The health and wealth of a nation are fundamentally linked. Healthier populations live longer, more productive lives, leading to greater economic prosperity.*

The Lancet, [Editorial](#), 16 March 2019





## WHY DO HEALTH COSTS INCREASE?

**Healthcare costs have been on a rising trajectory for decades. Ageing populations and rising prevalence of non-communicable diseases will continue to contribute to the growing cost burden facing European healthcare systems.<sup>1</sup>**

For over 50 years, developed countries have seen healthcare expenditures increase at an average rate of 2 percentage points per year above GDP growth.<sup>2</sup> Austerity measures implemented after the 2008 financial crisis led health spending to be in line with GDP.

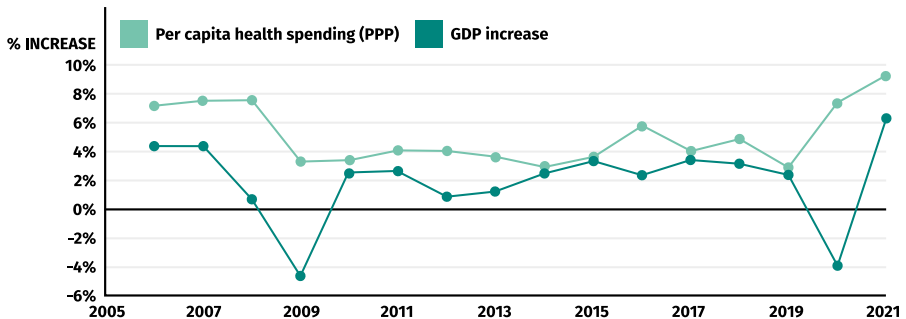
The COVID-19 pandemic triggered a sharp rise in health spending, and exposed major weaknesses in our health systems.<sup>3</sup> There is now a consensus that key investments are needed to strengthen health systems' resilience.<sup>4</sup>

The adoption of value-based healthcare can help meet the goals of effective and affordable care by addressing inefficiencies and quality issues.<sup>5</sup>

**FOR POLICY MAKERS STRUGGLING TO COPE WITH EVER-GROWING HEALTH CARE EXPENDITURE, THE OPPORTUNITY TO MOVE TOWARDS VALUE-BASED HEALTH CARE MUST BE PURSUED DECISIVELY.**

OECD (2017), *Tackling Wasteful Spending on Health*.

### ANNUAL GROWTH IN HEALTH SPENDING AND GDP, OECD AVERAGE



Source: OECD, *Ready for the Next Crisis? Investing in Health System Resilience*, 2023.<sup>4</sup>

1 Goryakin et al., *Assessing the future medical cost burden for the European health systems under alternative exposure-to-risks scenarios*, PLoS ONE, 2020.

2 World Economic Forum, McKinsey, *The Financial Sustainability of Health Systems*, 2012.

3 OECD/EU, *Health at a Glance: Europe 2022 - State of health in the EU cycle*.

4 OECD Health Policy Study, *Ready for the Next Crisis? Investing in Health System Resilience*, 2023.

5 EFPIA, *Value-based healthcare – an industry perspective*.



# DISEASE IS THE REAL COST, NOT THE TREATMENT

**Illness doesn't only affect people's health, but also their ability to contribute to society.**

Better health promotes economic growth by expanding the labor force and by boosting productivity, while also delivering immense social benefits.<sup>1</sup>

At the population level, lower productivity due to illness represents an economic loss to society. In 2020, illnesses and health problems cost €431.8 billion in Germany – a 28% increase from 2015 figures.<sup>2</sup>

According to the OECD, when the COVID-19 pandemic struck, European health systems were unprepared due to underinvestment.<sup>3</sup>

The lesson from the pandemic is that health-care is a strategic investment. Fiscal policy should integrate the value of preventing and treating disease as critical for achieving macro-economic objectives.<sup>4</sup>

**THE IMF SEES THE COST OF COVID PANDEMIC RISING BEYOND ITS \$12.5 TRILLION ESTIMATE.**

*Reuters*, January 20, 2022.

## HEALTHCARE IS AN INVESTMENT



Vaccinating all eligible women in EU27 against HPV would increase work productivity and labour income by **5.7M working hours and €387.0M** respectively.<sup>5</sup>



Boosting investment in the care of 11 leading cancers would provide a **3.7-fold return on investment by 2030** thanks to productivity gains.<sup>6</sup>



New curative treatments against hepatitis C improved patients' **work productivity by 16-20%**.<sup>7</sup>

1 McKinsey Global Institute, [Prioritizing health - A prescription for prosperity](#), July 2020.

2 [Statistisches Bundesamt](#) (Destatis). 27 July 2022.

3 OECD Health Policy Study, [Ready for the Next Crisis? Investing in Health System Resilience](#), 2023.

4 Rheinberger C., Herrera-Araujo D., Hammit J., [The value of disease prevention vs treatment](#), Journal of Health Economics, 2016.

5 EFPIA and Vintura, [Demonstrating the power of innovation in Europe](#), page 19, October 2022.

6 EFPIA, [Power up health systems](#), 2022.

7 Younossi Z. et al, [Impact of eradicating hepatitis C virus on the work productivity of chronic hepatitis C patients: an economic model from five European countries](#). J Viral Hepatitis, 2016.



## HEAVY FOCUS ON DRUG BUDGETS

**For over a decade prior to the COVID-19 pandemic, governments have been targeting drug expenditures as their main opportunity to achieve savings.**

As a response to the 2008-2010 financial and fiscal crisis, European governments implemented cost-containment measures in their healthcare systems. Pharmaceutical

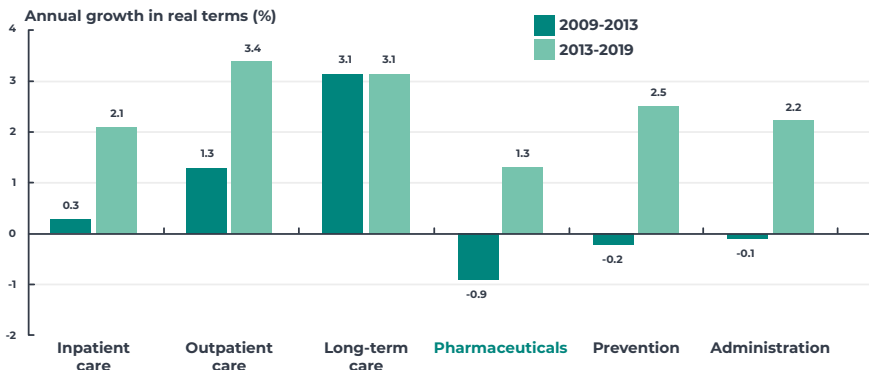
spending was one of their primary targets through price cuts, compulsory rebates, delisting of pharmaceuticals, industry-level clawbacks, etc. As a result, since the early 2010's, pharmaceutical spending is no longer the primary driver of increased healthcare cost growth.<sup>1,3</sup>

**AFTER THE FINANCIAL CRISIS, EU RETAIL PHARMACEUTICAL EXPENDITURE FELL BY AN ANNUAL AVERAGE RATE OF 0.7% BETWEEN 2008 AND 2012. SPENDING THEN RECOVERED BETWEEN 2012 AND 2016, RISING BY AN AVERAGE OF 0.8% PER YEAR.**

OECD/EU, Health at a Glance: Europe 2018.<sup>2</sup>

### ANNUAL GROWTH IN HEALTH EXPENDITURES FOR SELECTED SERVICES

OECD average, 2009–13 and 2013–19 (real terms)



Source: OECD Health at a Glance 2021, figure 7.16, page 199.

1 See OECD/EU, [Health at a Glance 2021: OECD Indicators](#), and [Health at a Glance: Europe 2022](#).

2 OECD/EU, [Health at a Glance: Europe 2018: State of Health in the EU Cycle](#).

3 IQVIA Institute, [Understanding Net Pharmaceutical Expenditure Dynamics in Europe](#), April 2022.



## MONEY WELL SPENT

**Across developed countries, drug spending is a small proportion of healthcare spending, representing 15% on average (ranging from 9–20%): This share “has remained stable to declining across almost all markets.”<sup>1</sup>**

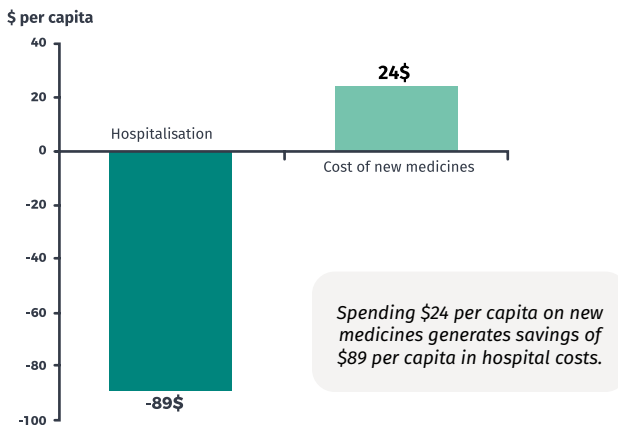
It is clear that simply decreasing drug spending – a minor part of health budget – will not solve the issue of healthcare cost increase. In fact, targeting cost-effective pharmaceutical interventions may lead to unintended consequences both in terms of health outcomes and long-term budget impact.

Rapid introduction and appropriate use of innovative medicines can help reduce the total cost of care, when it prevents or delays more expensive interventions such as hospitalisation. When access to innovative medicines is slowed, healthcare systems lose out on potentially greater savings, but more importantly on better health outcomes.<sup>2</sup>

**ALTHOUGH NEW DRUGS CAN APPEAR EXPENSIVE WHEN CONSIDERED IN ISOLATION, PHARMACEUTICAL INNOVATION LEADS TO COST SAVINGS ELSEWHERE IN THE SYSTEM THROUGH THE REDUCED USE OF HEALTH SERVICES LIKE HOSPITALS AND NURSING HOMES.**

Prof. Frank R. Lichtenberg, Columbia University Graduate School of Business.

### IMPACT OF USE OF NEW CARDIOVASCULAR TREATMENTS ON HOSPITALISATION COST (1995-2004)



Source: Frank R. Lichtenberg, [Have newer cardiovascular drugs reduced hospitalization? Evidence from longitudinal country level data on 20 OECD countries, 1995-2003](#). Health Economics, 2009.

1 IQVIA Institute, [Drug Expenditure Dynamics 1995–2020: Understanding medicine spending in context](#), October 2021.

2 IPHA, [New Medicines for Patients as Fast as in Europe: Need for Sustained Funding Growth](#), 2018.

# PHARMACEUTICAL EXPENDITURES

*The proportion of pharmaceutical expenditure in healthcare expenditure has remained either flat or reduced in most countries since 2000.*

IQVIA Institute, Understanding Net Pharmaceutical Expenditure Dynamics in Europe, April 2022.



# HOW MUCH DO WE SPEND ON DRUGS?

**According to the OECD, “spending on retail pharmaceuticals (including other medical non-durables) averaged €462 per person across the EU in 2020.”<sup>1</sup>**

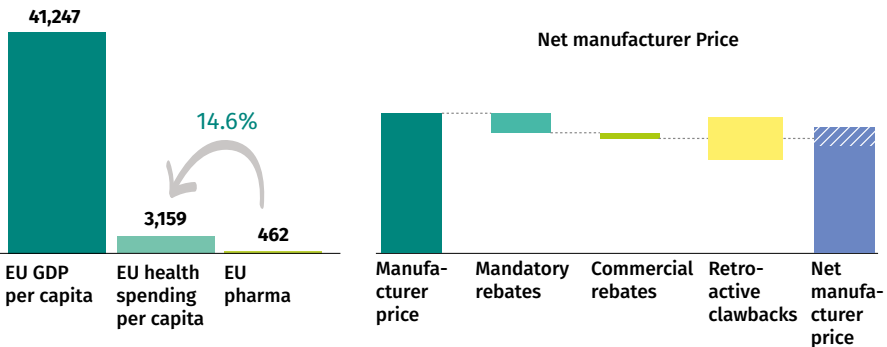
This figure represents less than 15% of the €3,159 per capita Europeans spent on healthcare the same year. However, this figure also includes over-the-counter products, as well as non-durable medical goods such as first aid kits or face masks. The OECD estimates that “around three out of every four euros spent on retail pharmaceuticals (including other medical non-durables) goes on prescription medicines.”<sup>1</sup>

Due to national differences in data collection and reporting, OECD spending data do not include pharmaceuticals used in hospitals, but OECD estimates it “can typically add another 20% to a country’s pharmaceutical bill.”<sup>1</sup> This level of uncertainty greatly varies across European countries. According to the IQVIA Institute, in a third of European countries, public data on pharmaceutical spending is either non-existent, unavailable, or incomplete.<sup>2</sup>

**INFORMATION ON PHARMACEUTICAL EXPENDITURE SHOULD BE MADE TRANSPARENT TO SUPPORT DECISION-MAKING.**

IQVIA Institute, April 2022.<sup>2</sup>

## PUTTING PHARMACEUTICAL EXPENDITURES IN PERSPECTIVE



Source: EUROSTAT, OECD/EU, Health at a Glance: Europe 2022.<sup>1</sup>

Source: IQVIA Institute, April 2022.<sup>2</sup>

1 OECD/EU, [Health at a Glance: Europe 2022 - State of health in the EU cycle](#).

2 IQVIA Institute, [Understanding Net Pharmaceutical Expenditure Dynamics in Europe](#), April 2022.



# SHARE OF DRUG SPENDING

**During the last decade, pharmaceutical spending has not been the driver of increased healthcare costs.**

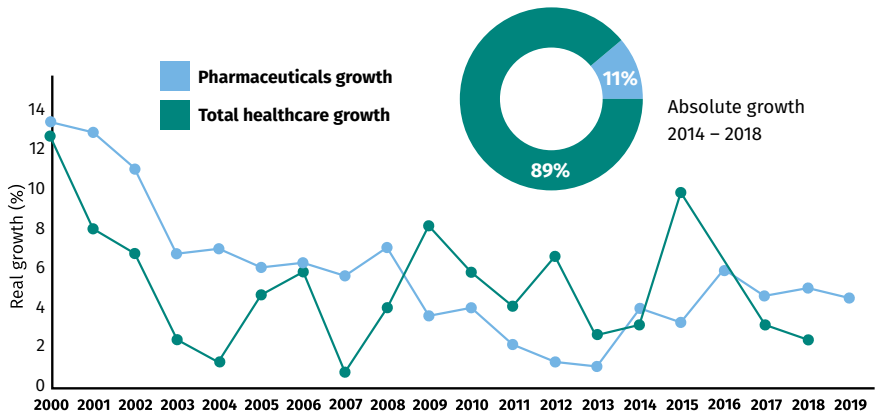
The topic of growth in pharmaceutical expenditure is regularly cited as the largest area of concern for European payers. However, while pharmaceutical spending was attracting most public debate, pharmaceutical expenditure represented only 11% of the absolute growth in healthcare expenditure during the five years prior to the pandemic (2014–2018). As this is lower than the ~15% it represents in health budgets, “it means that the share of pharmaceutical expenditure has been shrinking over this period.”<sup>1</sup>

The IQVIA Institute found that, “the share of pharmaceutical spending has been shrinking” in recent years. This results from pharmaceutical spending growth being inferior to growth rate of non-pharmaceutical interventions.<sup>1</sup>

**PHARMACEUTICAL EXPENDITURE IS UNDER CONTROL, BELOW PREDICTED HEALTHCARE EXPENDITURE GROWTH IN EUROPE, AND IN LINE WITH LONG-TERM ECONOMIC GROWTH RATES.**

Espin et al., 2018.<sup>2</sup>

## PHARMA GROWTH RATE FALLING SINCE 2000 - BELOW SHARE OF TOTAL HEALTH



Source: IQVIA Institute, *Understanding Net Pharmaceutical Expenditure Dynamics in Europe*, April 2022.

- 1 IQVIA Institute, *Understanding Net Pharmaceutical Expenditure Dynamics in Europe*, April 2022.
- 2 Espin et al., *Projecting Pharmaceutical Expenditure in EUS to 2021: Adjusting for the Impact of Discounts and Rebates*. Applied Health Economics and Health Policy, 2018.



## DRUG SPENDING IS STABLE AS A SHARE OF HEALTH BUDGETS

Since 2000, the amount spent on pharmaceuticals (retail and hospital) has remained at ~15% of healthcare expenditure across EU countries.<sup>1</sup>

While the last 20 years have seen dramatic changes in the type of medicines used, and the number of patients treated, the share of pharmaceutical spending relative to healthcare expenditure has remained either flat or reduced in most countries since 2000.<sup>1</sup>

Public debates generally focus on unit prices of medicines, but generally ignore (i) the actual budget impact - which depends on the number of patients, and (ii) what payers actually pay after discounts, mandatory rebates, clawbacks, budget caps, and other cost-containment measures.

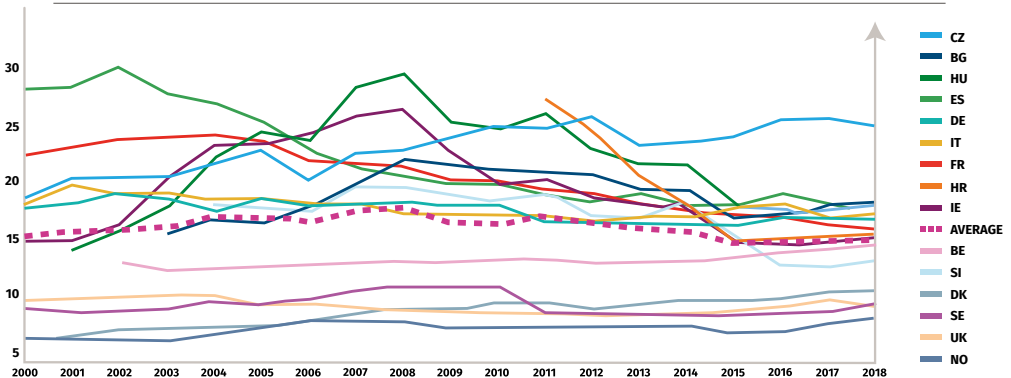
Moreover, what is reported as 'net pharmaceutical expenditure' represents more than pharmaceutical companies' sales, as it includes distribution costs, dispensing fees, and taxes. VAT rates in particular range from 25% in Denmark, 19% in Germany, 2.1% in France, to 0% in Sweden.<sup>2</sup>

**THE SHARE OF DRUG SPENDING HAS REMAINED STABLE TO DECLINING ACROSS ALMOST ALL MARKETS IN RECENT YEARS.**

IQVIA Institute, [Drug Expenditure Dynamics 1995–2020](#), October 2021.

### DRUG SPENDING AS SHARE OF TOTAL HEALTHCARE AT ~15%

Drug spending (retail and hospital) as % of healthcare spending in real PPP 2020\$, 2000–2028



Source: IQVIA Institute, April 2022.<sup>1</sup>

<sup>1</sup> IQVIA Institute, [Understanding Net Pharmaceutical Expenditure Dynamics in Europe](#), April 2022.

<sup>2</sup> BPI, [Pharma-Daten 2022](#).





# THE PUBLIC PRICE IS NOT WHAT THE PUBLIC PAYS

**When we read about the price of a medicine in the papers (including in academic articles), it refers to the publicly available price, or “list price”, which is almost never the price charged to health systems. The real, “net price” is lower and kept confidential, as it reflects rebates and other discounts negotiated by the payer.**

The net price is also difficult to calculate, as it can be further lowered through industry-level clawbacks or budget caps that apply retroactively and indiscriminately across all pharmaceutical spending.<sup>1</sup>

As sole purchasers and regulators, national payers benefit from significant power to set the price and reimbursement level of medicines be it through mandatory rebates or negotiation.

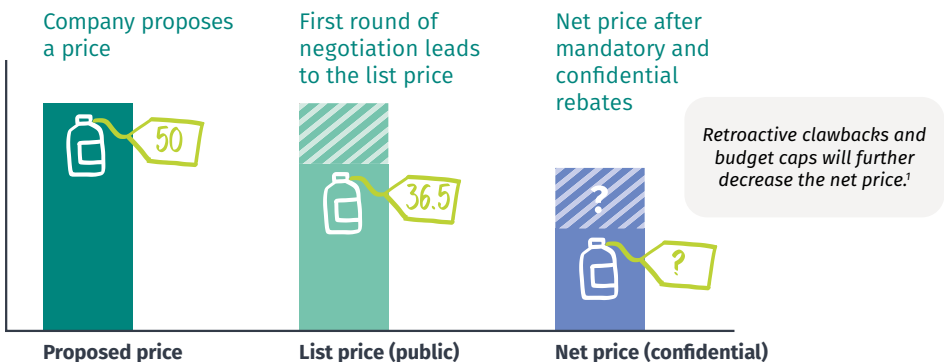
This position of power is illustrated by the numerous cost-containment measures that all European countries have deployed over the last decade to keep their pharmaceutical expenditure in check.

**PAYERS MAY NEGOTIATE WITH INDUSTRY UNDISCLOSED UP-FRONT DISCOUNTS, PRICE-VOLUME ARRANGEMENTS OR EXPENDITURE CAPS WITH EX-POST REBATES, ALL OF WHICH CAN REDUCE NET PRICES TO WELL BELOW THE LIST PRICES PROPOSED BY MANUFACTURERS.**

OECD Health Working Health Working Paper No.146, September 2022.<sup>2</sup>



## SIMPLIFIED VERSION OF A PRICE NEGOTIATION



<sup>1</sup> IQVIA Institute, [Understanding Net Pharmaceutical Expenditure Dynamics in Europe](#), April 2022.

<sup>2</sup> Eliana Barrenho and Ruth Lopert, [Exploring the consequences of greater price transparency on the dynamics of pharmaceutical markets](#), OECD Health Working Health Working Paper No.146, September 2022.



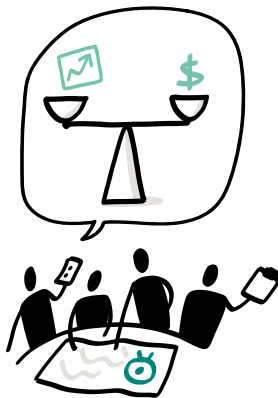
## INTERNATIONAL PRICE COMPARISON

**Can we sustain affordability of drugs across Europe if countries with very different GDP per capita, different level of healthcare spending, different epidemiology, and different public health priorities want the same price?**

Comparing pharmaceutical prices with other countries – called “external reference pricing” – is widely used across Europe. Hoping to benefit from the price negotiated by other countries – provided it is lower, payers include a basket of other countries’ price in their own pricing negotiations.

**PRICING TO MARKET IS INCREASINGLY NOT POSSIBLE IN AN ERA OF FREE TRADE AND EXTERNAL PRICE REFERENCING. THIS MAY WELL RESULT IN PROBLEMS IN THE AVAILABILITY AND AFFORDABILITY OF SOME MEDICINES IN SOME COUNTRIES.**

OECD, Pharmaceutical Pricing Policies in a Global Market.<sup>2</sup>



The most detrimental effect of external reference pricing is that it forces price convergence across countries that do not have the same level of GDP, healthcare spending, or health priorities.

By preventing companies from applying differential pricing, **external reference pricing may delay access to innovative drugs for patients in lower income countries**, as the narrower price band is above these countries affordability threshold.<sup>1</sup>

Pharmaceutical prices should be based on a variety of criteria, including the value of the product, patient benefits, the disease burden, government health priorities and physician requirements.

**SAVINGS FOR THE RICH,  
DELAYED ACCESS  
FOR THE POOR**



<sup>1</sup> Kaló et al., *Differential pricing of new pharmaceuticals in lower income European countries*, Expert Review of Pharmacoeconomics & Outcomes Research, 2013.

<sup>2</sup> OECD Health Policy Studies, *Pharmaceutical Pricing Policies in a Global Market*, September 2008.



# THE UNINTENDED CONSEQUENCES OF PRICE TRANSPARENCY

**Should wealthy countries benefit from the price paid by poorer countries? Will companies compete more once they know the price negotiated by their competitors? Is public interest better served by disclosing confidential prices, or by ensuring greater rebates? These are some of the questions that need to be asked when considering the calls for greater transparency of pharmaceutical prices.**

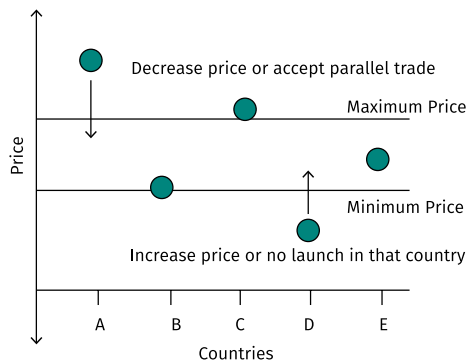
The official price of a pharmaceutical is public. However, this public price rarely represents the price paid, as it typically doesn't reflect the rebates, discounts, clawbacks, and other terms negotiated with payers. The price after negotiation ("net price") is generally kept confidential to ensure companies can apply differential pricing, i.e., adjust their price according to the ability to pay of different countries.<sup>1</sup>

NET PRICE TRANSPARENCY WOULD AMPLIFY ACCESS DELAYS ALREADY AFFECTING PATIENTS IN LOWER-INCOME MARKETS<sup>2</sup>

Authorities have often recognised the value of confidentiality as it facilitates greater rebates from companies.<sup>2</sup> Economic models have also shown that the disclosure of net prices results in price convergence - forcing companies into a narrower price band, which prices out lower-income countries.<sup>3,4</sup>

**LOWER-INCOME MARKETS COULD EXPECT PRICE INCREASES UNDER TRANSPARENT CONDITIONS, WHEREAS HIGHER-INCOME AND LOW-VOLUME MARKETS COULD EXPECT PRICE DECREASES.**

The consequences of greater net price transparency for innovative medicines in Europe, Charles River Associates.<sup>3</sup>



Source: Kalo et al., 2013.<sup>3</sup>

1 Danzon P.M., Towse A., [Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents](#). International Journal of Health Care Finance and Economics 3, 183-205 (2003).

2 For example, the Irish Information Commissioner ([case 170395, 13 April 2018](#)), and the Italian Consiglio di Stato ([sezione III sentenza n. 1213 filed on 17 March 2017](#)) recognized the existence of a higher general interest in maintaining price confidentiality.

3 Bentata P., Riccaboni M., Van Dyck W. et al. [The consequences of greater net price transparency for innovative medicines in Europe: Searching for a consensus](#). Charles River Associates. 2020.

4 Kaló et al., [Differential pricing of new pharmaceuticals in lower income European countries](#), Expert Review of Pharmacoeconomics & Outcomes Research, 2013.



## REWARD VALUE TO THE PATIENT

**Pricing and reimbursement systems should be based on patients' health outcomes, promote rapid access, reward innovation, and be predictable and transparent.**

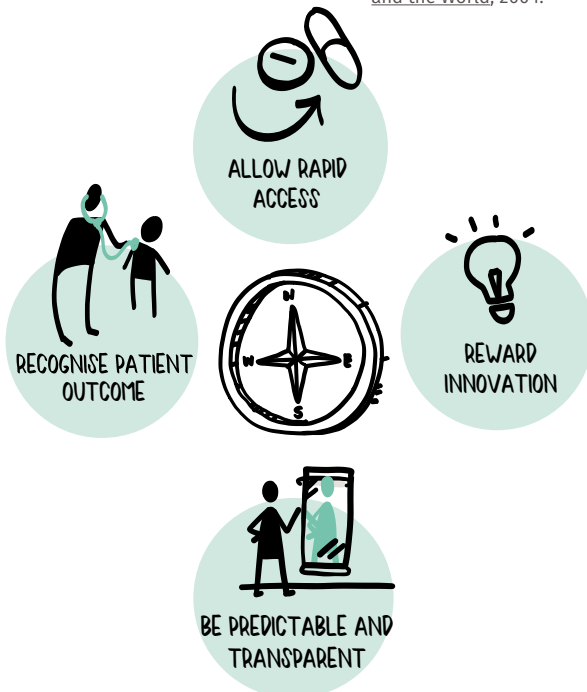
After marketing approval, pricing and reimbursement is a crucial step in ensuring that patients have access to innovative medicines.

At MSD we are engaged with payers to ensure we reach our common goals of rapid patient access, improved health outcomes, and sustainable budgets.

We strive to achieve mutually beneficial agreements with payers to ensure that our medicines and vaccines are accessible and affordable, while ensuring that we can continue to invest in the next generation of MSD inventions.

**IN EUROPE, [PRICING DECISIONS] REMAIN UNPREDICTABLE, [RESULTING] IN AN UNPREDICTABLE LOTTERY FOR COMPANIES WHO HAVE BROUGHT A PRODUCT THROUGH A SERIES OF REGULATORY HURDLES AND STILL DO NOT KNOW WHAT THE FINAL REIMBURSEMENT PRICE WILL BE.**

WHO Report, [Priority Medicines for Europe and the World](#), 2004.





# HEALTH TECHNOLOGY ASSESSMENT

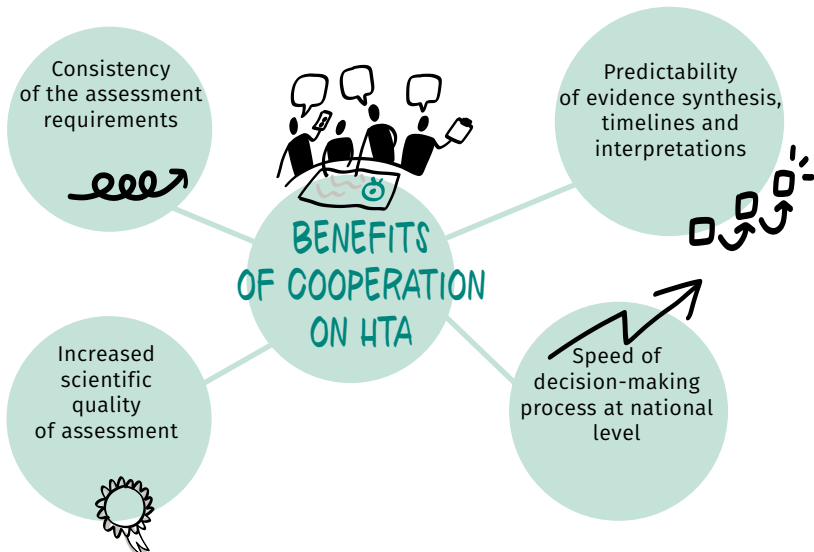
**Health Technology Assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, and robust manner.**

HTAs are currently conducted at the national level, but the EU is finalizing the implementation of a new Regulation on HTA that will harmonize clinical effectiveness assessments to inform national pricing and reimbursement decisions.

It is crucial that both private and public bodies that produce or review the evidence follow agreed upon, scientifically validated and transparent methodologies. HTA can be an important process through which the value of a medicine or vaccine can be investigated in the context of a set population's needs.

Harmonisation of HTA requirements is critical for patients to avoid duplicative work, such as unnecessary trials, potential delays, and access restrictions that are not based on the intrinsic properties of a medicine, but administrative requirements.

## TRANSPARENCY, SCIENTIFIC RIGOUR AND AN UNBIASED APPROACH TO EVIDENCE GENERATION ARE ESSENTIAL FEATURES OF HTA





# VALUE-BASED PRICING IS PATIENT-CENTRIC

## Payers want value... and then negotiate.

The goal of pharmaceutical pricing is to ensure that innovative medicines are affordable to healthcare systems, whilst also rewarding innovation that delivers value to society.<sup>1</sup>

The WHO defines value-based pricing as a method to set pharmaceutical prices “according to the measurable benefits that patients and health systems find in them”.<sup>2</sup> Value-based pricing allows health authorities to base their procurement decisions on criteria that matter to patients, healthcare systems, and society thus delivering a ‘triple win’.<sup>3</sup>

Examples of value include improved health outcomes and quality of life for patients, cost offsets and savings for health systems, and a healthier and more productive population for society.

By measuring health outcomes against the cost of delivering those outcomes, value-based pricing allows healthcare systems to promote patient-centred care and efficiency. Alternative pricing methods such as cost-plus approaches based on R&D and production costs are inefficient (no incentive to cut costs) and do not reflect the value of a medicine to society. It fails to signal to pharmaceutical companies where to focus their R&D investments, ie, what health authorities are willing to pay for.

Value-based pricing enables greater affordability, provided that pharmaceutical spending is integrated with other types of spending. For example, an innovative diabetes treatment that helps patients better manage their glucose level, thus improving their life and preventing visits to the emergency room, is value for money. However, such value can only be extracted if pharmaceutical budgets are not siloed from hospital budgets, so that cost offsets generated in other parts of the health system are taken into account.<sup>4</sup>



1 EFPIA, [A value-based approach to pricing](#), April 2023.

2 [Value-based pricing: WHO guideline on country pharmaceutical pricing policies: a plain language summary](#).

3 Office of Health Economics, [Delivering the Triple Win: A Value-Based Approach to Pricing](#), April 2023.

4 Vintura, [Broadening the Perspective: Recommendations for improving pharmaceutical affordability](#), 2023.

# SPECIAL CHALLENGES

*I have not failed. I've just found 10,000 ways that won't work.*

Thomas Edison



# THE GLOBAL HEALTH THREAT OF ANTIMICROBIAL RESISTANCE

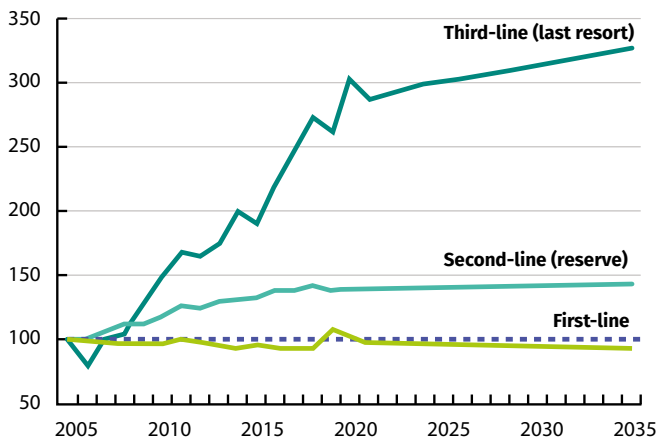
**The World Health Organisation considers antimicrobial resistance one of the greatest public health threats facing humanity.<sup>1</sup>**

Antibiotics have revolutionised infectious disease treatment, saving millions of lives worldwide. However, rising levels of resistance to antibiotics are reducing the effectiveness of these treatments and putting these health gains at risk. If left unchecked, resistance to last resort drugs against difficult-to-treat infections could be about 3.4 times higher by 2035 in the EU/EEA region compared to 2005.<sup>2</sup>

According to the ECDC, at least 35,000 people die annually from antimicrobial resistance in Europe alone.<sup>3</sup> Unless action is taken, we could revert to a world where simple infections are no longer treatable.

Antimicrobial resistance carries a heavy health and economic burden, including longer hospital stays, higher medical costs, and increased mortality. New antibiotics are urgently needed to address the growing threat of resistance.<sup>4</sup>

## ANTIMICROBIAL RESISTANCE INDEX – EU/EEA



Source: OECD, Embracing a One Health Framework to Fight AMR, figure 2.8.<sup>2</sup>

1 WHO, [Fact sheet on antimicrobial resistance](#), 17 november 2021.

2 OECD, [Embracing a One Health Framework to Fight Antimicrobial Resistance](#), 2023.

3 ECDC, [35,000 annual deaths from antimicrobial resistance in the EU/EEA](#), press release 17 November 2022.

4 Butler et al., [Analysis of the Clinical Pipeline of Treatments for Drug-Resistant Bacterial Infections: Despite Progress, More Action Is Needed](#), Antimicrobial Agents and Chemotherapy, 2022.





MSD has a long history of discovering and developing anti-infectives for both humans and animals. While many companies have pulled away, MSD is still active in the fight against antimicrobial resistance supporting solutions that promote prudent use and reduce the need for antibiotics.<sup>5</sup>

**THERE IS A WORRYING TREND OF DELAYED AVAILABILITY FOR NEW ANTIBIOTICS IN EUROPE [...] THE REASON IS THAT THE EUROPEAN MARKET IS LESS ATTRACTIVE BECAUSE OF LOW SALES AND LOW PRICES.**

Christine Årdal, Norwegian Institute of Public Health, Antimicrobial resistance and COVID-19 - How can Europe incentivise R&D to protect our future?, European Health Forum Gastein, 1 October 2020.

## ANTIMICROBIAL RESISTANCE – CHALLENGES AND SOLUTIONS



### SCIENTIFIC CHALLENGES

- ! Constantly evolving bacteria.
- ! Resistance difficult to predict.



### REGULATORY CHALLENGES

- ! Complex clinical trials.
- ! Complex regulatory pathways.



### ECONOMIC CHALLENGES

- ! Novel antibiotics are used sparingly to preserve effectiveness.
- ! Most reimbursement models undervalue novel antibiotics and disincentivize their use (esp., bundled payment and DRGs).<sup>6</sup>



### PUSH INCENTIVES

- ! **Reduce the risk of early investment in antibiotic R&D**

Incentives such as grants and refundable tax credits can stimulate pre-clinical and clinical R&D.



### DELINKED MECHANISMS

- ! **Reward innovation earlier in the product's life cycle**

New incentives, like transferable exclusivity vouchers, would decouple economic returns from sales volume, thus guaranteeing appropriate rewards for essential innovations.



### PAYMENT & HTA REFORM

- ! **Allow providers to use novel antibiotics appropriately and ensure that value assessment of novel antimicrobials includes cost and societal impact of AMR.**

<sup>5</sup> MSD is supporting the [Global AMR Action Plan](#), the [AMR Industry Alliance](#), and the [AMR Action Fund](#) among other activities in the fight against antimicrobial resistance. Accessed 21 March 2024.

<sup>6</sup> Bundled payments and Diagnosis-Related Groups prioritize cost containment. As a result, hospitals and providers are incentivised to use cheaper, older antibiotics to stay within budget, even when a novel antibiotic might be clinically superior (US Office of the Assistant Secretary for Planning and Evaluation, [Understanding Markets for Antimicrobial Drugs](#), Issue Brief, August 2023, [ASPE website](#)).



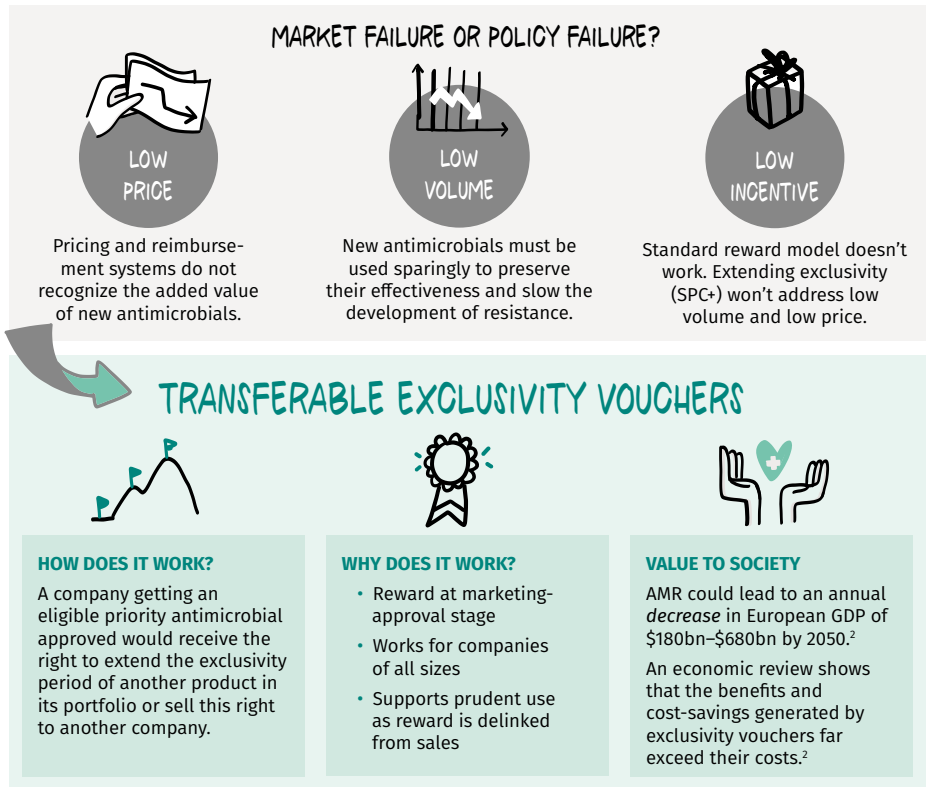
# A NEW INCENTIVE TO FIGHT MICROBES

## New incentives are needed to revitalise research and development of new antibiotics.

Drug resistance is a fact of life. This is why, in addition to prudent use of existing treatments, we need a constant stream of new antimicrobials to replace those lost to bacterial resistance.<sup>1</sup>

Unfortunately, due to low price and low volume, antimicrobial R&D has been drying up.<sup>2</sup>

To unlock R&D investment and replenish our pipeline at the required scale, we need a new type of incentive. Transferable exclusivity vouchers have been fully evaluated and are one of the most promising solutions to achieve this objective.<sup>3</sup>



1 WHO, [Lack of new antibiotics threatens global efforts to contain drug-resistant infections](#), 17 January 2020.

2 Christine Årdal, Norwegian Institute of Public Health, [Antimicrobial resistance and COVID-19 - How can Europe incentivise R&D to protect our future?](#), European Health Forum Gastein, 1 October 2020.

3 Charles River Associates, [A framework for assessing the potential net benefits realized through Transferable Exclusivity Extension \(TEE\) as an incentive for development of novel antimicrobials](#), 2022.



# ADDRESSING MEDICINE SHORTAGES

Given the impact on patient care, it is essential that shortages are addressed as a public health issue. The revision of the EU's general pharmaceutical legislation should span all value chain segments to close the gaps while supporting innovative and sustainable manufacturing and supply.

## MEDICINE AND VACCINE SHORTAGES ARE CAUSED BY MULTIPLE FACTORS



NATIONAL STOCKPILING  
REQUIREMENTS



EXPORT  
BANS



SUPPLY CHAIN  
DELAYS



PRODUCTION  
CHALLENGES



SUDDEN SURGE  
IN DEMAND



REGULATORY CONSTRAINTS  
REDUCING FLEXIBILITY

## SOLUTIONS

### DATA GATHERING AND TRANSPARENCY

→ To improve demand forecasting through EU-level platforms

### USE EMVS DATA

→ To collect information on supply and demand, and inform the European Shortages Monitoring Platform maintained by EMA

### PREVENT NATIONAL STOCKPILING

→ To ensure supply can meet demand where it's needed most

### ALLOW ELECTRONIC PRODUCT INFORMATION

→ To ensure manufacturing and supply flexibility

### BUILD FLEXIBLE & RESILIENT SUPPLY CHAINS

→ Adopt regulatory solutions that facilitate rapid reallocation across countries



## FASTER PATIENT ACCESS

**Depending on where they live, European patients will not access new medicines at the same time. Despite a centralized approval of medicines, a patient in Romania will wait seven times longer than a patient in Germany to have access to a new treatment for the same disease.<sup>1</sup>**

Even in the EU, health systems remain a national competency. Due to legal, organisational, and cultural differences, healthcare funding, delivery, and access greatly vary between countries. A medicine approved at the EU level will still be faced with at least 27 different pathways (not counting regions) before it can be available for patients in each member state.

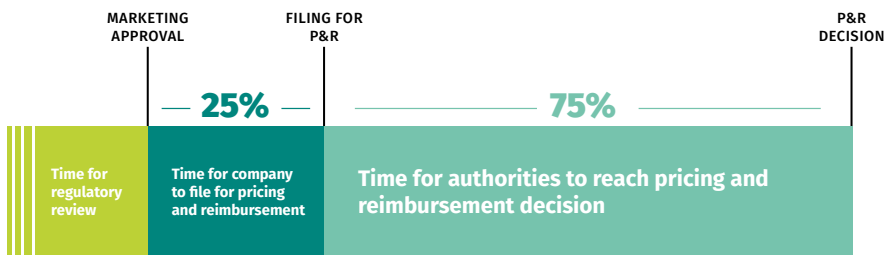
An analysis of the root causes of access delays identified three major choke points: regulatory processes – the time it takes for a medicine to be approved; filing for pricing and reimbursement (P&R) – the time it takes companies to constitute and file their P&R dossier; and pricing and reimbursement processes – time it takes authorities to reach the funding decision.<sup>2</sup>

Early results from the European Access Hurdles Portal<sup>3</sup> show that about a quarter of the delays for a new medicine to be available in a given country are due to companies' decision-making to file for P&R, while the rest of the delays (75%) is due to national P&R process and funding decision-making.

**THERE IS NO SINGLE ACTOR OR LEGISLATION THAT CAN ADDRESS THIS ISSUE IN ISOLATION. IF THERE WAS A SILVER BULLET, WE WOULD HAVE FOUND IT BY NOW.**

Nathalie Moll, Director General, [Faster, more equitable access to medicines across Europe](#), webinar, 3 May 2023.

### RELATIVE DURATION OF KEY STEPS BEFORE AVAILABILITY OF A MEDICINE



Source: EFPIA, [European Access Hurdles Portal: initial results](#), April 2023.

1 EFPIA, [Patients W.A.I.T. Indicator Survey 2022](#).

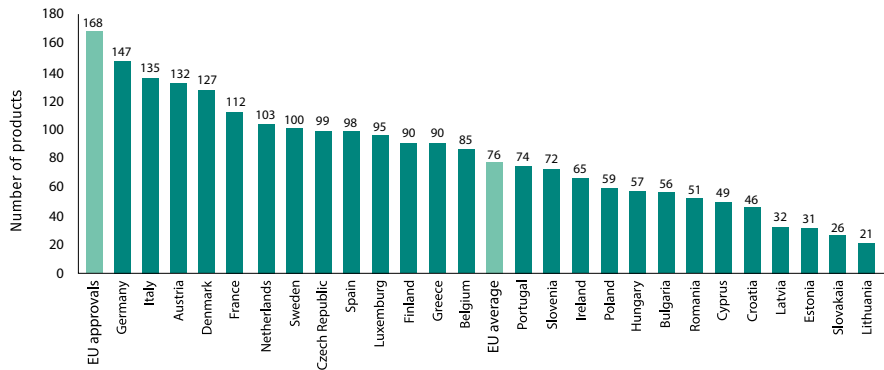
2 CRA/EFPIA, [The root cause of unavailability and delay to innovative medicines](#), April 2023.

3 Charles River Associates, [European Access Hurdles Portal: initial results](#), April 2023.



## NUMBER AND RATE OF MEDICINES AVAILABILITY (2018-2021)

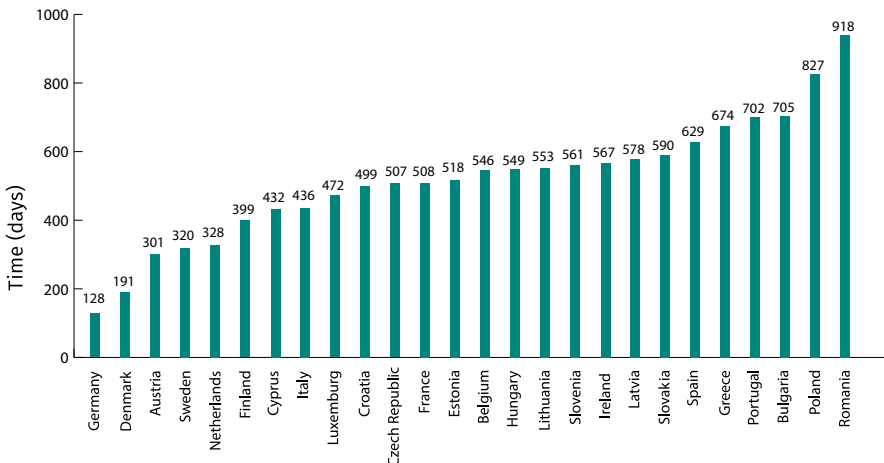
IQVIA, EFPIA Patient WAIT Indicator 2022 survey



Rate of availability, measured by the number of medicines available to patients in European countries as of 5th January 2023. For most countries this is the point at which the product gains access to the reimbursement list.

## TIME FROM CENTRAL APPROVAL TO AVAILABILITY (2018-2021)

IQVIA, EFPIA Patient WAIT Indicator 2022 survey



The time from central approval to availability is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list).

Source: EFPIA, Patient WAIT Indicator 2022 survey.



## ELECTRONIC PRODUCT INFORMATION

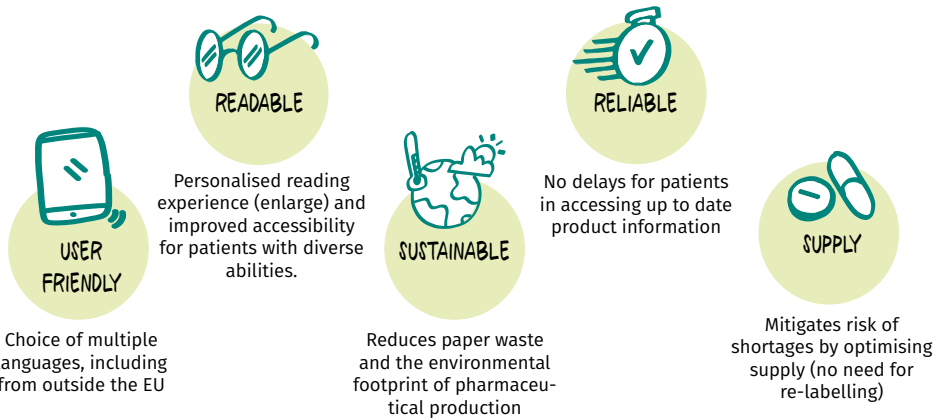
**Under EU law, medicinal products must be dispensed with a paper leaflet providing information about the product to help patients understand their treatment and how to use safely.**

Product leaflets provide important information, but the requirement to use a paper version does not provide the same level of flexibility available with electronic product information. For example, an electronic version can provide the most recent approved

information without any delay, thus increasing patient safety.

Electronic product information also facilitates multi-language information to be made available as more people move across Europe or come from non-EU countries. Electronic product information can also reduce the volume of paper and ink used in the production process, thus improving pharmaceutical products' environmental footprint.<sup>1</sup>

### BENEFITS OF ELECTRONIC PRODUCT INFORMATION



**ELECTRONIC PRODUCT INFORMATION  
IS BETTER FOR PATIENTS AND  
BETTER FOR THE PLANET!**

<sup>1</sup> Nauvelaerts K. and Tellner P, [Electronic Product Information – Making the latest medicine's information available for patients without any delay](#), EFPIA blog, 2 November 2022.

# BEYOND INNOVATION

*From finding solutions for some of the world's most debilitating diseases, to getting our medicines and vaccines to those in need and building more effective health systems, we are always on a mission to create a better world.*

Environmental, Social and Governance at [MSD](#)



## MSD FOR MOTHERS

Every two minutes, a woman dies from complications related to pregnancy and childbirth globally. Most of these deaths are preventable when women have access to modern contraception and quality maternal health care before, during, and after childbirth.

Launched in 2011, MSD for Mothers is our company's \$650 million global initiative to help create a world where no woman has to die while giving life. Today, MSD is working with more than 165 partners in more than 65 global sites to improve maternal health.<sup>1</sup>



Our efforts target three areas:

- Supporting **quality accreditation** of local health providers.
- Developing and deploying **private sector innovations** (eg, addressing postpartum hemorrhage<sup>2</sup>).
- Incorporating **local** and **community-led solutions**.

### CONTRIBUTIONS

**21M** women reached with programs promoting safe, high-quality, respectful care

**578K** providers trained to offer quality care

**160M** people reached through improved access to quality facilities

**15M** people with access to lifesaving medicines

**IN THE SUCCESSFUL COOPERATION WITH MSD FOR MOTHERS, MATERNAL MORTALITY IS PUT IN FOCUS. ACCESS TO MATERNAL HEALTHCARE IS A FUNDAMENTAL HUMAN RIGHT.**

Silvana Koch-Mehrin, Founder and President of Women Political Leaders Global Forum.

[Learn more about MSD for Mothers](#)

<sup>1</sup> See map of collaborations at [Where We Work](#).

<sup>2</sup> MSD for Mothers, [Helping to reduce maternal mortality through investments to address the #1 driver of maternal deaths - postpartum hemorrhage](#).





# NOBODY LEFT OUTSIDE

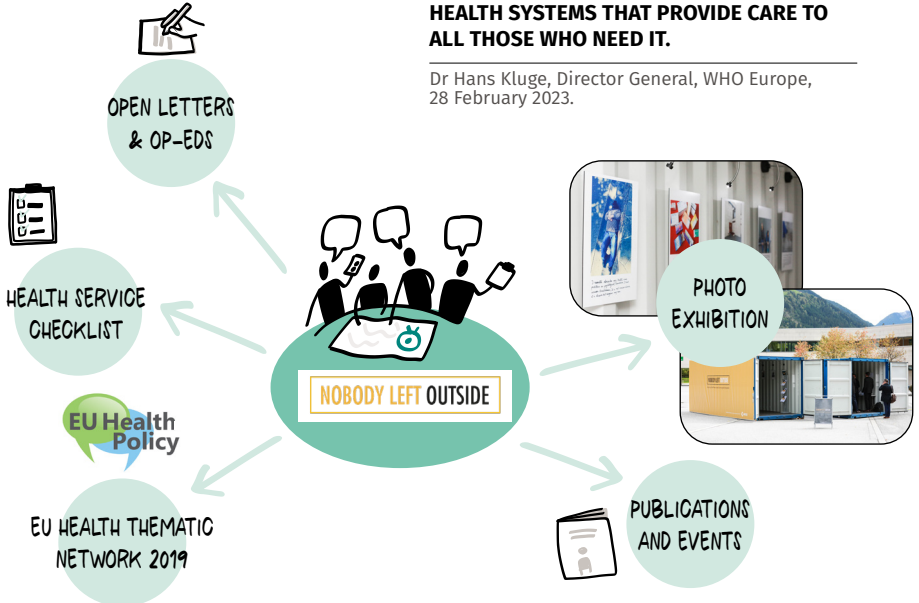
**Even in high-income countries, a large number of people are underserved by our health systems. This is particularly true for some of the most vulnerable and socially excluded groups such as LGBTI, sex workers, migrants, homeless, people who inject drugs, and prisoners.**

Underserved groups are often described as 'hard to reach', whereas, from their perspective, it is frequently the health services that are hard to reach. Highly stigmatised, members of these communities face organisational and legal barriers in accessing health care.

In 2017, MSD launched the [Nobody Left Outside](#) initiative with a group of NGOs representing marginalised communities. These organisations work together to identify shared challenges, discuss lessons learned through years of engagement, and seek integrated solutions to improve access to healthcare for the communities of people they represent.

**THE WORK OF NOBODY LEFT OUTSIDE SPEAKS SO STRONGLY TO THE PRINCIPLES OF WHAT WHO EUROPE STANDS FOR. WE HAVE A COMMON PURPOSE TO WORK TOWARDS INCLUSIVE AND ACCESSIBLE HEALTH SYSTEMS THAT PROVIDE CARE TO ALL THOSE WHO NEED IT.**

Dr Hans Kluge, Director General, WHO Europe,  
28 February 2023.



See [nobodyleftoutside.eu](https://nobodyleftoutside.eu) for more information about these initiatives, and NLO founding organisations.



# HEALTH LITERACY

**Health literacy empowers patients and citizens to play a more active role with regard to their health.**

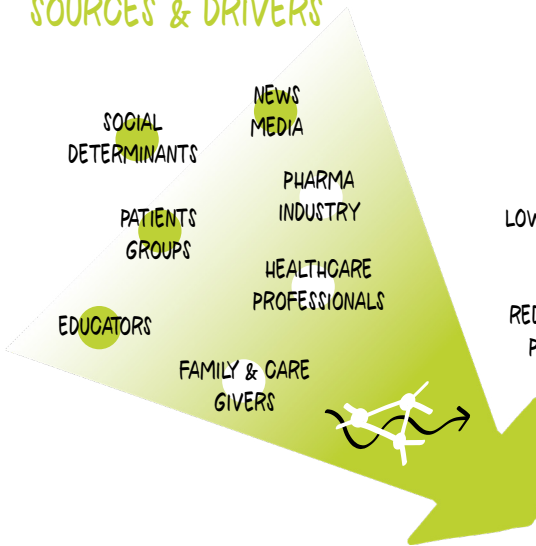
Health literacy is the ability to read, understand and act on health information. Over the years, MSD has been involved in a number of initiatives to promote better health through health literacy initiatives.

According to the European Health Literacy Survey, nearly half of all Europeans have inadequate and problematic health literacy skills.<sup>1</sup> Limited health literacy in Europe is thus not just a problem of a minority of the population, in contrast, it is a public health challenge.

**HEALTH LITERACY IS A STRONGER PREDICTOR OF AN INDIVIDUAL'S HEALTH STATUS THAN AGE, INCOME, EMPLOYMENT STATUS, EDUCATION LEVEL, RACE OR ETHNIC GROUP.**

Dr. Barry D. Weiss, Help Patients Understand – Health Literacy Educational Toolkit, American Medical Association, 2007.

## HEALTH LITERACY SOURCES & DRIVERS



## HEALTH LITERACY HEALTH OUTCOMES

- LOWER OVERALL COST
- REDUCED REPEAT PROCEDURES
- EFFICIENT USE OF CARE SERVICES
- OPTIMISED THERAPY
- REDUCED RISK BEHAVIOURS
- IMPROVED QUALITY OF LIFE
- MAKE THE HEALTHY CHOICE



<sup>1</sup> Kickbusch, Ilona, Pelikan, Jürgen M., Apfel, Franklin & Tsouros, Agis. (2013). Health Literacy. WHO Regional Office for Europe.



## ABOUT MSD

**For over 130 years, we've been guided by the view that great medicines and vaccines change the world.**

MSD is a research-intensive global healthcare leader developing innovative medicines, vaccines, and animal health products. We are pushing the boundaries of science with the hope and expectation that the medicines and vaccines we invent will lead to better health for society for generations to come.

We also demonstrate our commitment to increasing access to healthcare through far-reaching access programmes that bring our products to millions of people and animals who need them. For more, see our ESG report.<sup>1</sup>

MSD operates in more than 140 countries to deliver innovative health solutions. Worldwide, MSD employs more than 69,000 people, of which 19,500 are based in Europe (a third of our workforce) across 33 locations, representing over 90 nationalities.

Our values guide everything we do, and they serve as the foundation of trust. We recognise that a variety of perspectives is crucial to encourage innovation. We therefore strive for equal representation across our company, while promoting the best talent – as reflected by our 50/50 gender balance.

MSD is focused on addressing many of the world's unmet medical needs. Our journey to discovery is guided by science and inspired by patients. By dedicating over 20% of our revenues to R&D (22.6% in 2022), we are pioneering new approaches across a broad range of diseases, including cancer, infectious disease, and cardio-metabolic disorders to cite a few.

## MSD IN NUMBERS IN EUROPE

MORE THAN **19,500** EMPLOYEES

ABOUT **ONE THIRD** OF OUR TOTAL WORK FORCE

WITH A **50/50** GENDER BALANCE

PRESENT IN **26** EU MEMBER STATES

WITH **21** MANUFACTURING SITES

<sup>1</sup> See [MSD Environmental, Social & Governance progress report 2021–2022](#).

# PHARMACEUTICAL INNOVATION IS ONE OF THE GREATEST ACHIEVEMENTS OF OUR SOCIETIES

## FOR PATIENTS



PATIENTS LIVE LONGER, HEALTHIER,  
MORE PRODUCTIVE LIVES

## FOR SOCIETY



BETTER HEALTH IS A PILLAR  
OF OUR AGING SOCIETIES

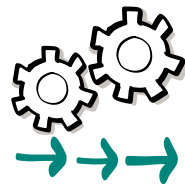


## FOR HEALTHCARE



NEW TREATMENTS MAKES  
HEALTH SYSTEMS MORE RESPONSIVE AND  
RESILIENT

## FOR ECONOMIES



PHARMA COMPANIES DRIVE  
HIGH-VALUE ECONOMIC GROWTH