

INTERNATIONAL FEDERATION  
OF PHARMACEUTICAL  
MANUFACTURERS &  
ASSOCIATIONS

# THE PHARMACEUTICAL INDUSTRY AND GLOBAL HEALTH

FACTS  
AND  
FIGURES  
2022



**IFPMA**



## FOREWORD



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*Director General, IFPMA*

I am proud to introduce the 2022 update of the “Facts & Figures Report”.

This compendium of facts and figures relating to the biopharmaceutical industry and global health aims to provide a snapshot of the work this industry undertakes today. This publication examines the most recent available data on biopharmaceutical innovation and global health, access to medicines and healthcare systems, as well as the economic footprint of the innovative biopharmaceutical industry. This includes key insights on the COVID-19 vaccines and treatments that were developed at record speed and manufactured in historic quantities by the innovative biopharmaceutical industry.

The COVID-19 pandemic has highlighted the biopharmaceutical industry essential role played in combating this public health crisis through its expertise, innovation, and resources. Beyond COVID-19, the biopharmaceutical industry is one of the most innovative sectors in the world, which over the past century has played a unique role in developing new and improved medicines and vaccines to prevent and treat diseases. It is also thanks to biopharmaceutical innovation that societies were able to thrive through full and healthy lives. This is a unique industry.

This publication underlines the ongoing commitment of the research-based biopharmaceutical industry to improving the quality of life for all people worldwide.

Our industry is working on innovations that are transforming healthcare and helping tackle unmet medical needs. Today, our scientists are discovering the new treatments that will transform the lives of future generations. The volume of clinical trials has increased in the last 5 years and there are currently over 9,000 compounds at different stages of development globally.

There are many promising success stories in the pipeline. There are curative therapies for Hepatitis B and HIV that may be able to eradicate the virus from infected cells, saving patients from life-long treatments. The decades of trial and tribulations that has led to the development of mRNA technology can be a life saving therapy for patients with aggressive forms of brain cancer. The future is uncertain, but as long as our industry continues to push the barriers of science, it should be a better one for all.

We hope that sharing some of the most recent and relevant facts and figures relating to our work can add value to evidence-based policymaking in the global health arena and foster further consideration for investments in resilient healthcare systems and enabling ecosystems in which further innovation can thrive.

# Key facts

## RESEARCH & DEVELOPMENT

- On average, researchers identify one promising compound among 5,000–10,000 screened. Researchers then extensively test the compound to ensure its efficacy and safety, a process that can take 10 to 15 years for both a medicine and a vaccine.
- In 2020, 53 new medicines were launched, while currently more than 9,000 compounds are at different stages of development globally.
- In 2021, the number of drugs in development for particular disease areas were:
  - Cancer: 3,148
  - Immunology: 1,677
  - Neurology: 1,668
  - Infectious diseases: 1,488
- The research-based biopharmaceutical industry is estimated to have spent USD 198 billion globally on biopharmaceutical R&D in 2020.

## THE ROLE OF BIOPHARMACEUTICALS IN WELL-FUNCTIONING HEALTHCARE SYSTEMS

- Patients in vulnerable healthcare systems are particularly challenged by high out-of-pocket expenditure.
- While health expenditure per capita varies across countries, spending on biopharmaceutical products as a share of health expenditure has broadly remained constant.
- Medicines and vaccines contribute to the sustainability of healthcare systems by generating savings, for example by substantially reducing costs in other areas of healthcare, such as hospital stays and long-term care costs.
- The Global Health Progress platform highlights 270 collaborations between the innovative biopharmaceutical industry and more than 1200 partners to support the Sustainable Development Goals (SDGs).

## ECONOMIC FOOTPRINT OF THE BIOPHARMACEUTICAL INDUSTRY

- Combined direct, indirect and induced effects of the biopharmaceutical industry's total contribution to the world's GDP is USD 1,838 billion.
- The biopharmaceutical industry employs approximately 5.5 million people worldwide, including through the manufacturing of generics medicines.
- Global sales of biopharmaceutical products continue growing and represent the international distribution of medical technology resulting from highly intensive R&D efforts in the exporting countries.
- As medical innovation is transmitted across the world, it contributes to significant gains in average life expectancy and quality of life.



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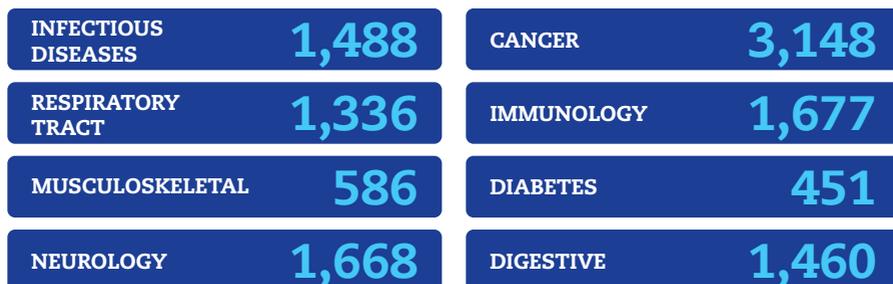
# EXECUTIVE SUMMARY

## Biopharmaceutical Innovation and Global Public Health

The research-based biopharmaceutical industry plays a vital role in developing new medicines and vaccines to prevent and treat diseases, improving the lives of patients worldwide. By investing billions of dollars and thousands of scientist-hours, it pushes the limits of science, fosters medical progress, and contributes to the prosperity of society.

On average, researchers identify one promising compound among 5,000–10,000 screened. Researchers then extensively test the compound to ensure its efficacy and safety, a process that can take 10 to 15 years for both a medicine and a vaccine.<sup>1</sup> In 2020, 53 new medicines were launched<sup>2</sup>, while currently more than 9,000 compounds are at different stages of development globally.<sup>3</sup>

### *Medicines in Development (Selected Categories)<sup>4</sup>*



1 PhRMA (2019) 2019 Biopharmaceutical in Perspective. Washington DC: Pharmaceutical Research and Manufacturers of America. Available at: <https://www.phrma.org/en/Report/Chart-Pack-Biopharmaceuticals-in-Perspective-Summer-2019>

2 U.S. Food and Drug Administration. Novel Drug Approvals for 2020. Available at: <https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2020>

3 Adis R&D Insight Database. Available at: <https://adis.springer.com> Visited October 2021 Adis R&D Insight Database. Available at: <https://adis.springer.com> Visited October 2021

4 Medicines in development may be attributed to more than one therapeutic area. Adis R&D Insight Database. Available at: <https://adis.springer.com> Visited October 2021

## Number of Novel Drugs Approved by the US Food and Drug Administration, 2008-2020<sup>5</sup>

YEAR	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Number of NMEs	29	25	31	35	26	35	44	35	51	56	27	55	62	48	53

Of all industrial sectors, the biopharmaceutical industry has consistently invested the most in R&D, even in times of economic turmoil and financial crisis. The research-based biopharmaceutical industry is estimated to have spent USD 198 billion globally on biopharmaceutical R&D in 2020.<sup>6</sup>

Compared with other high-technology industries, the annual spending by the biopharmaceutical industry is 8.1 times greater than that of the aerospace and defense industries, 7.2 times more than that of the chemicals industry, and 1.2 times more than that of the software and computer services industry.<sup>7</sup>

## Biopharmaceutical R&D Spending<sup>8</sup>



5 Statista - The Statistics Portal. (2021) Total number of novel drugs approved by CDER from 2008 to 2020. Statista. Available at: <https://www.statista.com/statistics/817534/annual-novel-drug-approvals-by-cder/>

6 Evaluate Pharma (2021) World Preview 2021, Outlook to 2026. London: Evaluate Ltd., p 23. Available at: [https://info.evaluate.com/rs/607-YGS-364/images/WorldPreviewReport\\_Final\\_2021.pdf](https://info.evaluate.com/rs/607-YGS-364/images/WorldPreviewReport_Final_2021.pdf)

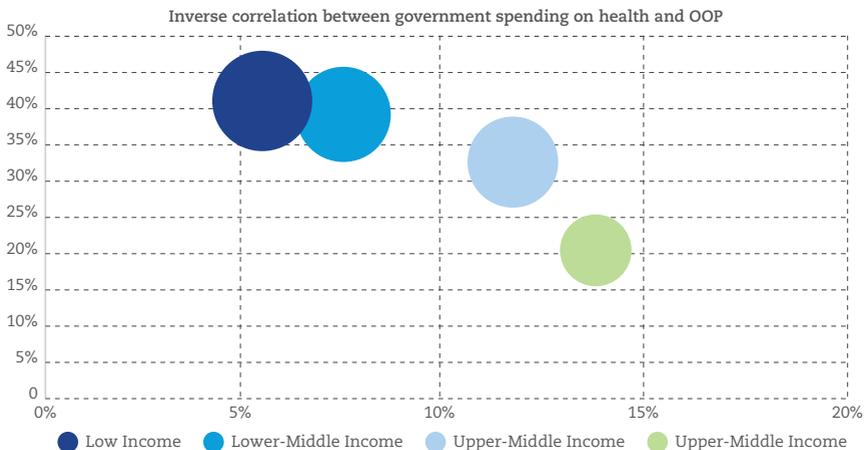
7 IFPMA Analysis based on: The 2020 EU Industrial R&D Investment Scoreboard; p 110. Available at: <https://op.europa.eu/en/publication-detail/-/publication/73e624aa-406c-11eb-b27b-01aa75ed71a1/language-en>

8 Evaluate Pharma (2019) World Preview 2019, Outlook to 2024. London: Evaluate Ltd., p 18. Available at: [https://info.evaluate.com/rs/607-YGS-364/images/EvaluatePharma\\_World\\_Preview\\_2019.pdf](https://info.evaluate.com/rs/607-YGS-364/images/EvaluatePharma_World_Preview_2019.pdf)

## The Role of Biopharmaceuticals in Well-Functioning Healthcare Systems

A robust healthcare system is an important pillar of every country's socio-economic development process.<sup>9</sup> Universal Health Coverage (UHC) is a core component of well performing health systems that are able to deliver health products, services, and care to patients. Patients in vulnerable healthcare systems are particularly challenged by high out-of-pocket (OOP) expenditure.

*Domestic General Government Health Expenditure (horizontal axis, % General Government Expenditure) and OOP (vertical axis, % Current Health Expenditure)*<sup>10</sup>



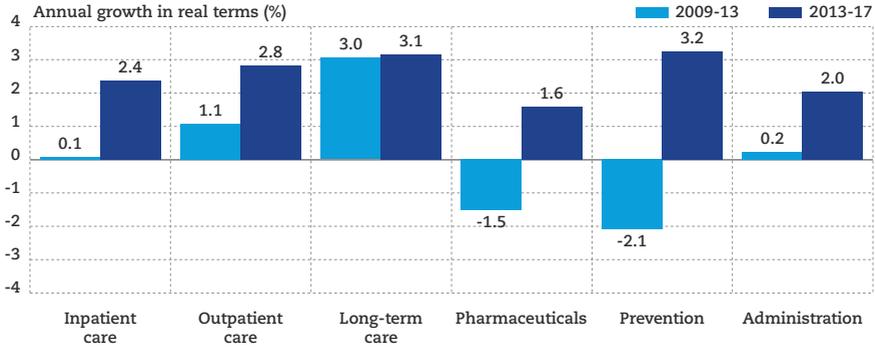
While health expenditure per capita varies across countries, spending on biopharmaceutical products as a share of health expenditure broadly remains constant.

9 UHC2030 Private Sector Constituency Statement: Private Sector contributions towards Universal Health Coverage. Available at: [https://www.uhc2030.org/fileadmin/uploads/uhc2030/Documents/Key\\_Issues/Private\\_Sector/UHC2030\\_Private\\_Sector\\_Constituency\\_Joint\\_Statement\\_on\\_UHC\\_FINAL.pdf](https://www.uhc2030.org/fileadmin/uploads/uhc2030/Documents/Key_Issues/Private_Sector/UHC2030_Private_Sector_Constituency_Joint_Statement_on_UHC_FINAL.pdf)

10 IFPMA Analysis based on data extracted from WHO, Global Health Observatory (GHO) data. Available at: <https://www.who.int/gho/en/> Visited November 2021.

World Bank Country Classifications: based on latest data available (2018).

### Annual Growth in Health Expenditure for Selected Services (Real Terms), OECD Average, 2009-13 and 2013-2017<sup>11</sup>



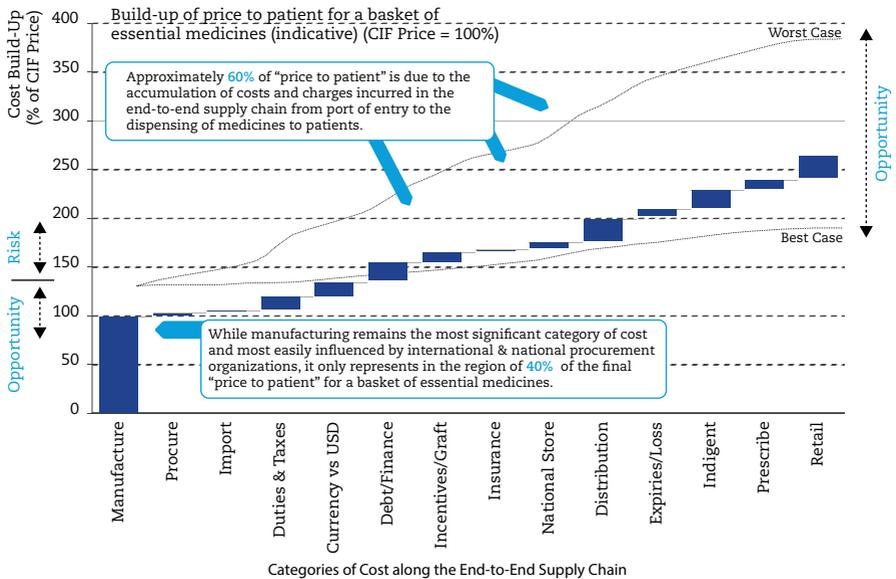
Medicines and vaccines contribute to the sustainability of healthcare systems by generating savings, for example by substantially reducing costs in other areas of healthcare, such as hospital stays and long-term care costs.<sup>12</sup>

Developing countries, especially least-developed countries, often have high mark-up costs that inflate the prices of essential medicines. These include distribution costs, import tariffs, port charges, importers' margins, value-added taxes on medicines, and high margins in the wholesale and retail components of the supply chain.

11 Note: Current health expenditure comprises personal health care (curative care, rehabilitative care, long-term care, ancillary services and medical goods) and collective services (prevention and public health services as well as administration – referring to governance and administration of the overall health system rather than at the health provider level). Curative, rehabilitative and long-term care can also be classified by mode of provision (inpatient, day care, outpatient and home care). OECD (2019), *Health at a Glance 2019: OECD Indicators*, OECD Publishing, Paris. Available at: <https://doi.org/10.1787/4dd50c09-en>

12 EFPIA (2021), *The pharmaceutical industry in figures 2021*. Available at: <https://www.efpia.eu/media/602709/the-pharmaceutical-industry-in-figures-2021.pdf>

## Examples of “Hidden” Costs of Pharmaceutical Procurement<sup>13</sup>

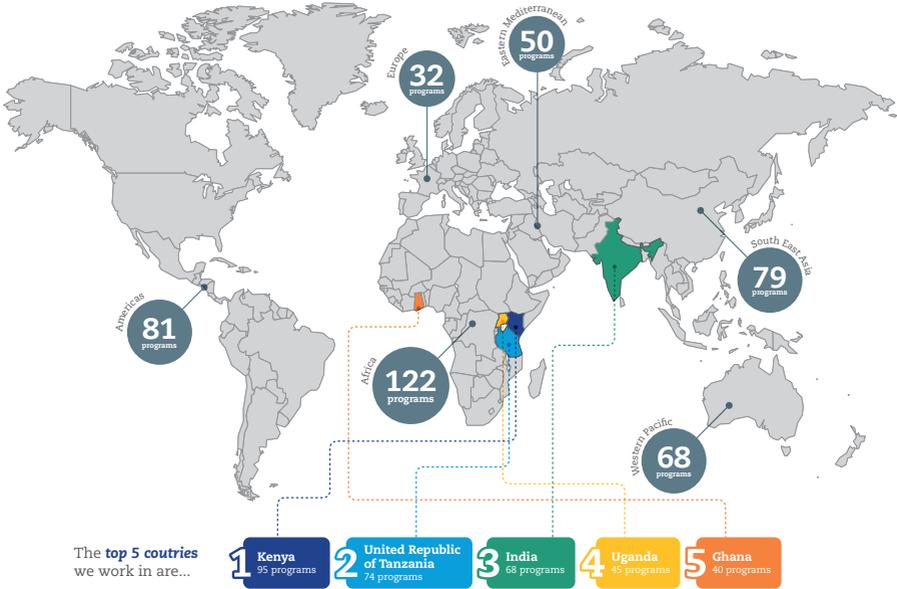


Research-based biopharmaceutical companies make a unique contribution to improving global health through the innovative medicines they develop. In addition, they have a strong track record of sustaining programs to improve the health of patients in low- and middle-income countries. These initiatives strengthen local healthcare capacity, educate patients and populations at risk, and conduct research and development (R&D) in diseases of the developing world. The Global Health Progress platform highlights 270 collaborations between the innovative biopharmaceutical industry and more than 1200 partners to support the Sustainable Development Goals (SDGs).<sup>14</sup>

13 Tackling the Triple Transition in Global Health Procurement. (2019). Final report of CGD’s working group on the future of global health procurement. Center for Global Development. Available at: <https://www.cgdev.org/sites/default/files/better-health-procurement-tackling-triple-transition.pdf>

14 Global Health Progress (2021). Official Website. Retrieved from Available at: <https://globalhealthprogress.org/>

Collaborations Between the Innovative Biopharmaceutical Industry and its Partners to Support the SDGs<sup>15</sup>



**Economic Footprint of the Biopharmaceutical Industry**

The biopharmaceutical industry makes major contributions to the prosperity of the world economy. It is a robust sector that has been one of the pillars of industrialized economies and is increasingly recognized as an important industry in the developing world as well.

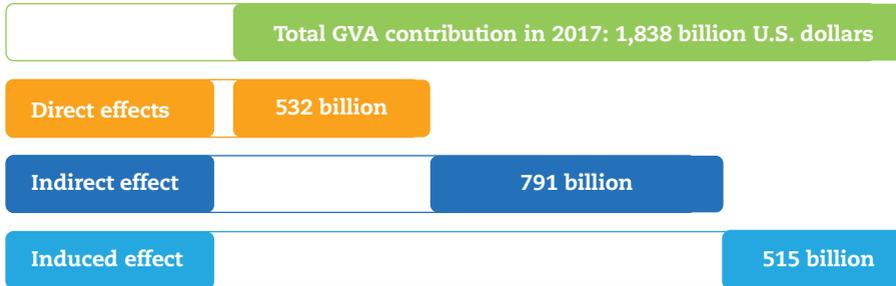
In 2018, the biopharmaceutical industry directly added roughly the GDP of the Netherlands (USD 532 billion)<sup>16</sup> to the world economy. In addition to the immediate economic effects it directly generates, industry also supported the global GDP with an additional USD 791 billion triggered by its consumption of intermediate inputs from other sectors through its global value chains. Moreover, the private consumption

<sup>15</sup> Global Health Progress (2021). Official Website: Available at: <https://globalhealthprogress.org/explore-our-collaborations/>

<sup>16</sup> WifOR (2020). The Global Economic Impact of the Pharmaceutical Industry. Available at: [https://www.ifpma.org/wp-content/uploads/2021/04/WifOR\\_Global\\_Economic\\_Footprint\\_Study\\_September\\_2020.pdf](https://www.ifpma.org/wp-content/uploads/2021/04/WifOR_Global_Economic_Footprint_Study_September_2020.pdf)

triggered by directly and indirectly generated income resulted in an extra USD 515 billion of GDP contribution to the global economy through induced effects. Therefore, combining direct, indirect and induced effects, the biopharmaceutical industry's total contribution to the world's GDP is USD 1,838 billion.<sup>17</sup>

*Direct, Indirect and Induced Gva Effects Triggered Through Economic Activities of the Global Biopharmaceutical Industry<sup>18</sup>*



The biopharmaceutical industry strongly contributes to employment in both developing and developed countries. In 2017, it employed approximately 5.5 million people worldwide, including through the manufacturing of generics medicines.<sup>19</sup> Through its expenditures on materials and services of other sectors, the global biopharmaceutical industry supported an additional 45.1 million indirect employees in other sectors along its supply chains. In addition, industry also supported 23.7 million jobs in other sectors induced by private consumption around the world through directly and indirectly generated income, such as childcare, retail, and more. Combined, industry's direct, indirect and induced effects on jobs amounted to 74.3 million employees in 2017.

<sup>17</sup> Ibid.

<sup>18</sup> Ibid.

<sup>19</sup> Ibid.

### Direct, Indirect and Induced Employment Effects Triggered Through Economic Activities of the Global Biopharmaceutical Industry<sup>20</sup>



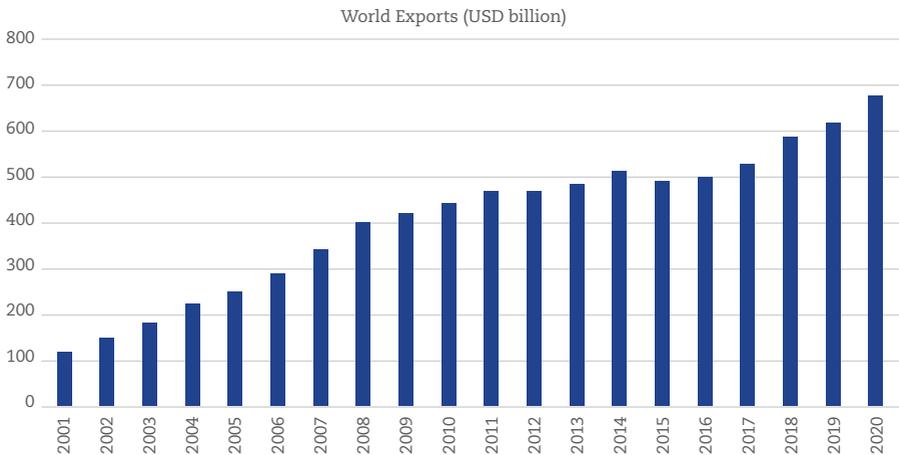
Global sales of biopharmaceutical products represent the international distribution of medical technology resulting from highly intensive R&D efforts in the exporting countries. At the same time, importing countries receive benefits through health improvements – even if they do not participate in R&D activities themselves.<sup>21</sup> As medical innovation is transmitted across the world, it contributes to significant gains in average life expectancy<sup>22</sup> and quality of life.

20 Ibid.

21 Kiriya N (2011) Trade and innovation: Pharmaceuticals. Available at: [https://read.oecd-ilibrary.org/trade/trade-and-innovation-pharmaceuticals\\_5kgdscrcv7jg-en#page1](https://read.oecd-ilibrary.org/trade/trade-and-innovation-pharmaceuticals_5kgdscrcv7jg-en#page1)

22 Ibid.

## World Biopharmaceutical Products Exports 2001-2020<sup>23</sup>



## Going Forward

Biopharmaceutical innovation is behind some of the greatest achievements in modern medicine. Today people live longer and healthier lives than previous generations. Unfortunately, not all communities have yet fully benefited from these medical advances. Addressing these issues is a complex challenge that requires long-term commitment from governments, civil society, and the private sector. The biopharmaceutical industry has been doing its part to help those in greatest need to also enjoy the benefits of medical progress. Much still needs to be done as the path forward requires a constant rethinking on how to maximize the innovative biopharmaceutical industry's positive impact on the health and prosperity for all societies. The biopharmaceutical industry will continue to invest in current and future pressing health challenges.

23 International Trade Center (ITC). International trade statistics 2001-2020, based on UN COMTRADE and ITC statistics. Retrieved from: Available at: <http://www.intracen.org/itc/market-info-tools/statistics-export-product-country/>



## Chapter 1

# BIOPHARMACEUTICAL INNOVATION AND GLOBAL PUBLIC HEALTH

The research-based biopharmaceutical industry plays a vital role in developing new medicines and vaccines to prevent and treat diseases, improving the lives of patients worldwide. Its key contribution to global health is turning fundamental research into innovative treatments. Industry's success rests on continuous innovation – for the prevention and treatment of common, complex, and neglected diseases, and for improvements in existing treatments and vaccines. Despite often challenging business conditions and one of the highest and stringent regulatory requirements of all sectors, the innovative biopharmaceutical industry undertakes investments that are amongst the riskiest of high- technology sectors. By investing billions of dollars and thousands of scientist-hours, it pushes the limits of science, fosters medical progress, and contributes to the prosperity of society.

In order to address public health challenges, the first step that a biopharmaceutical company takes is to invest in research and development (R&D) of new medicines and vaccines. This involves screening for chemical and biological compounds that exhibit the potential for treating new or existing conditions, or, in the case of vaccines, antigens that will stimulate the immune system to produce antibodies and thus protect against a specific disease.<sup>24</sup> On average, researchers identify one promising compound among 5,000–10,000 screened. Researchers then extensively test the compound to ensure its efficacy and safety, a process that can take 10 to 15 years for both a medicine and a vaccine.<sup>25</sup>

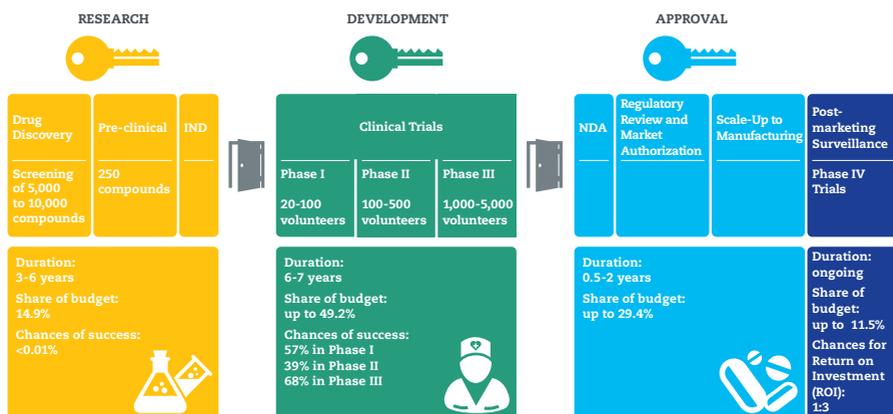
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24 Centers for Disease Control and Prevention (2021). Official Website: "Vaccines and Preventable Diseases". Available at: <https://www.cdc.gov/vaccines/vac-gen/default.htm>

25 PhRMA (2020) Biopharmaceutical in Perspective, Fall 2020. Washington DC: Pharmaceutical Research and Manufacturers of America. Available at: <https://www.phrma.org/resource-center/Topics/Advances-in-Treatment/Chart-Pack-Biopharmaceuticals-in-Perspective-Fall-2020>

The research-based biopharmaceutical industry has been involved in development of nearly all the medicines and vaccines currently on the market. Without the innovative biopharmaceutical industry, the generics industry would not exist. In 2020, 53 new medicines were launched,<sup>26</sup> while currently more than 9,000 compounds are at different stages of development globally.<sup>27</sup> The difference in these numbers highlights the many research hurdles that need to be overcome before compounds can be developed into safe and effective medicines.

Figure 1: The Research and Development Process<sup>28</sup>



26 U.S. Food and Drug Administration. Novel Drug Approvals for 2020. Available at: <https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2020>

27 Adis R&D Insight Database. Available at: <https://adis.springer.com> Visited October 2021

28 Pugatch Consilium (2015) Measuring the Global Biomedical Pulse. Available at: <https://www.pugatch-consilium.com/reports/BCI%202015%20-%20Measuring%20the%20Biomedical%20Pulse.pdf>;

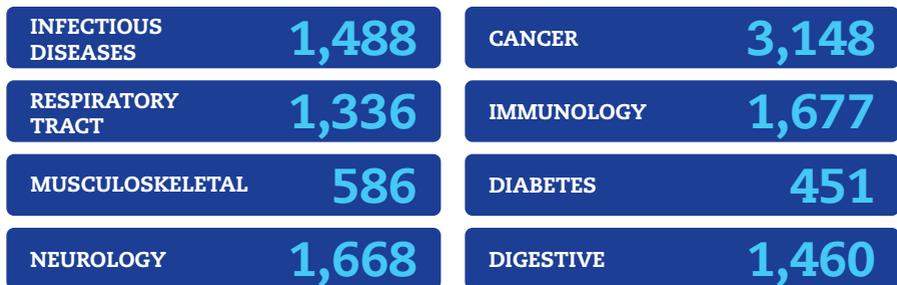
PhRMA (2021) PhRMA Annual Membership Survey. Washington DC: Pharmaceutical Research and Manufacturers of America, p 4. Available at: [https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/M-O/PhRMA\\_membership-survey\\_2021.pdf](https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/M-O/PhRMA_membership-survey_2021.pdf)

IQVIA Institute (2021). Global Trends in R&D. Available at: <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/global-trends-in-r-and-d/iqvia-institute-global-trends-in-rd-0521forweb.pdf>

## Biopharmaceutical R&D and its Impact on Global Health

Biopharmaceutical R&D has dramatically improved the lives of patients. Technological advances in research and development have opened many avenues of investigation to better prevent and treat diseases. During the 90s, for therapeutic areas such as cardiovascular disease, the understanding of the interplay of various genetic, environmental and lifestyle factors advanced considerably along with the available range of breakthrough preventive medicines. Nowadays, from cancer to mental and neurological disorders, the range of new and better biopharmaceutical products is continuously growing.<sup>29</sup> These medical discoveries, big and small, have increased life expectancy and resulted in a better quality of life for many. Over the last 60 years, globally, life expectancy has increased by around 20 years.<sup>30</sup> As the world continues to confront medical challenges, there are biopharmaceutical advancements and breakthroughs that are set to improve the lives of millions of people. Some of these successes are outlined below.

Figure 2: Medicines in Development (Selected Categories)<sup>31</sup>



29 Informa Pharma Intelligence (2021) Pharma R&D Annual Review 2021. London: Pharmaprojects, p.6 Available at: [https://pharmaintelligence.informa.com/~media/informa-shop-window/pharma/2021/files/infographic/pharmard\\_whitepaper.pdf](https://pharmaintelligence.informa.com/~media/informa-shop-window/pharma/2021/files/infographic/pharmard_whitepaper.pdf)

30 World Bank (2021), Life expectancy at birth, total (years). Available at: <https://data.worldbank.org/indicator/SP.DYN.LE00.IN>

31 Medicines in development may be attributed to more than one therapeutic area Adis R&D Insight Database. Available at: <https://adis.springer.com> Visited October 2021

## CANCER

Although great advancements have been made, the fight against cancer is one of the greatest global health challenges of our times. Thanks to DNA and genome mapping, the understanding of the different types of cancers and how to defeat them is constantly progressing. There are more than 200 different types of cancer, and each is diagnosed and treated in a particular way.<sup>32</sup>

As science evolves, biopharmaceutical companies provide medicines and vaccines to improve the lives of people. Innovative treatments have played a key role in saving and extending patients' lives. Between 1991 and 2018, in the US alone, nearly 3.2 million deaths caused by cancer were averted thanks also to innovative medicines.<sup>33</sup> Investments in R&D are providing tools and techniques to exponentially decrease costs of genetic sequencing that will allow clinicians to treat each cancer patient with a personalized combination of drugs. The field of immunotherapy holds much promise, as evidence has shown that increasing the strength of the patient's immune system to attack tumor cells can lead to a cancer-free diagnosis.<sup>34</sup> Another immunotherapy approach called adoptive cell transfer (ACT) collects and uses a patients' own immune cells to treat their cancer. One of the most advanced forms of ACT is CAR-T cell therapy. CAR-T cell therapy employs the use of T-cells. The latter play a critical role in orchestrating the immune response for killing cells infected by pathogens and can also target cancer cells. With the potential for this personalized treatment to be effective against a wide variety of aggressive cancers, expectations and hopes are running high. Developments in R&D could help, together with other essential building blocks such as access to healthcare and timely diagnosis, make a cancer-free world a reality.

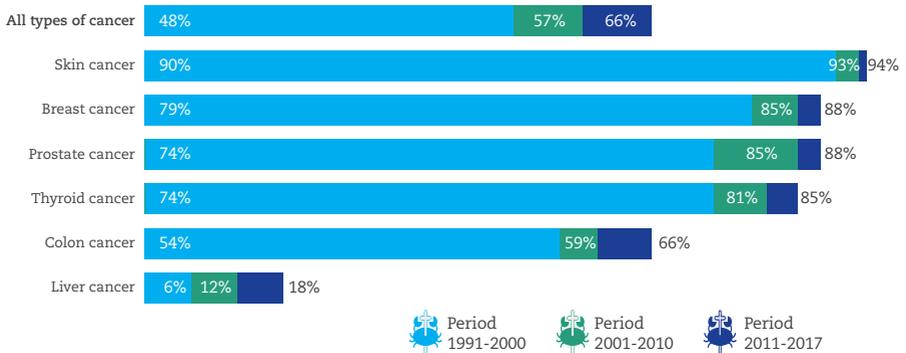
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32 United Kingdom National Health Service, last accessed October 2021. Available at: <https://www.nhs.uk/conditions/cancer/>

33 American Cancer Society, "Cancer Facts & Figures 2021", Available at: <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2021/cancer-facts-and-figures-2021.pdf>

34 National Cancer Institute 'CAR T Cells: Engineering patients' immune cells to treat their cancers', Available at: <https://www.cancer.gov/about-cancer/treatment/research/car-t-cells>

Figure 3: Five-year Survival Rates for Various Cancers, 1991-2000 vs 2001-2010 vs 2011-2017<sup>35</sup>



## HEPATITIS

Hepatitis has accompanied humanity throughout centuries. Once the viruses were identified, this finding contributed to a revolution in medicine that led to the development of a vaccine for Hepatitis A and B, which has dramatically reduced the mortality of the virus.

Despite these advances, the hepatitis C virus (HCV), which causes both acute and chronic infection, is the leading cause of liver cancer and the main reason for liver transplantation. An estimated 58 million people have chronic HCV infection contributing to around 290,000 deaths each year.<sup>36</sup> Step-by-step, scientists have improved HCV treatments, passing from 6% cure rates in 1991 to nearly 100% success rate today.<sup>37</sup> Today, the drugs used against HCV are the first that can completely cure a chronic viral illness, allowing millions of people to regain their health and live full and productive lives. This success was possible thanks to the improved understanding of the HCV molecular structure, together with sufficient investment and aligned global cooperation.

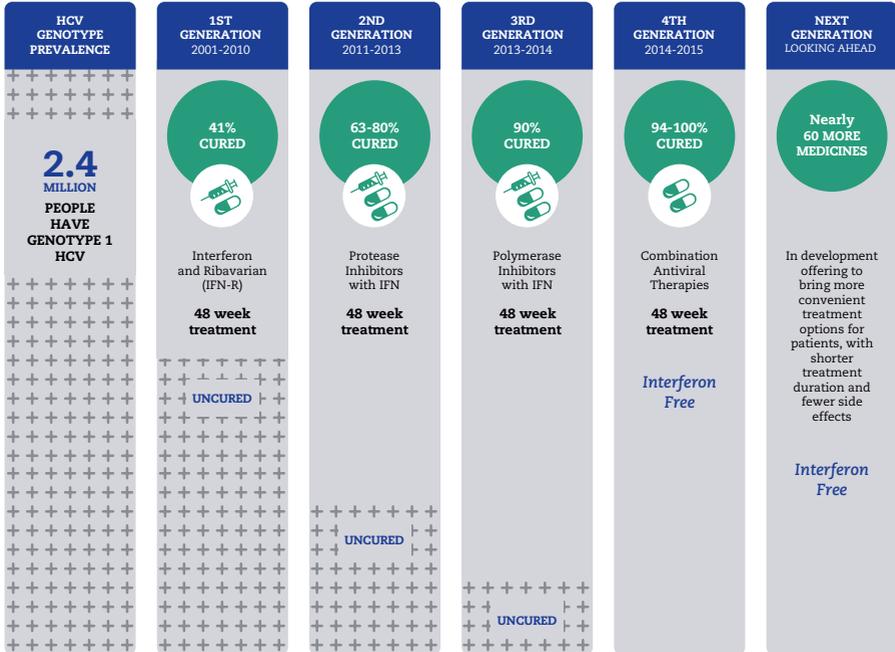
35 NEFARMA (2021) Medicines Monitor 2021 edition Available at: [https://vig-platform-axazmkc.netdna-ssl.com/production/documents/200594\\_VIG\\_MM2021\\_EN\\_DEF\\_02BS.pdf](https://vig-platform-axazmkc.netdna-ssl.com/production/documents/200594_VIG_MM2021_EN_DEF_02BS.pdf)

36 World Health Organization 'Hepatitis C', Available at: <https://www.who.int/news-room/fact-sheets/detail/hepatitis-c>

37 PhRMA (2020) Biopharmaceutical in Perspective, Fall 2020. Washington DC: Pharmaceutical Research and Manufacturers of America. Available at: <https://www.phrma.org/resource-center/Topics/Advances-in-Treatment/Chart-Pack-Biopharmaceuticals-in-Perspective-Fall-2020>

Direct acting antivirals made their debut in 2011, and were combined with other therapies, leading to a 12 week-long treatment course that cures without debilitating side effects.

Figure 4: Chronology of Hepatitis C treatment<sup>38</sup>



38 SustainAbility, May 2018. Report "50 years of global health progress". Geneva: IFPMA. Available at: <https://50years.ifpma.org/wp-content/uploads/2018/06/IFPMA50.pdf>

## HIV/AIDS

The human immunodeficiency virus (HIV), which causes acquired immunodeficiency syndrome, commonly known as AIDS, is an epidemic occurring in the present day.

The disease has impacted not only the medical field but also society. Much progress has been made in part due to the R&D efforts that transformed HIV from a death sentence to a manageable condition, extending the lives of millions of infected people and contributing to the prevention of the spreading of the disease. A major medical breakthrough in the fight against HIV/AIDS was the development of anti-retroviral (ARV) therapy.

With time, researchers discovered that combination therapy approaches – which work by combining drugs in different sequences – were far more effective than any single drug treatment, making these combinations the default treatment regimen.<sup>39</sup> ARV therapies can also eliminate the risk of transmission from the infected mother, to the child, throughout pregnancy, birth and breastfeeding.<sup>40</sup> Additional R&D efforts gave fruit to prescription medication, intended for PrEP (pre-exposure prophylaxis), that can be highly effective in preventing HIV from sexual intercourse or injectable drug use.<sup>41</sup> With the help of major medical discoveries, the research – based biopharmaceutical industry has developed more than 222 anti-retroviral Drugs for Global HIV/AIDS Relief, essential to control of the epidemic.<sup>42</sup> Research and development is also focusing on a vaccine against HIV, which would be a valuable complement to other preventive interventions, significantly contributing to the interruption of the chain of transmission of HIV.<sup>43</sup>

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39 Tseng et al. 'The evolution of three decades of antiretroviral therapy: challenges, triumphs and the promise of the future', 2014 Available at: <https://bpspubs.onlinelibrary.wiley.com/doi/pdf/10.1111/bcp.12403>

40 Hiv.gov Official Website (2018). Preventing Mother-to-Child Transmission of HIV. Available at: <https://www.hiv.gov/hiv-basics/hiv-prevention/reducing-mother-to-child-risk/preventing-mother-to-child-transmission-of-hiv>

41 Truvada Official Website. Available at: <https://www.truvada.com/>

42 U.S. Food and Drug Administration (2020) Antiretroviral Drugs Used in the Treatment of HIV Infection. Available at: <https://www.fda.gov/drugs/human-immunodeficiency-virus-hiv/hiv-treatment>

43 HIV Vaccines Trials Network (2022). Available at: <https://www.hvtn.org/hiv-study-basics/key-hiv-vaccine-topics.html>

Table 1: Decline in HIV/AIDS Death Rates<sup>44</sup>

	2000	2005	2010	2015	2016	2017	2018	2019	2020/ JUNE 2021
People living with HIV	<b>25.5 million</b> [20.5 million – 30.7 million]	<b>28.6 million</b> [23.0 million – 34.3 million]	<b>31.1 million</b> [25.0 million – 37.3 million]	<b>34.6 million</b> [27.7 million – 41.4 million]	<b>35.3 million</b> [28.3 million – 42.2 million]	<b>35.9 million</b> [28.8 million – 43.0 million]	<b>36.6 million</b> [29.3 million – 43.8 million]	<b>37.2 million</b> [29.8 million – 44.5 million]	<b>37.7 million</b> [30.2 million – 45.1 million]
New HIV Infections (total)	<b>2.9 million</b> [2.0 million – 3.9 million]	<b>2.4 million</b> [1.7 million – 3.4 million]	<b>2.1 million</b> [1.5 million – 2.9 million]	<b>1.8 million</b> [1.3 million – 2.4 million]	<b>1.7 million</b> [1.2 million – 2.4 million]	<b>1.7 million</b> [1.2 million – 2.3 million]	<b>1.6 million</b> [1.1 million – 2.2 million]	<b>1.5 million</b> [1.1 million – 2.1 million]	<b>1.5 million</b> [1.0 million – 2.0 million]
New HIV infections (aged 15+)	<b>2.3 million</b> [1.6 million – 3.2 million]	<b>2.0 million</b> [1.4 million – 2.7 million]	<b>1.8 million</b> [1.3 million – 2.5 million]	<b>1.6 million</b> [1.1 million – 2.2 million]	<b>1.5 million</b> [1.1 million – 2.1 million]	<b>1.5 million</b> [1.0 million – 2.1 million]	<b>1.4 million</b> [1.0 million – 2.0 million]	<b>1.4 million</b> [960 000 – 1.9 million]	<b>1.3 million</b> [910 000 – 1.8 million]
New HIV infections (aged 0–14)	<b>520 000</b> [340 000 – 820 000]	<b>480 000</b> [310 000 – 750 000]	<b>320 000</b> [210 000 – 510 000]	<b>190 000</b> [130 000 – 300 000]	<b>190 000</b> [120 000 – 290 000]	<b>180 000</b> [120 000 – 280 000]	<b>170 000</b> [110 000 – 260 000]	<b>160 000</b> [100 000 – 250 000]	<b>150 000</b> [100 000 – 240 000]
AIDS-related deaths	<b>1.5 million</b> [1.1 million – 2.2 million]	<b>1.9 million</b> [1.3 million – 2.7 million]	<b>1.3 million</b> [910 000 – 1.9 million]	<b>900 000</b> [640 000 – 1.3 million]	<b>850 000</b> [600 000 – 1.2 million]	<b>800 000</b> [570 000 – 1.2 million]	<b>750 000</b> [530 000 – 1.1 million]	<b>720 000</b> [510 000 – 1.1 million]	<b>680 000</b> [480 000 – 1.0 million]
People accessing antiretroviral therapy*	<b>560 000</b> [560 000 – 560 000]	<b>2.0 million</b> [2.0 million – 2.0 million]	<b>7.8 million</b> [6.9 million – 7.9 million]	<b>17.1 million</b> [14.6 million – 17.3 million]	<b>19.3 million</b> [16.6 million – 19.5 million]	<b>21.5 million</b> [19.6 million – 21.7 million]	<b>23.1 million</b> [21.9 million – 23.4 million]	<b>25.5 million</b> [24.5 million – 25.7 million]	<b>27.5 million</b> [26.5 million – 28.2 million]
HIV resources available**	<b>US\$ 5.1 billion</b>	<b>US\$ 9.3 billion</b>	<b>US\$ 16.6 billion</b>	<b>US\$ 20.3 billion</b>	<b>US\$ 20.7 billion</b>	<b>US\$ 22.3 billion</b>	<b>US\$ 22.0 billion</b>	<b>US\$ 21.6 billion</b>	<b>US\$ 21.5 billion</b>

44 UNAIDS (2021) Fact Sheet 2021. Geneva: United Nations AIDS. Available at: [https://www.unaids.org/en/resources/documents/2021/UNAIDS\\_FactSheet](https://www.unaids.org/en/resources/documents/2021/UNAIDS_FactSheet)

## CARDIOVASCULAR DISEASES

Cardiovascular diseases (CVDs) are a group of disorders affecting the heart and blood vessels, imposing a high societal and economic burden. Scientific progress and R&D efforts have led to innovative medicines that can save and extend lives.<sup>45</sup> The value of the hypocholesterolemic and antihypertensive drugs have largely demonstrated their efficacy, thanks to long-term studies demonstrating that lowering cholesterolemia and blood pressure are successful at reducing the risks of CVDs. Moreover, drugs utilized for surgeries that contributed to prevention of clotting and inhibit immune systems from rejecting transplanted organs have also been useful in the fight against CVDs.<sup>46</sup> Patients suffering from heart failure now have means to improve their quality of life through treatments that, together with improvements in care, prevention, and reduction in risk factors, have contributed to declines in cardiovascular mortality (see Table 2).

Companies are also exploring precision medicine which uses techniques that develop effective treatments and prevention strategies based on patients' genes, biomarkers, lifestyles, and environmental factors.<sup>47</sup> Innovative regimens based on progenitor cells, powerful cells with the ability to form new blood vessels are also emerging as promising approaches for the treatment of a variety of CVDs as this technique could play a key role in repairing damaged heart tissues.<sup>48</sup> CVDs will continue to be an emphasis for biopharmaceutical R&D as it continues to dominate the global stage as a great public health challenge creating stress on public health, healthcare systems, and national economies.

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45 World Health Organization. Fact Sheet Cardiovascular Diseases. Available at: [https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-\(cvds\)](https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds)) Accessed October 2021.

46 The Guardian, 'Statins prevent 80,000 heart attacks and strokes a year in UK, study finds' September 2017 Available at: <https://www.theguardian.com/society/2017/sep/06/statins-cut-the-risk-of-heart-disease-death-by-28-among-men-study-shows>

47 U.S. National Library of Medicine 'What is precision medicine?', accessed October 2021 Available at: <https://medlineplus.gov/genetics/understanding/precisionmedicine/definition/>

48 AstraZeneca 'Harnessing the power of cell therapy' (2021) Available at: <https://www.astrazeneca.com/r-d/next-generation-therapeutics/cell-therapies.html>

Table 2: Age-Standardised Rate of DALYs Lost from Cardiovascular Disease, by Sex, 1990 to 2015, Europe, Per 100,000 Population<sup>49</sup>

YEARS	1990	1995	2000	2005	2010	2015
Europe (males)	9,528	10,391	9,434	8,814	7,080	6,297
Europe (females)	5,384	5,710	5,215	4,728	3,819	3,391

Table 3: Rates of Hospital Discharges from CVD, 1990 to 2015, Europe, per 100,000 Population<sup>50</sup>

YEARS	1990	1995	2000	2005	2010	2015 (LATEST AVAILABLE 2013)
Europe (both sexes)	1,919	2,029	2,073	2,341	2,453	2,521

## DIABETES

Another chronic disease that continues to rise in incidence and prevalence is diabetes. A close link exists between diabetes type 2 and CVDs as having diabetes is a primary risk factor for CVDs.<sup>51</sup> The International Diabetes Federation published that in 2021, an estimated 537 million adults (20-79 years) are living with diabetes, and the condition caused 6.7 million deaths. Diabetes led to at least USD 966 billion dollars in health expenditure or 9% of total spending on adults.<sup>52</sup>

49 European Heart Network (2017). European Cardiovascular Disease Statistics 2017 edition. Available at: <https://ehnhheart.org/cvd-statistics/cvd-statistics-2017.html>

Notes: DALYs are defined as years of healthy life lost due to disease and are calculated as the sum of years lost due to premature death (YLLs) and years lived with disability (YLDs).

50 European Heart Network (2017). European Cardiovascular Disease Statistics 2017 edition. Available at: <https://ehnhheart.org/cvd-statistics/cvd-statistics-2017.html>

Notes: Hospital discharge rates describe the number of patients who leave hospital after receiving care per 100,000 population.

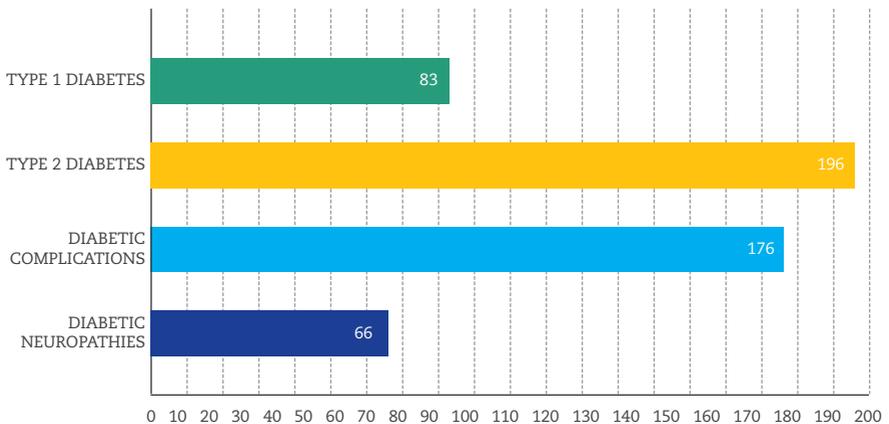
51 CDC official website (2021). Diabetes and your Heart. Available at: <https://www.cdc.gov/diabetes/library/features/diabetes-and-heart.html>

52 IDF Diabetes Atlas Tenth edition 2021. Available at: <https://www.idf.org/aboutdiabetes/what-is-diabetes/facts-figures.html>

Thanks to innovative treatments, delivery, and monitoring mechanisms, and the continuous reduction of side effects, patients' quality of life has improved. Insulin pens can now record the date, time, and amount of previous doses so that patients and healthcare providers can know exactly how much insulin the patient last took and when.<sup>53</sup> Insulin pumps can be tubing-free patches that adhere directly to the skin. Advances in injectable drugs also help lower blood sugar levels in patients with Type 2 diabetes with faster and longer lasting effects.

In addition to insulin, many new oral antidiabetic drugs have been created to help ease the burden of treatment administration on patients and adequately control blood glucose. Moreover, many non-invasive tests have been developed which measure glucose without the need to draw blood,<sup>54</sup> and recently, researchers have attempted to use patient saliva as a non-invasive test method.<sup>55</sup> Though diabetes is a persistent condition requiring constant attention, innovations in medicines and drug administration technology are empowering patients to effectively manage their disease.

Figure 5: Medicines in Development for Diabetes and Related Conditions<sup>56</sup>



53 PhRMA 'Medicines in Development for Diabetes: A report on diabetes and related conditions', 2016 Available at: <http://phrma-docs.phrma.org/files/dmfile/medicines-in-development-report-diabetes.pdf>

54 Fierce Biotech 'Apple is testing a non-invasive blood glucose monitor', 2017 Available at: <https://www.fiercebiotech.com/medical-devices/apple-testing-a-noninvasive-blood-glucose-monitor-cnbc>

55 Phys.Org 'Biological sensor can detect glucose levels in saliva more accurately and cost-efficiently than blood test', 2017 Available at: <https://phys.org/news/2017-05-biological-sensor-glucose-saliva-accurately.html>

56 Adis R&D Insight Database. Available at: <https://adis.springer.com> Visited January 2022

## VACCINES

Since the development of the first modern vaccine in the late 1700s, vaccines have saved millions of lives every year. Scientists have developed vaccines to protect individuals and their family from over 30 different infectious diseases – not just childhood, but at every age and stage of life, including recent vaccines to prevent meningococcal diseases, Ebola, malaria, COVID-19 and HPV-related cancers including cervical cancer. It is estimated that 4-5 million deaths are averted each year in all age groups and 32 million deaths could be avoided over the next 10 years.<sup>57</sup>

Vaccines help stop the spread of deadly and devastating diseases. The eradication of smallpox, declared in 1980, is one of the greatest achievements. Smallpox killed 300 million people in the 20th century alone. Today, the spread of poliovirus - the leading cause of permanent disability in children, with 1 in 200 having paralysis from it - is the lowest it's ever been, and eradication is realistic.<sup>58</sup> We are also close to eliminate measles and rubella. Just between 2000 and 2019, immunization campaigns cut the number of deaths caused by measles by an estimated 88%, saving more than 25.5 million lives, over that period.<sup>59</sup>

Vaccines can lower health inequalities and contribute to broader wellbeing and prosperity. After getting vaccines, children are less likely to miss school as adults to miss work due to illness and are therefore more likely to actively contribute to society for longer.<sup>60</sup> Vaccines also lower the burden of care on families and healthcare systems, preventing 24 million people in developing countries to fall into poverty by 2030.<sup>61</sup> For society, vaccines improve financial security, which can lead to greater investment and improved political and economic stability.<sup>62</sup> Between 2021 and 2030, for every USD 1 spent on vaccination in low- and middle-income countries between 2021 and 2030, USD

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57 WHO (2019), Facts in Pictures. Available at: <https://www.who.int/news-room/facts-in-pictures/detail/immunization>

58 IFPMA (2018). 50 Years of Global Health Progress. Available at: <https://50years.ifpma.org/wp-content/uploads/2018/06/IFPMA50.pdf>

59 Ibid.

60 VOICE (2021) Official Website. Available at: [https://immunizationevidence.org/featured\\_issues/vaccination-helping-children-think-learn-and-thrive/](https://immunizationevidence.org/featured_issues/vaccination-helping-children-think-learn-and-thrive/); ABPI (2021) Official Website "Economic and societal impacts of vaccines". Available at: <https://www.abpi.org.uk/value-and-access/vaccines/economic-and-societal-impacts-of-vaccines/>

61 WHO (2021). Immunization Agenda 2030 A global strategy to leave no one behind. Available at: [https://cdn.who.int/media/docs/default-source/immunization/strategy/ia2030/ia2030-draft-4-waha\\_b8850379-1fce-4847-bfd1-5d2c9d9e32f8.pdf?sfvrsn=5389656e\\_66&download=true](https://cdn.who.int/media/docs/default-source/immunization/strategy/ia2030/ia2030-draft-4-waha_b8850379-1fce-4847-bfd1-5d2c9d9e32f8.pdf?sfvrsn=5389656e_66&download=true)

62 GAVI (2021). Official Website: "Value of Vaccination". Available at: <https://www.gavi.org/vaccineswork/value-vaccination>

21 will be saved in health care costs, lost wages, and lost productivity due to illness and death.<sup>63</sup> Vaccination could prevent about USD 1510 billion in costs of illness in the world's 94 lowest-income countries, compared to no vaccination.<sup>64</sup>

Recent new vaccines help prevent and control outbreaks, tackling both endemic and pandemic diseases. The ground-breaking and long-awaited new malaria vaccine could help save the lives of more than 500,000 African children under the age of 5 who die from malaria every year<sup>65</sup>- malaria being the primary cause of childhood illness and death in sub-Saharan Africa.<sup>66</sup> The vaccine is the result of 30 years of research and development, and partnership between the biopharmaceutical industry and global health organizations. That is also the first vaccine for any parasitic disease developed so far and can contribute to saving lives of children at risk.<sup>67</sup> The long track record of developing solutions to combat a range of infectious diseases, including viruses with epidemic and pandemic potential such as those responsible for MERS, SARS, and Ebola, have allowed the industry to be ready to fast-track research and development for a COVID-19 vaccine.

At the time this publication is written we have safe and effective COVID-19 vaccines, developed in just under a year, which were fundamental to lowering the spread of the virus while also preventing deaths and hospitalisations. Industry continues to prioritize research to develop the next generation of COVID-19 vaccines, with over 40 vaccines currently in Phase 3 development.<sup>68</sup>

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63 Sim, S.Y., Watts, E., Constenla, D., Brenzel, L. and Patenaude, B.N., 2020. Return On Investment From Immunization Against 10 Pathogens In 94 Low-And Middle-Income Countries, 2011–30: Study estimates return on investment from immunization programs against ten pathogens for ninety-four low-and middle-income countries from 2011 to 2030. *Health Affairs*, 39(8), pp.1343-1353. Available at: <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2020.00103>

64 GAVI (2021). Official Website: "Value of Vaccination". Available at: <https://www.gavi.org/vaccineswork/value-vaccination>

65 WHO (2021). Official Website "Fact Sheet: Malaria". Available at: <https://www.who.int/en/news-room/fact-sheets/detail/malaria>

66 WHO (2021). Official Website "News release: WHO recommends groundbreaking malaria vaccine for children at risk". Available at: <https://www.who.int/news/item/06-10-2021-who-recommends-groundbreaking-malaria-vaccine-for-children-at-risk>

67 GSK (2021). GSK welcomes WHO recommendation for broad roll-out of its RTS,S/AS01e (RTS,S) malaria vaccine. Official website. Available at: <https://www.gsk.com/en-gb/media/press-releases/gsk-welcomes-gavi-decision-to-fund-the-roll-out-of-malaria-vaccines-for-children/>

68 Airfinity (2022). Last Accessed June 2022. Available at: <https://www.airfinity.com/>; GAVI (2021). Official Website "How next-generation COVID-19 vaccines could help to end the pandemic". Available at: <https://www.gavi.org/vaccineswork/how-next-generation-covid-19-vaccines-could-help-end-pandemic>

Figure 6: Timeline of WHO EUL for C-19 Vaccines<sup>69</sup>



Figure 7: COVID-19 Vaccines Pipeline Overview by R&D Stage<sup>70</sup>

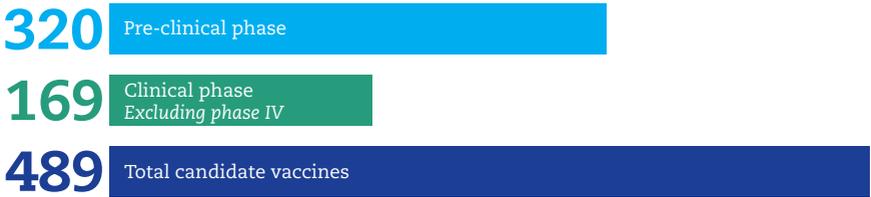


Figure 8: COVID-19 Vaccines in Clinical Development<sup>71</sup>



Vaccines can help to protect people from the health impacts of climate change, such as rotavirus, which thrive in warmer weather.<sup>72</sup> Climate change also exposes people in new areas to diseases like malaria, yellow fever, and dengue which are spread by insects and parasites that now can survive in newly warmer places. This can change the patterns and intensity of seasonal diseases. Vaccines can help make sure more people will be

69 WHO (2022). COVID-19 vaccines WHO EUL issued. Available at: <https://extranet.who.int/pqweb/vaccines/vaccinescovid-19-vaccine-eul-issued>

70 Airfinity (2022). Last Accessed June 2022. Available at: <https://www.airfinity.com/>  
 Note: \* AstraZeneca (University of Oxford) and Covishield (Serum Institute of India) are counted as one candidate, as well as Novavax and Covovax (Serum Institute of India).

71 Airfinity (2022). Last Accessed June 2022. Available at: <https://www.airfinity.com/>

72 Smith, K.R., A.Woodward, D. Campbell-Lendrum, D.D. Chadee, Y. Honda, Q. Liu, J.M. Olwoch, B. Revich, and R. Sauerborn, 2014: Human health: impacts, adaptation, and co-benefits. In: Climate Change 2014: Impacts, Adaptation, and Vulnerability. Part A: Global and Sectoral Aspects. Contribution of Working Group II to the Fifth Assessment Report of the Intergovernmental Panel on Climate Change [Field, C.B., V.R. Barros, D.J. Dokken, K.J. Mach, M.D. Mastrandrea, T.E. Billir, M. Chatterjee, K.L. Ebi, Y.O. Estrada, R.C. Genova, B. Girma, E.S. Kissel, A.N. Levy, S. MacCracken, P.R. Mastrandrea, and L.L.White (eds.)]. Cambridge University Press, Cambridge, United Kingdom and New York, NY, USA, pp. 709-754. Available at: [https://www.ipcc.ch/site/assets/uploads/2018/02/WGIIAR5-Chap11\\_FINAL.pdf](https://www.ipcc.ch/site/assets/uploads/2018/02/WGIIAR5-Chap11_FINAL.pdf)

protected from the impact of these changes.<sup>73</sup> Research has found that climate change could mean an estimated 8.4 billion people are at risk for malaria and dengue by the end of the 21st century, which is 4.7 billion more people compared to 1970-1999.<sup>74</sup> It also found that in the regions of Africa where yellow fever is common, climate change could lead 11% more deaths by 2050.<sup>75</sup>

Vaccines also serve as a frontline defense against antimicrobial resistance (AMR) - the biggest threats to human health globally.<sup>76</sup> Without antibiotics, childbirth, cancer treatment, routine surgery, and organ transplants bring a higher chance of serious and sometimes deadly infections. Vaccines can already protect against a number of common bacterial infections, such as Hib and pneumococcal infections. This lowers antibiotic use and the chance for bacteria to become resistant. The biopharmaceutical industry is also developing new vaccines to help protect against antibiotic-resistant bacteria such as *E. Coli*, Group B *Streptococcus* and *Staphylococcus aureus*, which could help lower the spread of AMR. Vaccines prevent viral infections, which are often treated inappropriately with antibiotics, and which can also give rise to secondary infections that require antibiotic treatment. Moreover, several viral infections, such as influenza, measles and respiratory syncytial virus (RSV), and most recently COVID-19, predispose to secondary bacterial infections, which then require antibiotic treatment.

Vaccines are one of the most important invention in global public health and the biopharmaceutical industry continues to develop new and improved vaccines to help prevent disease, save more lives, and bring the benefits of vaccination to everyone. There are 260 new vaccines being developed to protect against a number of diseases and pathogens which lack effective vaccines, including HIV, Zika, Norovirus, Alzheimer's disease, Lyme Disease, Respiratory Syncytial Virus (RSV), and Group B streptococcus.<sup>77</sup> New mRNA vaccines offer new hope for diseases such as flu, HIV, rabies, and malaria,

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73 WHO (2021). Immunization Agenda 2030 A global strategy to leave no one behind. Available at: [https://cdn.who.int/media/docs/default-source/immunization/strategy/ia2030/ia2030-draft-4-wha\\_b8850379-1fce-4847-bfd1-5d2c9d9e32f8.pdf?sfvrsn=5389656e\\_66&download=true](https://cdn.who.int/media/docs/default-source/immunization/strategy/ia2030/ia2030-draft-4-wha_b8850379-1fce-4847-bfd1-5d2c9d9e32f8.pdf?sfvrsn=5389656e_66&download=true)

74 Colón-González, F.J., Sewe, M.O., Tompkins, A.M., Sjödin, H., Casallas, A., Rocklöv, J., Caminade, C. and Lowe, R., 2021. Projecting the risk of mosquito-borne diseases in a warmer and more populated world: a multi-model, multi-scenario intercomparison modelling study. *The Lancet Planetary Health*, 5(7), pp.e404-e414. Available at: [https://www.thelancet.com/journals/lanph/article/PIIS2542-5196\(21\)00132-7/fulltext](https://www.thelancet.com/journals/lanph/article/PIIS2542-5196(21)00132-7/fulltext)

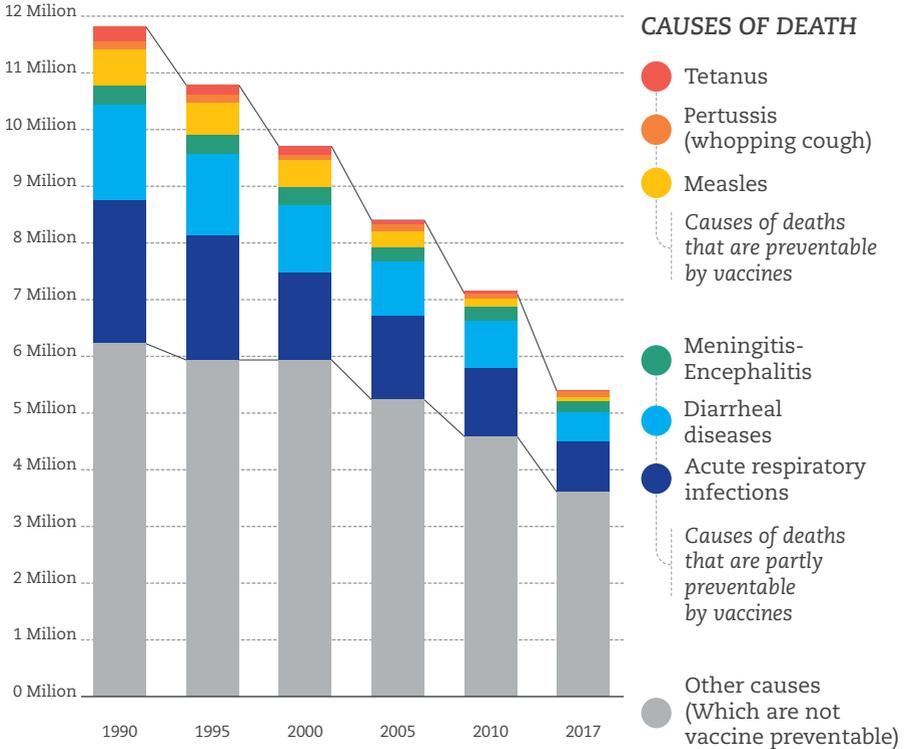
75 GAVI (2021). Official Website: "More people could be put at risk from yellow fever because of climate change". Available at: <https://www.gavi.org/vaccineswork/climate-change-could-put-thousands-more-risk-yellow-fever>

76 Vekemans, J., Hasso-Agopsowicz, M., Kang, G., Hausdorff, W.P., Fiore, A., Tayler, E., Klemm, E.J., Laxminarayan, R., Srikantiah, P., Friede, M. and Lipsitch, M., 2021. Leveraging vaccines to reduce antibiotic use and prevent antimicrobial resistance: a World Health Organization action framework. *Clinical Infectious Diseases*. Available at: <https://www.who.int/publications/m/item/leveraging-vaccines-to-reduce-antibiotic-use-and-prevent-antimicrobial-resistance>

77 PhRMA (2020). Medicines in development for Vaccines. Available at: <https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/medicines-in-development-for-vaccines-2020.pdf>

further exploring how this vaccine technology could be used to treat disease, for instance by training our immune systems to fight hard-to-treat cancers. We are also improving how vaccines are made, distributed and administered to make it easier for everyone and everywhere to benefit from their protection and to lower health inequalities.

Figure 9: Estimated Annual Number of Measles Deaths With and Without Vaccination Programs – Worldwide, 2000–2019<sup>78</sup>

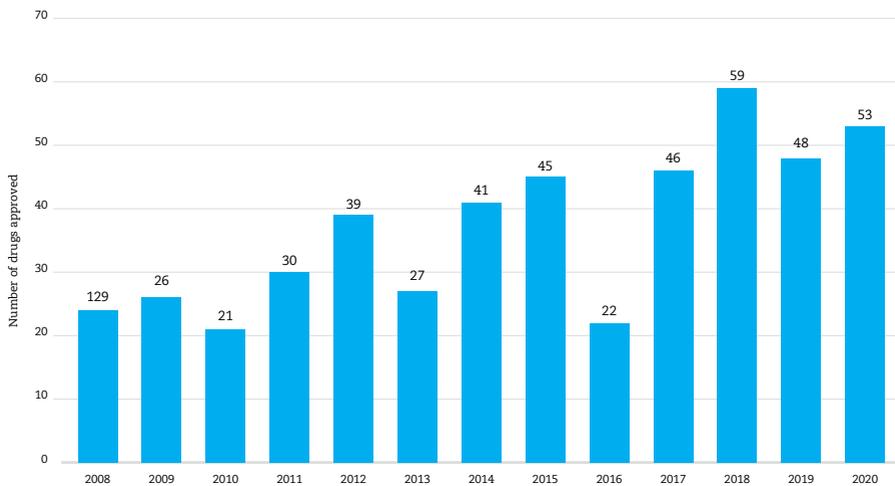


78 Patel MK, Goodson JL, Alexander JP Jr, Kretsinger K, Sodha SV, Steulet C, Gacic-Dobo M, Rota PA, McFarland J, Menning L, Mulders MN, Crowcroft NS. Progress Toward Regional Measles Elimination - Worldwide, 2000-2019. MMWR Morb Mortal Wkly Rep. 2020 Nov 13;69(45):1700-1705. <https://pubmed.ncbi.nlm.nih.gov/33180759/>. PMID: 33180759; PMCID: PMC7660667.

## A Look into the Biopharmaceutical Industry R&D Pipeline and Investments

In the 2016-2020 period alone, the FDA has approved 228 medicines that offer new hope to patients with hard-to-treat diseases, compared with 182 in the period 2011-2015.<sup>79</sup> More than 9,000 medicines are in development worldwide, with 1,488 drugs for infectious diseases; 3,148 for cancer; 451 for diabetes; and 1,668 for neurologic disorders between phase I and III of development.<sup>80</sup>

Figure 10: Number of Novel Drugs Approved by the US Food and Drug Administration, 2008-2020<sup>81</sup>



Today, the cost of developing a successful medicine can exceed, according to some studies, USD 2.6 billion<sup>82</sup>, compared to USD 179 million in 1970s.<sup>83</sup> This increase reflects the various technical, regulatory and economic challenges R&D pipelines must face.

79 IFPMA analysis based on Statista - The Statistics Portal (2021) Total number of novel drugs approved by CDER from 2008 to 2020. Statista. Available at: <https://www.statista.com/statistics/817534/annual-novel-drug-approvals-by-cder/>

80 Adis R&D Insight Database. Available at: <https://adis.springer.com> Visited October 2021

81 Statista - The Statistics Portal. (2021) Total number of novel drugs approved by CDER from 2008 to 2020. Statista. Available at: <https://www.statista.com/statistics/817534/annual-novel-drug-approvals-by-cder/>

82 DiMasi, J. A.; Grabowskib, H. G.; Hansenc, R. W. (2016) Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs. Journal of Health Economics. doi: Available at: <https://www.ncbi.nlm.nih.gov/pubmed/26928437>

83 PhRMA (2019) 2019 Biopharmaceutical in Perspective. Washington DC: Pharmaceutical Research and Manufacturers of America. Available at: <https://www.phrma.org/en/Report/Chart-Pack-Biopharmaceuticals-in-Perspective-Summer-2019>

Companies often experience lost R&D investments (that is, R&D expenditures that do not materialize in a market-approved medicine) because biopharmaceutical R&D is marked by high failure rates (see Figure 8). For example, an early-phase compound may have a promising outlook in the lab, but only preclinical and clinical trials will demonstrate its efficacy, quality, and safety for real world application. In addition, lost investments may increase when a failure occurs in later R&D phases. A phase III failure is significantly more costly than a preclinical failure because each phase is associated with a required investment (see Table 5).

Table 4: R&D Expenditures in the US, 2020<sup>84</sup>

FUNCTION	DOLLARS	SHARE
Pre-Human/Pre-Clinical	\$13,604.0	14.9%
Phase I	\$6,968.3	7.6%
Phase II	\$8,429.4	9.3%
Phase III	\$24,773.1	27.2%
Approval	\$3,932.5	4.3%
Phase IV	\$10,512.4	11.5%
Uncategorized	\$22,906.6	25.1%
TOTAL R&D	\$91,126.3	100.0%

Figure 11: Medicines in Development by Regulatory Phase Globally, 2021<sup>85</sup>

PHASE	
Phase III	2,353
Phase II/III	502
Phase II	4,084
Phase I/II	1,989
Phase I	3,928

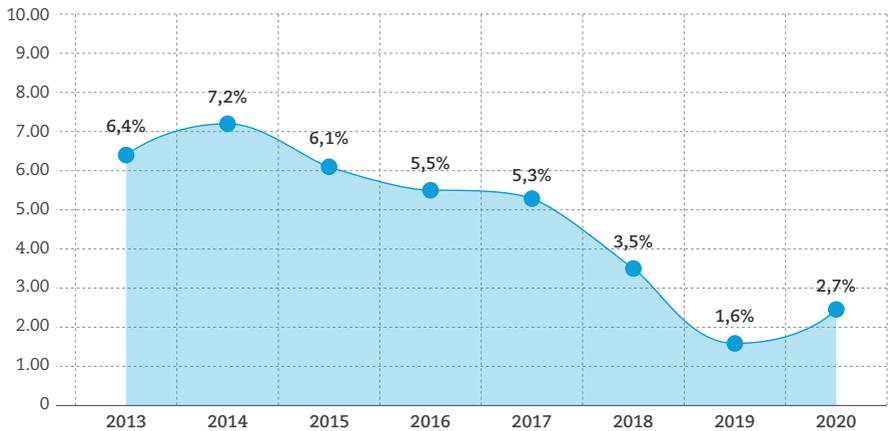
84 Notes: All figures include company-financed R&D only. Total values may be affected by rounding. PhRMA (2021) PhRMA Annual Membership Survey. Washington DC: Pharmaceutical Research and Manufacturers of America, p 4. Available at: [https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/M-O/PhRMA\\_membership-survey\\_2021.pdf](https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/M-O/PhRMA_membership-survey_2021.pdf)

85 Adis R&D Insight Database. Available at: <https://adis.springer.com> Visited October 2021

Figure 12: R&D Composite Success Rate and Average Phase Success Rates Phase I to Filing, 2010–2020<sup>86</sup>



Figure 13: Internal Rate of Return on Late Stage Pipeline for Large Cap Biopharmaceutical Companies, 2010 – 2020<sup>87</sup>



86 IQVIA Institute (2021). Global Trends in R&D, May 2021 Available at <https://www.iqvia.com/en/insights/the-iqvia-institute/reports/global-trends-in-r-and-d>

87 Deloitte LLP (2021) Seeds of change: Measuring the return from pharmaceutical innovation 2020. Available at: <https://www2.deloitte.com/uk/en/pages/life-sciences-and-healthcare/articles/measuring-return-from-pharmaceutical-innovation.html>

Figure 13 represents a Deloitte analysis that measures the return from pharmaceutical innovation by tracking over time a cohort of the 12 largest biopharmaceutical companies by 2009 R&D spending. This sample is used as a proxy to measure the industry's Internal Rate of Return (IRR), which is based on the total spending to launch assets (obtained from publicly available sources, such as audited balance sheets and third party providers) and an estimate of future revenue generated from the launch of those assets.

Rising R&D costs and lowering returns on R&D (see Figure 13) have been accompanied by more stringent testing requirements. In addition, once a medicine receives regulatory approval, national health authorities require companies to track and report patients' experiences (referred to as "pharmacovigilance"). These reporting requirements are becoming stricter, raising the investment cost in a given medicine as long as it is being marketed.

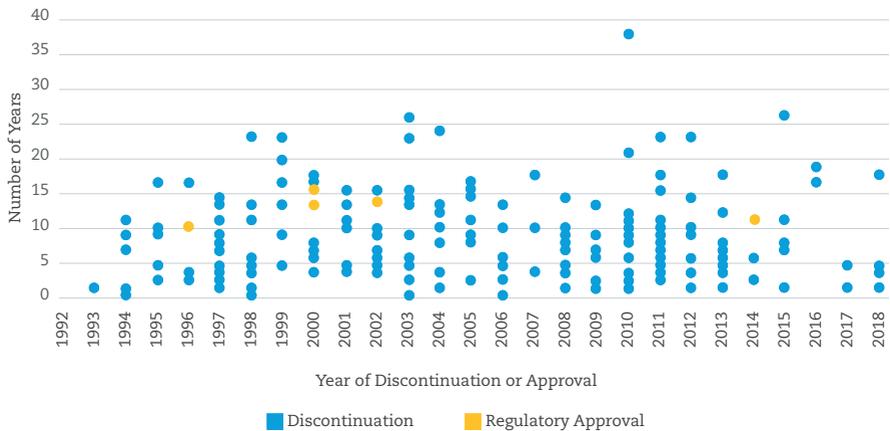
Table 5: Trends in Clinical Trial Protocol Complexity<sup>88</sup>

TYPICAL PHASE III PROTOCOL (MEAN OF TOTAL NUMBERS)	2001-2005 THEN	2011-2015 NOW	INCREASE IN COMPLEXITY
Endpoints	7	13	+86%
Procedures	110	187	+70%
Eligibility Criteria	31	50	+61%
Data Points Collected	494,236	929,203	+88%

<sup>88</sup> Getz KA, Campo RA. New benchmarks characterizing growth in protocol design complexity. *Therapeutic Innovation & Regul Sci.* 2018;52(1):22-28. See also: PhRMA (2019) 2019 Biopharmaceutical in Perspective. Washington DC: Pharmaceutical Research and Manufacturers of America. Available at: <https://www.phrma.org/en/Report/>

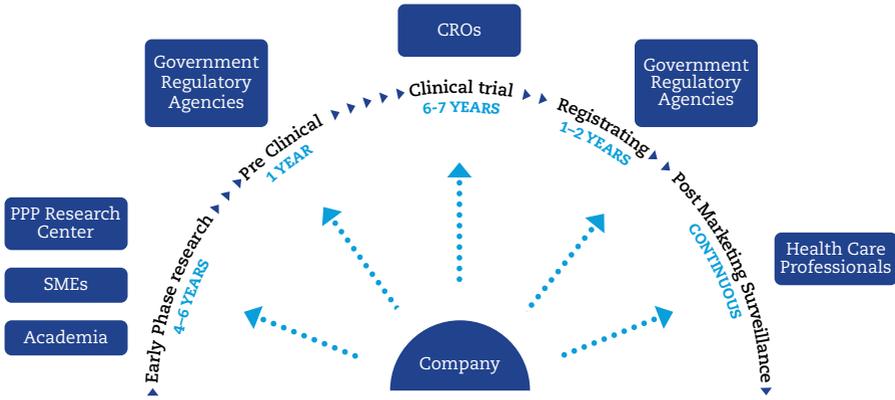
Industry's efforts to tackle Alzheimer's diseases illustrates how complex and challenging the biopharmaceutical R&D process is. The total number of people with dementia is projected to reach 78 million in 2030, and between 60 and 70% of those dementias could progress into Alzheimer's disease.<sup>89</sup> However, to date, only five drugs have ever received regulatory approval, without being able to address the underlying causes of this disease. Over the last decade, 86 projects failed, while only one medicine received regulatory approval. Recently, the U.S. FDA approved a new drug under the accelerated approval pathway.<sup>90</sup> Despite these advancements, showing promises from scientific discoveries and R&D, the fight against dementia continues. In the meantime, the estimated yearly cost to treat and care for people with dementia is USD 1.3 trillion.<sup>91</sup>

Figure 14: Number of Years Since Product's First Filing to Discontinuation or Regulatory Approval of Alzheimer's therapies<sup>92</sup>



Instead of abandoning the R&D, given the low rate of success industry has tried to adopt new models of innovation to address these issues head-on. New and novel collaborations and business models such as joint ventures between biopharmaceutical companies and other external entities, including academia and cross sector collaborations, are synergistic ways to increase the productivity of biopharmaceutical research by facilitating partnerships involving academia and the public and private sectors. These collaborations facilitate the sharing of expertise, know how, and technologies such as compound databases.

Figure 15: Biopharmaceutical R&D Network<sup>93</sup>



93 IFPMA (2013) The New Frontiers of Biopharmaceutical Innovation. Geneva: International Federation of Pharmaceutical Manufacturers & Associations, p 9. Available at: <https://www.ifpma.org/resource-centre/incremental-innovation-adapting-to-patient-needs/>

## Incremental Innovation

As science advances and technology becomes more efficient, the biopharmaceutical industry also seeks to implement these beneficial changes in currently available treatments. Incremental innovation is the process of improving existing medicines or expanding therapeutic classes to increase therapeutic efficacy, safety, and quality.

These improvements are made based on technologic progress and acquired experience, aiming to improve the manner it affects patients and are often dependent on feedback of healthcare professionals.

Incremental innovation can expand existing therapeutic classes by improving complex molecular structures, reformulating medicines to improve patient administration, or exploring new uses for existing medicines. For example, one way to improve a medicine's therapeutic efficacy profile is to ensure that patients comply with dosing requirements. Thus, a once-a-day formulation of a medicine often improves patients' compliance to dosing regimens.

The case is similar with existing vaccines that can also be continuously improved. New technologies enable vaccines to be reformulated to include new, desirable qualities such as improved temperature stability. By combining multiple vaccines into one vial or delivery devices, vaccine industry can further limit the number of vaccines and doses that need to be shipped, and more vaccines can be delivered to LICs and LMICs. Adjuvants, the parts of a vaccine that enhance the body's immune response to a vaccine, are also constantly being improved.<sup>94</sup>

Regardless whether an improvement is a new formulation, an expansion to an existing therapeutic class, or a newly identified medicinal use, incremental innovation involves just the same level of R&D and clinical trial inputs as first-in-class medicines.<sup>95</sup> Because biopharmaceutical innovation is the sum of various activities, incremental innovation can be misconstrued as "trivial." Often incremental innovation is incorrectly equated with industry trying to extend the life of the patent and pre-empt generic versions

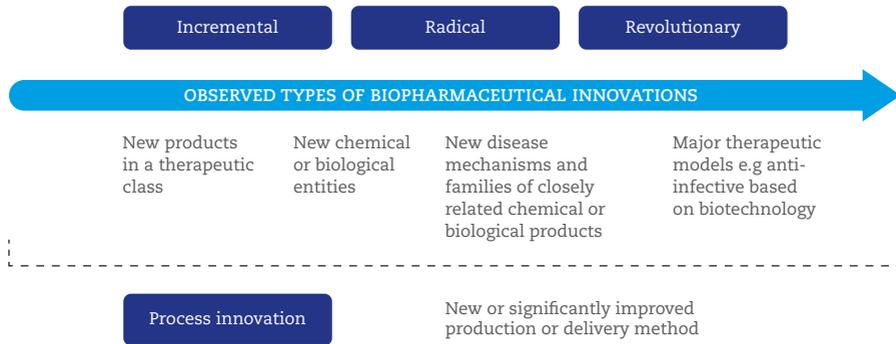
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94 Pulendran, B., Arunachalam, P.S. and O'Hagan, D.T., 2021. Emerging concepts in the science of vaccine adjuvants. *Nature Reviews Drug Discovery*, 20(6), pp.454–475. Available at: <https://www.nature.com/articles/s41573-021-00163-y>; O'Hagan, D.T., Lodaya, R.N. and Lofano, G., 2020, November. The continued advance of vaccine adjuvants—'we can work it out'. In *Seminars in immunology* (p. 101426). Academic Press. Available at: <https://www.sciencedirect.com/science/article/pii/S1044532320300427>

95 IFPMA (2013) *Incremental Innovation: Adapting to Patient's Needs*. Geneva: International Federation of Pharmaceutical Manufacturers & Associations, p 6. Available at: <https://www.ifpma.org/resource-centre/incremental-innovation-adapting-to-patient-needs/>

of first-in-class medicines. To the contrary, incremental innovation is innovation that should be reviewed by the intellectual property systems on its own merit and wholly independent of the term of the first-in-class medicine.<sup>96</sup>

Figure 16: Categories of Biopharmaceutical Innovation<sup>97</sup>



## Biopharmaceutical Industry R&D Investments

Of all industrial sectors, the biopharmaceutical industry has consistently invested the most in R&D, even in times of economic turmoil and financial crisis (see figure 13). The research-based biopharmaceutical industry is estimated to have spent USD 198 billion globally on biopharmaceutical R&D in 2020.<sup>98</sup>

Compared with other high-technology industries, the annual spending by the biopharmaceutical industry is 8.1 times greater than that of the aerospace and defense industries, 7.2 times more than that of the chemicals industry, and 1.2 times more than that of the software and computer services industry.<sup>99</sup>

<sup>96</sup> Ibid.

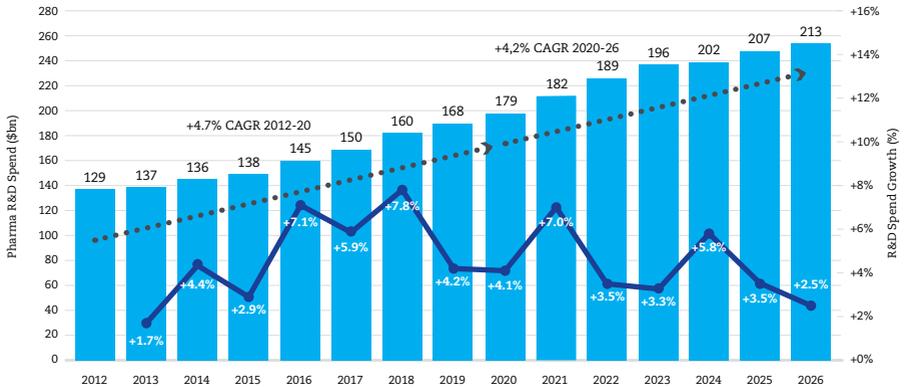
<sup>97</sup> Ibid.

<sup>98</sup> Evaluate Pharma (2021) World Preview 2021, Outlook to 2026. London: Evaluate Ltd., p 23. Available at: [https://info.evaluate.com/rs/607-YGS-364/images/WorldPreviewReport\\_Final\\_2021.pdf](https://info.evaluate.com/rs/607-YGS-364/images/WorldPreviewReport_Final_2021.pdf)

<sup>99</sup> IFPMA Analysis based on: The 2020 EU Industrial R&D Investment Scoreboard; p 110. Available at: <https://op.europa.eu/en/publication-detail/-/publication/73e624aa-406c-11eb-b27b-01aa75ed71a1/language-en>

Since 2015 alone, innovative biopharmaceutical companies invested more than a trillion dollars in R&D.<sup>100</sup> R&D intensity by the innovative biopharmaceutical industry in the world amounts to 15.4%.<sup>101</sup> In 2020 alone, the biopharmaceutical industry registered 10,767 patents through the Patent Cooperation Treaty (PCT) of the World Intellectual Property Organization.<sup>102</sup> No other business sector has such high levels of R&D intensity.

Figure 17: Biopharmaceutical R&D Spending<sup>103</sup>



100 Evaluate Pharma (2021) World Preview 2021, Outlook to 2026. London: Evaluate Ltd., p 23. Available at: [https://info.evaluate.com/rs/607-YGS-364/images/WorldPreviewReport\\_Final\\_2021.pdf](https://info.evaluate.com/rs/607-YGS-364/images/WorldPreviewReport_Final_2021.pdf)

101 The 2020 EU Industrial R&D Investment Scoreboard; p 110. Available at: <https://op.europa.eu/en/publication-detail/-/publication/73e624aa-406c-11eb-b27b-01aa75ed71a1/language-en>

102 WIPO (2021) Patent Cooperation Treaty Yearly Review – The International Patent System. Geneva: World Intellectual Property Organization, p 36. Available at: [https://www.wipo.int/edocs/pubdocs/en/wipo\\_pub\\_901\\_2021.pdf](https://www.wipo.int/edocs/pubdocs/en/wipo_pub_901_2021.pdf)

103 Evaluate Pharma (2021) World Preview 2021, Outlook to 2026. London: Evaluate Ltd., p 23. Available at: [https://info.evaluate.com/rs/607-YGS-364/images/WorldPreviewReport\\_Final\\_2021.pdf](https://info.evaluate.com/rs/607-YGS-364/images/WorldPreviewReport_Final_2021.pdf)

Table 6: R&D Investments by Sector<sup>104</sup>

RANK	SECTOR	R&D IN 2019, € BN	1-YEAR CHANGE, %	NET SALES, € BN	1-YEAR CHANGE, %	R&D INTENSITY, %	OPERATING PROFITS, € BN	1-YEAR CHANGE, %	PROFITABILITY, %	EMPLOYEES, MILLION	1-YEAR CHANGE, %
1	Pharmaceuticals & Biotechnology	166.8	10.0	1043.9	7.5	15.4	143.1	12.8	14.7	2.7	2.0
2	Software & Computer Services	142.7	20.6	1212.6	11.2	11.8	186.7	-0.9	15.4	3.4	6.7
3	Technology Hardware & Equipment	139.6	8.9	1557.1	0.3	9.0	195.0	-17.8	12.6	3.8	8.5
4	Automobiles & Parts	132.7	1.9	2749.4	-1.0	4.8	115.4	-22.5	4.3	7.5	-3.0
5	Electronic & Electrical Equipment	68.9	6.3	1352.1	1.8	5.1	113.9	-19.8	8.5	5.5	1.4
6	Industrial Engineering	32.5	6.4	996.4	3.9	3.3	89.5	-3.8	9.1	3.6	1.4
7	Chemicals	23.1	-3.2	964.9	-4.3	2.4	86.0	-23.7	9.0	1.8	-2.6
8	Aerospace & Defence	20.6	4.3	518.4	6.4	4.0	46.6	-7.5	9.1	1.6	3.2
9	General Industrials	20.4	0.5	672.1	0.1	3.0	48.7	34.6	7.4	2.2	3.5
10	Construction & Materials	19.2	20.3	1048.9	9.8	1.8	70.4	5.6	6.7	3.1	2.2
11	Health Care Equipment & Services	18.9	9.3	495.1	8.1	3.8	43.3	14.5	8.8	1.6	4.6
12	Leisure Goods	16.5	3.5	269.6	-1.1	6.1	25.3	-0.5	9.4	0.7	1.4
13	Banks	11.4	5.6	351.7	0.4	3.2	90.3	-14.9	25.7	1.6	-0.7
14	Oil & Gas Producers	9.9	5.2	2725.5	-3.3	0.4	304.2	-23.8	11.2	1.8	-2.2
15	Household Goods & Home Construction	9.0	3.5	360.6	4.6	2.5	35.3	34.9	9.8	1.2	0.4
<b>Total 38 industries</b>		904.7	8.9	21039.9	1.9	4.3	2060.1	-10.2	9.9	55.8	1.3

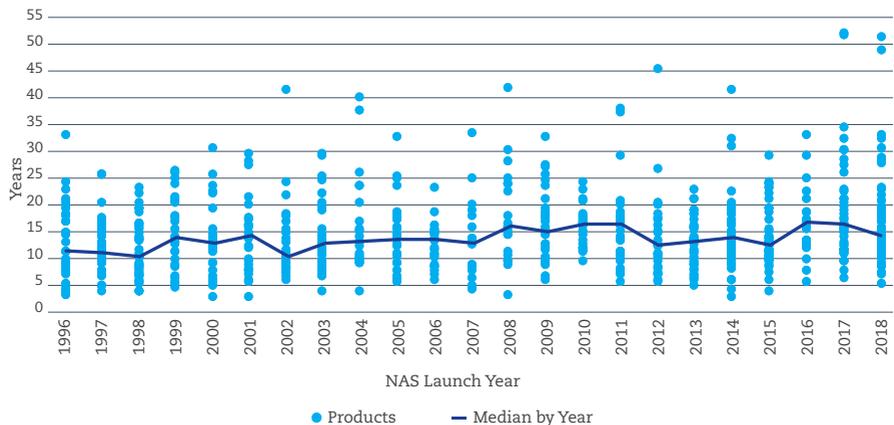
Further evidence of the biopharmaceutical's intensity can be found in Europe. According to European Commission statistics, 23 of the 50 leading global R&D firms in 2018 were

<sup>104</sup> The 2020 EU Industrial R&D Investment Scoreboard; p 110. Available at: <https://op.europa.eu/en/publication-detail/-/publication/73e624aa-406c-11eb-b27b-01aa75ed71a1/language-en>

biopharmaceutical companies.<sup>105</sup> In 2019, R&D spending by the biopharmaceuticals and biotechnology sector grew by 10% from the previous year, strengthening its position as the top R&D investing sector.<sup>106</sup> These numbers are a clear demonstration of the significant contribution the biopharmaceutical sector makes to the world economy.

All countries have the potential to attract investments and foster innovation. A robust innovation ecosystem is fostered through a number of enabling conditions, such as access to world-class talents, political and financial stability, regulatory frameworks that protect and reward innovation, and sound intellectual property (IP) protection. The legal certainty provided by IP is particularly relevant given the long innovation cycle of the biopharmaceutical industry. Such large investments need assurance of their security and stability in the long term. In 2018, new active substances (NASs) took a median of 13.7 years to launch from the time of their patent filing in the United States.<sup>107</sup>

Figure 18: Median Time from First Patent Filing to Launch by New Active Substances Launch Year, United States, 1996-2018<sup>108</sup>



105 The 2018 EU Industrial R&D Investment Scoreboard; p 96. Available at: <https://ec.europa.eu/jrc/en/publication/2018-eu-industrial-rd-investment-scoreboard>

106 The 2020 EU Industrial R&D Investment Scoreboard; p 110. Available at: <https://op.europa.eu/en/publication-detail/-/publication/73e624aa-406c-11eb-b27b-01aa75ed71a1/language-en>

107 IQVIA Institute (2019). The Changing Landscape of Research and Development, Apr.2019 Available at: <https://www.iqvia.com/insights/the-iqvia-institute/reports/the-changing-landscape-of-research-and-development>

108 Ibid.

Table 7: Enabling Factors of Biopharmaceutical Innovation<sup>109</sup>

<b>EARLY STAGE RESEARCH</b>	World class research institutions Highly trained workforce (retained or attracted back to the country) Clusters of innovative companies providing support on core technologies (high throughput screening, gene sequencing, etc.) Partnership encouraging environment
<b>CLINICAL TRIALS</b>	Efficient regulatory system for appraising clinical trials design Supportive and well-regulated system for enrolment Strong medical schools and clinicians for designing Managing and reporting trials design Growing market receptive to innovation

Providing sufficient market incentives in a competitive marketplace is a collective investment that drives life-saving innovations and delivers improved health outcomes.<sup>110</sup> This applies for currently identified health issues – including effective treatments for Alzheimer’s disease, cancers and non-communicable diseases – as well as planning for and preventing future pandemic and health crises. As we have seen with the current COVID-19 crisis, investments in emergency preparedness and prevention are just as important as searches for cures. An enabling environment for biopharmaceutical R&D is also critical to allow companies to switch gear in times of pandemics and reprioritize their efforts to address the emergency. This is the case of the current COVID-19 pandemic where hundreds of efforts are undergoing to find new or readapt diagnostics, vaccines, and treatments to manage and defeat SARS-CoV-2.

In certain cases, such as the fight against Antimicrobial Resistance (AMR), Neglected Tropical Diseases (NTDs) or the development of treatments for rare diseases, inefficiencies in the market dynamics can and should be addressed. This is best done through sustainable and sufficient incentives that help overcome the scientific, regulatory, and economic challenges and sustain industry’s investments in the discovery of a pipeline of new products. AMR in the form of drug-resistant superbugs could soon cause over USD 3 trillion in GDP loss per year worldwide.<sup>111</sup> The same challenges apply to

109 Charles River Associates (2012), Policies that encourage innovation in middle-income countries. (Boston, MA: Charles River Associates, 2012). Available at: [https://www.ifpma.org/wp-content/uploads/2012/01/CRA\\_Policies\\_that\\_encourage\\_innovation\\_in\\_middle-income\\_countries\\_Key\\_Findings\\_Web.pdf](https://www.ifpma.org/wp-content/uploads/2012/01/CRA_Policies_that_encourage_innovation_in_middle-income_countries_Key_Findings_Web.pdf)

110 IFPMA. (2019). Achieving a healthier and sustainable future for all. Retrieved from Available at: [https://www.ifpma.org/wp-content/uploads/2019/09/IFPMA\\_Policy\\_Perspectives\\_on-UHC\\_Full\\_Report.pdf](https://www.ifpma.org/wp-content/uploads/2019/09/IFPMA_Policy_Perspectives_on-UHC_Full_Report.pdf)

111 Naylor et al ‘Estimating the burden of antimicrobial resistance: a systematic literature review’, 2018 Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5918775/>

other diseases. For instance, Ebola virus caused Liberia's economy to decline by 8% from 2013 to 2014.<sup>112</sup> Tuberculosis (TB) could cost the global economy almost USD 1 trillion by 2030.<sup>113</sup> Pandemic influenza is estimated to have a potential yearly cost of USD 500 billion.<sup>114</sup> These examples show that investments in biopharmaceutical industry, or lack thereof, can have global effects.

## Antimicrobial Resistance

Each year, 1.27 million deaths are estimated to be directly attributable to AMR, with close to 5 million deaths associated with AMR.<sup>115</sup> AMR is a growing challenge, posing a significant threat to people's health, healthcare systems, and ultimately to economic development. Resistance to second and third-line antibiotics is expected to be 70% higher in 2030 compared to 2005 in OECD countries, and compromise many basic procedures of modern medicine, such as surgeries. In the same period, resistance to third-line treatments will double across EU countries. By 2050, around 10 million people could die annually due to AMR, without prompt and effective action.<sup>116</sup>

Poor discovery prospects, combined with weaker returns, means that the arsenal of antibiotics is declining, after peaking in 2000. Moreover, it has been 35 years since a new antibiotic class has been introduced for treatment.<sup>117</sup> Approvals for infectious disease NMEs have plummeted across many pathogen types, while the number of antibiotics that become obsolete and lose its efficacy due to resistance exceeds new approvals.<sup>118</sup> Of the companies that successfully developed and launched an antibiotic in the past decade, several have gone bankrupt or were sold off.<sup>119</sup>

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112 Bloom et al 'Epidemics and Economics', 2018 Available at: <https://www.imf.org/external/pubs/ft/fandd/2018/06/economicrisks-and-impacts-of-epidemics/bloom.htm>

113 Burki 'The global cost of tuberculosis', 2018 Available at: [https://www.thelancet.com/journals/lanres/article/PIIS2213-2600\(17\)30468-X/fulltext](https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(17)30468-X/fulltext)

114 Fan et al 'The Inclusive Cost of Pandemic Influenza Risk', 2016 Available at: <https://www.nber.org/papers/w22137>

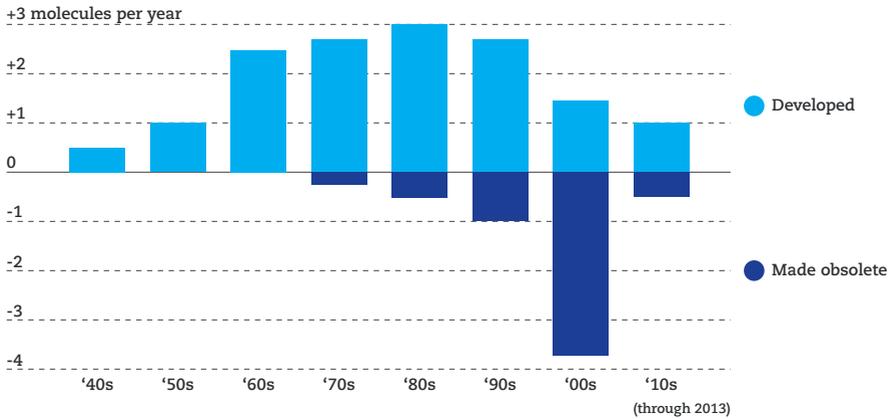
115 Murray, C.J., Ikuta, K.S., Sharara, F., Swetschinski, L., Aguilar, G.R., Gray, A., Han, C., Bisignano, C., Rao, P., Wool, E. and Johnson, S.C., 2022. Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis. *The Lancet*. Available at: [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)02724-0/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02724-0/fulltext)

116 World Health Organization (2019). New report calls for urgent action to avert antimicrobial resistance crisis. Available at: <https://www.who.int/news/item/29-04-2019-new-report-calls-for-urgent-action-to-avert-antimicrobial-resistance-crisis>

117 Silver, L.L., 2011. Challenges of antibacterial discovery. *Clinical microbiology reviews*, 24(1), pp.71-109. Available at: <https://pubmed.ncbi.nlm.nih.gov/21233508/>

118 AMR Industry Alliance, 2021. Progress Report. Available at: <https://www.amrindustryalliance.org/progress-report/>

119 McKenna, M., 2020. The antibiotic paradox: why companies can't afford to create life-saving drugs. *Nature*, 584(7821), pp.338-342. Available at: <https://www.nature.com/articles/d41586-020-02418-x>

Figure 19: Newly Developed Antibiotics vs. Attrition<sup>120</sup>

Hence, AMR requires action across all government sectors and society.<sup>121</sup> Given the growing public health and economic burdens posed by antimicrobial resistance, there is an urgent need to reinvigorate the antimicrobial pipeline. This is particularly critical given the long development times (10 – 15 years) for new medicines and vaccines. Recent estimates suggest that at a global scale, an incentive in the range of USD 2.2 – 4.8 billion per antibiotic is required.<sup>122</sup> A recent study also showed that there are significant differences in access to recently developed antibiotics in HICs – something that can be addressed by incorporating the broader societal value of antibiotics in their valuation and reimbursement.<sup>123</sup>

Vaccines are a critical complementary tool to mitigate the threat of AMR. Vaccines prevent commonly-acquired bacterial infections, whose treatment would require antimicrobial medicines, reducing the opportunity for bacteria to develop resistance. For instance, after the use of the *Haemophilus influenzae* type b conjugate vaccine was

120 Kinch, M., Hoyer, D. et al. "An analysis of FDA-approved drugs for infectious disease: antibacterial agents." Yale Center for Molecular Discovery. Web. 2017. Available at: <http://www.sciencedirect.com/science/article/pii/S1359644614002761>

121 WHO, 2020. Key Facts, Antimicrobial resistance. Official Website. Available at: <https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance>

122 Outterson, K., 2021. Estimating The Appropriate Size Of Global Pull Incentives For Antibacterial Medicines: Study examines global antibacterial pull incentives. *Health Affairs*, 40(11), pp.1758-1765. Available at: <https://www.healthaffairs.org/doi/10.1377/hlthaff.2021.00688>

123 Outterson, K., Orubu, E.S., Rex, J., Årdal, C. and Zaman, M.H., 2022. Patient Access in 14 High-Income Countries to New Antibacterials Approved by the US Food and Drug Administration, European Medicines Agency, Japanese Pharmaceuticals and Medical Devices Agency, or Health Canada, 2010–2020. *Clinical Infectious Diseases*, 74(7), pp.1183-1190. Available at: <https://academic.oup.com/cid/advance-article-abstract/doi/10.1093/cid/ciab612/6319400?redirectedFrom=fulltext>

recommended in Canada in 1988, cases of Hib disease dropped by 97% from 1986 to 2017.<sup>124</sup> Vaccines also prevent viral infections, which are often treated inappropriately with antibiotics, and which can also give rise to secondary infections that require antibiotic treatment.

Despite great challenges, around 100 life-sciences companies and associations globally are promoting research and development of new therapies to fight AMR, investing in various innovative R&D therapies, both antibiotic and non-antibiotic.<sup>125</sup> Based on the aggregated estimates of 56 companies, in 2019 and 2020, the private sector invested more than USD 1.8-1.9 billion annually in R&D dedicated to AMR-related products. The private sector is investing in a broad range of projects, including 54 antibiotics and antifungals, 12 vaccines, 13 diagnostic platforms or assays, 14 non-traditional approaches, and 1 other AMR- relevant product.<sup>126</sup> In July 2020, 23 biopharmaceutical companies partnered with non- governmental stakeholders to respond to this urgent threat by launching a USD 1 billion AMR Action Fund with a goal of delivering up to 4 novel antibiotics by the end of the decade. The AMR Action Fund will provide much-needed support and investment for the complex and expensive later stages of development – temporarily sustaining the fragile antibiotic pipeline, which is close to collapse, and preventing promising early- stage assets supported by recent push funding from governments and others from withering on the vine. While the Fund itself will not solve the economic challenges, it will provide governments with the time to make the necessary economic policy reforms needed to build a vibrant and sustainable antibiotic pipeline.<sup>127</sup>

If governments can create market conditions where there is a sustainable return on investment, the biopharmaceutical industry and private investors have demonstrated their willingness to take on the risk and uncertainty that comes with the development and commercialization of a new antibiotic. Given the unique challenges and dynamics of the antibiotics market, unique measures are needed to establish an economic environment that will incentivize sufficient long-term investment into antibiotic R&D.<sup>128</sup>

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124 Public Health Agency of Canada, 2020. Vaccine preventable disease: surveillance report to December 31, 2017 (Public Health Agency of Canada, Ottawa, 2020). Available at: [https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/vaccine-preventable-disease-surveillance-report-december-31-2017.html#\\_Invasive\\_disease\\_due](https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/vaccine-preventable-disease-surveillance-report-december-31-2017.html#_Invasive_disease_due)

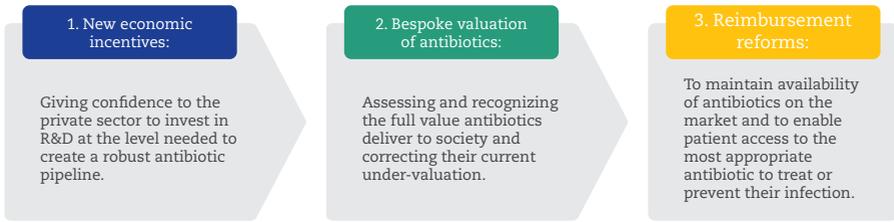
125 AMR Industry Alliance, 2021. Progress Report. Available at: <https://www.amrindustryalliance.org/progress-report/>

126 Ibid.

127 The AMR Action Fund. Official Website. Available at: <https://www.amractionfund.com/>

128 IFPMA (2021). AMR Policy Position: Global Principles on Incentivizing Antibiotic R&D. Available at: <https://www.ifpma.org/resource-centre/global-principles-on-incentivizing-antibiotic-rd/>

Figure 20: The Proposed Way Forward to Enable Antibiotic R&D



## Pandemic Preparedness

As a science-driven industry that aims to address some of the world's biggest healthcare challenges, the biopharmaceutical industry is uniquely positioned to respond rapidly to emerging threats caused by new pathogens, such as COVID-19. It has gained profound scientific insights from decades of experience in developing solutions for infectious diseases such as MERS, SARS, Ebola and influenza as well as in working with health authorities and regulators to swiftly bring safe and effective medicines, vaccines and diagnostics to patients.

Some of the IFPMA members are active in the Coalition for Epidemic Preparedness Innovation (CEPI), which was created as a direct response to calls from four independent expert reports into the Ebola epidemic that called for a new system for stimulating the development of vaccines against epidemic threats. The CEPI infrastructure has been a great asset in the rapid response to COVID-19.

IFPMA companies have also engaged through many years with the World Health Organization on the Pandemic Influenza Preparedness Framework (PIP). Through the PIP Framework, influenza vaccine and antiviral manufacturers have helped the WHO secure 420 million doses of influenza vaccine and 10 million doses of antivirals to be used in the event of an influenza pandemic.<sup>129</sup> IFPMA member companies have also contributed most of the USD 198 million voluntary donations collected by 30 June 2020, by the WHO PIP Framework.

<sup>129</sup> Pandemic Influenza Preparedness Framework: 18-month progress report, 1 January 2020–30 June 2021.

Geneva: World Health Organization; 2021. Available at: <https://apps.who.int/iris/bitstream/handle/10665/348731/9789240037168-eng.pdf?sequence=1>

In addition to CEPI and PIP, companies have been engaged, alone or in collaboration with partners, in a variety of projects to address new health emergencies. Within this context, a notable example of partnerships to address health emergencies has been the creation of the Access to COVID-19 Tools (ACT) Accelerator, of which the innovative biopharmaceutical industry became a founding member. The ACT Accelerator aims to provide equitable access to vaccines, treatments and diagnostics.<sup>130</sup>

## LESSONS LEARNED FROM THE COVID-19 PANDEMIC

Since the beginning of the COVID-19 pandemic, all stakeholders have worked together to outrun a virus that has so far proven faster than we have been. The significant efforts and associated learnings accumulated since early 2020 have enabled the biopharmaceutical industry to gather 10 insights to inform the current crisis and the future course.<sup>131</sup>

# 1

### Health Security Starts with Pathogen Surveillance and Sharing

Immediate and unfettered access to pathogens and their genetic information is essential.

# 2

### Partnerships Accelerate R&D and Manufacturing

Effective voluntary partnerships spanning the globe accelerate research and development and manufacturing for COVID-19 vaccines and therapeutics.

# 3

### Advance Market Commitments Support Manufacturing Scale-Up for Global Pandemic Response

Advance market commitments for vaccines and therapeutics allow for vital supplemental investments in production capacity and voluntary technology transfer.

# 4

### Innovation Is Essential for Preparedness and Response

Global legal frameworks supporting innovation are essential to the continuous pursuit of safe and effective vaccines and need to be maintained.

# 5

### Global Upstream Supply Chains Disruptions Put Production and Distribution at Risk

Proposed investments to expand manufacturing capacity must also build capacity for sufficient, efficient and rapid supply of critical commodities and raw materials.

130 IFPMA (2020). "IFPMA Statement on the launch of a new global collaboration to accelerate the development, production and equitable access to new COVID-19 tools". Available at: <https://www.ifpma.org/resource-centre/ifpma-statement-on-the-launch-of-a-new-global-collaboration-to-accelerate-the-development-production-and-equitable-access-to-new-covid-19-tools/>

131 IFPMA (2022) Applying Lessons Learned From Covid-19 To Create A Healthier, Safer, More Equitable World. Available at: [https://www.ifpma.org/wp-content/uploads/2022/05/IFPMA\\_COVID-19\\_Pandemic\\_Lessons\\_Learned\\_May\\_2022.pdf](https://www.ifpma.org/wp-content/uploads/2022/05/IFPMA_COVID-19_Pandemic_Lessons_Learned_May_2022.pdf)

6

**An Established Procurement Mechanism for Low-Income Countries Is Vital**

When a pandemic is declared, technical assistance and sufficient, dedicated, and sustainable financing must be available immediately to procure goods for countries with limited or no capacity to finance their own pandemic purchases.

7

**Regulatory Agility and Convergence Guard Safety and Speed of Access**

Vaccines and therapeutics can be developed in record time thanks in no small part to the extraordinary degree of collaboration between industry and national and regional regulatory authorities.

8

**Vaccine Nationalism Imperils Everyone**

Policies like export restrictions and vaccine hoarding, regardless of global public health need, have intensified and likely prolonged the COVID-19 pandemic.

9

**Delivery Infrastructure Must Be Strengthened**

Strong national resilient health systems and global health security are two sides of the same coin.

10

**Vaccine Confidence Is Critical for Success**

Concerted, cross-sector action to build public trust is critical now and will need to be maintained long after the pandemic has ended.

## R&D for Diseases that Disproportionately Affect the Developing World

### NEGLECTED TROPICAL DISEASES

Over 1 billion people – or one in eight globally – are affected by neglected tropical diseases (NTDs) and the World Health Organization (WHO) has targeted 20 specific NTDs for elimination or control.<sup>132</sup> Some NTDs can have lifelong consequences for individuals, while others lead to acute infections that can be fatal. These diseases – whose names are not commonly known – include Buruli ulcer disease, dengue, cholera, trachoma, and guinea worm disease, and primarily affect poor people in tropical and subtropical areas.

Despite the promising trends in neglected disease funding, funding for WHO-defined NTDs has remained largely flat for the past and was 10% lower in 2018 than it was in

<sup>132</sup> WHO (2021). Ending the neglect to attain the Sustainable Development Goals: A road map for neglected tropical diseases 2021–2030. Available at: <https://www.who.int/publications/i/item/9789240010352>

2009.<sup>133</sup> Despite often low commercial incentives, investment from the innovative biopharmaceutical industry in this space has continued to grow over the past and has increased five-fold since 2018. NTDs demand a distinct innovation model because the potential market does not adequately support R&D investments on a commercial basis. In this context, various biopharmaceutical companies have collaborated with different stakeholders to form product development partnerships (PDPs), which bring together the expertise and resources of different players including academia, industry, private foundations, and governments. These partnerships are often funded by public or philanthropic organizations, as well as by industry. Overall, the latter was the third largest funder for research for neglected diseases, investing USD 513 million in 2019.<sup>134</sup> This was significantly higher than 2009 (up 60%), and is part of a decade-long upward trend in industry investment in neglected disease R&D.<sup>135</sup>

IFPMA members have made significant progress to develop new technologies — medicines, vaccines, and pesticides — to combat NTDs. IFPMA members currently have over 89 projects in progress.<sup>136</sup> Since 2018, the number of projects, The R&D projects targeting TB and NTDs have increased. Through its many partnerships, the research-based biopharmaceutical industry is helping to construct innovative models to develop and deliver essential healthcare for patients living in the poorest areas of the world.

The industry collaborations take many forms, including Product Development Partnerships (PDPs), research consortiums, technology transfers and building technical expertise to develop, manufacture, register and distribute products. Companies provide in-kind contributions that are targeted to enhance R&D for NTDs. Although difficult to quantify, these inputs are a significant investment and include sharing of intellectual property assets to condense the time needed to find and develop new, promising treatments, along with providing access to research facilities, hosting and training scientists, and forgoing licenses or providing royalty-free licenses on co-developed products.

PDPs currently have a healthy pipeline. For instance, the Drugs for Neglected Diseases initiative (DNDi) aims to deliver new treatments for many critical diseases and has a pipeline of 45 projects and more than 20 new chemical entities, with 22 ongoing clinical

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133 Barofsky J and Schneider J. 2017. Promoting private sector involvement in neglected tropical disease research and development. Available at: [https://www.brookings.edu/wp-content/uploads/2017/12/br\\_health4\\_optimized\\_final.pdf](https://www.brookings.edu/wp-content/uploads/2017/12/br_health4_optimized_final.pdf)

134 Policy Cures Research (2020). 2020 G-Finder 2020 Neglected Disease Research and Development: Where to now? . Available at: [https://policy-cures-website-assets.s3.ap-southeast-2.amazonaws.com/wp-content/uploads/2021/04/15055816/G-FINDER-2020\\_Final-Report.pdf](https://policy-cures-website-assets.s3.ap-southeast-2.amazonaws.com/wp-content/uploads/2021/04/15055816/G-FINDER-2020_Final-Report.pdf)

135 Ibid.

136 Access to Medicine Foundation (2021). Access to Medicines Index 2021. 2021. Available at: [https://accessmedicinefoundation.org/media/uploads/downloads/613f5fb390319\\_Access\\_to\\_Medicine\\_Index\\_2021.pdf](https://accessmedicinefoundation.org/media/uploads/downloads/613f5fb390319_Access_to_Medicine_Index_2021.pdf)

trials at 83 sites in 28 countries.<sup>137</sup> Since 2013, the Global Health Innovative Technology (GHIT) Fund has invested USD 261 million in 105 projects to create new drugs, vaccines, and diagnostics for NTDs, malaria, and TB. As of the fourth quarter of 2021, this included 57 discovery projects, 33 preclinical projects, and 15 clinical trials in LMICs.

## HIV, TB, MALARIA

In addition to neglected tropical diseases, HIV, tuberculosis (TB) and malaria affect billions of people around the world. According to the WHO, communicable diseases, which also include Hepatitis C, are 6 of the top 10 causes of death in low-income countries, including malaria (6th), tuberculosis (8th) and HIV/AIDS (9th), causing around 20% of deaths worldwide, more than 10 million deaths per year.<sup>138</sup>

Recently, the prevention and treatment of HIV, tuberculosis and malaria has demonstrated significant improvements to stop the spread and burden of the disease. During the last 40 years, breakthrough innovations and cross-sector collaborations have transformed the global response to the HIV epidemic; between 2000 and 2016, notable progress has been made in TB diagnosis and treatment, saving an estimated 66 million lives,<sup>139</sup> between 2000 and 2019, the rate of new cases of malaria fell by 29% globally and an estimated 7.6 million malaria deaths have been averted globally since 2000.<sup>140</sup>

More action and innovation are needed to achieve a world without HIV, TB and malaria. The biopharmaceutical industry continues to invest in R&D to discover novel solutions. R&D pipeline counts more than 260 projects to fight these diseases.<sup>141</sup>

Partnerships are central in tackling the biggest challenges in our journey towards finding treatments and vaccines. Initiatives where the biopharmaceutical industry is collaborating in order to accelerate efforts include the International Partnership for

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137 DNDi (2021) Drugs for Neglected Diseases initiative. Official Website visited on October 2021. Available at: <https://dndi.org/research-development/portfolio/>

138 WHO (2020). WHO Official Website. Visited on October 2021. Available at: <https://www.who.int/news/item/09-12-2020-who-reveals-leading-causes-of-death-and-disability-worldwide-2000-2019>; WHO (2021). Global Health Observatory. Global Health Estimates 2019: Deaths by Cause, Age, Sex, by Country and by Region, 2000-2019. Accessed on October 2021. Available at: <https://www.who.int/data/gho/data/themes/mortality-and-global-health-estimates/ghe-leading-causes-of-death>

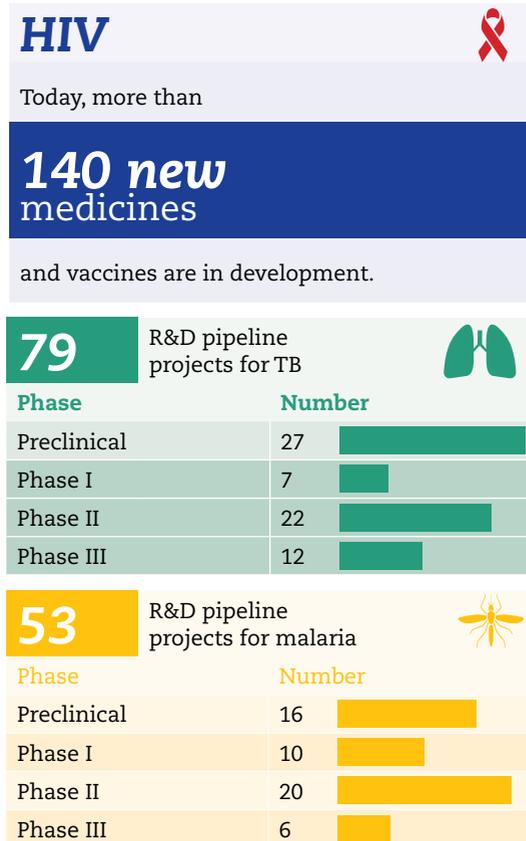
139 World Health Organization (2021). Global TB Report 2021. p.18. Available at: <https://www.who.int/publications/i/item/9789240037021>

140 World Health Organization (2020). World Malaria Report. p.32 Available at: <https://www.who.int/publications/i/item/9789240015791>

141 Adis R&D Insight Database. Available at: <https://adis.springer.com> Visited October 2021

Microbicides (IPM) and the International AIDS Vaccine Initiative (IAVI).<sup>142</sup> Partnerships have been central to developing novel TB treatments which provide patients with simpler, shorter treatment options and have the potential to transform access to treatment for vulnerable populations.<sup>143</sup> With regards to malaria, PDPs help to develop innovative prevention and diagnosis interventions, and mHealth programs help to prevent medicine stock-outs and improve treatment supply.<sup>144</sup>

Figure 21: R&D Pipeline Projects for HIV, TB and Malaria<sup>145</sup>



<sup>142</sup> Leem, IFPMA (2019). "Stepping up the fight: INDUSTRY COLLABORATION TO END HIV, TUBERCULOSIS AND MALARIA". [online] Available at: [https://www.ifpma.org/wp-content/uploads/2019/09/IFPMA\\_Leem\\_HIV-Malaria-TB.pdf](https://www.ifpma.org/wp-content/uploads/2019/09/IFPMA_Leem_HIV-Malaria-TB.pdf)

<sup>143</sup> Ibid.

<sup>144</sup> Ibid.

<sup>145</sup> Adis R&D Insight Database. Available at: <https://adis.springer.com> Visited October 2021



## Chapter 2

# THE ROLE OF BIOPHARMACEUTICALS IN WELL-FUNCTIONING HEALTHCARE SYSTEMS

A robust and resilient healthcare system is an important pillar of every country's socio-economic development process.<sup>146</sup> Universal Health Coverage (UHC) is a core component of well performing health systems that are able to deliver health products, services, and care to patients.<sup>147</sup> While these health systems face major challenges posed by urbanisation, changes of lifestyles, ageing populations, climate change as well as evolving epidemiological trends, their success requires joint efforts and collaborations between all the key health actors. As such, the research-based biopharmaceutical industry plays an essential role in innovating and, together with other crucial stakeholders, contributing to access to medicines and vaccines and support to the overall healthcare structure.

## The Building Blocks of Healthcare Systems

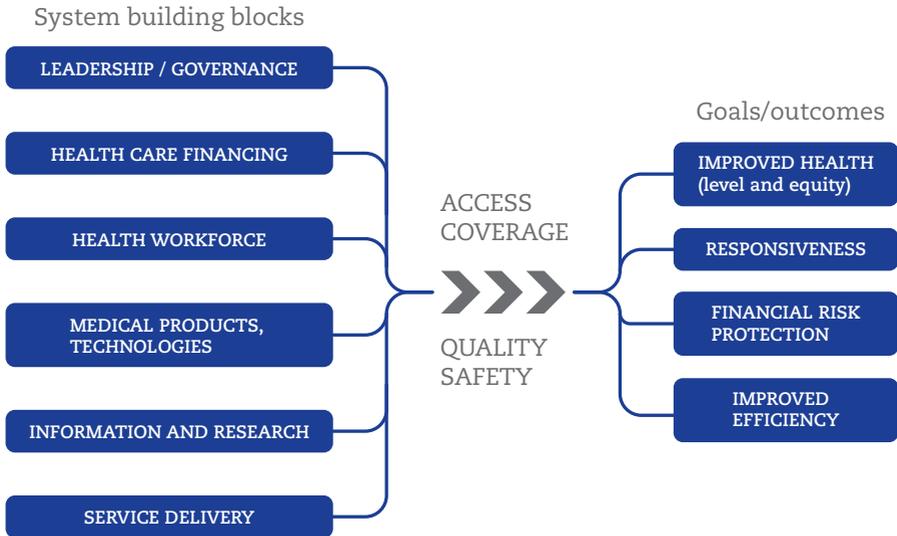
According to the WHO, a health system is built on six building blocks: service delivery; health workforce; information; medical products, vaccines, and technologies; financing; and leadership/governance.<sup>148</sup> A well-functioning healthcare system also enables productive relationships between governments, healthcare professionals, patients and communities, and the healthcare industry.

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146 UHC2030 International Health Partnership (2019). UHC 2030 Private Sector Constituency Statement: Private Sector contributions towards Universal Health Coverage. Available at: [https://www.uhc2030.org/fileadmin/uploads/uhc2030/Documents/Key\\_Issues/Private\\_Sector/UHC2030\\_Private\\_Sector\\_Constituency\\_Joint\\_Statement\\_on\\_UHC\\_FINAL.pdf](https://www.uhc2030.org/fileadmin/uploads/uhc2030/Documents/Key_Issues/Private_Sector/UHC2030_Private_Sector_Constituency_Joint_Statement_on_UHC_FINAL.pdf)

147 IFPMA (2012) The Changing Landscape on Access to Medicines. Geneva: International Federation of Pharmaceutical Manufacturers and Associations, Chapter 2. Available at: <https://www.ifpma.org/wp-content/uploads/2016/01/ChangingLandscapes-Web.pdf>

148 World Health Organization, 2010. Monitoring the building blocks of health systems: a handbook of indicators and their measurement strategies. World Health Organization. Available at: <https://apps.who.int/iris/bitstream/handle/10665/258734/9789241564052-eng.pdf>

Figure 22: The WHO Health System Framework<sup>149</sup>

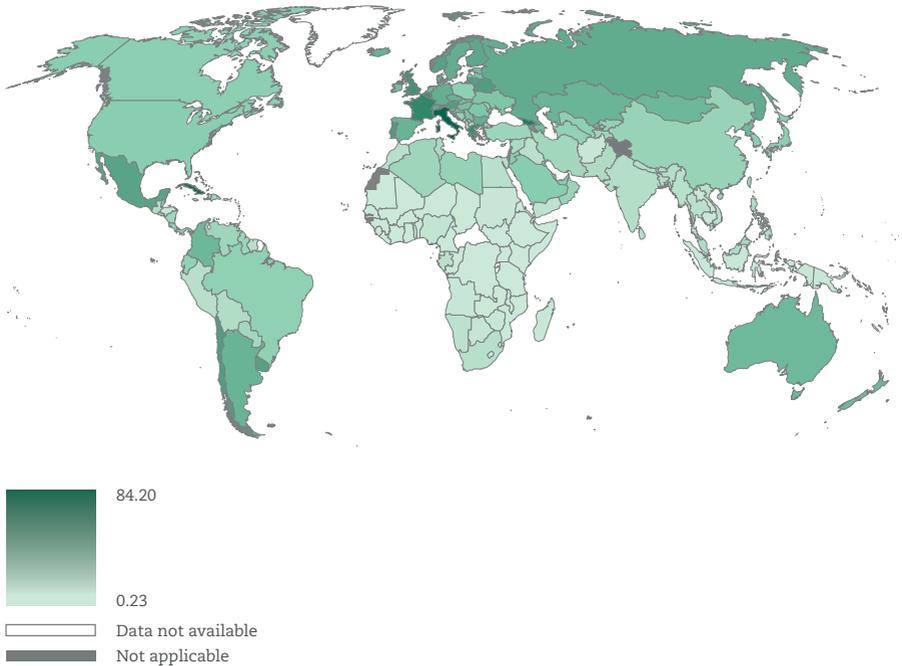
Pharmaceuticals play a pivotal role in any healthcare system. A well-performing healthcare system must ensure that biopharmaceutical products meet quality requirements and are appropriately procured, distributed to the different healthcare facilities, and prescribed by properly trained professionals.

Doctors, nurses, pharmacists, and other health professionals form the cornerstone for the delivery of care within healthcare systems. Not only do they diagnose, treat, and follow up patients with the right care, they also facilitate adequate patient adherence to treatment. Taking the wrong medicines or not adhering to appropriate treatments can have deleterious effects on patients' health. However, the availability of physicians varies greatly; in Austria, there are 52 doctors for every 10,000 inhabitants, while in Senegal there is only 1 per 10,000.<sup>150</sup>

149 World Health Organization, 2010. Monitoring the building blocks of health systems: a handbook of indicators and their measurement strategies. World Health Organization. Available at: <https://apps.who.int/iris/bitstream/handle/10665/258734/9789241564052-eng.pdf>

150 World Bank (2021) Physicians (per 1,000 People). Washington DC: The World Bank Group. Year: Latest. Accessed October 2021 Available at: <https://data.worldbank.org/indicator/SH.MED.PHYS.ZS>

Figure 23: Relative Density of Physicians per 10,000 Population (Latest Available Year)<sup>151</sup>



The 2020 State of the World's Nursing<sup>152</sup> report found that the world would need 6 million more nurses by 2030 to reach global health targets.<sup>153</sup> Shortages of health care workers are felt most acutely in low – and middle-income countries.

151 WHO (2021) Global Health Observatory Data Repository: Density of Physicians (Total Number per 1,000 Population). Geneva: World Health Organization. Available at: [https://www.who.int/gho/health\\_workforce/physicians\\_density/en/](https://www.who.int/gho/health_workforce/physicians_density/en/)

152 WHO(2020). Available at: <https://apps.who.int/iris/bitstream/handle/10665/331673/9789240003293-eng.pdf>

153 WEF(2020). Available at: <https://www.weforum.org/agenda/2020/04/nursing-report-who-nurses-coronavirus-pandemic-health-goals/>

## Health as a Long-term Investment

In terms of funding, healthcare systems require sufficient and sustainable allocation of resources in order to perform well. Public health and the strengthening of healthcare systems have different priority levels in many countries, and the resources made available to the health sector vary significantly from country to country. For instance, in 2001, all African Union countries pledged to allocate at least 15% of their annual budget to improve the health sector as part of The Abuja Declaration. Following this, many African countries have made strides in increasing domestic investments in health, but few countries have achieved this goal.<sup>154</sup> A report by the World Bank in 2008 found that the private sector delivered about half of Africa's health products and services, demonstrating the important role cross-sector collaboration played a decade ago and continue to play.<sup>155</sup>

The coronavirus crisis has revealed the importance of national and sub-national health systems: together, these systems comprise the foundation of global health security. Strong and resilient health systems are the best defence not only against outbreaks and pandemics, but also against the multiple health threats that people around the world face every day. The world currently spends approximately USD 8.3 trillion on health each year, or 10% of global gross domestic product (GDP). While spending has increased steadily,<sup>156</sup> concerning public health gaps exist, especially in rural or conflict-ridden areas where access is difficult where infrastructure is lacking, or in specific therapeutic areas such as NCDs.

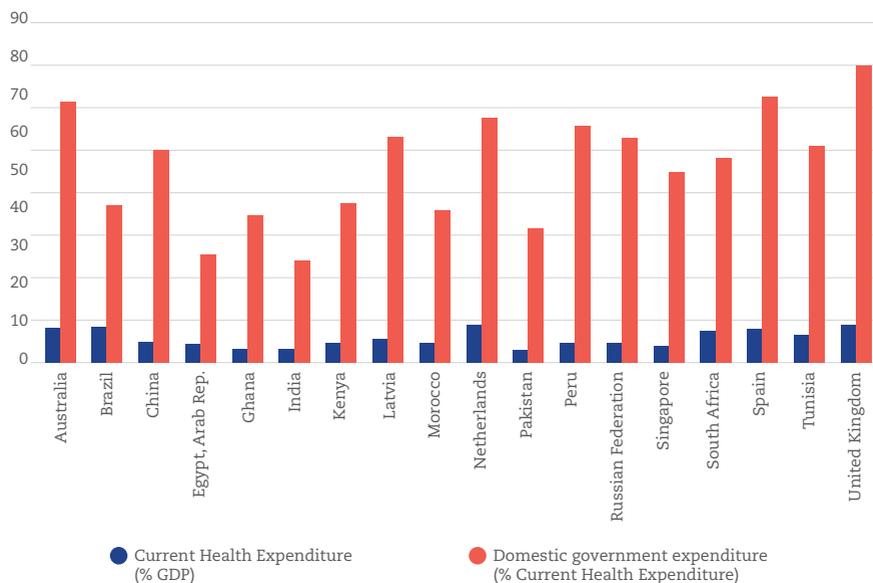
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154 African Union. (2019). Africa Scorecard on Domestic Financing for Health. Accessed October 2021. Available at: <https://scorecard.africa/table>

155 World Bank. (2008). The Business of Health in Africa: Partnering with the private sector to improve people's lives. Available at: <https://documents.worldbank.org/pt/publication/documents-reports/documentdetail/878891468002994639/the-business-of-health-in-africa-partnering-with-the-private-sector-to-improve-peoples-lives>

156 WHO (2020). Global spending on health 2020: weathering the storm. Available at: <https://www.who.int/publications/i/item/9789240017788>

Figure 24: Total Health Expenditure as a Percentage of GDP, and Public Health Expenditure as a Percentage of the Total Health Expenditure, 2018<sup>157</sup>



Strong healthcare systems also require strategic long-term planning and political commitment. Health authorities should put in place efficient regulatory pathways, and minimize inefficiencies in the supply chain, such as taxes and tariffs.

157 World Bank (2021) Health Expenditure. Latest year available: 2018. Washington DC: The World Bank Group. Available at: <https://data.worldbank.org/indicator/SH.XPD.GHED.CH.ZS> ; <https://data.worldbank.org/indicator/SH.XPD.CHEX.GD.ZS>

## Healthcare systems investments and savings from biopharmaceutical innovation

While health expenditure per capita varies among countries (see figure 21), spending on biopharmaceutical products as a share of health expenditure has broadly remained constant (see figure 22). Recently, the OECD also published a detailed analysis on spending for healthcare services, including inpatient care, outpatient care, long-term care, pharmaceuticals, prevention and administration. From 2009 to 2017, in OECD countries, the average spending on medicines fluctuated between – 1.5% and +1.6%, with an average close to 0%, showing that, even at a more granular level, spending on medicines grew at the slowest pace compared to the other services (see figure 23).<sup>158</sup>

Altogether, medicines constitute a relatively low share of overall healthcare costs in most countries: according to OECD statistics, the average expenditure on biopharmaceuticals across OECD members is  $\pm 15\%$  of health expenditure, though this figure varies from country to country.<sup>159</sup> In the next decade, the share of costs of other healthcare services, such as medical procedures and their management, is even projected to be ten times greater than costs of prescription medicines.<sup>160</sup>

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158 OECD (2021), Health at a Glance 2021: OECD Indicators, OECD Publishing, Paris. Available at: [https://www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance-2021\\_ae3016b9-en](https://www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance-2021_ae3016b9-en)Note: statistics based on retail pharmaceuticals consumption.

159 OECD (2021), Health at a Glance 2021: OECD Indicators, OECD Publishing, Paris. [https://www.oecd-ilibrary.org/sites/ae3016b9-en/1/3/9/1/index.html?itemId=/content/publication/ae3016b9-en&\\_csp\\_=ca413da5d44587bc56446341952c275e&itemIGO=oecd&itemContentType=book](https://www.oecd-ilibrary.org/sites/ae3016b9-en/1/3/9/1/index.html?itemId=/content/publication/ae3016b9-en&_csp_=ca413da5d44587bc56446341952c275e&itemIGO=oecd&itemContentType=book)

160 PhRMA. (2017). Prescription medicines: international costs in context. Available at: <https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA-International-Costs-in-Context-2017-03-02.pdf>

Figure 25: Expenditure on retail pharmaceuticals per capita, 2019 (or nearest year)<sup>161</sup>

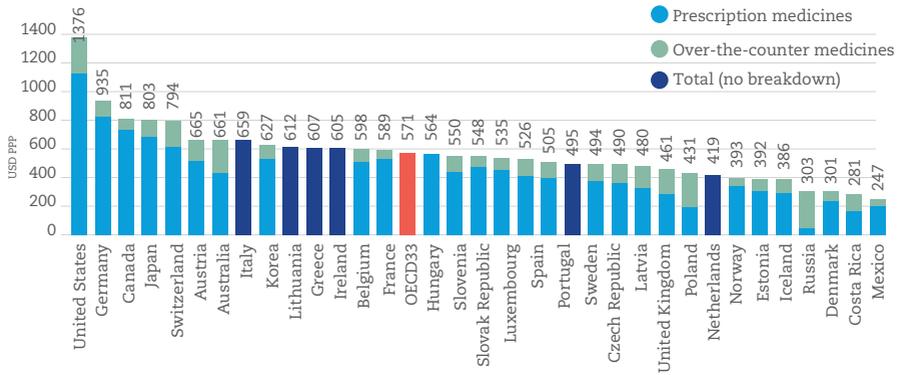
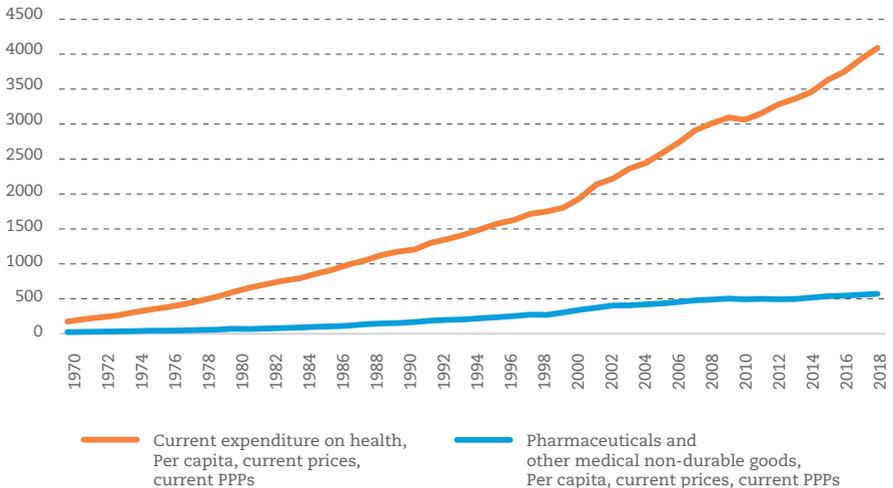


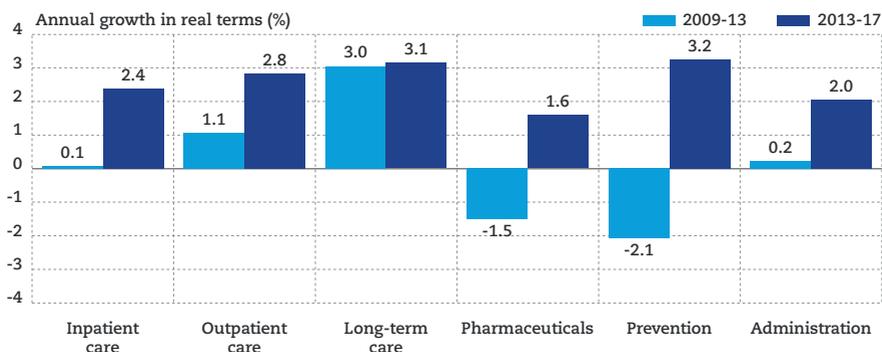
Figure 26: Per Capita Expenditure on Health and Pharmaceuticals, OECD Countries<sup>162</sup>



161 OECD (2021), Health at a Glance 2021: OECD Indicators, OECD Publishing, Paris. [https://www.oecd-ilibrary.org/sites/ae3016b9-en/1/3/9/1/index.html?itemId=/content/publication/ae3016b9-en&\\_csp\\_ca413da5d44587bc56446341952c275e&itemIGO=oecd&itemContentType=book](https://www.oecd-ilibrary.org/sites/ae3016b9-en/1/3/9/1/index.html?itemId=/content/publication/ae3016b9-en&_csp_ca413da5d44587bc56446341952c275e&itemIGO=oecd&itemContentType=book)

162 IFPMA analysis based on data extracted from OECD Data Available at: <https://data.oecd.org/> Accessed November 2021

Figure 27: Annual Growth in Health Expenditure for Selected Services (Real Terms), OECD Average, 2009-13 and 2013-2017<sup>163</sup>



Medicines contribute to the sustainability of healthcare systems by generating savings, for example by substantially reducing costs in other areas of healthcare, such as hospital stays and long-term care costs.<sup>164</sup>

As such, vaccination plays a key role in driving down costs related to healthcare both in developed and in developing countries. In the case of the human papillomavirus (HPV), vaccination has proven cost-effective for developed and developing countries alike:

- In Germany, HPV vaccination is cost-effective from both the payer and society perspective, as EUR 1 invested in HPV vaccination saves EUR 3.3 in terms of prevented medical costs and productivity losses due to premature mortality.<sup>165</sup>
- In Vietnam, supported by the Gavi program, HPV vaccination has proven to be cost-effective.<sup>166</sup>

163 Note: Current health expenditure comprises personal health care (curative care, rehabilitative care, long-term care, ancillary services and medical goods) and collective services (prevention and public health services as well as administration – referring to governance and administration of the overall health system rather than at the health provider level). Curative, rehabilitative and long-term care can also be classified by mode of provision (inpatient, day care, outpatient and home care). OECD (2019), *Health at a Glance 2019: OECD Indicators*, OECD Publishing, Paris. Available at: <https://doi.org/10.1787/4d50c09-en>

164 EFPIA (2021), *The pharmaceutical industry in figures 2021*. Available at: <https://www.efpia.eu/media/602709/the-pharmaceutical-industry-in-figures-2021.pdf>

165 Damm, O., Horn, J., Mikolajczyk, R. T., Kretzschmar, M. E., Kaufmann, A. M., Deleré, Y., ... & Greiner, W. (2017). Cost-effectiveness of human papillomavirus vaccination in Germany. *Cost Effectiveness and Resource Allocation*, 15(1), 18. Available at: <https://resource-allocation.biomedcentral.com/articles/10.1186/s12962-017-0080-9>

166 Van Minh, H., My, N. T. T., & Jit, M. (2017). Cervical cancer treatment costs and cost-effectiveness analysis of human papillomavirus vaccination in Vietnam: a PRIME modeling study. *BMC health services research*, 17(1), 353. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/28506297>

Assessing immunization in Gavi-supported countries on a broad scale, and taking into account healthcare costs, lost wages and productivity due to illness, as well as the broader benefits of people living healthier lives, there is a USD 54 return on every USD 1 invested.<sup>167</sup> In addition, an assessment of return on investment (ROI) has found that every dollar invested in immunization in low – and middle-income countries over a decade is estimated to result in a return of 26 times the initial costs, just taking into account the cost of illness. When considering broader economic and social benefits, the ROI for immunization was 51 times the vaccination investment.<sup>168</sup>

The COVID-19 pandemic has further highlighted the positive impact of immunization campaigns on the economy and society. Recent estimates value the social benefits of COVID-19 vaccines at USD 71 trillion, which is equivalent to 83% of the global GDP.<sup>169</sup> This great benefit to society is due to the lives saved, conditions improved, and the lifting of lockdown and social restriction measures, which far outweighs the spending by healthcare systems for COVID-19 vaccines.

## Key Challenges in Access to Biopharmaceutical Products

Even though the biopharmaceutical industry is deeply engaged in the access to medicines debate to find sustainable solutions for patients worldwide, availability of some products in developing countries can be difficult and complex. The reason for this is that there are different roadblocks along the delivery route that may include the quality of the healthcare system, its general infrastructure, access to insurance, and government policies on import tariffs and taxes. Patients in vulnerable healthcare systems are particularly challenged by high out-of-pocket (OOP) expenditure. In low – and lower-middle income countries, around 41% and 39% respectively of health expenditure is paid OOP, compared to 20% in high-income countries (see figure 24).<sup>170</sup>

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167 GAVI, The Vaccine Alliance (2021). Facts and figures: Statistics measuring our impact on global immunisation. Available at: <https://www.gavi.org/programmes-impact/our-impact/facts-and-figures>

168 Sim, S.Y., Watts, E., Constenla, D., Brenzel, L. and Patenaude, B.N., 2020. Return On Investment From Immunization Against 10 Pathogens In 94 Low-And Middle-Income Countries, 2011–30: Study estimates return on investment from immunization programs against ten pathogens for ninety-four low-and middle-income countries from 2011 to 2030. *Health Affairs*, 39(8), pp.1343-1353. Available at: <https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.00103>

169 World Intellectual Property Report 2022: The direction of innovation. Geneva: WIPO. Available at: <https://www.wipo.int/edocs/pubdocs/en/wipo-pub-944-2022-en-world-intellectual-property-report-2022.pdf>

170 IFPMA Analysis based on data extracted from WHO, Global Health Observatory (GHO) data. Available at: <https://www.who.int/data/gho> Visited November 2021. World Bank Country Classifications: based on latest data available (2018).

High OOP spending on health causes a significant number of households to face catastrophic health expenditure: 8.1% and 12.4% of households respectively in low- and lower-middle income countries.<sup>171</sup>

Around the world, almost 800 million people allocate more than 10% of their household budget to healthcare, while OOP spending pushes nearly 100 million people into extreme poverty each year.<sup>172</sup> According to the literature, there is a clear inverse relationship between life expectancy and OOP expenditure (see Figure 25), implying that better health outcomes also require appropriate financial protection.<sup>173</sup> In low- and middle income countries, almost 90% of spending on medicines are OOP.

Public financing is essential for countries to make sustainable progress towards universal health coverage (UHC). Achievement of UHC may require domestic fiscal reform to increase the total resources available and to reduce the share from OOP expenditures. While public financing is essential, this does not mean that governments have to deliver all health services themselves. A combination of effective government regulation and hybrid of private and public healthcare service provision can support equitable access to healthcare across a range of socioeconomic groups and ensure efficient use of funds to facilitate the provision of sustainable high-quality care.<sup>174</sup> Total health expenditures range from 3.2% of General Government Expenditure (GGE) in Equatorial Guinea to 22.5% of GGE in the United States. On average, low-income countries spend 5.4% of on financing healthcare systems, whereas high-income countries spend more than 13.7% on health.

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171 Bloom, D., Khoury, A. & Subbaraman R. (2018). The promise and peril of universal health care. *Science*, 261 Available at: <https://www.ncbi.nlm.nih.gov/pubmed/30139847>

172 World Bank Group/WHO (2017). Tracking universal health coverage: 2017 global monitoring report. Washington, DC and Geneva; 2017. Available at: <https://apps.who.int/iris/bitstream/handle/10665/259817/9789241513555-eng.pdf>

173 Ranabhat, C.L., Atkinson, J., Park, M.B., Kim, C.B. and Jakovljevic, M., 2018. The influence of universal health coverage on life expectancy at birth (LEAB) and healthy life expectancy (HALE): a multi-country cross-sectional study. *Frontiers in pharmacology*, 9. Available at: <https://www.frontiersin.org/articles/10.3389/fphar.2018.00960/full>

Ranabhat C. L., Park M., Kim C., Kim C., Jeonh H., Koh S., et al. (2018b). Influence of key health related indicators on adult mortality: result from UN member countries. *Iran. J. Public Health* 47, 794–802. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6077630/>

Jakovljevic M., Getzen T. E. (2016). Growth of global health spending share in low and middle income countries. *Front. Pharmacol.* Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5348507/>

174 IFPMA. (2019). Achieving a healthier and sustainable future for all. Retrieved from Available at: [https://www.ifpma.org/wp-content/uploads/2019/09/IFPMA\\_Policy\\_Perspectives\\_on\\_UHC\\_Full\\_Report.pdf](https://www.ifpma.org/wp-content/uploads/2019/09/IFPMA_Policy_Perspectives_on_UHC_Full_Report.pdf)

Figure 28: Domestic General Government Health Expenditure (Horizontal Axis, % General Government Expenditure) and OOP (% Current Health Expenditure)<sup>175</sup>

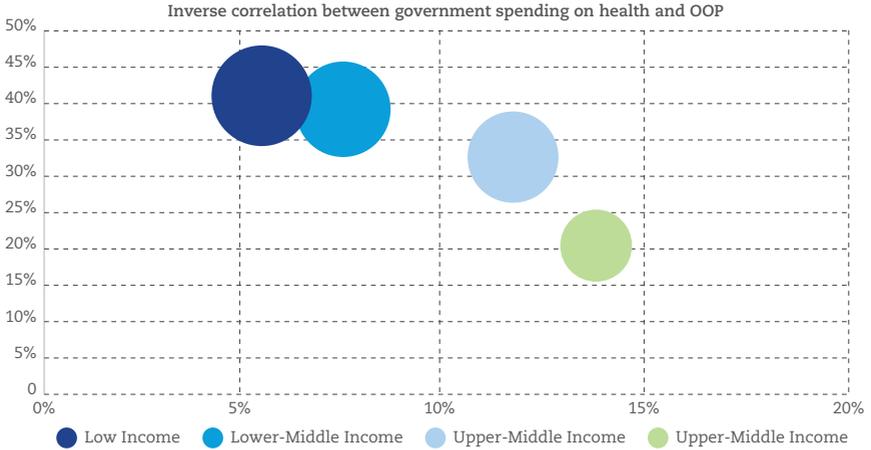
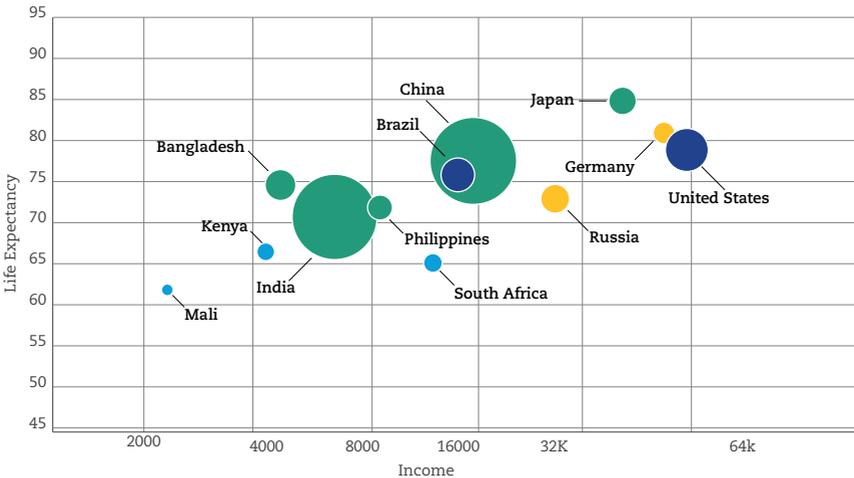


Figure 29: Correlation between Income per Person and Life Expectancy, 2018<sup>176</sup>



175 IFPMA Analysis based on data extracted from WHO, Global Health Observatory (GHO) data. Available at: <https://www.who.int/data/gho> Visited November 2021.

World Bank Country Classifications: based on latest data available (2018).

176 Size of the circles reflects the country population. Gapminder (2021) Global Trends: Wealth & Health of Nations. Accessed November 2021. Latest data available, 2019. Available at [https://www.gapminder.org/tools/#\\$chart-type=bubbles](https://www.gapminder.org/tools/#$chart-type=bubbles)

Poverty and wealth inequality creates or aggravates multiple barriers to biopharmaceutical products. In addition to poor health infrastructure in many low-income countries, there are often serious shortages of doctors, nurses, pharmacists, and other healthcare professionals. Challenges arise particularly in rural areas, where healthcare facilities are located at a considerable distance from patients and the transport network is often precarious. Lack of health literacy can further hinder access to medicines. The disparities are also significant in terms of healthcare workers. There are three physicians per 10,000 inhabitants in low-income countries compared with 30 in high-income countries. Likewise, low-income countries have about 7 hospital beds per 10,000 inhabitants whereas the average for high-income countries is 53.<sup>177</sup> These divergences in wealth and resources have a decisive impact on people's health. In low-income countries, 68 out of 1,000 children die before their fifth birthday compared with five out of 1,000 in high-income countries.<sup>178</sup>

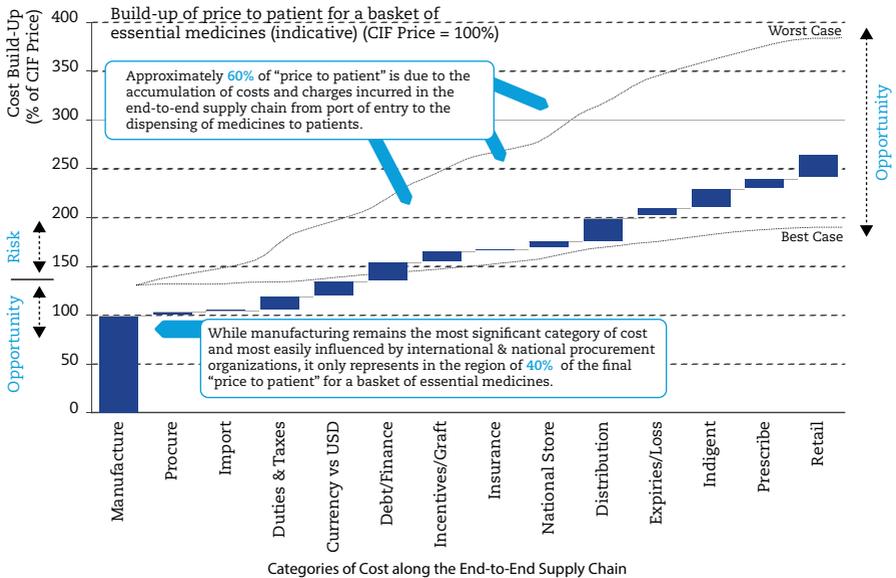
Developing countries, especially least-developed countries, often have high mark-up costs that inflate the prices of essential medicines. For instance, according to a study focused on a sample of African countries which analysed the cost structure of HIV, malaria, TB and other essential medicines, 60% of the final "price to patient" is determined by national and sub-national distribution.<sup>179</sup> These include distribution costs, import tariffs, port charges, importers' margins, value-added taxes on medicines, and high margins in the wholesale and retail components of the supply chain (see Figure 26).

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177 World Bank (2021) Health Indicators. Washington DC: The World Bank Group. Latest year available. Accessed November 2021 Available at: <https://data.worldbank.org/indicator/SH.MED.PHYS.ZS>; <https://data.worldbank.org/indicator/SH.MED.BEDS.ZS>

178 World Bank (2021) Mortality Rate, under-5 (per 1,000 Live Births). Washington DC: The World Bank Group. Accessed November 2021 Available at: <https://data.worldbank.org/indicator/SH.DYN.MORT>

179 Tackling the Triple Transition in Global Health Procurement. (2019). Final report of CGD's working group on the future of global health procurement. Center for Global Development. Available at: <https://www.cgdev.org/sites/default/files/better-health-procurement-tackling-triple-transition.pdf>

Figure 30: Examples of “Hidden” Costs of Pharmaceutical Procurement<sup>180</sup>

Moreover, poor people with limited or no access to adequate nutrition, safe water, and sanitation are also often unable to afford even basic health products and services. Contrary to widespread belief, it is rarely high-tech solutions but rather primary care interventions that successfully combat poverty-related diseases. Poverty alleviation in general consists of targeted interventions. Some of these programs include better nutrition for mothers, mass vaccination campaigns, access to basic antibiotics, bed nets for malaria prevention, and condom use programs to prevent the spread of HIV/AIDS and other sexually transmitted diseases. These efforts are highly effective in reducing preventable mortality (see Table 9).

Table 8: Selected Infrastructure Indicators, 2020<sup>181</sup>

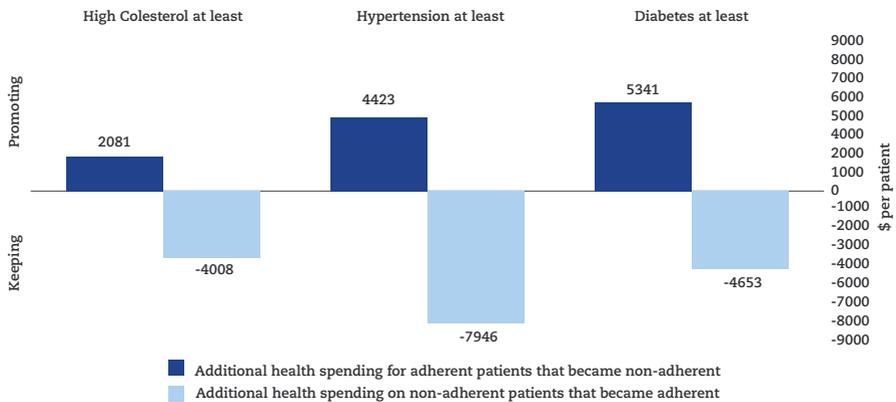
	INFRASTRUCTURE* (QUALITY OF TRADE AND TRANSPORT RELATED INFRASTRUCTURE) (1= LOW, 5 = HIGH) (E.G., PORTS, RAILROADS, ROADS, INFORMATION TECHNOLOGY)	PEOPLE USING AT LEAST BASIC SANITATION SERVICES (% OF POPULATION)	PEOPLE USING AT LEAST BASIC DRINKING WATER SERVICES (% OF POPULATION)
Arab World	2.61	84	89
East Asia & Pacific	3.05	91	94
Europe & Central Asia	3.13	97	98
Heavily indebted poor countries	2.16	28	61
High income	3.48	99	100
Latin America & Caribbean	2.47	89	97
Least developed countries	2.13	37	67
Low income	2.08	29	59
Lower middle income	2.36	70	89
Middle income	2.46	79	92
North America	3.90	100	100
South Asia	2.33	69	91
Sub-Saharan Africa	2.20	33	64
Upper middle income	2.58	92	96
World	2.72	78	90

181 World Bank (2021) Infrastructure. Washington DC: The World Bank Group. Available at: <https://data.worldbank.org/indicator/LP.LPI.INFR.XQ>; <https://data.worldbank.org/indicator/SH.STA.BASS.ZS>; <https://data.worldbank.org/indicator/SH.H2O.BASW.ZS>

\*Note: Infrastructure latest values available: 2018.

High OOP expenditure and other barriers can lead to poor adherence. Every year, in Europe, low patient adherence contributes to the death of nearly 200,000 people.<sup>182</sup> Lack of patient adherence costs European and US healthcare systems, respectively EUR 125 billion, and USD 105 billion annually because of emergency care, hospitalizations and outpatient visits that could be avoided.<sup>183</sup> Reasons for poor patient adherence can be high out-of-pocket expenditure and other barriers.<sup>184</sup> In the case of diabetes, hypertension and hyperlipidemia, for every additional USD spent on biopharmaceuticals for patients who do adhere, USD 3 to 13 can be saved on avoidable emergency department visits and hospitalizations.<sup>185</sup>

Figure 31: Total Spending on Health Services For Variations of Patients' Adherence<sup>186</sup>



182 Khan, R. and Socha-Dietrich, K., 2018. Investing in medication adherence improves health outcomes and health system efficiency. Available at: [https://www.oecd-ilibrary.org/social-issues-migration-health/investing-in-medication-adherence-improves-health-outcomes-and-health-system-efficiency\\_8178962c-en](https://www.oecd-ilibrary.org/social-issues-migration-health/investing-in-medication-adherence-improves-health-outcomes-and-health-system-efficiency_8178962c-en)

183 Ibid.

184 Morgan, S.G. and Lee, A., 2017. Cost-related non-adherence to prescribed medicines among older adults: a cross-sectional analysis of a survey in 11 developed countries. *BMJ open*, 7(1), p.e014287. Available at: <https://bmjopen.bmj.com/content/7/1/e014287>

185 Khan, R. and Socha-Dietrich, K., 2018. Investing in medication adherence improves health outcomes and health system efficiency. Available at: [https://www.oecd-ilibrary.org/social-issues-migration-health/investing-in-medication-adherence-improves-health-outcomes-and-health-system-efficiency\\_8178962c-en](https://www.oecd-ilibrary.org/social-issues-migration-health/investing-in-medication-adherence-improves-health-outcomes-and-health-system-efficiency_8178962c-en)

186 Kymes, Steven M., et al. "Association among change in medical costs, level of comorbidity, and change in adherence behavior." *The American journal of managed care* 22.8 (2016): e295-301 Available at: [https://www.researchgate.net/publication/306549667\\_Association\\_among\\_change\\_in\\_medical\\_costs\\_level\\_of\\_comorbidity\\_and\\_change\\_in\\_adherence\\_behavior](https://www.researchgate.net/publication/306549667_Association_among_change_in_medical_costs_level_of_comorbidity_and_change_in_adherence_behavior)

Note: The outcome modeled was the spending on medical service utilization for three or more conditions patients for all inpatient and outpatient services, regardless of whether they were paid by the insurer or patient, without including the pharmacy costs.

To deliver optimal benefits to patients, ensuring access to healthcare is a starting point, which has to be supplemented with further efforts in ensuring that the health care delivered is of adequate quality. Poor-quality care is now a bigger barrier to reducing mortality than insufficient access to healthcare.<sup>187</sup> Substandard and falsified (SF) medical products pose a threat to individual patients' health and to health systems globally. These products can cause harm to patients, fail to treat the diseases for which they were intended, and undermine patients trust in health systems.<sup>188</sup> For instance, according to a study funded by the WHO, each year, in sub-Saharan Africa, SF antimalarials contribute an additional 72 000–267 000 deaths.<sup>189</sup> SF medicines are a global issue: according to the Pharmaceutical Security Institute's 2019 report, 150 countries were reported to have been impacted by pharmaceutical crime.<sup>190</sup> However, low- and middle-income countries carry the greatest burden. In a systematic literature review, the prevalence of SF medicines in low- and middle-income countries was 13.6% overall (19.1% for antimalarials and 12.4% for antibiotics).<sup>191</sup> This can also trigger a negative socioeconomic impact, contributing to related loss in productivity and adding expenses to the individual and national health system. Data on the estimated economic impact range widely from USD 10 billion to USD 200 billion.<sup>192</sup>

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187 High-quality health systems in the Sustainable Development Goals era: time for a revolution; Kruk, Margaret E et al.; *The Lancet Global Health* (2018), Volume 6, Issue 11, e1196 – e1252; Available at: [https://www.thelancet.com/journals/langlo/article/PIIS2214-109X\(18\)30386-3/fulltext](https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(18)30386-3/fulltext)

188 WHO Official Website. Available at: <https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products>

189 World Health Organization. "A study on the public health and socioeconomic impact of substandard and falsified medical products." (2017). Available at: <https://apps.who.int/iris/handle/10665/331690>

190 PSI official website. Available at: <https://www.psi-inc.org/geographic-distribution>

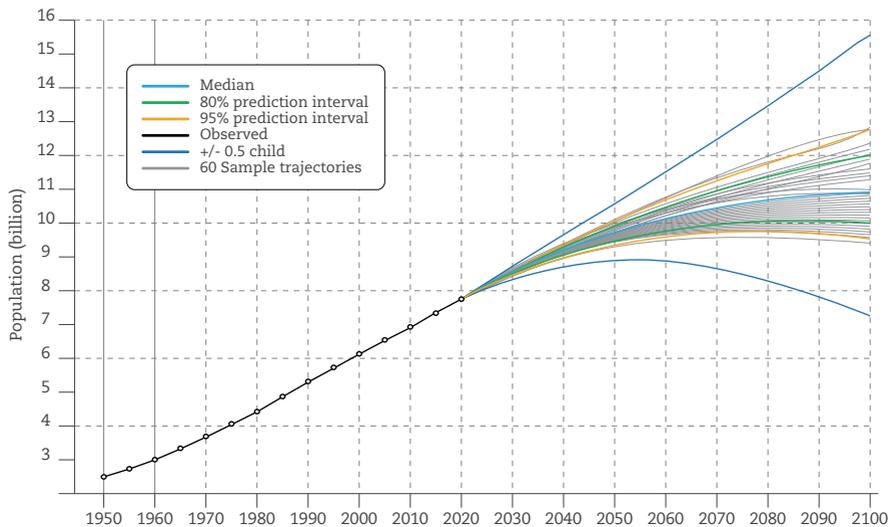
191 Ozawa S, Evans DR, Bessias S, et al. Prevalence and Estimated Economic Burden of Substandard and Falsified Medicines in Low- and Middle-Income Countries: A Systematic Review and Meta-analysis. *JAMA Netw Open*. 2018;1(4):e181662. <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2696509>

192 Ibid.

## Looking Ahead: Adapting Healthcare to Demographic Changes

Healthcare systems must respond to the needs of a constantly growing global population. According to estimates published by the UN, the world's population has been increasing steadily, and is expected to reach 8.5 billion in 2030, which is an 8% increase from 7.9 billion in 2021, and will further grow to 9.7 billion in 2050.<sup>193</sup>

Figure 32: Total World Population, Past Trends and Future Predictions, 1950 – 2100<sup>194</sup>



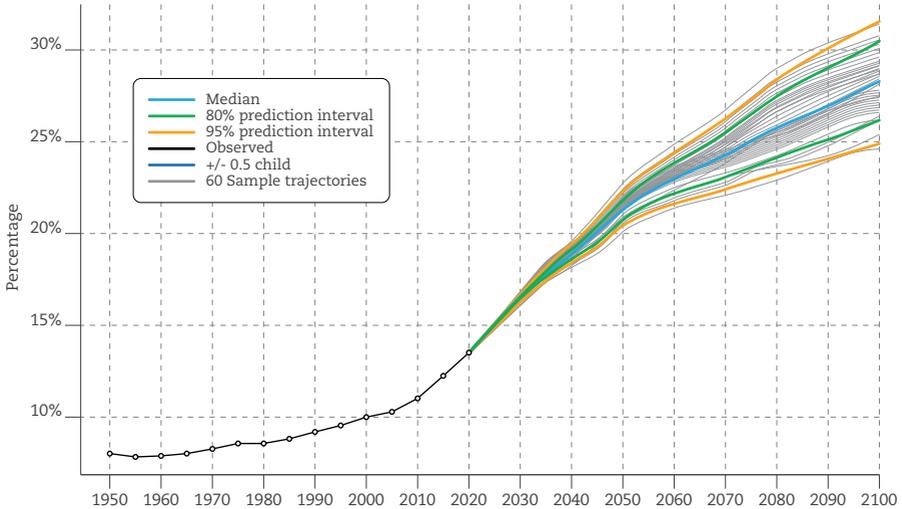
While the overall size of the population is increasing, the distribution of the individuals by age is also changing. Globally, people over 65 are the fastest-growing age group, and health systems must increasingly accommodate the needs of a population that

193 United Nations, Department of Economic and Social Affairs, Population Division, 2019. World Population Prospects 2019. Available at: <https://population.un.org/wpp/>. Note: 2021 figure is an elaboration by worldometer based on same UN statistics. Available at: <https://www.worldometers.info/world-population/>

194 United Nations, Department of Economic and Social Affairs, Population Division, 2019. World Population Prospects 2019. Available at: <https://population.un.org/wpp/>

requires more health interventions.<sup>195</sup> By 2050, the share of the population over 65 years old is expected to double in various regions of the world. By 2050, in Europe and North America, one in four people could be aged 65 or over.<sup>196</sup>

Figure 33: Percentage of World Population Aged 60 Years or Over<sup>197</sup>



This global demographic shift will undoubtedly put more pressure on health systems as they will see increases in the rates of illness and chronic conditions and greater demand for elderly care all contributing to increases in health spending (see Figure 30).<sup>198</sup> An older population suffers from health problems usually associated with chronic conditions, especially noncommunicable diseases (NCDs), as well as being more susceptible to co-morbidities. These diseases include heart disease, stroke, cancer,

195 Williams, G., Cylus, J., Roubal, T., Ong, P., Barber, S. and World Health Organization, 2019. Sustainable health financing with an ageing population: will population ageing lead to uncontrolled health expenditure growth?. Available at: <https://apps.who.int/iris/handle/10665/331977>

196 United Nations, Department of Economic and Social Affairs, Population Division, 2019. World Population Prospects 2019. Available at: <https://population.un.org/wpp/>

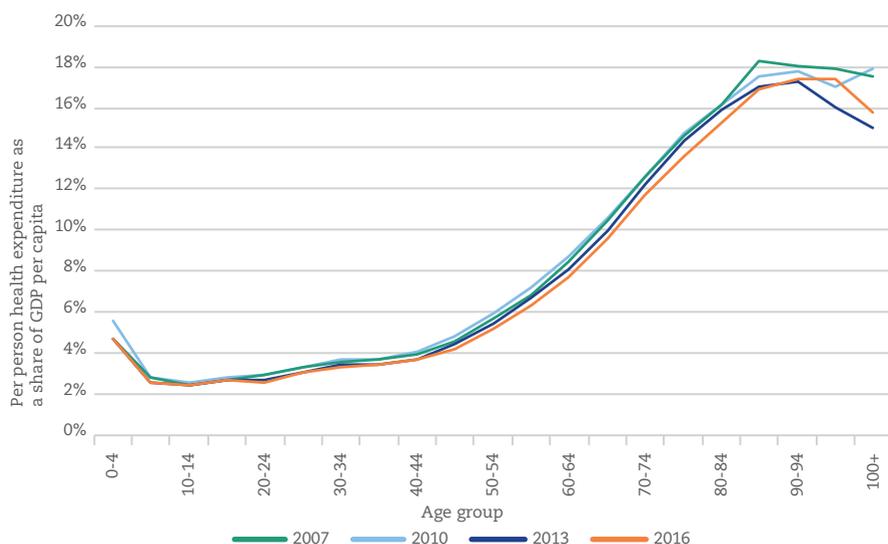
197 United Nations, Department of Economic and Social Affairs, Population Division, 2019. World Population Prospects 2019. Available at: <https://population.un.org/wpp/>

198 OECD (2017), Health at a Glance 2017: OECD Indicators, OECD Publishing, Paris Available at: [https://www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance-2017\\_health\\_glance-2017-en](https://www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance-2017_health_glance-2017-en)

diabetes and chronic lung disease. NCDs are responsible for around 71% of all the deaths worldwide (see Figure 31).<sup>199</sup> Over three quarters of NCDs deaths occur in low-and middle-income countries, which are facing a fast-growing burden of chronic diseases.<sup>200</sup>

Older adults also have an increased vulnerability to contracting infectious diseases and developing a severe form of illness – for instance influenza or bacterial pneumonia, among others. Immunizing the population through the life course can prevent unnecessary hospital admissions and mortality from vaccine-preventable diseases, indirectly reduce the spread of antimicrobial resistance and reduce the possibility of developing serious complications from vaccine-preventable illnesses in people with some chronic conditions like diabetes, respiratory or cardiovascular disease.<sup>201</sup>

Figure 34: Per Person Health Expenditure by Age Group, 2007-2016, EU average<sup>202</sup>



199 WHO Official Website. Noncommunicable diseases and their risk factors. Link: Available at: [https://www.who.int/health-topics/noncommunicable-diseases#tab=tab\\_1](https://www.who.int/health-topics/noncommunicable-diseases#tab=tab_1)

200 Ibid.

201 IFPMA (2019). Implementing a Life-Course Approach to Immunization: Lessons learned from international bestpractice in policy and programming. Available at: [https://www.ifpma.org/wp-content/uploads/2019/08/IFPMA\\_HPP\\_Life\\_Course\\_Immunization\\_Full\\_Report.pdf](https://www.ifpma.org/wp-content/uploads/2019/08/IFPMA_HPP_Life_Course_Immunization_Full_Report.pdf)

202 Williams, G., Cylus, J., Roubal, T., Ong, P., Barber, S. and World Health Organization, 2019. Sustainable health financing with an ageing population: will population ageing lead to uncontrolled health expenditure growth?. Available at: <https://apps.who.int/iris/handle/10665/331977>

Figure 35: Non Communicable Diseases as % of Causes of Death<sup>203</sup>

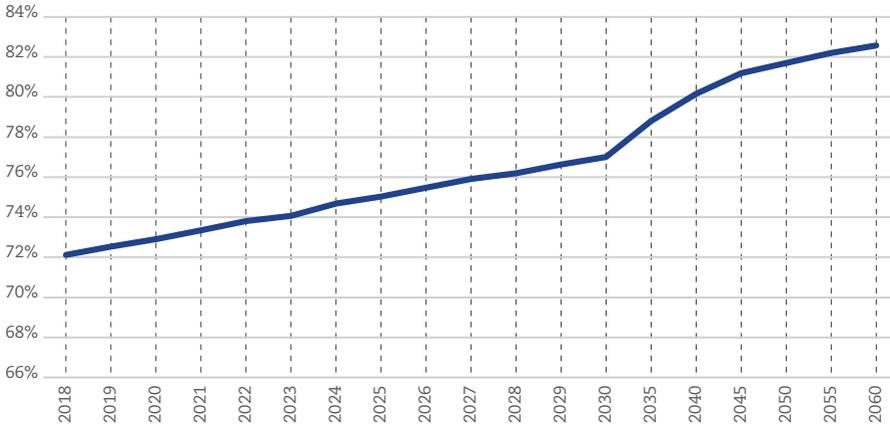
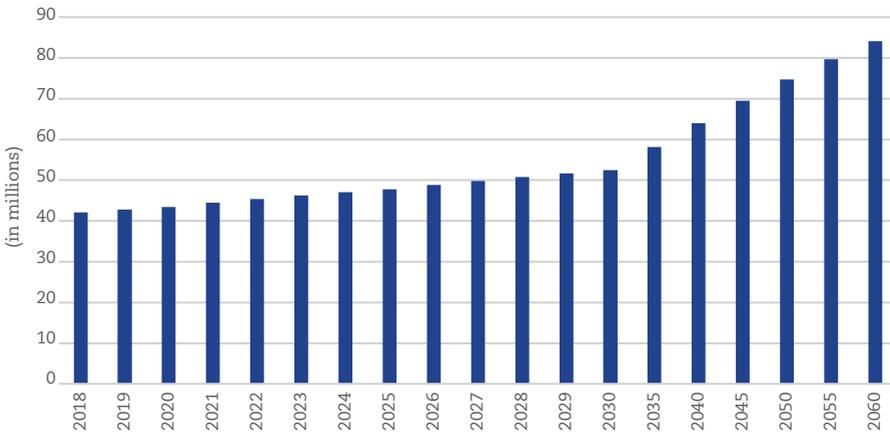


Figure 36: Number of deaths caused by Non Communicable Diseases<sup>204</sup>



203 World Health Organization (2018). Projections of mortality and causes of death, 2017-2060. Available at: <https://www.who.int/data/global-health-estimates>

204 Ibid.

As outlined, chronic diseases and non-communicable diseases consume most health spending. In Switzerland, 80% of total healthcare costs are spent on NCDs.<sup>205</sup> At a global level, cardiovascular disease is the leading driver of spending on chronic disease, accounting for an average of 12 to 16.5 percent of total health system spending.<sup>206</sup>

Where challenges exist, innovative products and services follow. Technological progress will help release the mounting pressure from healthcare systems budgets strained by the ageing population. Genomics, big data, predictive analytics and precision medicines will greatly contribute to advances in disease prevention. The rapid development of digital health solutions can greatly improve the lives of patients and families, while reducing healthcare spending, by allowing patients to receive medical treatments in their homes.<sup>207</sup>

## Biopharmaceutical Industry's Initiatives to Improving Access

Research-based biopharmaceutical companies make a unique contribution to improving global health through the innovative medicines they develop. In addition, they have a strong track record of sustaining programs to improve the health of patients in low- and middle-income countries. These initiatives strengthen local healthcare capacity, educate patients and populations at risk, and conduct research and development (R&D) in diseases of the developing world. The Global Health Progress platform highlights over 270 collaborations between the innovative biopharmaceutical industry and more than 1200 partners to support the Sustainable Development Goals (SDGs).<sup>208</sup> These collaborations are helping to bring different actors together – governments, academia, multilateral organizations, other private sectors, local NGOs and more – to catalyse cross-sector initiatives to tackle health related challenges, as well as address gender equality and education issues.

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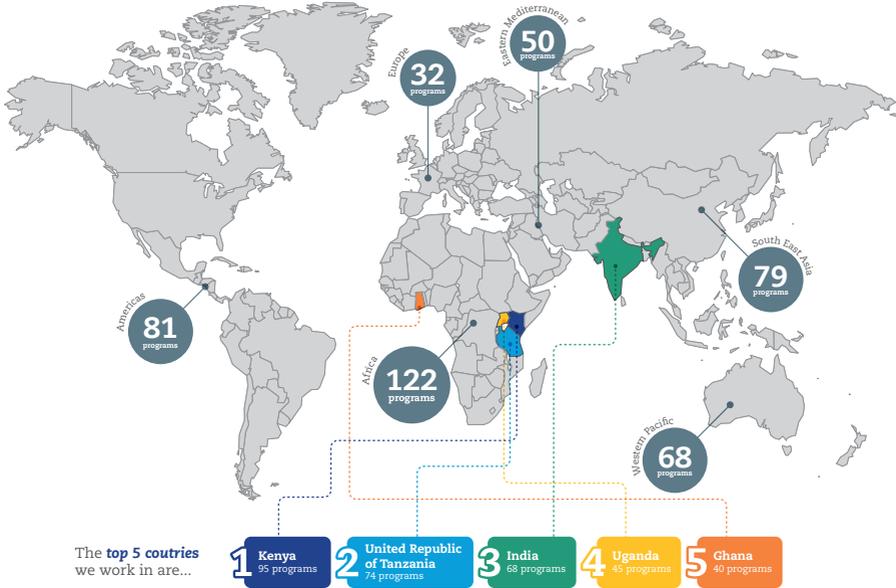
205 Dr. med. Carlos Beat Quinto, Mitglied des FMH-Zentralvorstandes (2018). Nichtübertragbare Krankheiten – unterschiedliche Perspektiven. SCHWEIZERISCHE ÄRZTEZEITUNG. Available at: <https://saez.ch/article/doi/saez.2018.17023>

206 Muka et al. (2015). The global impact of non-communicable diseases on health care spending and national income: A systematic review. *European Journal of Epidemiology*, 30(4), 251. Available at: <https://pubmed.ncbi.nlm.nih.gov/25595318/>

207 Thomas Allvin (2019). EFPIA. An ageing population – the good, the bad and the silver lining. EFPIA, July 2019. Available at: <https://www.efpia.eu/news-events/the-efpia-view/blog-articles/an-ageing-population-the-good-the-bad-and-the-silver-lining/>

208 Global Health Progress (2021). Official Website. Retrieved from Available at: <https://globalhealthprogress.org/>

Figure 37: Collaborations Between the Innovative Biopharmaceutical Industry and its Partners to Support the SDGs<sup>209</sup>

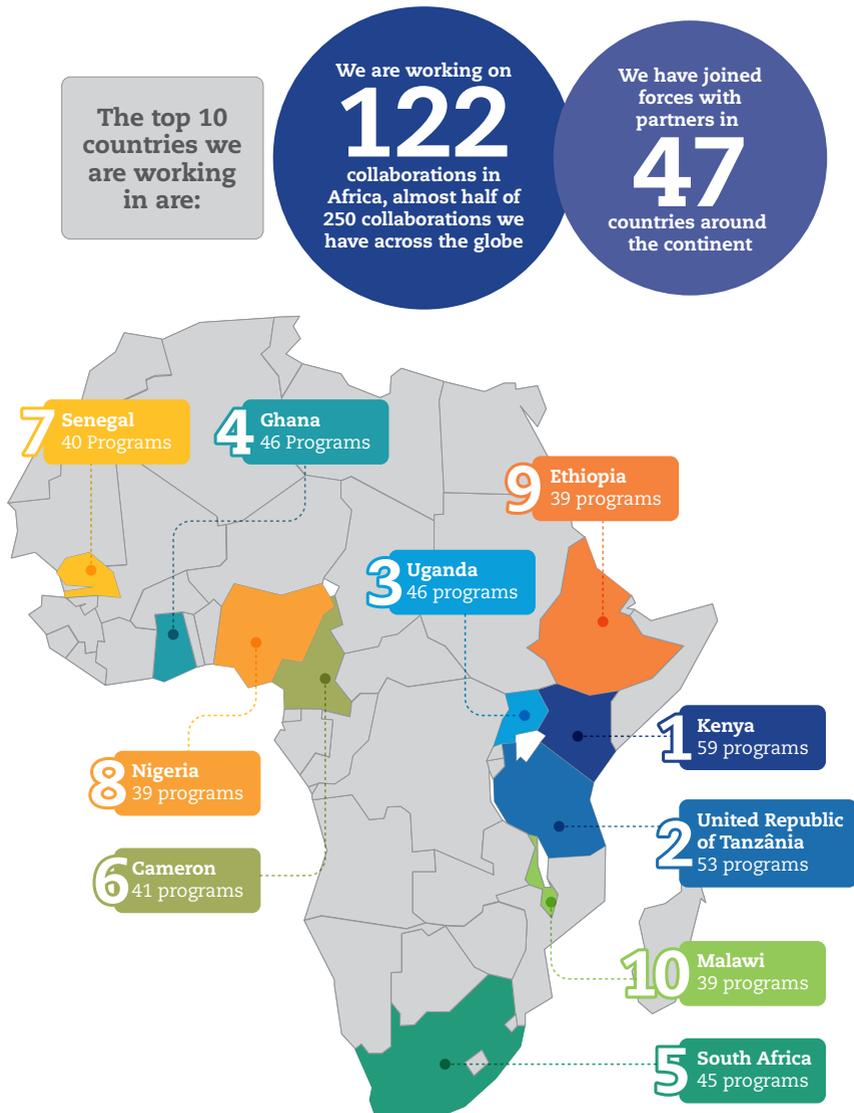


As Africa's population continues to grow, it is estimated to reach 2.5 billion people by 2050, investments in robust health systems are key to inclusive and sustainable growth. In 2019, African Union countries reiterated their pledge to allocate 15% of their annual budget to the health sector.<sup>210</sup> The innovative biopharmaceutical industry is committed to tackling health challenges and supporting the SDGs, moving beyond traditional corporate social responsibility (CSR) to align programs to government priorities by strengthening health systems and developing innovative solutions to increase access to care and treatment. IFPMA members are working on 122 collaborations in Africa, almost half of the 250 collaborations across the globe, joining forces with partners in 47 countries across the continent.

<sup>209</sup> Ibid.

<sup>210</sup> African Union. (2014). Africa Scorecard on Domestic Financing for Health. Available at: <https://scorecard.africa/>

Figure 38: Collaborations in Africa Between the Innovative Biopharmaceutical Industry and its Partners to Support the SDGs<sup>211</sup>



## ACCESS ACCELERATED

Launched in January 2017, Access Accelerated<sup>212</sup> is an initiative that is implementing scalable and sustainable non-communicable disease solutions in low – and middle-income countries by helping the public and private sectors work better together. With more than 20 member companies currently working on 107 public health programs in 136 countries, Access Accelerated is the largest collective industry effort to address inequities in NCD care.

Access Accelerated informs health policies, accelerates public and private investment, and advances meaningful partnerships to build strong and resilient health systems that deliver health care for all. The initiative is built to scale – by partnering across the biopharmaceutical industry and with multilaterals, leading non-profit partners, people living with NCDs and local governments, Access Accelerated combines disease area and public health expertise with local insights and catalytic resources. Access Accelerated currently focuses on digital health, supply chain strengthening and community-based approaches to primary healthcare – areas where the industry’s collective effort is needed and can make an impact.

Access Accelerated believes in a future where no one dies prematurely from treatable, preventable diseases and where all people living with, or at risk of, NCDs have access to appropriate, quality, and affordable prevention, treatment and care. By changing the way we work together, Access Accelerated is helping millions of people around the world live healthier and more productive lives.

212 Access Accelerated. Official Website (2022). Available at: <https://accessaccelerated.org/>

## Biopharmaceutical industry's three priorities to urgently increase access to COVID-19 vaccines

Over the past years, our collective efforts in mounting a response to the pandemic have materialized. By mid 2022, COVAX delivered over 1.5 bn doses of COVID-19 vaccines, while over 5 billionn doses have been delivered to Low- and Low-Middle Income countries.<sup>213</sup> Nevertheless vaccine equity remains a shared concern. All relevant stakeholders must redouble efforts to support countries as they mobilize to execute national vaccine rollouts and remove barriers to the efficient distribution and administration of vaccine doses. The health system bottlenecks are multiple - leadership and coordination, financing, health workforce, in-country supply chain, and data systems.

To urgently increase access to COVID-19 vaccines, innovative biopharmaceutical companies will continue to work with all relevant stakeholders on the following three overarching priorities and supporting activities:<sup>214</sup>

- Step Up Support For Country Readiness To Roll Out Covid-19 Vaccine Doses
- Contribute To Equitable Distribution Of Covid-19 Vaccine Doses
- Continue To Drive Innovation

COVID-19 vaccine acceptance is a key concern that can derail the global efforts to control the spread of the virus. In addition, this may have a broader impact on confidence in all other vaccines. Vaccine companies are playing an important role in building and sustaining vaccine confidence by developing high quality, safe and effective vaccines.

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213 UNICEF (2022), COVID-19 Vaccine Market Dashboard. Available at: <https://www.unicef.org/supply/covid-19-vaccine-market-dashboard>

214 IFPMA (2022). Three priorities to urgently increase access to COVID-19 vaccines Available at: [https://www.ifpma.org/wp-content/uploads/2022/02/Press\\_Release\\_Three-Priorities-Increase-Access-COVID-19-Vaccines-2.pdf](https://www.ifpma.org/wp-content/uploads/2022/02/Press_Release_Three-Priorities-Increase-Access-COVID-19-Vaccines-2.pdf)



## Chapter 3

# ECONOMIC FOOTPRINT OF THE BIOPHARMACEUTICAL INDUSTRY

The biopharmaceutical industry makes major contributions to the prosperity of the world economy. It is a robust sector that has been one of the pillars of industrialized economies and is increasingly recognized as an important industry in the developing world as well. It contributes to employment (direct, indirect, and induced), trade, research and development investments, and technological capacity building. It is also a necessary foundation for the existence of the generic drug industry.

Table 9: Key Indicators of the Biopharmaceutical Industry's Economic Footprint in Europe<sup>215</sup>

 INDUSTRY (EFPIA TOTAL)	2000	2010	2019	2020
 Production	127,504	199,730	293,213	310,000 (e)
 Exports (1) (2)	90,935	276,357	473,753	515,000 (e)
 Imports	68,841	204,824	333,626	360,000 (e)
 Trade balance	22,094	71,533	140,127	155,000 (e)
 R&D expenditure	17,849	27,920	37,754	39,000 (e)
 Employment (units)	556,506	701,059	823,882	830,000 (e)
 R&D employment (units)	88,397	116,253	121,594	125,000 (e)
 Total pharmaceutical market value at ex-factory prices	89,449	153,684	227,404	240,500 (e)
 Payment for pharmaceuticals by statutory health insurance systems (ambulatory care only)	76,909	129,464	140,374	149,500 (e)

215 EFPIA (2021) The Pharmaceutical Industry in Figures. Brussels: European Federation of Pharmaceutical Industries and Associations (2021), p 3 Available at: <https://www.efpia.eu/media/602709/the-pharmaceutical-industry-in-figures-2021.pdf>

## Biopharmaceutical R&D and Production

The biopharmaceutical industry's activities have a strong and positive influence on the global economy. This economic footprint is most visible in the form of investments in manufacturing and R&D, but it often has other beneficial socioeconomic impacts, such as continuous improvements in academic research and knowledge creation. It also stimulates the establishment and growth of companies that support parts of the research and production process.

Through its economic activity, the global biopharmaceutical industry contributes to the United Nations' Sustainable Development Goal 8: Promote economic growth, employment, and work for all. The research-based biopharmaceutical industry is particularly economically active in production and R&D helping to address Goal 8 and the previously mentioned Goals 3 and 17. Globally, the production value of the biopharmaceutical industry amounted to USD 1.2 trillion in 2018, more than USD 200 billion higher than in 2014.<sup>216</sup>

In 2018, the biopharmaceutical industry directly added roughly the GDP of the Netherlands (USD 532 billion)<sup>217</sup> to the world economy. In addition to the immediate economic effects it directly generates, industry also supported the global GDP with an additional USD 791 billion triggered by its consumption of intermediate inputs from other sectors through its global value chains. Example of these intermediates include chemical compounds and active ingredients used in other industries. Moreover, the private consumption triggered by directly and indirectly generated income resulted in an extra USD 515 billion of GDP contribution to the global economy through induced effects. Therefore, combining direct, indirect and induced effects, the biopharmaceutical industry's total contribution to the world's GDP is USD 1,838 billion.<sup>218</sup>

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216 WifOR (2020). The Global Economic Impact of the Pharmaceutical Industry. Available at: [https://www.ifpma.org/wp-content/uploads/2021/04/WifOR\\_Global\\_Economic\\_Footprint\\_Study\\_September\\_2020.pdf](https://www.ifpma.org/wp-content/uploads/2021/04/WifOR_Global_Economic_Footprint_Study_September_2020.pdf)

217 Ibid.

218 Ibid.

Figure 39: Development of the Gross Value Added and the Annual Growth Rate (Red Line) in Comparison to the Worldwide GDP (Blue Line)<sup>219</sup>

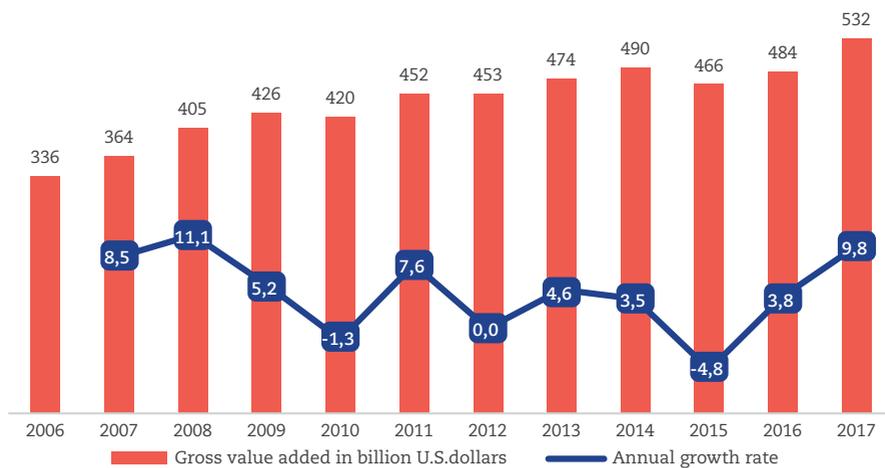
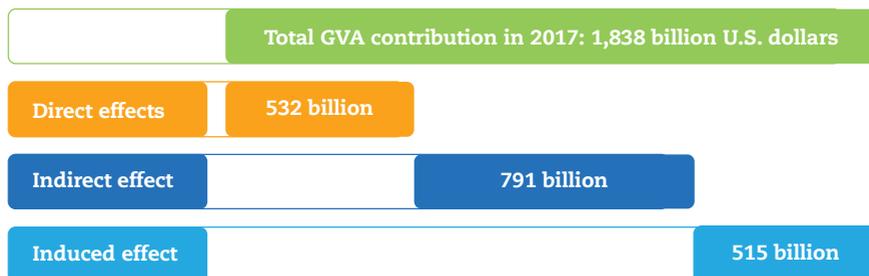


Figure 40: Direct, indirect and induced GVA effects triggered through economic activities of the global biopharmaceutical industry<sup>220</sup>



<sup>219</sup> Ibid.

<sup>220</sup> Ibid.

## Biopharmaceutical Industry Employment

The biopharmaceutical industry strongly contributes to employment in both developing and developed countries. In 2017, it employed approximately 5.5 million people worldwide, including through the manufacturing of generics medicines.<sup>221</sup> Industry provides jobs through direct employment and induces the creation of many more indirect jobs in every country it operates. In the United States, every job in the biopharmaceutical industry supported about 5 jobs outside the biopharmaceutical sector, in areas from manufacturing and construction to childcare, retail, accounting, and more.<sup>222</sup> Spending on services and supplies totalled USD 589 billion, translating into more than 4 million jobs in this country.<sup>223</sup>

Through its expenditures on materials and services of other sectors, the global biopharmaceutical industry supported an additional 45.1 million indirect employees in other sectors along its supply chains. In addition, industry also supported 23.7 million jobs in other sectors induced by private consumption around the world through directly and indirectly generated income, such as childcare, retail, and more. Combined, industry’s direct, indirect and induced effects on jobs amounted to 74.3 million employees in 2017.

Figure 41: Direct, Indirect and Induced Employment Effects Triggered Through Economic Activities of the Global Biopharmaceutical Industry<sup>224</sup>



221 Ibid.

222 Tecomy Partnes LLC & PhRMA (2019) The Economic Impact of the US Biopharmaceutical Industry: 2017 National and State Estimates, p 1. Available at: <https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/D-F/Economic-Impact-US-Biopharmaceutical-Industry-December-2019.pdf>

223 Ibid.

224 WifOR (2020). The Global Economic Impact of the Pharmaceutical Industry. Available at: [https://www.ifpma.org/wp-content/uploads/2021/04/WifOR\\_Global\\_Economic\\_Footprint\\_Study\\_September\\_2020.pdf](https://www.ifpma.org/wp-content/uploads/2021/04/WifOR_Global_Economic_Footprint_Study_September_2020.pdf)

On top of directly or indirectly creating jobs, the biopharmaceutical industry's presence also leads to dissemination of knowledge in the workforce. Employees working for a biopharmaceutical company often receive qualified training and are exposed to new technologies and processes. This knowledge becomes an asset for the entire workforce, as the employees may later change jobs or start their own companies, hence fostering economic development.

## Transfer of Technology

Transfer of advanced technology is essential for economic development. It is one means by which low – and lower middle-income countries can accelerate the acquisition of knowledge, experience, and equipment related to advanced, innovative industrial products and processes. Technology transfer has the potential to help improve health faster and across many geographies. It also benefits the overall economy by increasing the reliability of supply, decreasing reliance on imports, and raising the competence of the local workforce.<sup>225</sup>

Table 10: Selected Examples of Technology Transfer<sup>226</sup>

COMPANY	INITIATIVE	GEOGRAPHIC REGION	DISEASE AREA	SINCE
Astellas Pharma Inc	Collaborative Research to Discover Anti-protozoan Parasite Drugs	Americas	Neglected Tropical Diseases (NTDs)	2016
Johnson & Johnson	10-year TB initiative	Global Commitment	Infectious and Parasitic Disease	2018
Multi-Company Partnership	Neglected Tropical Disease Drug Discovery Booster	Global Commitment	Neglected Tropical Diseases (NTDs)	2015
Pfizer Inc	Antimicrobial Innovative Vaccines	Global Commitment	Infectious and Parasitic Disease	2015
Eli Lilly and Company	Lilly 30x30	Africa Americas Europe South-East Asia Western Pacific	Non-communicable Diseases Infectious and Parasitic Disease	2016

225 IFPMA (2021) Technology Transfer: A Collaborative Approach to Improve Global Health. The Biopharmaceutical Industry Experience. Geneva: International Federation of Pharmaceutical Manufacturers and Associations. Available at: [https://www.ifpma.org/wp-content/uploads/2021/12/IFPMA\\_Tech-Transfer\\_A-collaborative-approach-to-improve-global-health\\_Position-Paper.pdf](https://www.ifpma.org/wp-content/uploads/2021/12/IFPMA_Tech-Transfer_A-collaborative-approach-to-improve-global-health_Position-Paper.pdf)

226 Global Health Progress. Official Website. Retrieved from Available at: <https://globalhealthprogress.org/>

Biopharmaceutical companies engage in technology transfer for a variety of reasons. While decisions are sometimes taken on a philanthropic basis, to ensure sustainability these collaborations can also be driven by commercial rationales and market conditions. These in turn are heavily influenced by policy and regulatory decisions made by national governments and leading philanthropic donors.

Figure 42: Critical Factors for Creating Favorable Conditions for Biopharmaceutical Technological Transfers<sup>227</sup>



Technology transfer has been fundamental to the global pharmaceutical industry's ability to rapidly scale up production of COVID-19 vaccines. Since the outset of the COVID-19 pandemic, the biopharmaceutical has been undertaking exceptional, extraordinary measures to bring vaccines to patients. The sector has shown its openness to new approaches and collaborations to respond to the urgent needs of the pandemic. According to the Airfinity database, as of June 2022, just for vaccines there are over 380 manufacturing and production deals, of which over 80% involving technology transfer. After one year since the first COVID-19 vaccine was administered, voluntary collaboration to share innovation has been a key enabler for manufacturing output to reach 11,2 billion doses in 2021.<sup>228</sup>

227 IFPMA (2021) Technology Transfer: A Collaborative Approach to Improve Global Health. The Biopharmaceutical Industry Experience. Geneva: International Federation of Pharmaceutical Manufacturers and Associations. Available at: [https://www.ifpma.org/wp-content/uploads/2021/12/IFPMA\\_Tech-Transfer\\_A-collaborative-approach-to-improve-global-health\\_Position-Paper.pdf](https://www.ifpma.org/wp-content/uploads/2021/12/IFPMA_Tech-Transfer_A-collaborative-approach-to-improve-global-health_Position-Paper.pdf)

228 Airfinity Database (2021). Accessed on December 2021. Available at: <https://www.airfinity.com/>

Figure 43: Timeline on collaborations and manufacturing agreements for C-19 vaccines<sup>229</sup>

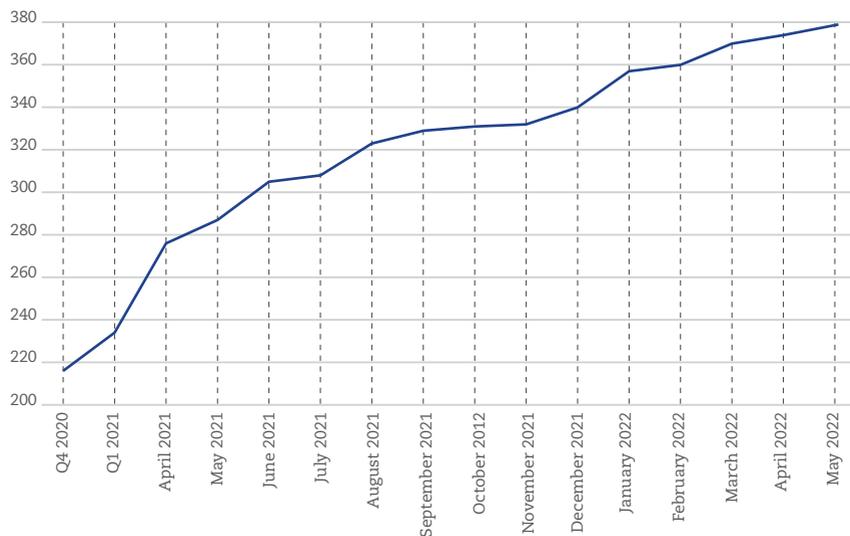
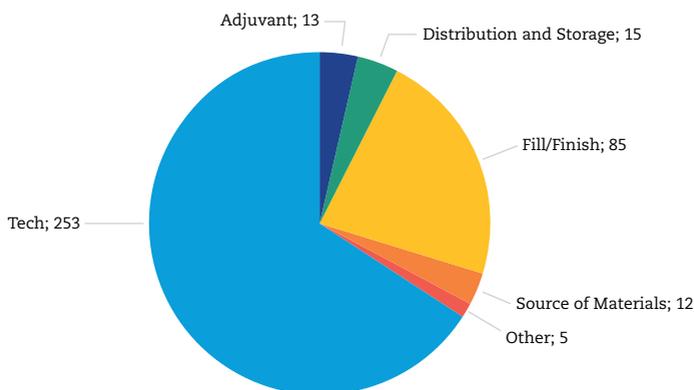


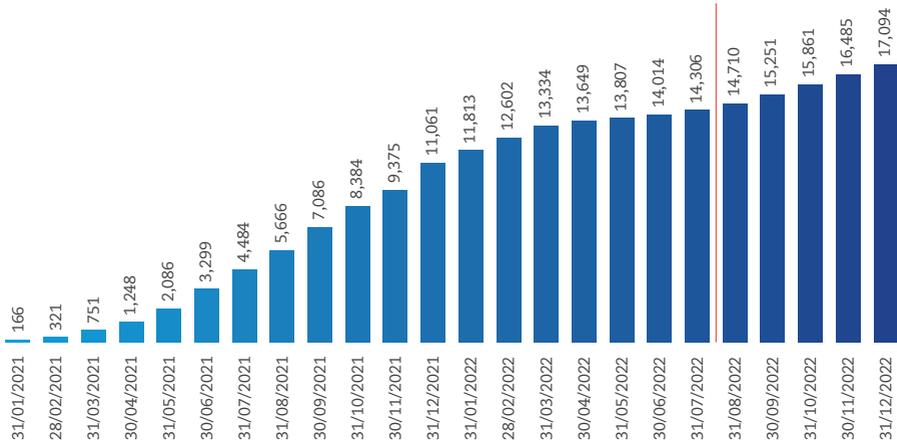
Figure 44: Cooperations for COVID-19 Vaccine manufacturing<sup>230</sup>



229 IFPMA Analysis based on Airfinity Database (2020-2022). Available at: <https://www.airfinity.com/>

Note: Monthly values are based on latest figure available for the time period. Quarter values are based on the latest figure available from the second month of the Quarter.

230 Airfinity Database (2022). Accessed on June 2022. Available at: <https://www.airfinity.com/>

Figure 45: Vaccine Production Forecast (Bn doses)<sup>231</sup>

## Trade in Biopharmaceuticals

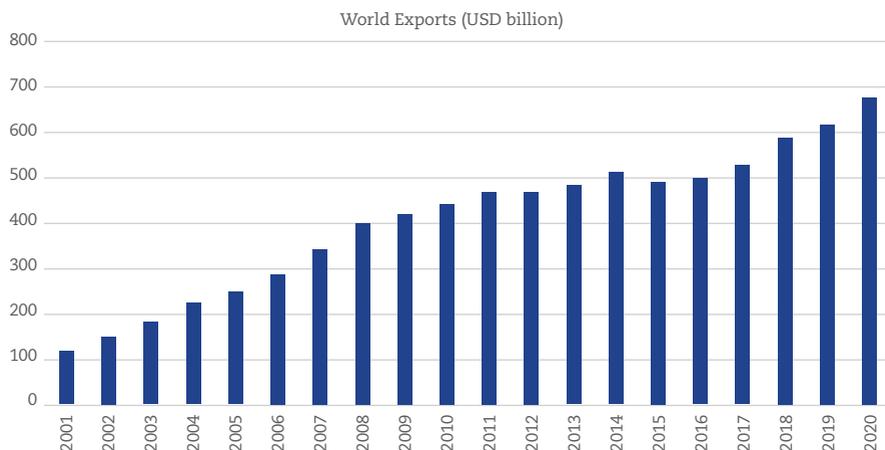
Global sales of biopharmaceutical products represent the international distribution of medical technology resulting from highly intensive R&D efforts in the exporting countries. At the same time, importing countries receive benefits through health improvements – even if they do not participate in R&D activities themselves.<sup>232</sup>

As medical innovation is transmitted across the world, it contributes to significant gains in average life expectancy<sup>233</sup> and quality of life.

<sup>231</sup> Ibid.

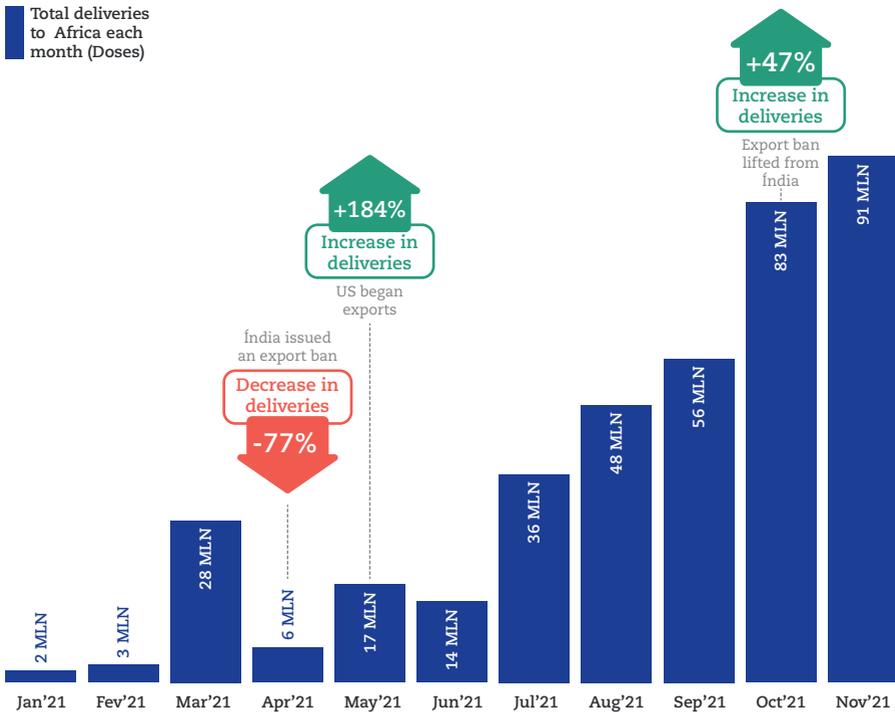
<sup>232</sup> Byaro, M., Nkonoki, J. and Mayaya, H., 2021. The contribution of trade openness to health outcomes in sub-Saharan African countries: A dynamic panel analysis. *Research in Globalization*, 3, p.100067. Available at: <https://www.sciencedirect.com/science/article/pii/S2590051X21000320>

<sup>233</sup> Ibid.

Figure 46: World Biopharmaceutical Products Exports 2001-2020<sup>234</sup>

The COVID-19 pandemic highlighted the importance of open trade of pharmaceuticals, particularly during health emergencies. In 2021, just as COVID-19 vaccine production was ramping up, trade restrictions severely impeded the flow of both raw materials and commodities, as well as drug samples and finished products. For example, the US invoked the Defense Production Act, which prioritizes US crisis response. In the midst of its first COVID-19 wave in the Spring of 2021, India imposed a ban on vaccine exports, sharply curtailing supply to COVAX, and upending immunization plans for 91 low- and lower-middle income countries, including a significant share of African countries. When the US and India export resumed, monthly deliveries to Africa increased by 184% and 47% just in the following month. To support equitable access to COVID-19 vaccines it is key to enable and facilitate open trade. This includes the effective implementation of the African Continental Free Trade Area (AfCFTA), eliminate Non-Trade Barriers, and foster international supply chain security.

234 International Trade Center (ITC). International trade statistics 2001-2020, based on UN COMTRADE and ITC statistics. Retrieved from: Available at: <http://www.intracen.org/itc/market-info-tools/statistics-export-product-country/>

Figure 47: Total deliveries of COVID-19 vaccines to Africa per month<sup>235</sup>

## The Biopharmaceutical Market of the Future

The IQVIA Institute predicts that the biopharmaceutical market will exceed USD 1.750–1.780 trillion by 2026, an increase of nearly USD 350 billion from the USD 1.423 trillion recorded in 2021.<sup>236</sup> This growth is mainly derived from market expansion in pharmerging countries<sup>237</sup> and developed countries, although at lower growth rate, together with the adoption of a wave of new technologies. Pharmerging market countries are those that are projected to increase their pace of growth in the near future

<sup>235</sup> Airfinity Database (2022). Accessed on June 2022. Available at: <https://www.airfinity.com/>

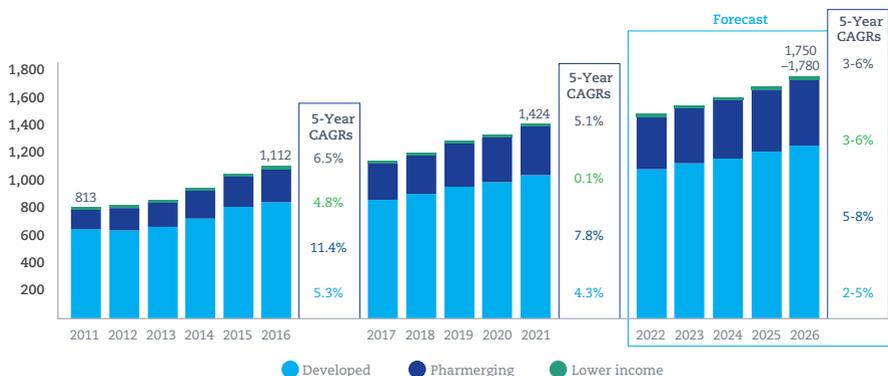
<sup>236</sup> IQVIA Institute (2021). Global Medicines Use in 2022: Outlook to 2026. Available at: <https://www.iqvia.com/insights/the-iqvia-institute/reports/the-global-use-of-medicines-2022>

<sup>237</sup> Ibid.

Notes: Pharmerging countries are defined based on per capita income below \$30,000 and a five-year aggregate pharmaceutical growth over \$1 billion.

and include countries such as Argentina, Mexico, Poland, and Pakistan. The projected growth of biopharmaceutical sales in Africa is also set to play a key role up to 2022. The continent's pharma market stands to grow at a CAGR of 5.9 percent between 2018 and 2022.<sup>238</sup>

Figure 48: Global Spending on Medicines, USD bn <sup>239</sup>



The United States share of global spending will increase from USD 580 billion in 2021 to around USD 699 billion in 2026, while the top 5 European countries' share of spending will grow from USD 210 billion to USD 261 billion. Meanwhile, pharmerging countries will spend USD 470–500 billion in 2026 from 354 in 2021.<sup>240</sup> By 2022, the African continent is set to reach a total of over USD 25 billion.<sup>241</sup>

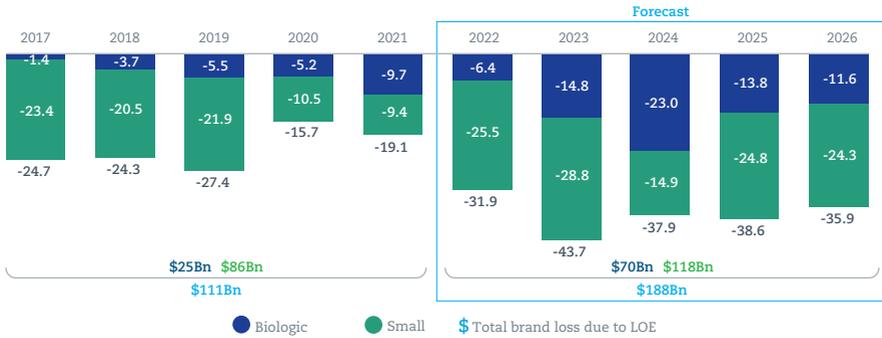
238 Pharma Boardroom (2020). Africa Pharma Market Snapshot 2020. Pharma Boardroom analysis based on IQVIA Institute data. Retrieved from: Available at: <https://pharmaboardroom.com/facts/africa-pharma-market-snapshot-2020/>

239 IQVIA Institute (2021). Global Medicines Use in 2022: Outlook to 2026. Available at: <https://www.iqvia.com/insights/the-iqvia-institute/reports/the-global-use-of-medicines-2022>

240 Ibid

241 Pharma Boardroom (2020). Africa Pharma Market Snapshot 2020. Pharma Boardroom analysis based on IQVIA Institute data. Retrieved from: Available at: <https://pharmaboardroom.com/facts/africa-pharma-market-snapshot-2020/>

Figure 49: Savings from generics and biosimilars, 2017–2026, Developed markets, USD Bn<sup>242</sup>



Part of the biopharmaceutical industry's economic footprint includes branded products, which will account for most of global biopharmaceutical growth in 2026.<sup>243</sup> However, as patents expire in developed markets, that share is expected to decline. New competition from generic and biosimilar drugs over the next five years will reduce prescription drug spending by USD 188 billion, between 2021 and 2026, in developed countries.

By 2026, biosimilar competition in the biologics market will increase, leading to as much as over USD 100 bn consumer savings per year.<sup>244</sup> Through all these various pathways, the biopharmaceutical industry will continue to leave effective and beneficial footprints as they undertake public health challenges.

242 IQVIA Institute (2021). Global Medicines Use in 2022: Outlook to 2026. Available at: <https://www.iqvia.com/insights/the-iqvia-institute/reports/the-global-use-of-medicines-2022>

243 Ibid.

244 Ibid.

Table 11: Global invoice spending and growth in selected countries<sup>245</sup>

	2021 SPENDING US\$BN	2017–2021 CAGR	2026 SPENDING US\$BN	2022–2026 CAGR
<b>Global</b>	<b>1,423.5</b>	<b>5.1%</b>	<b>\$1,750–1,780</b>	<b>3–6%</b>
<b>Developed</b>	1,050.4	4.3%	\$1,240–1,270	2–5%
10 Developed	935.2	4.3%	\$1,100–1,130	2–5%
United States	580.4	4.9%	\$685–715	2.5–5.5%
Japan	85.4	-0.5%	\$73–93	-2–1%
EU4+UK	209.7	4.8%	\$245–275	3–6%
Germany	64.6	6.2%	\$76–96	4.5–7.5%
France	42.0	3.0%	\$48–52	2–5%
United Kingdom	36.6	5.9%	\$46–50	4–7%
Italy	36.5	3.0%	\$41–45	2–5%
Spain	29.8	5.4%	\$32–36	1.5–4.5%
Canada	27.4	5.2%	\$32–36	3–6%
South Korea	17.9	6.0%	\$21–25	3.5–6.5%
Australia	14.4	0.6%	\$15–19	1.5–4.5%
Other Developed	115.2	4.7%	\$132–152	3–6%
<b>Pharmerging</b>	354.2	7.8%	\$470–500	5–8%
China	169.4	6.1%	\$190–220	2.5–5.5%
Brazil	31.6	11.7%	\$47–51	7.5–10.5%
India	25.2	11.1%	\$37–41	8–11%
Russia	18.8	11.4%	\$27–31	7.5–10.5%
Other Pharmerging	109.2	8.3%	\$151–171	6.5–9.5%
<b>Lower Income Countries</b>	19.0	0.1%	\$21–25	2.5–5.5%

245 Ibid.

## Conclusion

Biopharmaceutical innovation is behind some of the greatest achievements in modern medicine. Today people live longer and healthier lives than previous generations.

Medical advances allow people to enjoy better quality of life and increase their productivity, contributing to the overall prosperity of society. The benefits of biopharmaceutical innovation extend into the creation of jobs, the spur of technology, and represents an important source of income.

Unfortunately, not all communities have yet fully benefited from these medical advances. Poverty and great wealth inequality between and within countries mean that many do not have access to even the simplest healthcare interventions. These disparities may be as well reflected in the developing COVID-19 crisis where access to resilient health systems is a critical factor for infection management.

Addressing these issues is a complex challenge that requires long-term commitment from governments, civil society, and the private sector. The biopharmaceutical industry has been doing its part to help those in greatest need to also enjoy the benefits of medical progress. Much still needs to be done as the path forward requires a constant rethinking on how to maximize the research-based industry's positive impact on the health and prosperity for all societies. The biopharmaceutical industry will continue to invest in current and future pressing health challenges.

## About the IFPMA

*The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) represents research-based pharmaceutical companies and associations across the globe. Based in Geneva, IFPMA has official relations with the United Nations and engages on multiple platforms such as G7, G20 and OECD, contributing industry expertise to help the global health community find sustainable solutions to today's pressing health concerns.*

**[www.ifpma.org](http://www.ifpma.org)**



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