

INTERNATIONAL FEDERATION
OF PHARMACEUTICAL
MANUFACTURERS &
ASSOCIATIONS

THE PHARMACEUTICAL INDUSTRY AND GLOBAL HEALTH

FACTS
AND
FIGURES
2021



IFPMA

FOREWORD



Thomas Cueni
Director General, IFPMA

I am proud to introduce the 2021 update of the “Facts & Figures Report”.

This year’s update comes during unprecedented times, as the entire world is facing the COVID-19 pandemic, a deadly condition induced by SARS-CoV-2, a coronavirus which emerged in the last days of 2019. COVID-19’s impact is dramatic and our lives and livelihoods have been impacted beyond all recognition. The COVID-19 pandemic has shone a light on the biopharmaceutical industry essential role played in combating this public health crisis through its expertise, innovation, and resources.

We are pulling out all the stops to discover and manufacture at scale treatments and vaccines. Industry has recognized from the outset, that no-one alone can bring solutions quickly to those who need them. We have therefore teamed up with biotech, academics, governments and international organizations. Major biopharmaceutical companies have also joined forces in a manner never seen before.

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 biopharmaceutical industry.

The research-based 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 into through full and healthy lives. This is a unique industry. This uniqueness is even more accentuated as the entire planet is looking for solutions to tackle COVID-19.

Beyond COVID-19, 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. In 2020 alone, around 5,000 clinical trials were started to investigate and develop new treatments and vaccines, despite the disruption caused by the COVID19 pandemic.

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 2018, 59 new medicines were launched, while currently more than 8,000 compounds are at different stages of development globally.
- In 2020, the number of drugs in development for particular disease areas were:
 - Cancer: 2,740
 - Immunology: 1,535
 - Neurology: 1,498
 - Infectious diseases: 1,213
- The research-based biopharmaceutical industry is estimated to have spent USD 179 billion globally on biopharmaceutical R&D in 2018.

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 as a share of GDP has increased in various 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 250 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.



FOCUS SECTION ON COVID-19

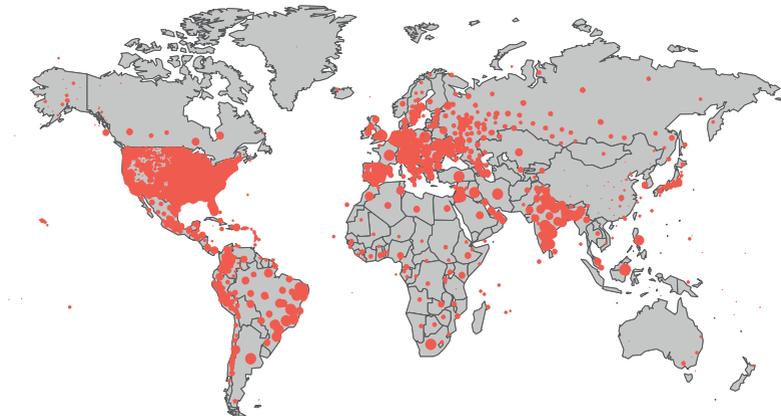
Introduction

COVID-19 is an infectious disease caused by a newly discovered coronavirus, which was first identified in December 2019. The virus that causes COVID-19 is a new coronavirus, named SARS-CoV-2, that has spread throughout the world. People infected with SARS-CoV-2 experience symptoms that can range from mild or no symptoms to severe illness. The severe complications can lead to death.

The scientific community, including biopharmaceutical companies, is actively working to learn more about the whole range of short- and long-term health effects associated with COVID-19. As the pandemic unfolds, it is possible to notice that many organs besides the lungs are affected by COVID-19 and there are many ways the infection can affect someone's health. As of March 2021, COVID-19 has caused the death of more than 2,8 million people and infected more than 129m people in all parts of the world.

COVID-19 – Public Health Impact.¹

Global Cases 129.828.051	Global Deaths 2.830.839	Global Recovered 73.571.886
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¹ COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU). Last accessed on March 2021. Available at: <https://coronavirus.jhu.edu/map.html>

As viruses spread and replicate, they frequently change through mutation, and new variants of a virus are expected to occur over time. Variants can result in changes in transmissibility, clinical presentation and severity, or they may have impact on countermeasures, including diagnostics, therapeutics and vaccines.

As SARS-CoV-2 proliferated around the world, scientists have identified multiple variants of the virus that causes COVID-19. Notable variants include the B.1.1.7, first identified in the UK; the B.1.351, emerged in South Africa; and the P.1, identified in Brazil. These variants seem to enable the coronavirus to spread faster from person to person, and more infections could result in more people getting sick or dying, increased strain on healthcare systems and society.²

In order to control the epidemic, governments have been putting in place extensive public health and social measures to avoid overwhelming of health services and substantial excess morbidity and mortality. These policies can be of different nature, ranging from personal protective measures, such as hand hygiene and mask wearing, to physical distancing measures, such as stringent movement restrictions, closure of non-essential businesses or remote working.³

The COVID-19 pandemic has had tragic health repercussions and, together with the measures put in place by governments to protect public health, has caused profound social and economic impact around the world.

The Biopharmaceutical Industry is Leading the Way in Developing Vaccines, Treatments and Diagnostics

Since the beginning of this crisis, the biopharmaceutical industry has made addressing the pandemic⁴ its top priority, devoting its resources, expertise, know-how, and intellectual assets to developing potential treatments, diagnostics and vaccines at unprecedented pace, while committing to and engaging in unprecedented levels of international collaboration and coordination.

2 CDC Official Website. Last Accessed March 2021. Available at :<https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant.html>

3 Our World in Data, 2021. Last Accessed: March 2021. Available at: <https://ourworldindata.org/grapher/internal-movement-covid>

4 IFPMA COVID-19 Hub. Available at Available at: <https://www.ifpma.org/covid19/>

The innovative biopharmaceutical industry is a founding member of and has been actively engaged in the Access to COVID-19 Tools (ACT) Accelerator⁵, which aims to provide equitable access to vaccines, treatments and diagnostics. Several biopharmaceutical companies have also joined the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership⁶ set up by the National Institutes of Health (NIH) to develop a coordinated research strategy for prioritizing and speeding up development of the most promising treatments and vaccines. The Corona Accelerated R&D in Europe (CARE) consortium,⁷ brought together a coalition of 37 globally renowned academic institutions, biopharmaceutical companies, including various IFPMA members, and non-profit research organizations, committed to the development of therapeutics.

The biopharmaceutical industry is leading the way in developing vaccines, treatments & diagnostics, bringing their unique expertise in R&D and manufacturing of therapeutics, vaccines and diagnostics to the table.⁸ As of February 2021, there are almost 1,000 clinical trials⁹ ongoing, targeting COVID-19 treatments and vaccines. The Intellectual property (IP) system has been the driving force behind the many innovations that will help overcome the pandemic, giving rise to nearly all of the molecules, platforms, and other technologies that have enabled industry to target COVID-19, and helping to ensure the resources and conditions needed to see the development of promising treatments and vaccines through to approval.

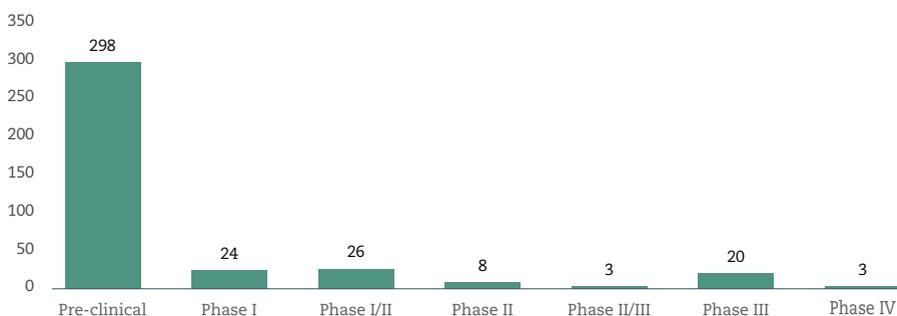
Vaccines

Several biopharmaceutical companies are researching vaccine candidates and sharing existing technologies in a way that can be leveraged to allow a rapid upscale of production once a vaccine candidate is identified. As of February 2021, there are

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- 5 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/>
 - 6 National Institutes of Health (2020). News Releases: «NIH to launch public-private partnership to speed COVID-19 vaccine and treatment options». Available at: <https://www.nih.gov/news-events/news-releases/nih-launch-public-private-partnership-speed-covid-19-vaccine-treatment-options>
 - 7 European Commission (2020). «Corona Accelerated R&D in Europe». Available at: <https://cordis.europa.eu/project/id/101005077>
 - 8 IFPMA (2020). Global Biopharmaceutical Industry Commitment to Address Coronavirus Public Health Crisis. Available at: <https://www.ifpma.org/resource-centre/global-biopharmaceutical-industry-commitment-to-address-coronavirus-public-health-crisis/>
 - 9 Airfinity (2021). Last Accessed February 2021. Available at: <https://www.airfinity.com/>

approximately 382 vaccine candidates in development, of which 24 in Phase I, 34 in Phase II and 23 in Phase III.¹⁰ One year after the pandemic, the fruits of the innovative efforts of biopharmaceutical companies are already starting to materialize, with stringent regulatory agencies authorizing the first vaccines to prevent COVID-19. As of March 2021, the US Food and Drug Administration (FDA) has authorized Pfizer-BioNTech, Janssen and Moderna COVID-19 vaccines¹¹, while the European Medicines Agency (EMA)¹² has granted a conditional marketing authorization Pfizer-BioNTech, Janssen, Moderna and AstraZeneca's COVID-19 vaccines.

COVID-19 Vaccines Pipeline Overview by R&D Stage¹³



The biopharmaceutical industry is 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,¹⁴ as of February 2021, just for vaccines there are 234 manufacturing and production deals, showing that the sector is in active discussions to increase manufacturing capacity to ensure availability of vaccines. The same database also shows that, always to ensure access to vaccines, there are currently 110 supply deals that have been signed, with additional 48 in talks.¹⁵

10 Airfinity (2021). Last Accessed February 2021. Available at: <https://www.airfinity.com/>

11 US Food & Drug Administration, Official Website (2021), "COVID-19 Vaccines". Available at: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines>

12 European Medicines Agency, Official Website (2021), "Treatments and vaccines for COVID-19: authorised medicines". Available at: <https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/treatments-vaccines-covid-19-authorized-medicines#-covid-19-vaccines-section>

13 Airfinity (2020). Last Accessed February 2021. Available at: <https://www.airfinity.com/>

14 Airfinity (2021). Last Accessed February 2021. Available at: <https://www.airfinity.com/>

15 Airfinity (2021). Last Accessed February 2021. Available at: <https://www.airfinity.com/>

Various biopharmaceutical companies have announced that they will offer their vaccines at cost or at socially responsible prices and that they are considering differential pricing by country. They will also allocate millions of doses to the COVAX Facility, an international mechanism to ensure that each participating country has fair and equitable access.¹⁶ COVAX announced to be on track to deliver at least 2 billion doses by the end of the year.¹⁷ Various IFPMA members have reached advance purchase agreements or statement of intent with the Facility, including:¹⁸ Pfizer and BioNTech (40 million doses), GSK and Sanofi (200 million doses), J&J (500 million doses), AstraZeneca (300 million doses). The early estimates of herd immunity indicate the need of approximately 60%-90%¹⁹ of population to get a COVID-19 vaccine in order to reach herd immunity across the globe. While stakeholders are partnering and working together to find a solution to the global pandemic, COVID-19 vaccine acceptance is a key concern that could 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.

The public have questions about the safety of vaccines which have been developed as never before. Vaccine companies are playing an important role in building and sustaining vaccine confidence by developing high quality, safe and effective vaccines. IFPMA launched a digital campaign called #TeamVaccines²⁰ showing how the biopharmaceutical industry embraces rigorous independent scientific evaluation and robust independent approval processes. This shows not just scientifically, but also in the way the COVID-19 vaccines are being produced, distributed and monitored.

Therapeutics

IFPMA members have been reviewing their drug portfolios for safe and effective assets that could help with the development of new or repurposed treatments. As of February 2021, there are over 1000 clinical trials²¹ for therapeutics, of which 190 in Phase 3.

16 Gavi, the Vaccine Alliance (2021). Official Website. Available at: <https://www.gavi.org/covax-facility>

17 World Health Organization, Official website (2021). Available at: <https://www.who.int/news/item/22-01-2021-covax-announces-new-agreement-plans-for-first-deliveries>

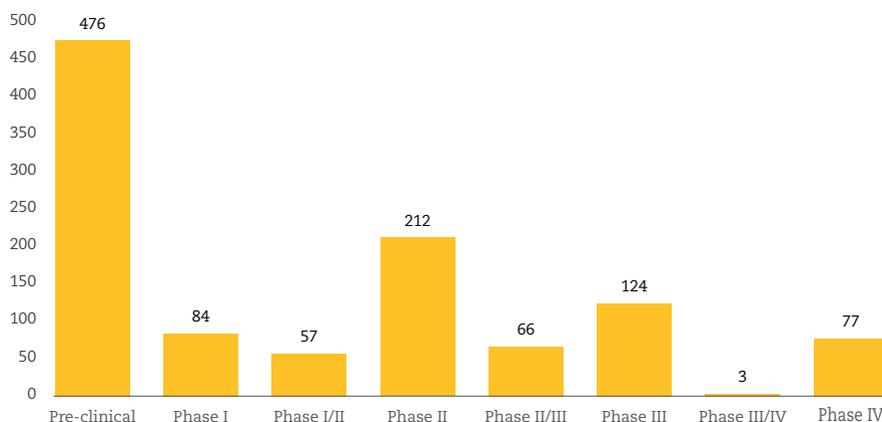
18 IFPMA COVID-19 Hub (2021). Last Accessed, February 2021. Available at: <https://www.ifpma.org/covid19/>

19 Youyang Gu, March 8, 2021. Path to Normality : 2021 Outlook of COVID-19 in the US. Available at: <https://covid19-projections.com/path-to-herd-immunity/>

20 IFPMA Official Website. Last Accessed, March 2021. Available at: <https://teamvaccines.ifpma.org/>

21 Airfinity (2021). Last Accessed February 2021. Available at: <https://www.airfinity.com/>

COVID-19 Therapeutics Pipeline Overview by R&D Stage²²



The biopharmaceutical industry has demonstrated its speed and efficiency in collaborating and delivering fast solutions not only on scientific discovery but also in scaling up manufacturing and supply. According to the Airfinity database, as of February 2021, just for therapeutics there are 60 manufacturing and production deals, showing that the sector is in active discussions to increase manufacturing capacity to ensure availability of therapeutics.²³ The examples below illustrate various initiatives IFPMA companies are undertaking to enhance access:²⁴

- Eli Lilly and Company (Lilly) and the Bill & Melinda Gates Foundation have entered into an agreement to facilitate access to future Lilly therapeutic antibodies under development for the prevention and treatment of COVID-19, to benefit low- and middle-income countries.
- Gilead Sciences has entered into voluntary licensing agreements with 9 generics manufacturers to further expand supply of remdesivir to 127 countries that represent nearly all low-income and lower-middle income countries. Moreover, Gilead has expanded its global network manufacturing sites, including by partnering with industry peers, to add manufacturing capacity around the world. Pfizer announced a multi-year agreement with Gilead to manufacture and supply remdesivir.

²² Airfinity (2021). Last Accessed February 2021. Available at: <https://www.airfinity.com/>

²³ Airfinity (2021). Last Accessed February 2021. Available at: <https://www.airfinity.com/>

²⁴ IFPMA COVID-19 Hub (2021). Last Accessed February 2021. Available at: <https://www.ifpma.org/covid19/>

- Merck KGaA, IAVI, and Serum Institute of India (SSI) are collaborating to develop and manufacture a neutralizing monoclonal antibodies (mAbs) co-invented by IAVI and Scripps Research as innovative interventions to address the COVID-19 pandemic.
- Roche and Regeneron joined forces to significantly increase global supply of REGN-COV2, Regeneron's investigational antiviral antibody combination, to at least three and a half times the original capacity, with the potential for even further expansion.

The biopharmaceutical industry efforts in developing and delivering COVID-19 therapeutics and vaccines play a vital role in helping control the spread of the virus and treat people from the worst symptoms of SARS-CoV2. As well as reducing the tragic loss of life and helping to get the pandemic under control, introduction of a vaccine could prevent the loss of USD 375 billion to the global economy every month.²⁵

Economic Impact of COVID-19 at a Glance:²⁶

In 2020, the COVID-19 pandemic resulted in a collapse of global economic activity, with an estimated 3.5 percent contraction in 2020.²⁷ The impact on the economy was reflected also on the job market, with an estimated 114 million full time equivalent jobs lost in 2020.²⁸

Aggressive and swift monetary, fiscal, and financial sector policies have helped prevent worse outcomes.²⁹ Governments are taking a wide range of measures in response to the pandemic, with countries spending over USD 14 trillion to deal with the economic consequences of COVID-19.³⁰

While there are expectations that a robust economic recovery will occur in 2021, the global economy is still facing high levels of uncertainty. The world GDP is projected

25 Gavi, the Vaccine Alliance (2021). Official Website. Last accessed February 2021. Available at: <https://www.gavi.org/covax-facility>

26 World Bank Global Economic Prospects – Pandemic, Recession: The Global Economy in Crisis, Available at: <https://www.worldbank.org/en/publication/global-economic-prospects>

27 International Monetary Fund (2021), World Economic Outlook, January. Available at: <https://www.imf.org/en/Publications/WEO/Issues/2021/01/26/2021-world-economic-outlook-update>

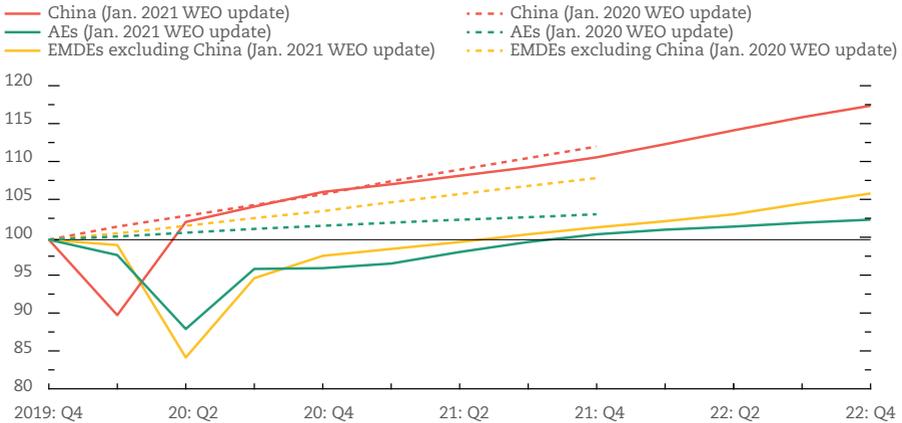
28 International Labour Organization (2021). ILO Monitor: COVID-19 and the world of work. 7th edition. Available at: https://www.ilo.org/wcmsp5/groups/public/@dgreports/@dcomm/documents/briefingnote/wcms_767028.pdf

29 International Monetary Fund (2021), World Economic Outlook, January. Available at: <https://www.imf.org/en/Publications/WEO/Issues/2021/01/26/2021-world-economic-outlook-update>

30 International Monetary Fund (2021) Fiscal Monitor Reports. Available at: <https://www.imf.org/en/Publications/FM>

to grow 5.5 percent in 2021 and 4.2 percent in 2022.³¹ The latest forecasts indicate a persistent work deficit in 2021. The social repercussions could be significant, with 90 million people likely to be pushed into extreme poverty by 2021.³² The recovery will depend heavily on controlling the spread of the pandemic, with widespread deployment of effective vaccines playing a key role.

Estimates of Economic Impact of Covid-19 and Recovery Forecasts (Index 2019, Q4=100)³³



Source: IMF staff estimates.

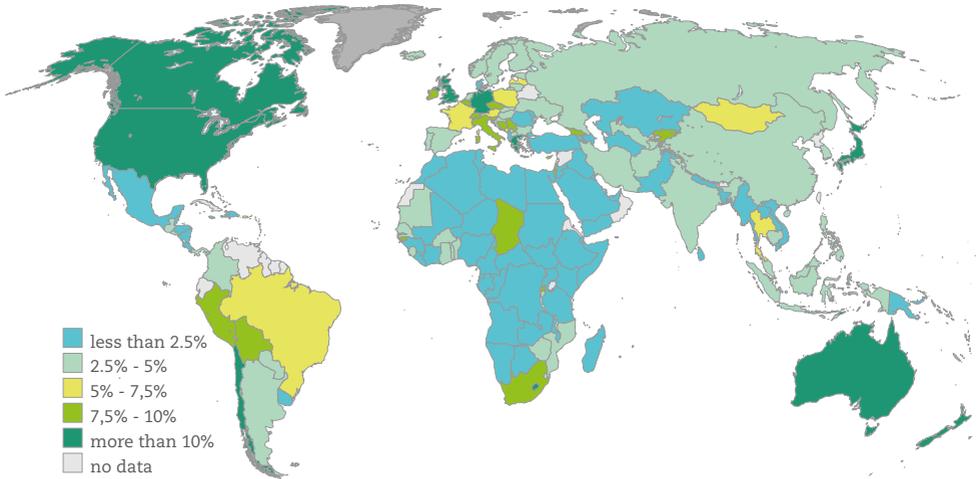
Note: AEs = advanced economies; EMDEs = emerging market and developing economies; WEO = World Economic Outlook.

31 International Monetary Fund (2021), World Economic Outlook, January. Available at: <https://www.imf.org/en/Publications/WEO/Issues/2021/01/26/2021-world-economic-outlook-update>

32 International Monetary Fund (2021), World Economic Outlook, January. Available at: <https://www.imf.org/en/Publications/WEO/Issues/2021/01/26/2021-world-economic-outlook-update>

33 International Monetary Fund (2021), World Economic Outlook, January. Available at: <https://www.imf.org/en/Publications/WEO/Issues/2021/01/26/2021-world-economic-outlook-update>

Additional Spending and Forgone Revenue in Response to the COVID-19 Pandemic (% of 2020 GDP)³⁴



34 International Monetary Fund (2021), Database of Country Fiscal Measures in Response to the COVID-19 Pandemic; and IMF staff estimates. Available at: <https://www.imf.org/en/Topics/imf-and-covid19/Fiscal-Policies-Database-in-Response-to-COVID-19>



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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.³⁵ In 2018, 62 new medicines were launched³⁶, while currently more than 8,000 compounds are at different stages of development globally.³⁷

*Medicines in Development (Selected Categories)*³⁸

INFECTIOUS DISEASES	1,213	CANCER	2,740
RESPIRATORY TRACT	450	IMMUNOLOGY	1,535
MUSCULOSKELETAL	317	DIABETES	503
NEUROLOGY	1,498	DIGESTIVE	1,323

35 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>

36 U.S. Food and Drug Administration. New Drug Approvals 2019. Visited January 2020. Available at: <https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2019>

37 Adis R&D Insight Database. Available at: <https://adis.springer.com> Visited June 2020

38 Medicines in development may be attributed to more than one therapeutic area. Adis R&D Insight Database. Available at: <https://adis.springer.com> Visited June 2020

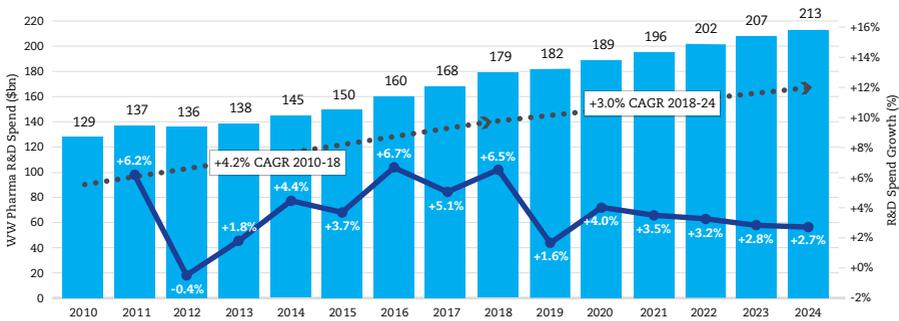
Number of New Chemical and Biological Entities Approved by the US Food and Drug Administration, 2006-2018³⁹

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

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 179 billion globally on biopharmaceutical R&D in 2018.⁴⁰

Compared with other high-technology industries, the annual R&D spending by the biopharmaceutical industry is 7.3 times greater than that of the aerospace and defense industries, 6.5 times more than that of the chemicals industry, and 1.5 times more than that of the software and computer services industry.⁴¹

Biopharmaceutical R&D Spending⁴²



39 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

40 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

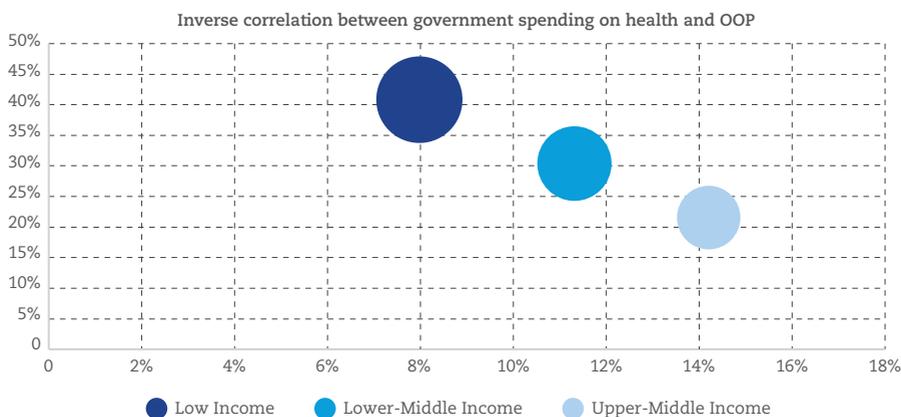
41 IFPMA Analysis based on: European Commission (2018). The 2018 EU Industrial R&D Investment Scoreboard; p 104. Available at: <http://iri.jrc.ec.europa.eu/scoreboard18.html>

42 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

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, and a sound enabling policy environment for the biopharmaceuticals industry⁴³ is a fundamental condition for its good performance.⁴⁴ 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)

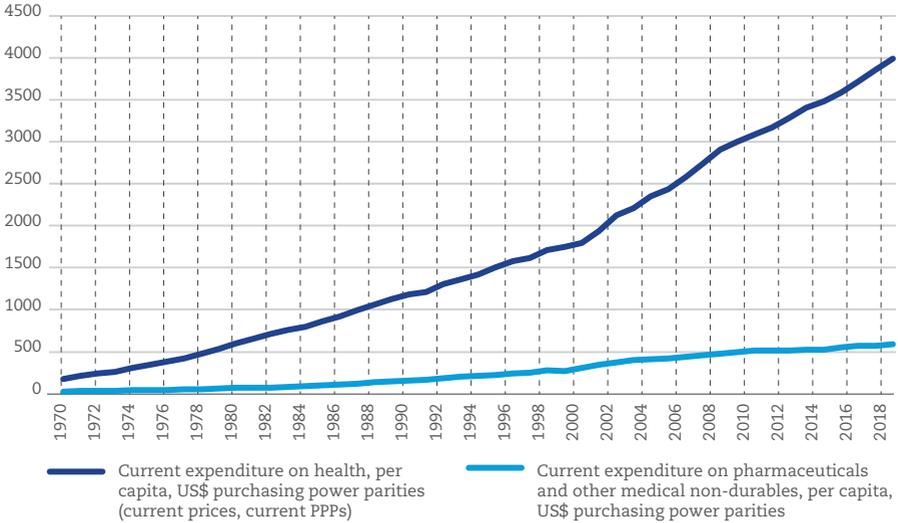


While health expenditure as a share of GDP has increased in various countries, spending on biopharmaceutical products as a share of health expenditure has broadly remained constant.

43 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

44 WHO (2007) Everybody's Business: Strengthening Health Systems to Improve Health Outcomes. Geneva: World Health Organization, p 3. Available at: http://www.who.int/healthsystems/strategy/everybodys_business.pdf

Per Capita Expenditure on Health and Pharmaceuticals, OECD Countries⁴⁵



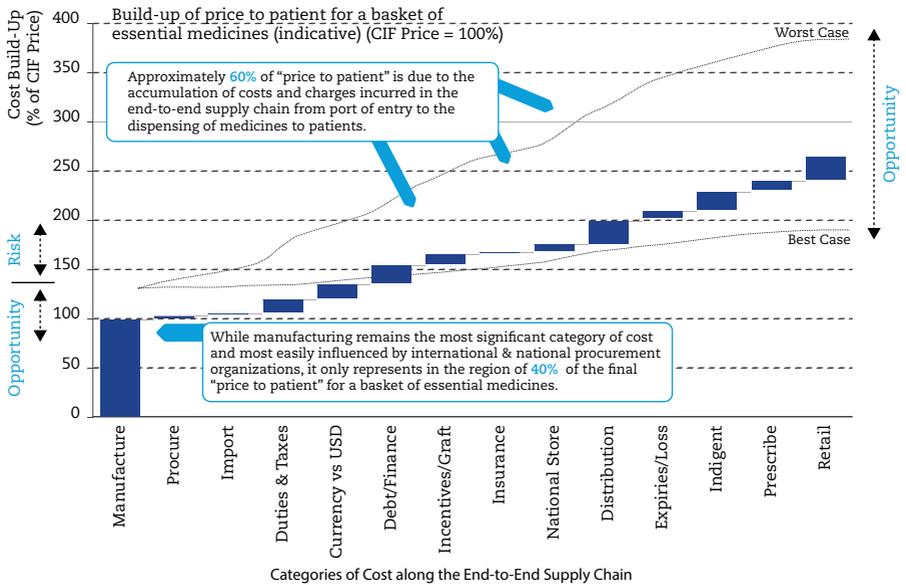
Medicines and vaccines contribute to the sustainability of healthcare systems by generating savings, for example by substantially reducing costs in other areas of healthcare, such as hospital stays and long-term care costs.⁴⁶

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.

⁴⁵ IFPMA analysis based on data extracted from OECD Data Available at: <https://data.oecd.org/> Accessed 2019

⁴⁶ EFPIA (2019), The pharmaceutical industry in figures 2019. Available at: <https://www.efpia.eu/media/413006/the-pharmaceutical-industry-in-figures.pdf>

Examples of “Hidden” Costs of Pharmaceutical Procurement⁴⁷

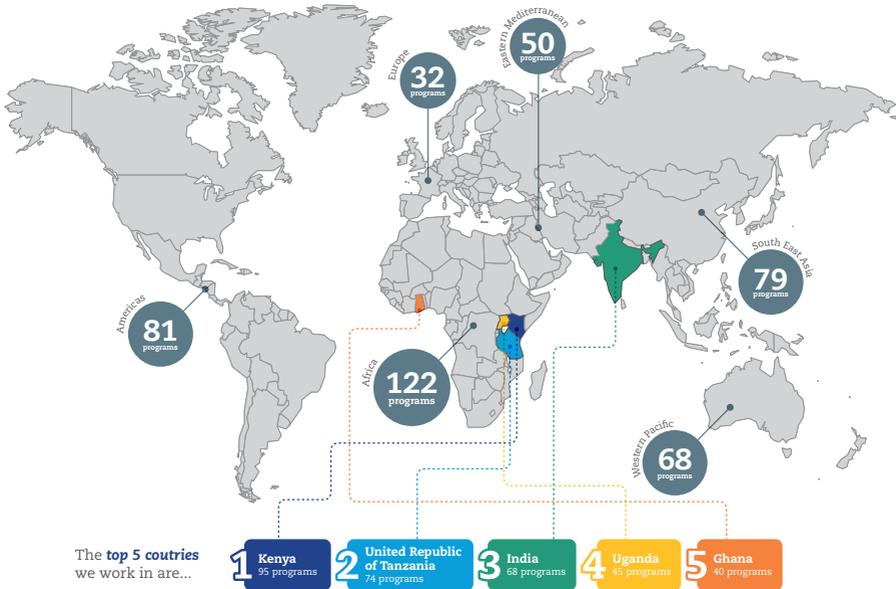


Research-based biopharmaceutical companies make a unique contribution to improving global health through the innovative medicines they develop. In addition, they have a strong track record of sustaining programs to improve the health of patients in low- and middle-income countries. These initiatives 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 250 collaborations between the innovative biopharmaceutical industry and more than 1200 partners to support the Sustainable Development Goals (SDGs).⁴⁸

47 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>

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

Collaborations Between the Innovative Biopharmaceutical Industry and its Partners to Support the SDGs⁴⁹



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)⁵⁰ 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 triggered by directly and indirectly generated income resulted in an extra USD 515

49 Global Health Progress (2019). Official Website: Available at: <https://globalhealthprogress.org/explore-our-collaborations/>

50 WifOR (2020). The Global Economic Impact of the Pharmaceutical Industry.[correct with id/ etc at layout]

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.⁵¹

Direct, Indirect and Induced Gva Effects Triggered Through Economic Activities of the Global Biopharmaceutical Industry⁵²



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.⁵³ 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.

51 WifOR (2020). The Global Economic Impact of the Pharmaceutical Industry.

52 WifOR (2020). The Global Economic Impact of the Pharmaceutical Industry.

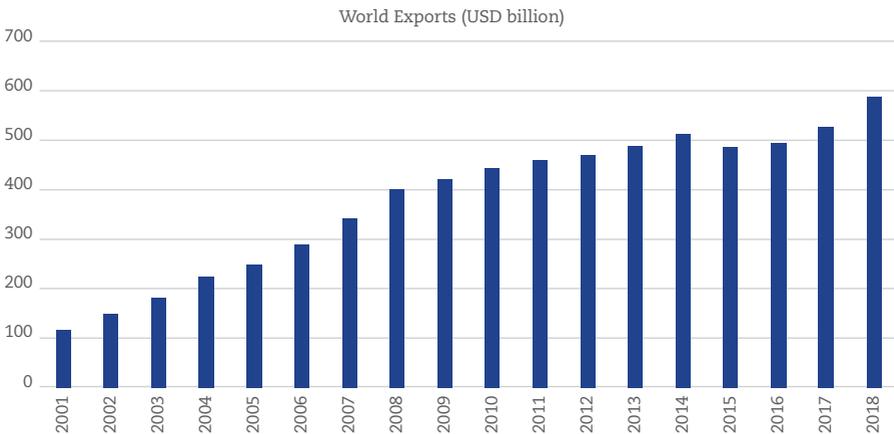
53 WifOR (2020). The Global Economic Impact of the Pharmaceutical Industry.

Direct, Indirect and Induced Employment Effects Triggered Through Economic Activities of the Global Biopharmaceutical Industry⁵⁴



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.⁵⁵ As medical innovation is transmitted across the world, it contributes to significant gains in average life expectancy⁵⁶ and quality of life.

World Biopharmaceutical Products Exports 2001-2018⁵⁷



⁵⁴ WifOR (2020). The Global Economic Impact of the Pharmaceutical Industry.

⁵⁵ Kiriya N (2010) Trade and innovation: Pharmaceuticals, p. 26

⁵⁶ Kiriya N (2010) Trade and innovation: Pharmaceuticals, p. 26

⁵⁷ International Trade Center (ITC). International trade statistics 2001-2019, based on UN COMTRADE and ITC statistics. Retrieved from: Available at: <http://www.intracen.org/itc/market-info-tools/statistics-export-product-country/>

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 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.

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.⁵⁸ 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.⁵⁹

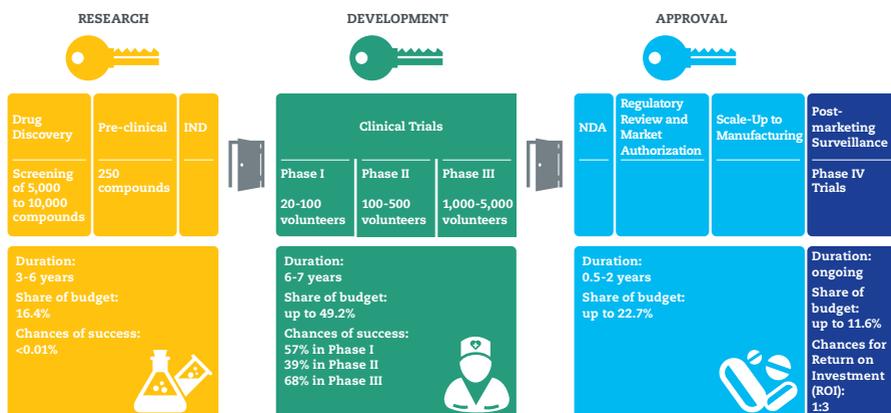
The research-based biopharmaceutical industry has been involved in development of nearly all the medicines and vaccines currently on the market. Without the innovative

58 Centers for Disease Control and Prevention. Official Website: "Vaccines and Preventable Diseases". Available at: <https://www.cdc.gov/vaccines/vpd/vpd-vac-basics.html>

59 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>

biopharmaceutical industry, the generics industry would not exist. In 2018, 62 new medicines were launched,⁶⁰ while currently more than 8,000 compounds are at different stages of development globally.⁶¹ 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 Process⁶²



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

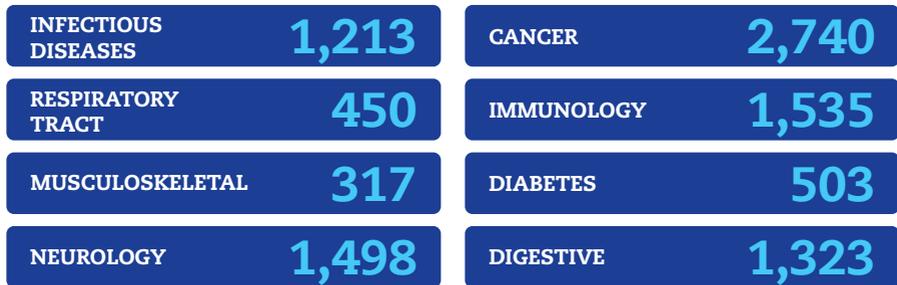
60 U.S. Food and Drug Administration. New Drug Approvals 2019. Visited January 2020. Available at: <https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2019>

61 Adis R&D Insight Database. Available at: <https://adis.springer.com> Visited June 2020

62 Pugatch Consilium (2015) Measuring the Global Biomedical Pulse. Available at: <http://www.pugatchconsilium.com/reports/BCI%202015%20-%20Measuring%20the%20Biomedical%20Pulse.pdf>;
PhRMA (2019) 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/PhRMA_2019_membership_survey_Final.pdf
IQVIA Institute (2019). The Changing Landscape of Research and Development Available at: <https://www.healthindustryhub.com.au/wp-content/uploads/2019/05/the-changing-landscape-of-research-and-development.pdf>

growing.⁶³ These medical discoveries, big and small, have increased life expectancy and resulted in a better quality of life for many. Over the last 50 years, globally, life expectancy has increased by around 20 years.⁶⁴ 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)⁶⁵



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 disease and how to defeat it is constantly progressing. There are more than 200 different types of cancer, and each is diagnosed and treated in a particular way.⁶⁶

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 2015, in the US alone, nearly 2.4 million deaths caused by cancer were averted thanks also to innovative medicines.⁶⁷ Investments in R&D

63 Pharma Intelligence (2019) Pharma R&D Annual Review 2019. London: Pharmaprojects, p.6 Available at: <https://pharmaintelligence.informa.com/~media/informa-shop-window/pharma/2019/files/whitepapers/pharma-rd-review-2019-whitepaper.pdf>

64 World Bank (2019), Life expectancy at birth, total (years). Available at: <https://data.worldbank.org/indicator/SP.DYN.LE00.IN>

65 Medicines in development may be attributed to more than one therapeutic area Adis R&D Insight Database. Available at: <https://adis.springer.com> Visited June 2020

66 United Kingdom National Health Service, last accessed October 2020. Available at: <https://www.nhs.uk/conditions/cancer/>

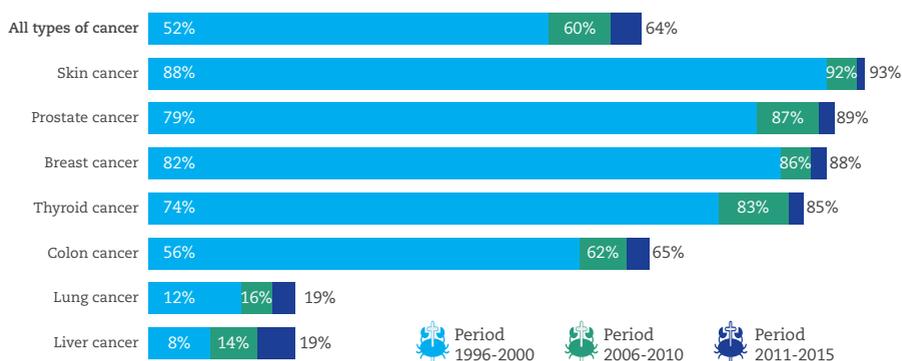
67 American Cancer Society, 'Facts & Figures 2018: Rate of Deaths From Cancer Continues Decline', Available at: <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2018/cancer-facts-and-figures-2018.pdf>

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.⁶⁸ 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, which play a critical role in orchestrating the immune response and killing cells infected by pathogens. 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 make a cancer-free world a reality.

Figure 3: Five-year Survival Rates for Various Cancers, 1996-2000 vs 2006-2010 vs 2011-2015⁶⁹

SURVIVAL RATE FOR CANCER PATIENTS HAS INCREASED

INCREASE IN FIVE-YEAR SURVIVAL RATE OF PATIENTS WITH DIFFERENT TYPES OF CANCER



HEPATITIS

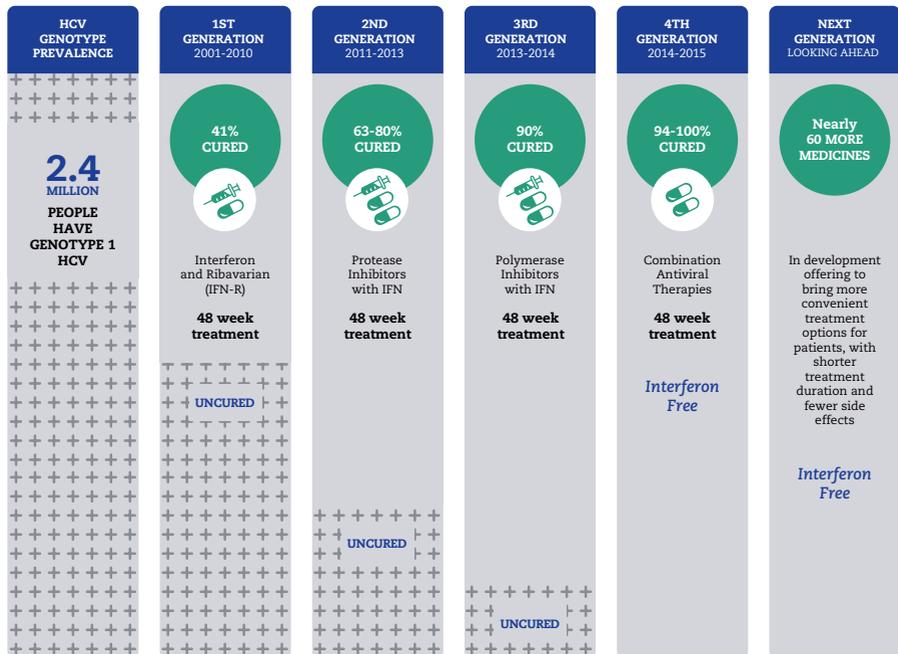
Hepatitis has accompanied humanity throughout centuries. Once the viruses were identified, this finding contributed to a revolution in medicine that led to the development of a vaccine for Hepatitis A and B, which has dramatically reduced the mortality of the virus.

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

69 NEFARMA (2019) Medicines Monitor 2019-2020 edition Available at: <https://www.vereniginginnovatievegeneesmiddelen.nl/website/over-de-vereniging/publicaties/publicaties/-medicines-monitor-2019-2020>

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 71 million people have chronic HCV infection contributing to around 400,000 deaths each year.⁷⁰ Step-by-step, scientists have improved HCV treatments, passing from 6% cure rates in 1991 to nearly 100% success rate today.⁷¹ 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. 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 treatment⁷²



70 World Health Organization 'Hepatitis C', Available at: <http://www.who.int/mediacentre/factsheets/fs164/en/>

71 PhRMA (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>

72 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.⁷³ ARV therapies can also eliminate the risk of transmission from the infected mother, to the child, throughout pregnancy, birth and breastfeeding.⁷⁴ 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.⁷⁵ 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.⁷⁶ 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.⁷⁷

73 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>

74 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>

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

76 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>

77 WHO Official Website (2020). Available at: <https://www.who.int/hiv/topics/vaccines/Vaccines/en/>

Table 1: Decline in HIV/AIDS Death Rates⁷⁸

	2000	2005	2010	2015	2016	2017	2018	2019
People living with HIV	24.0 million [20.0 million – 28.2 million]	27.3 million [22.8 million – 32.1 million]	30.7 million [25.6 million – 36.1 million]	34.9 million [29.1 million – 40.9 million]	35.7 million [29.8 million – 41.9 million]	36.5 million [30.4 million – 42.8 million]	37.3 million [31.0 million – 43.6 million]	38.0 million [31.6 million – 44.5 million] ⁷⁹
New HIV Infections (total)	2.7 million [2.0 million – 3.7 million]	2.4 million [1.8 million – 3.2 million]	2.1 million [1.6 million – 2.9 million]	1.9 million [1.4 million – 2.5 million]	1.8 million [1.3 million – 2.4 million]	1.8 million [1.3 million – 2.4 million]	1.7 million [1.2 million – 2.3 million]	1.7 million [1.2 million – 2.2 million] ⁷⁹
New HIV infections (aged 15+)	2.2 million [1.7 million – 3.0 million]	1.9 million [1.4 million – 2.6 million]	1.8 million [1.4 million – 2.5 million]	1.7 million [1.2 million – 2.3 million]	1.6 million [1.2 million – 2.2 million]	1.6 million [1.2 million – 2.1 million]	1.5 million [1.1 million – 2.1 million]	1.5 million [1.1 million – 2.0 million] ⁷⁹
New HIV infections (aged 0–14)	480 000 [300 000 – 750 000]	440 000 [280 000 – 700 000]	310 000 [200 000 – 500 000]	190 000 [120 000 – 290 000]	180 000 [110 000 – 280 000]	170 000 [110 000 – 270 000]	160 000 [99 000 – 250 000]	150 000 [94 000 – 240 000] ⁷⁹
AIDS-related deaths	1.4 million [1.0 million – 2.0 million]	1.7 million [1.2 million – 2.4 million]	1.1 million [830 000 – 1.6 million]	830 000 [610 000 – 1.2 million]	800 000 [580 000 – 1.1 million]	760 000 [550 000 – 1.1 million]	730 000 [530 000 – 1.0 million]	690 000 [500 000 – 970 000]
People accessing antiretroviral therapy*	590 000 [590 000 – 590 000]	2.0 million [2.0 million – 2.0 million]	7.8 million [6.9 million – 7.9 million]	17.2 million [14.7 million – 17.4 million]	19.3 million [16.6 million – 19.5 million]	21.5 million [19.5 million – 21.7 million]	23.1 million [21.8 million – 23.4 million]	25.4 million [24.5 million – 25.6 million] ⁷⁹
Resources available for HIV (low – and middle-income countries)*	US\$ 4.8 billion**	US\$ 9.4 billion**	US\$ 15.0 billion**	US\$ 18.0 billion***	US\$ 18.4 billion***	US\$ 19.9 billion***	US\$ 19.0 billion***	US\$ 18.6 billion***⁷⁹

78 UNAIDS (2018) Fact Sheet 2018 Statistics. Geneva: United Nations AIDS. Available at: http://www.unaids.org/sites/default/files/media_asset/UNAIDS_FactSheet_en.pdf

CARDIOVASCULAR DISEASES

Cardiovascular diseases (CVDs) are a group of disorders affecting the heart and blood vessels, imposing a high societal and economic burden. While innovative medicines have had tremendous success saving and extending lives, CVD remains the leading cause of death worldwide today.⁷⁹ Research in this field has advanced largely due to evidence-based long-term epidemiological studies which demonstrate that drugs lowering the levels of cholesterol and antihypertensive drugs lowering blood pressure values 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.⁸⁰ 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.⁸¹ 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.⁸² 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.

79 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 February 2019.

80 The Guardian, 'Statins prevent 80,000 heart attacks and strokes a year in UK, study finds' September 2016 Available at: <https://www.theguardian.com/society/2016/sep/08/statins-prevent-80000-heart-attacks-and-strokes-a-year-in-uk-study-finds>
University of Minnesota 'Risk paradigm refined', accessed March 2018 Available at: <http://www.epi.umn.edu/cvdepi/history-gallery/risk-paradigm-refined/>

81 U.S. National Library of Medicine 'What is precision medicine?', accessed March 2018 Available at: <https://ghr.nlm.nih.gov/primer/precisionmedicine/definition>

82 AstraZeneca 'Searching for a cure for heart failure', accessed March 2018 Available at: <https://www.astrazeneca.com/what-science-can-do/stories/cardiac-regeneration.html>

Table 2: Age-Standardised Rate of DALYs Lost from Cardiovascular Disease, by Sex, 1990 to 2015, Europe, Per 100,000 Population⁸³

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 Population⁸⁴

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, in both Type 1 and Type 2. A close link exists between diabetes type 2 and CVDs as having diabetes is a primary risk factor for CVDs.⁸⁵ The WHO published that in 2016, an estimated 1.6 million deaths were directly caused by diabetes. Another 2.2 million deaths were attributable to high blood glucose levels in 2012.⁸⁶

Thanks to innovative treatments and delivery mechanisms, the wide choice of medicines and the continuous reduction of side effects patients' quality of life has improved. The delivery of treatments has progressed a lot, improving quality of life. Insulin pens can now record the date, time, and amount of previous doses so that patients and

83 European Heart Network (2017). European Cardiovascular Disease Statistics 2017 edition. Available at: <http://www.ehnheart.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).

84 European Heart Network (2017). European Cardiovascular Disease Statistics 2017 edition. Available at: <http://www.ehnheart.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.

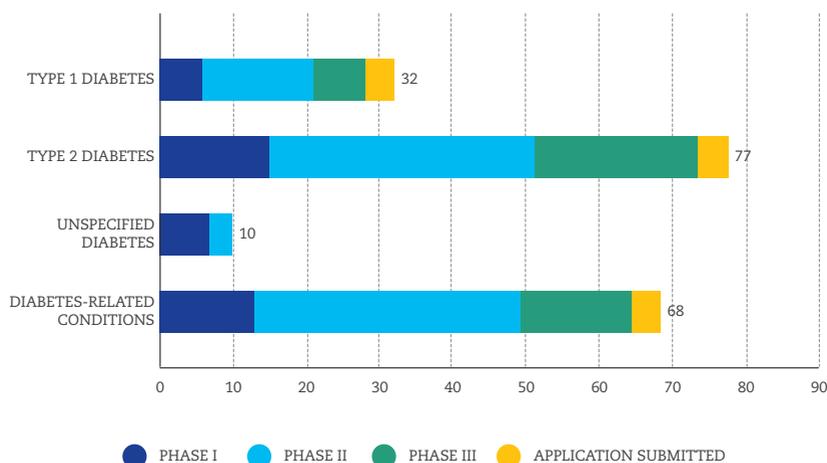
85 CDC official website (2020). Diabetes and your Heart. Available at: <https://www.cdc.gov/diabetes/library/features/diabetes-and-heart.html#:~:text=People%20with%20diabetes%20are%20also,your%20risk%20for%20heart%20disease.>

86 World Health Organization. Fact Sheet Diabetes. Available at: <https://www.who.int/en/news-room/fact-sheets/detail/diabetes>. Accessed February 2019.

healthcare providers can see exactly how much insulin the patient last took and when.⁸⁷ 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 less localized irritation but 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,⁸⁸ and recently, researchers have attempted to use patient saliva as a noninvasive test method.⁸⁹ Though diabetes is a persistent condition requiring constant attention, innovations in drug administration technology alongside high grade medication are empowering patients to effectively manage their disease with confidence.

Figure 5: Medicines in Development for Diabetes and Related Conditions*⁹⁰



* some medicines are in more than one category.

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

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

89 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>

90 PhRMA (2019). 2019 Medicines in Development for Diabetes and Related Conditions. Available at: <https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/M-O/MID-Diabetes-Drug-List-2019.pdf>

VACCINES

Since the development of the first modern vaccine in the late 1700s, vaccines have earned their reputation of being one of the safest, most effective, and cost-effective medical technologies ever developed.⁹¹ It is estimated that immunization currently prevents 2-3 million deaths each year in all age groups.⁹² Thanks to previous investigative efforts, such as the elaboration of the germ theory – the identification of organisms that cause a disease – and improvements in cell culture technologies, scientists have developed vaccines against infectious diseases including smallpox, diphtheria, tetanus, anthrax, cholera, plague, typhoid, TB, polio, measles, mumps, rubella, hepatitis A and B, chicken pox, pneumonia and, influenza, with many more are in the pipeline⁹³. Just between 2000 and 2017, immunization campaigns cut the number of deaths caused by measles by an estimated 80%, saving more than 21 million lives, over that period.⁹⁴ Future vaccine R&D investment strategies will focus on data and technology-led advancements to better understanding of immune responses and pathogen interactions.

Vaccines also serve as a frontline defense against antimicrobial resistance (AMR).⁹⁵ Vaccines prevent infection, and hence reduce the need to use (and misuse) antibiotics, thus being a critical complementary tool to mitigate the risks of AMR. They also hold up broader gains in education and economic development.⁹⁶

Vaccines are one of the most important invention in global public health and the biopharmaceutical industry will continue to prioritize tackling public health challenges at scale. The long track record of developing solutions to combat a range of infectious diseases, including viruses with epidemic 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 there are more than 200 active projects aimed at finding a viable vaccine to combat the SARS-CoV-2 virus.⁹⁷

91 Blume 'Lock in, the state and vaccine development: Lessons from the history of polio vaccines', 2004 Available at: <https://m.sussex.ac.uk/webteam/gateway/file.php?name=blume-polioarticle-in-research-policy.pdf&site=25>

92 WHO (2019), "10 Facts on Immunization". Available at: <https://www.who.int/features/factfiles/immunization/en/>

93 World Health Organization 'Vaccines and diseases', Available at: <http://www.who.int/immunization/diseases/en/>

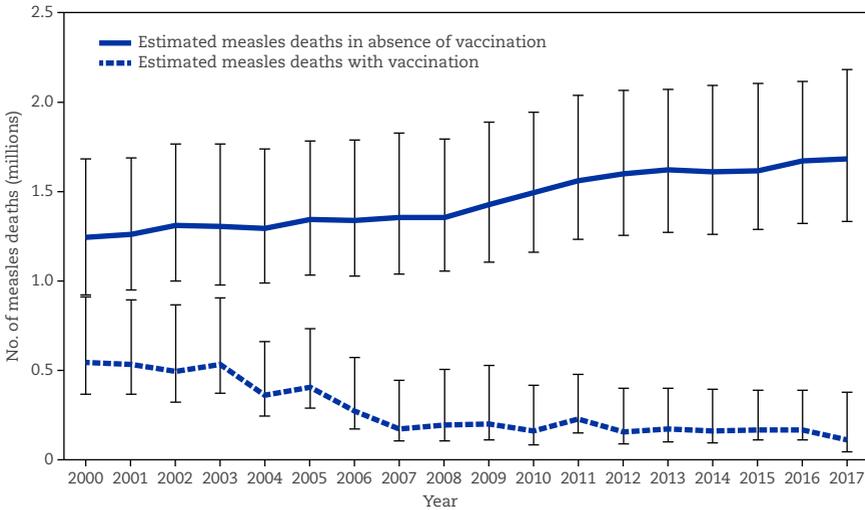
94 GAVI Alliance (2018). Dabbagh A, Laws RL, Steulet C, et al. Progress Toward Regional Measles Elimination — Worldwide, 2000–2017. *MMWR Morb Mortal Wkly Rep* 2018;67:1323–1329. DOI: Available at: <http://dx.doi.org/10.15585/mmwr.mm6747a6>

95 WHO official website (2019). Available at: <https://www.who.int/news-room/facts-in-pictures/detail/immunization>

96 WHO official website (2019). Available at: <https://www.who.int/news-room/facts-in-pictures/detail/immunization>

97 World Health Organization (2020). Draft landscape of COVID-19 candidate vaccines. Available at: <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>

Figure 6: Estimated Annual Number of Measles Deaths With and Without Vaccination Programs – Worldwide, 2000–2017⁹⁸



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

In the 2014–2018 period alone, the FDA has approved 251 medicines that offer new hope to patients with hard-to-treat diseases, compared with 175 in the period 2009–2013.⁹⁹ More than 8,000 medicines are in development worldwide, with 1,213 drugs for infectious diseases; 2,740 for cancer; 503 for diabetes; and 1,498 for neurologic disorders between phase I and III of development.¹⁰⁰

98 GAVI Alliance (2018). Dabbagh A, Laws RL, Steulet C, et al. Progress Toward Regional Measles Elimination — Worldwide, 2000–2017. *MMWR Morb Mortal Wkly Rep* 2018;67:1323–1329. DOI: Available at: <http://dx.doi.org/10.15585/mmwr.mm6747a6>
Note: Deaths prevented by vaccination are indicated by the area between estimated deaths with vaccination and those without vaccination (cumulative total of 21.1 million deaths prevented during 2000–2017). Error bars represent upper and lower 95% confidence limits around the point estimate.

99 IFPMA analysis based on U.S. Food and Drug Administration Official Website. Available at: <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/default.htm>. Visited March 2019

100 Adis R&D Insight Database. Available at: <https://adis.springer.com> Visited June 2020

Table 4: Number of New Chemical and Biological Entities Approved by the US Food and Drug Administration, 2006-2018¹⁰¹

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

Today, the cost of developing a successful medicine can exceed, according to some studies, USD 2.6 billion¹⁰², compared to USD 179 million in 1970s.¹⁰³ This increase reflects the various technical, regulatory and economic challenges R&D pipelines must face. 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 5: R&D Expenditures in the US, 2018¹⁰⁴

FUNCTION	DOLLARS	SHARE
Pre-Human/Pre-Clinical	\$13,069.0	16.4%
Phase I	\$7,749.4	9.7%
Phase II	\$8,436.0	10.6%
Phase III	\$23,033.2	28.9%
Approval	\$2,647.6	3.3%
Phase IV	\$9,230.2	11.6%
Uncategorized	\$15,437.4	19.4%
TOTAL R&D	\$79,602.8	100.0%

Notes: All figures include company-financed R&D only. Total values may be affected by rounding.

Source: Pharmaceutical Research and Manufacturers of America, PhRMA Annual Membership Survey, 2019.

101 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

102 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>

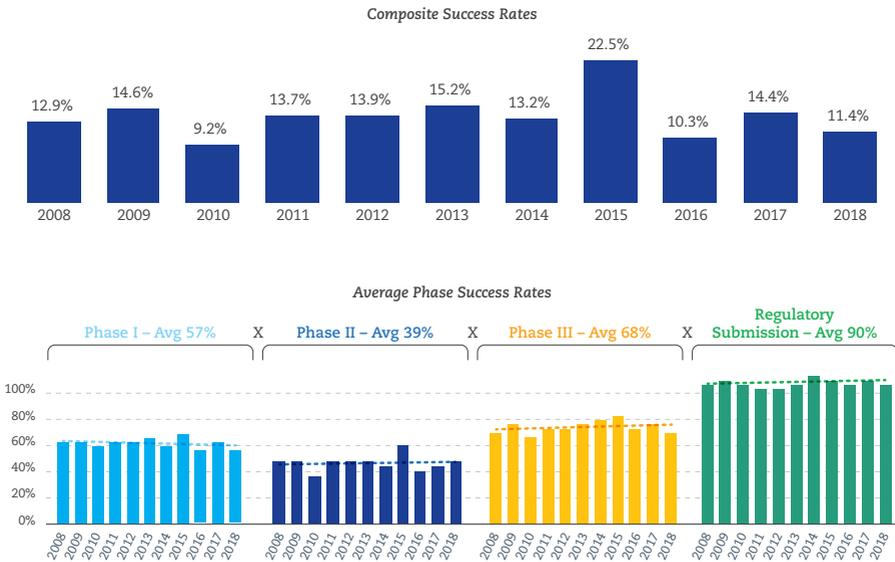
103 PhRMA (2019) 2019 Biopharmaceutical in Perspective. Washington DC: Pharmaceutical Research and Manufacturers of America. Available at: <https://www.phrma.org/en/Report/Chart-Pack-Biopharmaceuticals-in-Perspective-Summer-2019>

104 PhRMA (2019) 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/P-R/PhRMA_2019_membership_survey_Final.pdf

Figure 7: Medicines in Development by Regulatory Phase Globally, 2020¹⁰⁵

PHASE	
Phase III	2,178
Phase II/III	393
Phase II	3,752
Phase I/II	1,643
Phase I	3,461

Figure 8: Phase Transition Success Rates and Likelihood of Approval for All Medicines and Modalities, 2008 – 2018¹⁰⁶



105 Adis R&D Insight Database. Available at: <https://adis.springer.com> Visited June 2020

106 IQVIA Institute (2019). The Changing Landscape of Research and Development, Apr.2019 Available at: <https://www.healthindustryhub.com.au/wp-content/uploads/2019/05/the-changing-landscape-of-research-and-development.pdf>

Figure 9: Internal Rate of Return on Late Stage Pipeline for Large Cap Biopharmaceutical Companies, 2010 – 2019¹⁰⁷

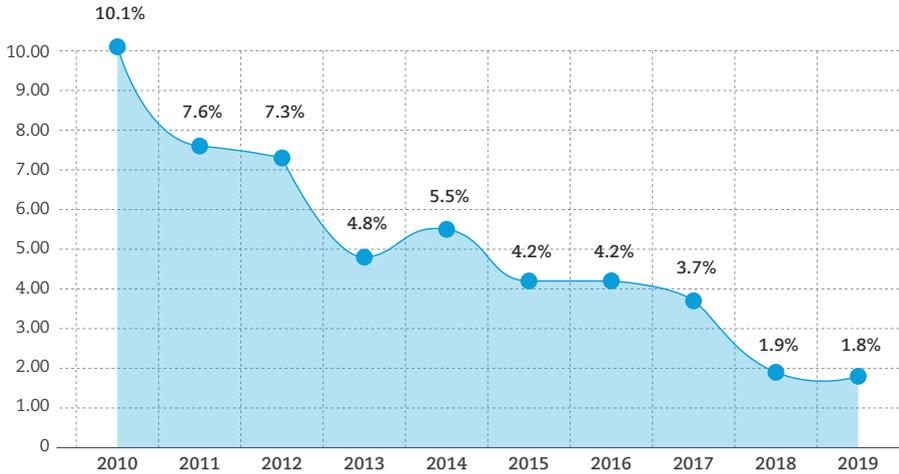


Figure 9 represents a Deloitte analysis that measures the return from pharmaceutical innovation by tracking over time a cohort of the 12 largest biopharmaceutical companies by 2009 R&D spending. This sample is used as a proxy to measure the industry's Internal Rate of Return (IRR), which is based on 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 9) 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.

107 Deloitte LLP (2019) Ten years on: Measuring the return from pharmaceutical innovation 2019. Available at: <https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/life-sciences-health-care/deloitte-uk-ten-years-on-measuring-return-on-pharma-innovation-report-2019.pdf>

Table 6: Trends in Clinical Trial Protocol Complexity¹⁰⁸

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%

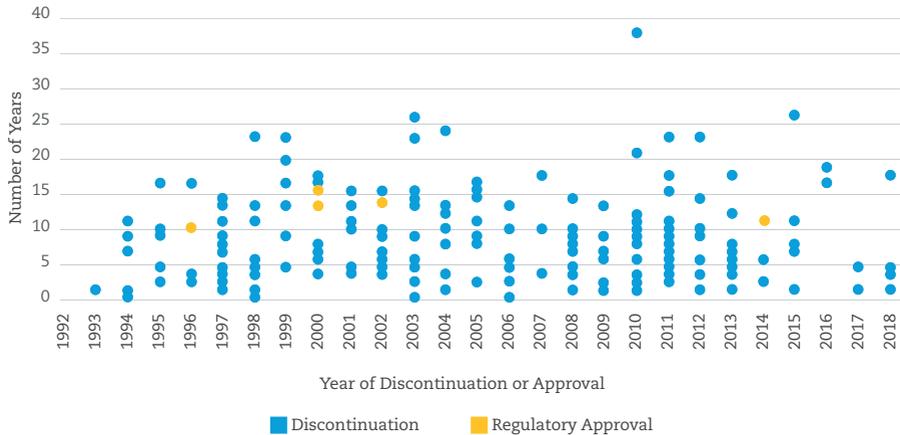
Industry's efforts to tackle Alzheimer's diseases illustrates how complex and challenging the biopharmaceutical R&D process is. The total number of people with dementia is projected to reach 82 million in 2030, and between 60 and 70% of those dementias could progress into Alzheimer's disease.¹⁰⁹ However, 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. In the meantime, the estimated yearly cost to treat and care for people with dementia is USD 1 trillion.¹¹⁰

108 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/Chart-Pack-Biopharmaceuticals-in-Perspective-Summer-2019>

109 WHO (2019). Fact Sheets on Dementia. Available at: <https://www.who.int/news-room/fact-sheets/detail/dementia> Visited January 2020

110 Aitken, M., Kleinrock, M., Simorellis, A., & Nass, D. (2019). The Global Use of Medicine in 2019 and Outlook to 2023: Forecasts and Areas to Watch. Parsippany, NJ: IQVIA Institute for Human Data Science. Available at: <https://www.iqvia.com/insights/the-iqvia-institute/reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023>

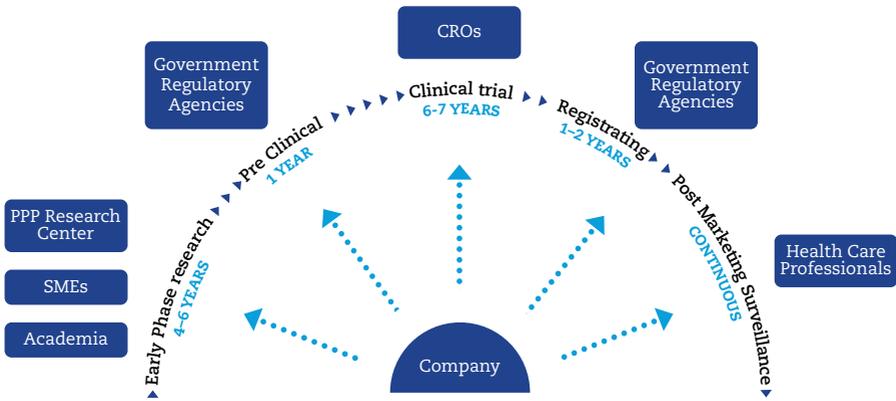
Figure 10: Number of Years Since Product's First Filing to Discontinuation or Regulatory Approval of Alzheimer's therapies¹¹¹



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.

111 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>

Notes: The exhibit shows the time from patent filing to the end of clinical development, whether that was a discontinuation of the program or market approval; this does not show a discontinuation of a single clinical trial. Line extensions of marketed therapies are included with original global approval of the molecule

Figure 11: Biopharmaceutical R&D Network¹¹²

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.

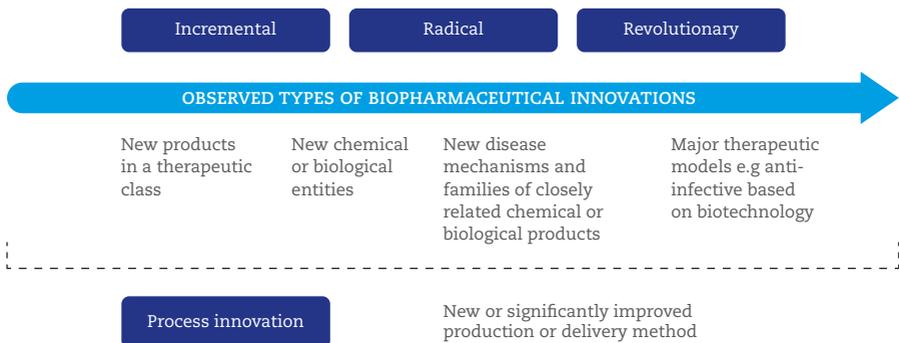
The case is similar with existing vaccines that can also be continuously improved. New technologies enable vaccines to be reformulated to include new, desirable qualities such as improved temperature stability. By combining multiple vaccines into one vial or delivery devices, vaccine industry can further limit the number of vaccines and

112 IFPMA (2012) 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/>

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.¹¹³

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.¹¹⁴ 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 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.¹¹⁵

Figure 12: Categories of Biopharmaceutical Innovation¹¹⁶



113 IFPMA (2016). Innovation for a Healthier World. Geneva: International Federation of Pharmaceutical Manufacturers & Associations, Available at: https://www.ifpma.org/wp-content/uploads/2016/02/IFPMA_Vaccine_Healthier_World_verF.pdf

114 IFPMA (2012) 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/>

115 IFPMA (2012) 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/>

116 IFPMA (2012) 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/>

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 179 billion globally on biopharmaceutical R&D in 2018.¹¹⁷

Compared with other high-technology industries, the annual spending by the biopharmaceutical industry is 7.3 times greater than that of the aerospace and defense industries, 6.5 times more than that of the chemicals industry, and 1.5 times more than that of the software and computer services industry.¹¹⁸

In the United States, R&D investments of biopharmaceutical companies have grown consistently over the past 15 years, and more than doubled the publicly-funded National Institutes of Health's (NIH) expenditures in 2019.¹¹⁹ R&D intensity by the research-based biopharmaceutical industry in the world amounts to 15%.¹²⁰ In 2018 alone, the biopharmaceutical industry registered 9,114 patents through the Patent Cooperation Treaty (PCT) of the World Intellectual Property Organization.¹²¹ No other business sector has such high levels of R&D intensity.

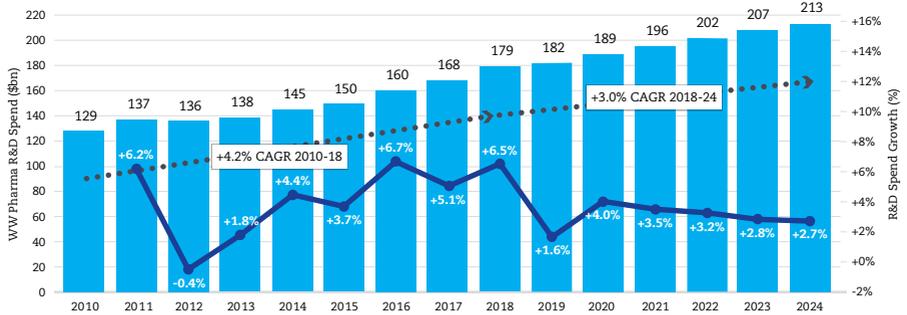
117 Evaluate Pharma (2019) *World Preview 2019, Outlook to 2024*. London: Evaluate Ltd., p 18. Available at: https://info.evaluate.com/rs/607-YGS-364/images/EvaluatePharma_World_Preview_2019.pdf

118 IFPMA Analysis based on: European Commission (2018). *The 2018 EU Industrial R&D Investment Scoreboard*; p 104. Available at: <http://iri.jrc.ec.europa.eu/scoreboard18.html>

119 European Commission (2018) *The 2018 EU Industrial R&D Investment Scoreboard*; p 104. Available at: <http://iri.jrc.ec.europa.eu/scoreboard18.html>

120 NIH (National Institutes of Health) (2019) *NIH Budget*. Available at: <http://www.nih.gov/about/budget.html>

121 WIPO (2019) *Patent Cooperation Treaty Yearly Review – The International Patent System*. Geneva: World Intellectual Property Organization, p 40. Available at: https://www.wipo.int/edocs/pubdocs/en/wipo_pub_901_2019.pdf

Figure 13: Biopharmaceutical R&D Spending¹²²Table 7: R&D Investments by Sector¹²³

RANK	SECTOR	R&D IN 2017/18, € BN	ONE – YEAR CHANGE, %	NET SALES, € BN	ONE – YEAR CHANGE, %	R&D INTENSITY, %	OPERATING PROFITS, € BN	ONE – YEAR CHANGE, %	PROFITABILITY, %	EMPLOYEES, MILLION	ONE – YEAR CHANGE, %
1	Pharmaceuticals & Biotechnology	138.9	7.6	911.7	5.1	15.0	132.0	-10.6	14.9	2.5	2.3
2	Technology Hardware & Equipment	117.2	10.8	1348.4	10.7	8.7	177.9	18.4	14.0	3.7	1.2
3	Automobiles & Parts	117.0	7.1	2590.4	7.3	4.5	167.5	10.8	6.5	7.4	3.7
4	Software & Computer Services	94.4	13.6	1116.8	14.3	8.4	171.7	17.4	15.4	3.7	5.9
5	Electronic & Electrical Equipment	57.3	12.4	1174.1	10.0	4.9	126.6	32.9	10.8	5.0	3.7
6	Industrial Engineering	26.7	6.1	828.6	8.8	3.2	73.4	38.1	9.1	3.3	2.9

122 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

123 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>

RANK	SECTOR	R&D IN 2017/18, € BN	ONE – YEAR CHANGE, %	NET SALES, € BN	ONE – YEAR CHANGE, %	R&D INTENSITY, %	OPERATING PROFITS, € BN	ONE – YEAR CHANGE, %	PROFIT – ABILITY, %	EMPLOYEES, MILLION	ONE – YEAR CHANGE, %
7	Chemicals	21.5	5.1	826.8	13.1	2.6	100.1	17.4	12.2	1.7	1.7
8	General Industrials	20.0	-0.6	689.7	6.0	2.9	50.8	-9.2	7.4	2.3	-4.1
9	Aerospac & Defence	19.0	-4.3	474.8	2.4	4.0	48.8	21.9	10.3	1.6	0.1
10	Health Care Equipment & Services	14.7	8.5	404.8	6.7	3.6	35.2	2.5	8.7	1.3	6.4
11	Leisure Goods	14.0	1.7	249.9	10.5	5.6	21.2	38.6	8.5	0.8	0.2
12	Construction & Materials	13.0	12.1	944.0	7.7	1.4	85.0	54.2	9.0	3.1	1.7
13	Banks	10.3	2.2	386.9	2.3	2.7	104.0	55.4	30.8	1.6	4.7
14	Fixed Line Telecommunications	8.4	4.9	490.4	0.8	1.7	66.2	4.0	13.7	1.3	-0.9
15	Oil & Gas Producers	7.9	2.4	2119.3	21.3	0.4	122.9	274.1	5.8	2.2	-1.9
Total 39 industries		736.4	8.3	18448.0	9.8	4.0	1909.3	22.6	10.5	55.0	2.1

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 biopharmaceutical companies.¹²⁴ In 2018, R&D spending by the biopharmaceuticals and biotechnology sector grew by 6.5% from the previous year, strengthening its position as the top R&D investing sector.¹²⁵ 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 protection (IP). The legal

124 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>

125 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>

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.¹²⁶

Figure 14: Median Time from First Patent Filing to Launch in by New Active Substances Launch Year, United States, 1996-2018¹²⁷

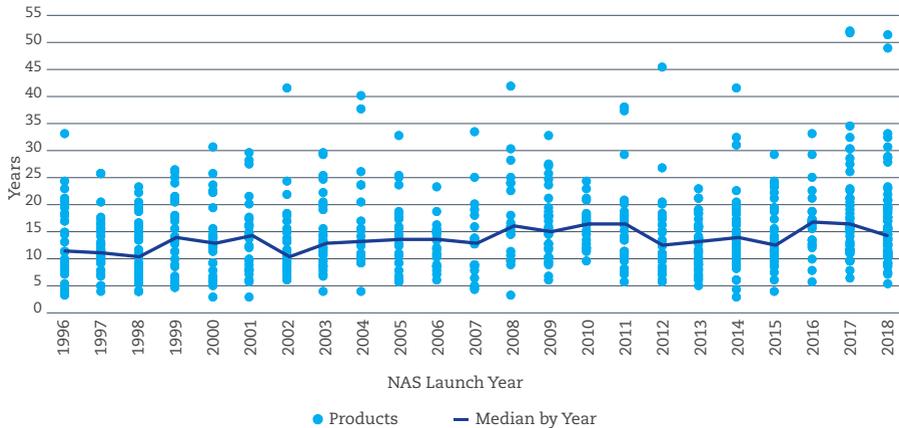


Table 8: Enabling Factors of Biopharmaceutical Innovation¹²⁸

EARLY STAGE RESEARCH	<ul style="list-style-type: none"> 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
CLINICAL TRIALS	<ul style="list-style-type: none"> 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

126 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>

127 IQVIA Institute (2019). The Changing Landscape of Research and Development, Apr.2019 Available at: <https://www.healthindustryhub.com.au/wp-content/uploads/2019/05/the-changing-landscape-of-research-and-development.pdf>

128 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

Providing sufficient market incentives in a competitive marketplace is a collective investment that drives life-saving innovations and delivers improved health outcomes.¹²⁹ 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. Antimicrobial resistance (AMR) in the form of drug-resistant superbugs could soon cause over USD 3 trillion in GDP loss per year worldwide.¹³⁰ The same challenges apply to other diseases. For instance, Ebola virus caused Liberia’s economy to decline by 8% from 2013 to 2014.¹³¹ Tuberculosis (TB) could cost the global economy almost USD 1 trillion by 2030.¹³² Pandemic influenza is estimated to have a potential yearly cost of USD 500 billion.¹³³ These examples show that investments in biopharmaceutical industry, or lack thereof, can have global effects.

129 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

130 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/>

131 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>

132 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)

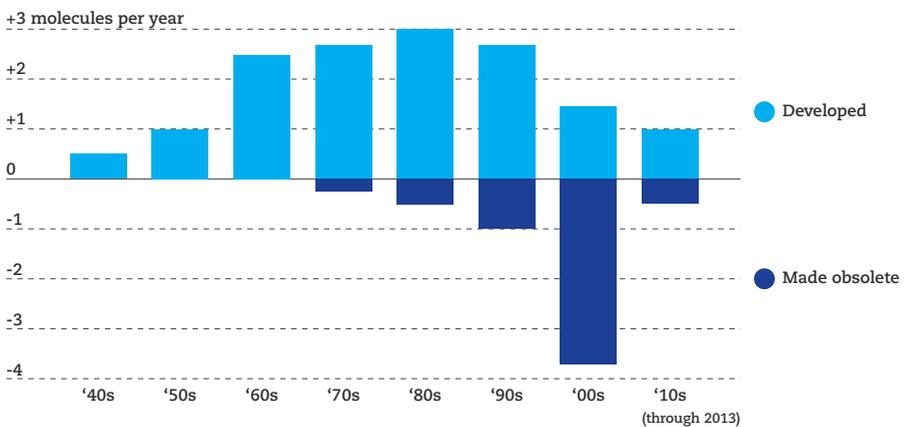
133 Fan et al ‘The Inclusive Cost of Pandemic Influenza Risk’, 2016 Available at: <https://www.nber.org/papers/w22137>

Antimicrobial Resistance

Each year, a growing number of infectious pathogens causes the death of an estimated 700,000 people.¹³⁴ Antimicrobial resistance (AMR) is increasing, 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.¹³⁵

Poor discovery prospects, combined with weaker returns, means that the arsenal of antibiotics is declining, after peaking in 2000. 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.¹³⁶

Figure 15: Newly Developed Antibiotics vs. Attrition¹³⁷



134 What are drug-resistant infections? Wellcome Trust. Web. 2019. Available at: <https://wellcome.ac.uk/news/what-are-drug-resistant-infections>

135 O'Neill, J. (2016). Tackling Drug-Resistant Infections Globally: Final Report and Recommendations. Review on Antimicrobial Resistance. Available at: https://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf

136 AMR Industry Alliance, 2018. Tracking Progress to Address R&D, Available at: https://www.amrindustryalliance.org/wp-content/uploads/2018/01/AMR_Industry_Alliance_Progress_Report_January2018.pdf

137 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>

Hence, AMR requires action across all government sectors and society.¹³⁸ 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.

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 recommended in Canada in 1988, cases of Hib disease dropped by 97% from 1986 to 2015.¹³⁹ 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.¹⁴⁰ Based on the aggregated estimates of 56 companies, in 2018, the private sector invested more than USD 1.6 billion in R&D dedicated to AMR-related products. The private sector is investing in a broad range of projects, including 24 antibiotics and antifungals, 11 vaccines, 16 diagnostic platforms or assays, 10 non-traditional approaches, and 1 other AMR-relevant product.¹⁴¹ 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.¹⁴²

138 WHO, 2018. Key Facts, Antimicrobial resistance. Official Website, visited November 2019 Available at: <https://www.who.int/en/news-room/fact-sheets/detail/antimicrobial-resistance>

139 Public Health Agency of Canada. Vaccine preventable disease: surveillance report to December 31, 2015 (Public Health Agency of Canada, Ottawa, 2017)

140 AMR Industry Alliance, 2020. Progress Report. Available at: <https://www.amrindustryalliance.org/wp-content/uploads/2020/01/AMR-2020-Progress-Report.pdf>

141 AMR Industry Alliance, 2020. Progress Report. Available at: <https://www.amrindustryalliance.org/wp-content/uploads/2020/01/AMR-2020-Progress-Report.pdf>

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

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.¹⁴³

Figure 16: The Proposed Way Forward to a Sustainable 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

143 IFPMA AMR Policy Position: Global Principles on Incentivizing Antibiotic R&D. (2021)

event of an influenza pandemic. IFPMA member companies have also contributed most of the US\$198 million voluntary donations collected by 30 June 2020, by the WHO PIP Framework.

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. But much still needs to be done. With this in mind, the WHO has developed a global “R&D Blueprint”, which is a global strategy and preparedness plan that allows the rapid activation of research and development activities during epidemics. Its aim is to fast-track the availability of effective tests, vaccines and medicines that can be used to save lives and avert large scale crises.

R&D for Diseases that Disproportionately Affect the Developing World

NEGLECTED TROPICAL DISEASES

Over 1.5 billion people – or one in five globally – are affected by neglected tropical diseases (NTDs) and the World Health Organization (WHO) has targeted 20 specific NTDs for elimination or control.¹⁴⁴ 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 last 10 years and was 10% lower in 2018 than it was in 2009.¹⁴⁵ Despite often low commercial incentives, investment from the innovative biopharmaceutical industry in this space has continued to grow over the past 12 years 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

144 WHO. 2019. Neglected tropical diseases: treating over one billion people for the fourth successive year. Available at: https://www.who.int/neglected_diseases/news/treating-over-one-billion-people-for-the-fourthsucessive-year/en/

145 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

academia, industry, private foundations, and governments. These partnerships are often funded by public or philanthropic organizations, as well as by industry. In 2018, industry contributed about 24% of the total research funding for malaria, 23% for dengue, and 14% for tuberculosis.¹⁴⁶ Overall, it was the third largest funder for research for neglected diseases, investing a record high of USD 694 million in 2018.¹⁴⁷ This was significantly higher than the previous year (up 20%), and represents the highest ever level of private sector investment in neglected disease R&D.

IFPMA members have made significant progress to develop new technologies — medicines, vaccines, and pesticides — to combat NTDs. Fifteen pharmaceutical companies are conducting R&D on 14 NTDs. IFPMA members currently have over 90 projects in progress (about 80% of them involve an external partner).¹⁴⁸ Since 2014, the number of projects, undertaken in-house or in PDPs, has more than doubled. 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 (IP) 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 over 20 ongoing clinical trials of which thirteen are already available.¹⁴⁹ Since 2011, WIPO Re:Search has

146 G-Finder (2019) Neglected Disease Research and Development: UNEVEN PROGRESS. Available at: <https://s3-ap-southeast-2.amazonaws.com/policy-cures-website-assets/app/uploads/2020/02/11150341/G-Finder2019.pdf>

147 G-Finder (2019) Neglected Disease Research and Development: UNEVEN PROGRESS. Available at: <https://s3-ap-southeast-2.amazonaws.com/policy-cures-website-assets/app/uploads/2020/02/11150341/G-Finder2019.pdf>

148 Access to Medicine Index. 2019. First Independent Ten-Year Analysis: Are pharmaceutical companies making progress when it comes to global health?. Available at: https://accessmedicinefoundation.org/media/uploads/downloads/5d93329e141cb_Access-to-Medicine-Index-10-Year-Analysis.pdf

149 DNDi (2019) Drugs for Neglected Diseases initiative. Official Website visited on October 2019. Available at: <https://www.dndi.org/diseases-projects/portfolio/>

facilitated 156 IP-sharing collaborations and 10 ongoing collaborations are advancing critical solutions for neglected diseases along the product development pathway. Since 2013, the Global Health Innovative Technology (GHIT) Fund has invested USD 209 million in 91 projects to create new drugs, vaccines, and diagnostics for NTDs, malaria, and TB. As of the first quarter of 2020, this includes 26 discovery projects, 20 preclinical projects, and 6 clinical trials in LMICs.¹⁵⁰

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, cause more than 4 million deaths per year.¹⁵¹

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, break through 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 53 million lives;¹⁵² between 2000 and 2015, the rate of new cases of malaria fell by 37% globally and an estimated 6.8 million malaria deaths have been averted globally since 2001.¹⁵³

More action and innovation are needed to achieve a world without HIV, TB and Malaria.¹⁵⁴ We continue to invest in R&D to discover novel solutions. R&D pipeline counts more than 180 projects to fight these diseases.¹⁵⁵

150 IFPMA, VFA, JPMA (2020). Collaborating to end Neglected Tropical Diseases: Catalyzing Innovation and Partnerships. Available at: https://www.ifpma.org/wp-content/uploads/2020/05/IFPMA-VFA-JPMA_NTDs_Report-1.pdf

151 WHO Official Website. Visited on May 2020. Available at: <https://www.who.int/about/structure/organigram/htm/en/>

152 World Health Organization (2018). Global TB Report 2018. [online] Available at: https://www.who.int/tb/publications/global_report/en/
World Health Organization (2018). TB Fact Sheet 2018. [online] Available at: https://www.who.int/tb/publications/factsheet_global.pdf?ua=1

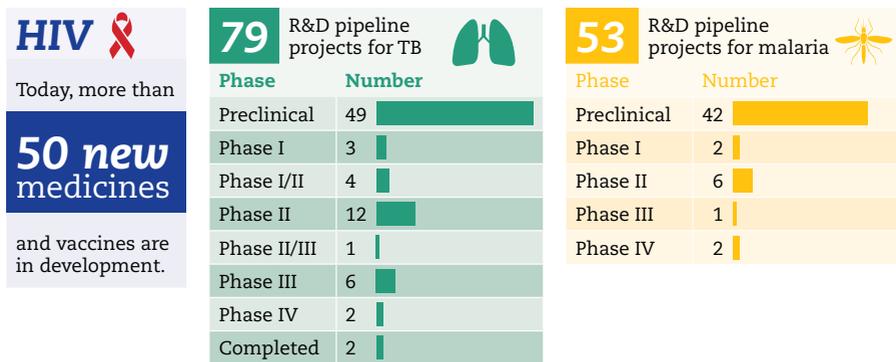
153 World Health Organization (2015). World Malaria Report. [online] Available at: https://apps.who.int/iris/bitstream/handle/10665/200018/9789241565158_eng.pdf?sequence=1

154 World Health Organization (2017). Global Action Plan on HIV Drug Resistance 2017-2021. [online] Available at: <https://apps.who.int/iris/bitstream/handle/10665/255883/9789241512848-eng.pdf;jsessionid=4528FF629D57AC75A8F696117A3BEA7A?sequence=1>

155 PhRMA (2017). Medicines in Development for HIV 2017 Report. [online] Available at: <https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/HIV-MIDReport-2017.pdf>
IFPMA (2018). R&D Pipeline for Tuberculosis. [online] Available at: https://www.ifpma.org/wp-content/uploads/2018/08/IFPMA_TB_RD_Pipeline_FINAL.pdf
IFPMA (2017). R&D Pipeline for Malaria. [online] Available at: https://www.ifpma.org/wp-content/uploads/2017/04/IFPMA_RD_Pipeline_Malaria_April_2017.pdf

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 Microbicides (IPM) and the International AIDS Vaccine Initiative (IAVI).¹⁵⁶ 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.¹⁵⁷ 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.¹⁵⁸

Figure 17: R&D Pipeline Projects for HIV, TB and Malaria¹⁵⁹



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

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

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

159 PhRMA (2017). Medicines in Development for HIV 2017 Report. [online] Available at: <https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/HIV-MIDReport-2017.pdf>
 IFPMA (2018). R&D Pipeline for Tuberculosis. [online] Available at: https://www.ifpma.org/wp-content/uploads/2018/08/IFPMA_TB_RD_Pipeline_FINAL.pdf
 IFPMA (2017). R&D Pipeline for Malaria. [online] Available at: https://www.ifpma.org/wp-content/uploads/2017/04/IFPMA_RD_Pipeline_Malaria_April_2017.pdf



Chapter 2

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, and a sound enabling policy environment for the biopharmaceuticals industry¹⁶⁰ is a fundamental condition for its good performance.¹⁶¹ Universal Health Coverage (UHC) is a core component of well performing health systems, which are complex mechanisms through which health products, services, and care are delivered to patients.¹⁶² At the same time, they face major challenges posed by demographic changes, as well as epidemiological trends. The success of health systems requires joint effort and collaboration between all the key health actors. As such, the research-based biopharmaceutical industry plays an essential role in providing access to medicines and vaccines and support to the overall healthcare structure.

The Building Blocks of Healthcare Systems

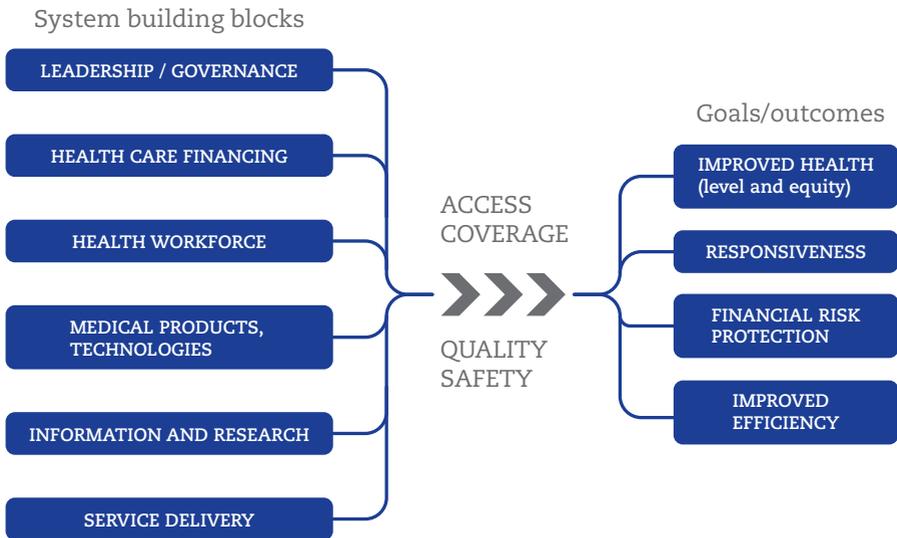
According to the WHO, a health system is built on six building blocks: service delivery; health workforce; information; medical products, vaccines, and technologies; financing; and leadership/governance.¹⁶³ A well-functioning healthcare system also promotes productive relationships between governments, patients, and the healthcare industry.

160 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

161 WHO (2007) *Everybody's Business: Strengthening Health Systems to Improve Health Outcomes*. Geneva: World Health Organization, p 3. Available at: http://www.who.int/healthsystems/strategy/everybodys_business.pdf

162 IFPMA (2012) *The Changing Landscape on Access to Medicines*. Geneva: International Federation of Pharmaceutical Manufacturers and Associations, Chapter 2. Available at: <http://www.ifpma.org/fileadmin/content/Publication/2012/ChangingLandscapes-Web.pdf>

163 WHO (2016) *The WHO Health Systems Framework*. Geneva: World Health Organization. Available at: http://www.wpro.who.int/health_services/health_systems_framework/en

Figure 18: The WHO Health System Framework¹⁶⁴

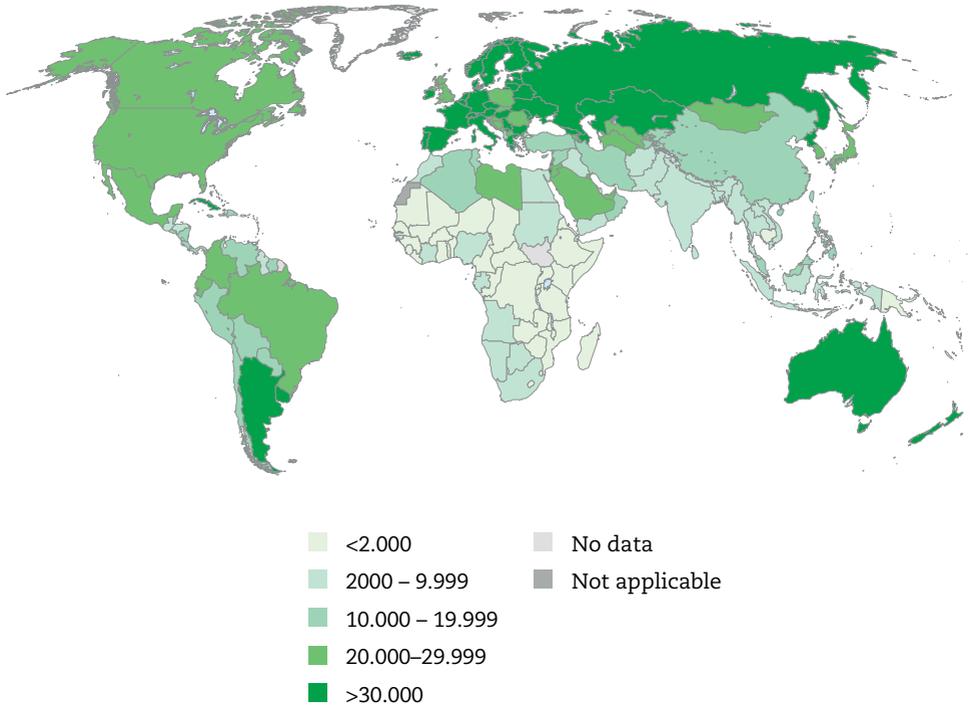
Pharmaceuticals play a pivotal role in any healthcare system. A well-performing healthcare system must ensure that biopharmaceutical products meet quality requirements and are appropriately procured, distributed to the different healthcare facilities, and prescribed by properly trained professionals.

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 51 doctors for every 10,000 inhabitants, while in Senegal there is only 1 per 10,000.¹⁶⁵

164 WHO (2016) The WHO Health Systems Framework. Geneva: World Health Organization. Available at: http://www.wpro.who.int/health_services/health_systems_framework/en

165 World Bank (2016) Physicians (per 1,000 People). Washington DC: The World Bank Group. Accessed November 2019 Available at: <http://data.worldbank.org/indicator/SH.MED.PHYS.ZS>

Figure 19: Relative Density of Physicians per 1,000 Population (Latest Available Year)¹⁶⁶



The 2020 State of the World's Nursing¹⁶⁷ report found that the world would need 6 million more nurses by 2030 to reach global health targets.¹⁶⁸ Shortages of health care workers are felt most acutely in low – and middle-income countries.

¹⁶⁶ WHO (2019) 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/

¹⁶⁷ WHO, Accessed 2020. Available at: <https://apps.who.int/iris/bitstream/handle/10665/331673/9789240003293-eng.pdf>

¹⁶⁸ WEF, Accessed 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 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.¹⁶⁹ A report by the World Bank in 2007 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.¹⁷⁰

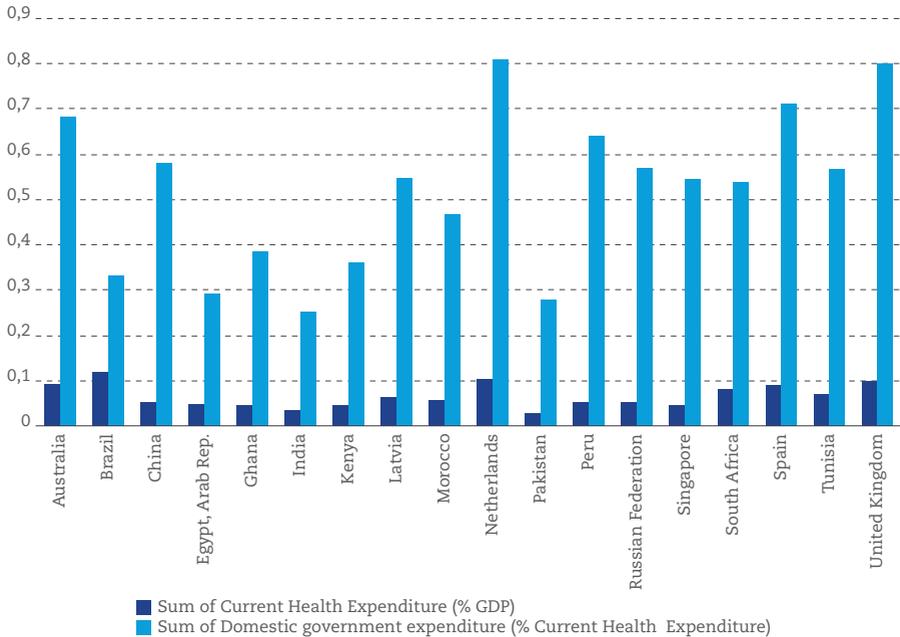
The coronavirus crisis has revealed the importance of national and sub-national health systems: together, these systems comprise the foundation of global health security. Strong and resilient health systems are the best defence not only against outbreaks and pandemics, but also against the multiple health threats that people around the world face every day. The world currently spends approximately \$7.5 trillion on health each year, or 10% of global gross domestic product (GDP). While spending has increased steadily,¹⁷¹ dangerous public health gaps exist, especially in rural or conflict-ridden areas where access is difficult, and infrastructure is lacking.

169 African Union. (2016). Africa Scorecard on Domestic Financing for Health. [online] Available at: https://au.int/sites/default/files/newsevents/workingdocuments/34086-wd-au_scorecard_-_final_english.pdf

170 World Bank. (2008). The Business of Health in Africa: Partnering with the private sector to improve people's lives.

171 United Nations, Accessed 2020. Available at: <https://news.un.org/en/story/2019/09/1046772>

Figure 20: Total Health Expenditure as a Percentage of GDP, and Public Health Expenditure as a Percentage of the Total Health Expenditure, 2016¹⁷²



Strong healthcare systems also require strategic long-term planning and political commitment. Health authorities should not only make necessary resources available, but also procure medicines and vaccines effectively and minimize inefficiencies and unnecessary mark-ups in the supply chain, such as taxes and tariffs.

172 World Bank (2019) Health Expenditure. Washington DC: The World Bank Group. Available at: <https://data.worldbank.org/indicator?tab=all>

Healthcare systems investments and savings from biopharmaceutical innovation

While health expenditure as a share of GDP has increased in various 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).¹⁷³

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 20% of health expenditure, though this figure varies from country to country.¹⁷⁴ For 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.¹⁷⁵

173 OECD (2019), Health at a Glance 2019: OECD Indicators, OECD Publishing, Paris. Available at: <https://doi.org/10.1787/4dd50c09-en>

174 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

175 PhRMA. (2017). Prescription medicines: international costs in context. Available at: <https://www.phrma.org/en/Report/Prescription-Medicines---International-Costs-in-Context>

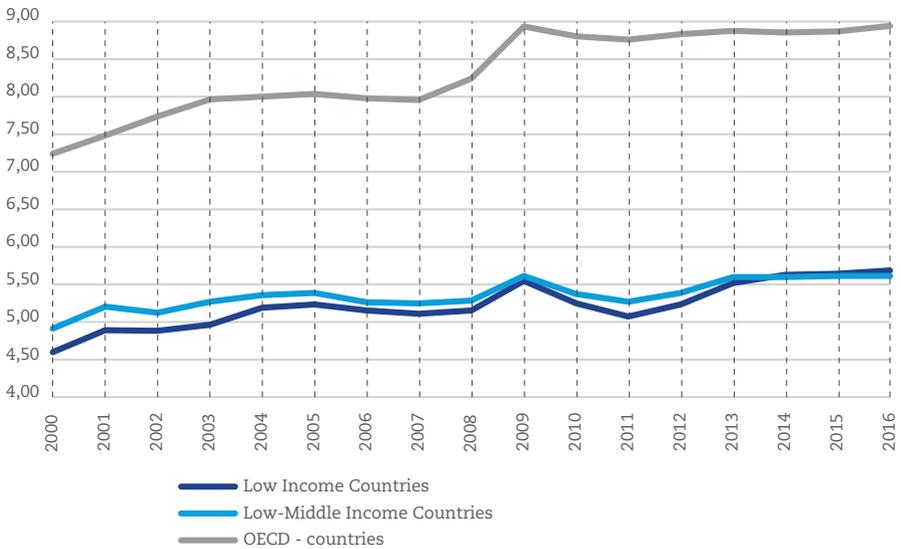
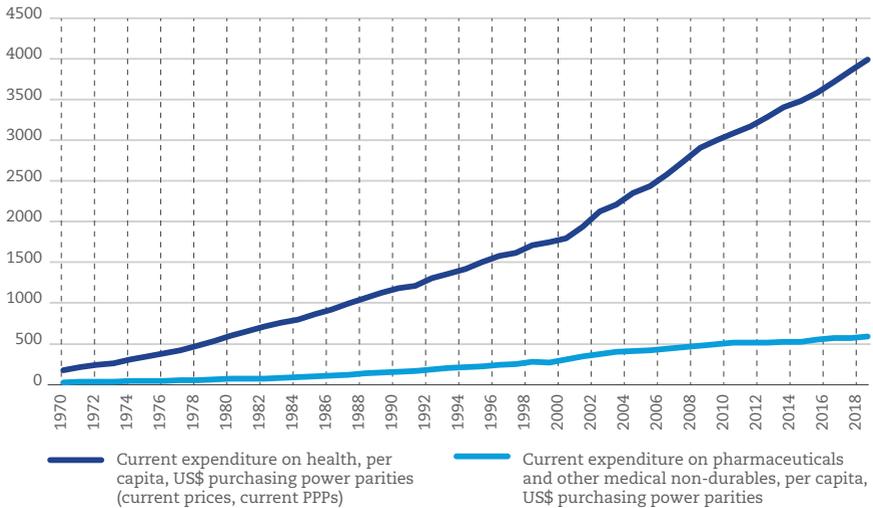
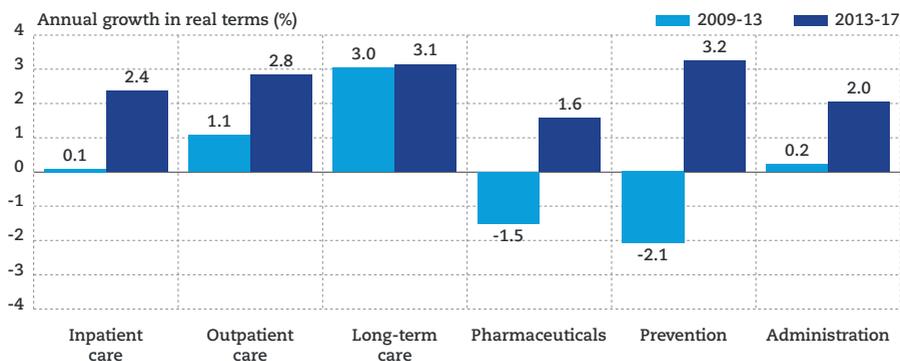
Figure 21: Spending on Health, %GDP¹⁷⁶Figure 22: Per Capita Expenditure on Health and Pharmaceuticals, OECD Countries¹⁷⁷176 IFPMA analysis based on data extracted from World Bank Open Data. Available at: <https://data.worldbank.org/> Accessed 2019177 IFPMA analysis based on data extracted from OECD Data Available at: <https://data.oecd.org/> Accessed 2019

Figure 23: Annual Growth in Health Expenditure for Selected Services (Real Terms), OECD Average, 2009-13 and 2013-2017¹⁷⁸



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.¹⁷⁹

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.¹⁸⁰
- In Vietnam, supported by the Gavi program, HPV vaccination has proven to be cost-effective¹⁸¹

178 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>

179 EFPIA (2019), The pharmaceutical industry in figures 2019. Available at: <https://www.efpia.eu/media/413006/the-pharmaceutical-industry-in-figures.pdf>

180 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>

181 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.¹⁸² In addition, an assessment of return on investment (ROI) has found that every dollar invested in childhood immunization in low – and middle-income countries over a decade is estimated to result in a return of 16 times the initial costs, just taking into account the cost of illness. When considering broader economic and social benefits, the ROI for immunization was 44 times the vaccination investment.¹⁸³

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 40% and 30% respectively of health expenditure is paid OOP, compared to 22% in high-income countries (see figure 24).¹⁸⁴ 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.¹⁸⁵

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.¹⁸⁶ According to the literature, there is a clear inverse

182 GAVI, The Vaccine Alliance (2020). Facts and figures: Statistics measuring our impact on global immunisation. Available at: <https://www.gavi.org/programmes-impact/our-impact/facts-and-figures>

183 Ozawa, S., Clark, S., Portnoy, A., Grewal, S., Brenzel, L. and Walker, D.G., 2016. Return on investment from childhood immunization in low-and middle-income countries, 2011–20. *Health Affairs*, 35(2), pp.199-207. Available at: <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2015.1086?siteid=healthaff&keytype=ref&ijkey=VETMVFcGpCXbc>

184 IFPMA analysis of non-weighted average of health expenditure based on WHO dataset. Latest values from 2016. Available at: <https://apps.who.int/nha/database/Select/Indicators/en> Last accessed November 2019

185 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>

186 World Bank Group/WHO (2017). Tracking universal health coverage: 2017 global monitoring report. Washington, DC and Geneva; 2017. Available at: https://www.who.int/healthinfo/universal_health_coverage/report/2017/en/

relationship between life expectancy and OOP expenditure (see Figure 25), implying that better health outcomes also require appropriate financial protection.¹⁸⁷ 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.¹⁸⁸ Total health expenditures range from 3.4% of GDP in Equatorial Guinea to 17.1% of GDP in the United States. On average, low-income countries spend 5.4% of GDP on financing healthcare systems, whereas high-income countries spend more than 12.6% on health.

187 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/>

188 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

Figure 24: Domestic General Government Health Expenditure (Horizontal Axis, % General Government Expenditure) and OOP (% Current Health Expenditure)¹⁸⁹

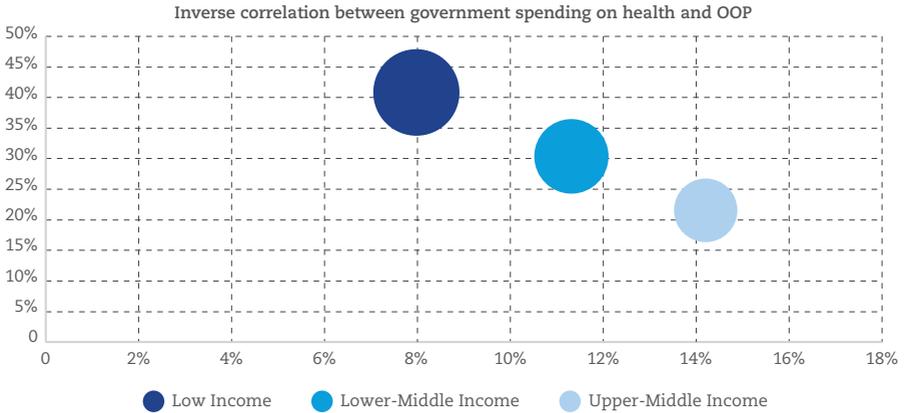
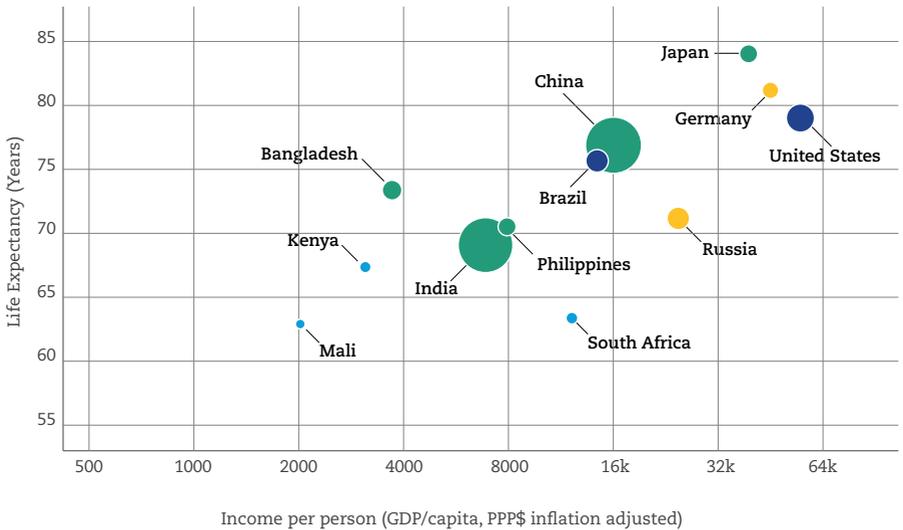


Figure 25: Correlation between Income per Person and Life Expectancy, 2018¹⁹⁰



189 IFPMA Analysis based on data extracted from WHO, Global Health Observatory (GHO) data. Available at: <https://www.who.int/gho/en/> Visited October 2019.

Notes: Non-weighted average of countries based on latest data available.

190 Size of the circles reflects the country population. Gapminder (2018) Global Trends: Wealth & Health of Nations. Accessed November 2019. Available at: <https://www.gapminder.org/tools/#Schart-type=bubbles>

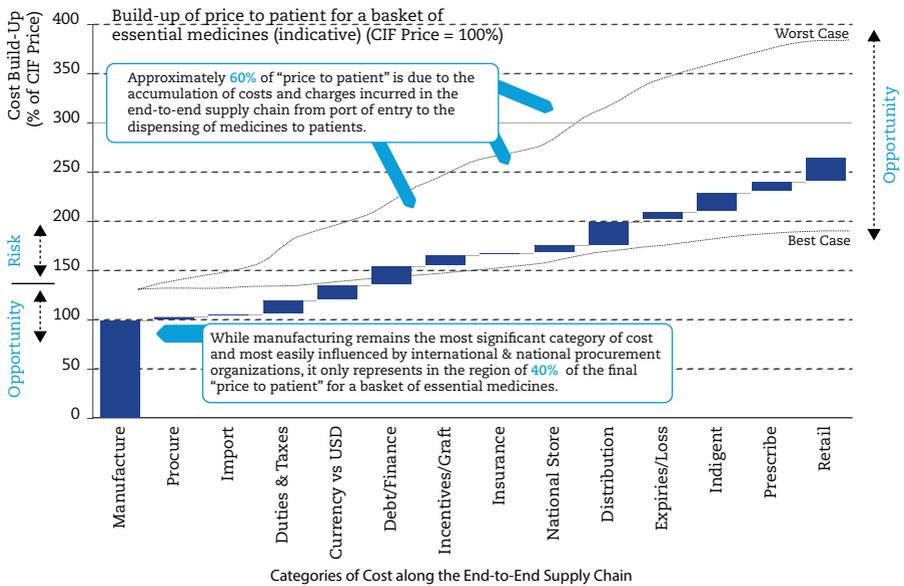
Poverty and wealth inequality creates or aggravates multiple barriers to biopharmaceutical products. In addition to poor health infrastructure in many low-income countries, there are often serious shortages of doctors, nurses, pharmacists, and other healthcare professionals. Challenges arise particularly 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 12 hospital beds per 10,000 inhabitants whereas the average for high-income countries is 41.¹⁹¹ 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.¹⁹²

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 other essential medicines, 60% of the final "price to patient" is determined by national and sub-national distribution.¹⁹³ 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).

191 World Bank (2015) Health Indicators. Washington DC: The World Bank Group. Accessed November 2019 Available at: <http://data.worldbank.org/indicator#topic-8>

192 World Bank (2018) Mortality Rate, under-5 (per 1,000 Live Births). Washington DC: The World Bank Group. Accessed November 2019 Available at: <http://data.worldbank.org/indicator/SH.DYN.MORT>

193 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 26: Examples of “Hidden” Costs of Pharmaceutical Procurement¹⁹⁴

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).

194 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>

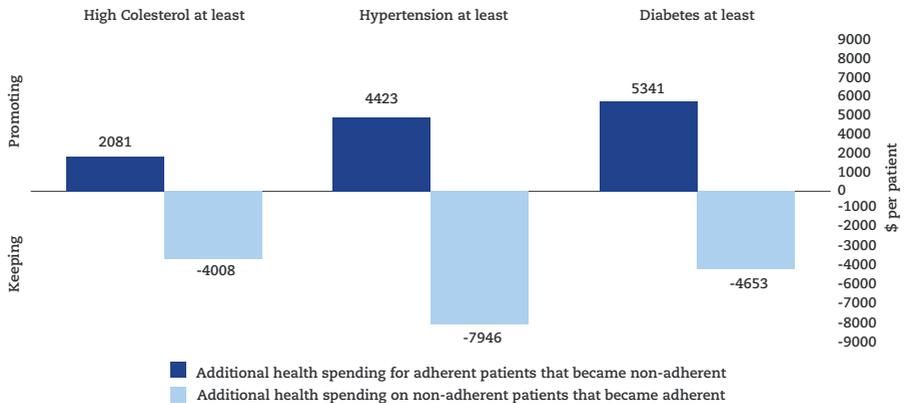
Table 9: Selected Infrastructure Indicators, 2015¹⁹⁵

	INFRASTRUCTURE (QUALITY OF TRADE AND TRANSPORT RELATED INFRASTRUCTURE (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	79.60	80,85	86,97
East Asia & Pacific	3.05	77,07	94,04
Europe & Central Asia	3.13	96,03	98,10
Heavily indebted poor countries	16.30	24,84	54,71
High income	84.60	99,17	99,45
Latin America & Caribbean	2.47	85,69	96,19
Least developed countries	20.80	32,16	61,79
Low income	2.07	29,12	56,07
Lower middle income	2.37	52,90	85,30
Middle income	55.00	66,05	90,18
North America	100.00	99,82	99,17
South Asia	2.33	46,50	88,16
Sub-Saharan Africa	2.20	28,27	57,55
Upper middle income	2.54	81,00	95,67
World	57.60	68,01	88,46

195 World Bank (2019) Infrastructure. Washington DC: The World Bank Group. Available at: <http://data.worldbank.org/topic/infrastructure> Accessed 2019

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.¹⁹⁶ 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.¹⁹⁷ Reasons for poor patient adherence can be high out-of-pocket expenditure and other barriers.¹⁹⁸ 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.¹⁹⁹

Figure 27: Total Spending on Health Services For Variations of Patients' Adherence²⁰⁰



196 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

197 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

198 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>

199 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

200 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

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.²⁰¹ 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.²⁰² 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.²⁰³ 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.²⁰⁴ 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).²⁰⁵ 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 \$10 billion to \$200 billion.²⁰⁶

201 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)

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

203 World Health Organization. "A study on the public health and socioeconomic impact of substandard and falsified medical products." (2017). Available at: <https://www.who.int/publications/i/item/study-on-public-health-socioeconomic-impact-substandard-falsified-medical-products-978-92-4-151343-2>

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

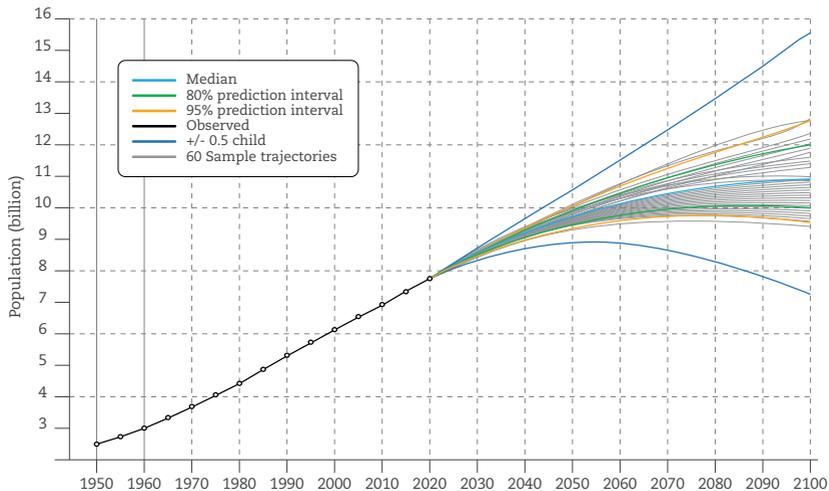
205 Ozawa S, Evans DR, Bessias S, et al. Prevalence and Estimated Economic Burden of Substandard and Falsified Medicines in Low – and Middle-Income Countries: A Systematic Review and Meta-analysis. *JAMA Netw Open*. 2018;1(4):e181662. doi:10.1001/jamanetworkopen.2018.1662

206 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. doi:10.1001/jamanetworkopen.2018.1662

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 a 10% increase from 7.7 billion in 2019, and will further grow to 9.7 billion in 2050.²⁰⁷

Figure 28: Total World Population, Past Trends and Future Predictions, 1950 – 2100²⁰⁸



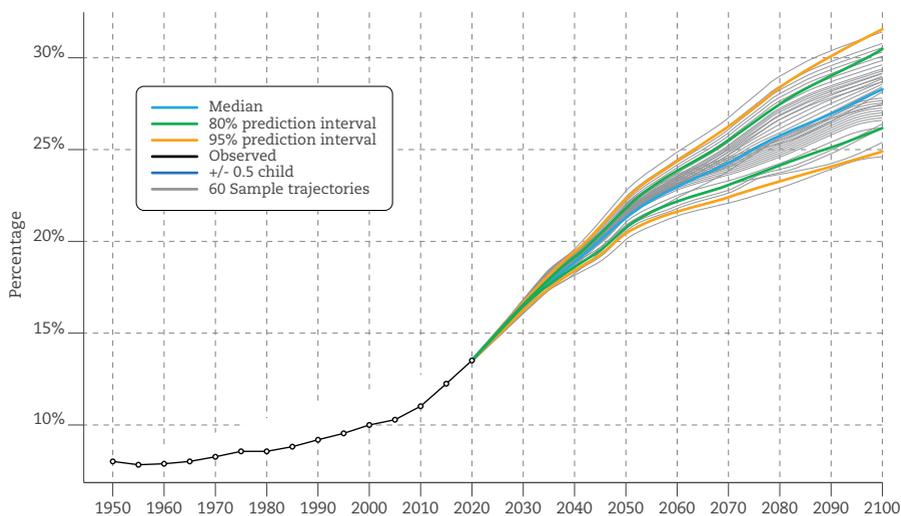
While the overall size of the population is increasing, the distribution of the individuals by age is also changing. Globally, people over 65 are the fastest-growing age group, and health systems must increasingly accommodate the needs of a population that requires more health interventions.²⁰⁹ By 2050, 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.²¹⁰

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

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

209 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/bitstream/handle/10665/329382/19978073-eng.pdf?sequence=1&isAllowed=y>

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

Figure 29: Percentage of World Population Aged 60 Years or Over²¹¹

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).²¹²

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, diabetes and chronic lung disease. NCDs are responsible for around 70% of all the deaths worldwide (see Figure 31).²¹³ Around three quarters of NCD deaths occur in low-and middle-income countries, which are facing a fast-growing burden of chronic diseases.²¹⁴

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

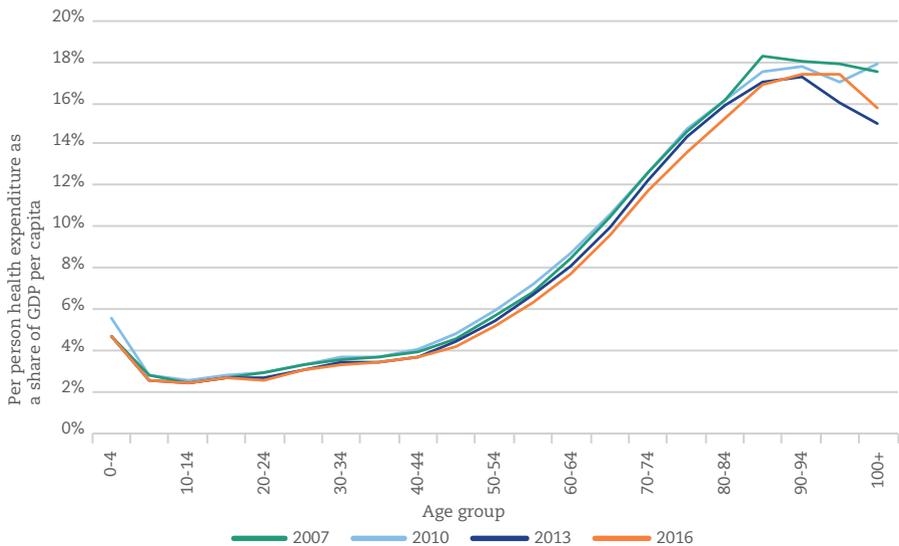
212 OECD (2017), Health at a Glance 2017: OECD Indicators, OECD Publishing, Paris Available at: https://www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance-2017_health_glance-2017-en

213 WHO Official Website. Noncommunicable diseases and their risk factors. Link: Available at: <https://www.who.int/ncds/introduction/en/> Accessed October 2019

214 WHO Official Website. Noncommunicable diseases and their risk factors. Link: Available at: <https://www.who.int/ncds/introduction/en/> Accessed October 2019

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.²¹⁵

Figure 30: Per Person Health Expenditure by Age Group, 2007-2016, EU average²¹⁶



215 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

216 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/bitstream/handle/10665/329382/19978073-eng.pdf>

Figure 31: Non Communicable Diseases as % of Causes of Death²¹⁷

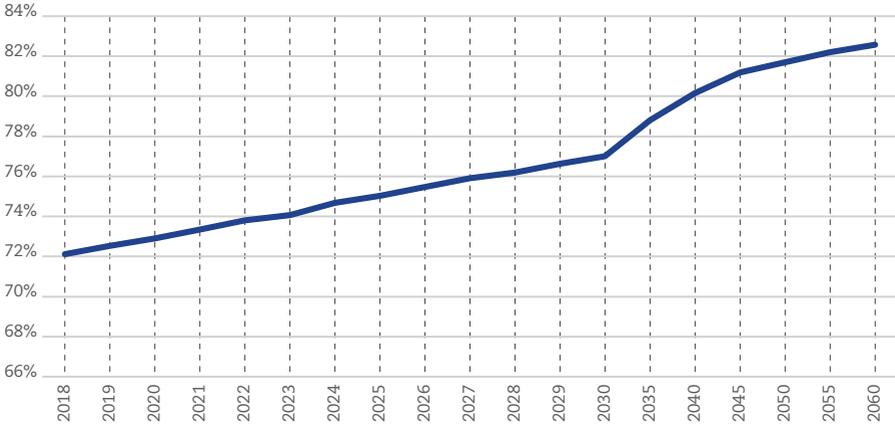
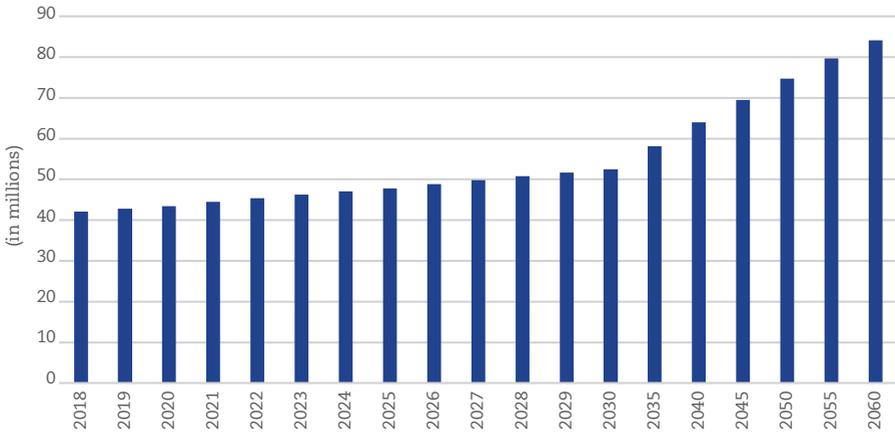


Figure 32: Number of deaths caused by Non Communicable Diseases²¹⁸



217 World Health Organization (2018). Projections of mortality and causes of death, 2017-2060. Available on the WHO website at Available at: http://www.who.int/healthinfo/global_burden_disease/projections/en/

218 World Health Organization (2018). Projections of mortality and causes of death, 2017-2060. Available on the WHO website at Available at: http://www.who.int/healthinfo/global_burden_disease/projections/en/

As outlined, chronic diseases and non-communicable diseases consume most health spending. In Switzerland, 80% of total healthcare costs are spent on NCDs.²¹⁹ 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.²²⁰

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.²²¹

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 250 collaborations between the innovative biopharmaceutical industry and more than 1200 partners to support the Sustainable Development Goals (SDGs).²²² 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.

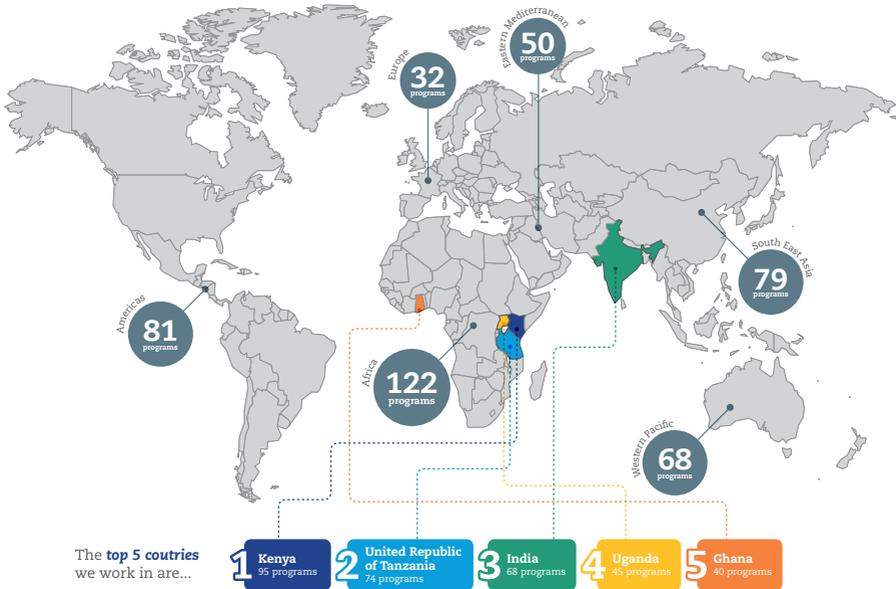
219 Swiss Federal Office of Public Health (FOPH) and Swiss Conference of the Cantonal Ministers of Public Health (CMPH) (2016). The challenge of non-communicable diseases. Available at: <https://www.bag.admin.ch/dam/bag/en/dokumente/nat-gesundheitsstrategien/ncd-strategie/ncd-kurzversion.pdf.download.pdf/ncd-kurzversion.pdf>

220 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://www.ncbi.nlm.nih.gov/pubmed/25595318>

221 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/>

222 Global Health Progress (2019). Official Website. Retrieved from Available at: <https://globalhealthprogress.org/>

Figure 33: Collaborations Between the Innovative Biopharmaceutical Industry and its Partners to Support the SDGs²²³

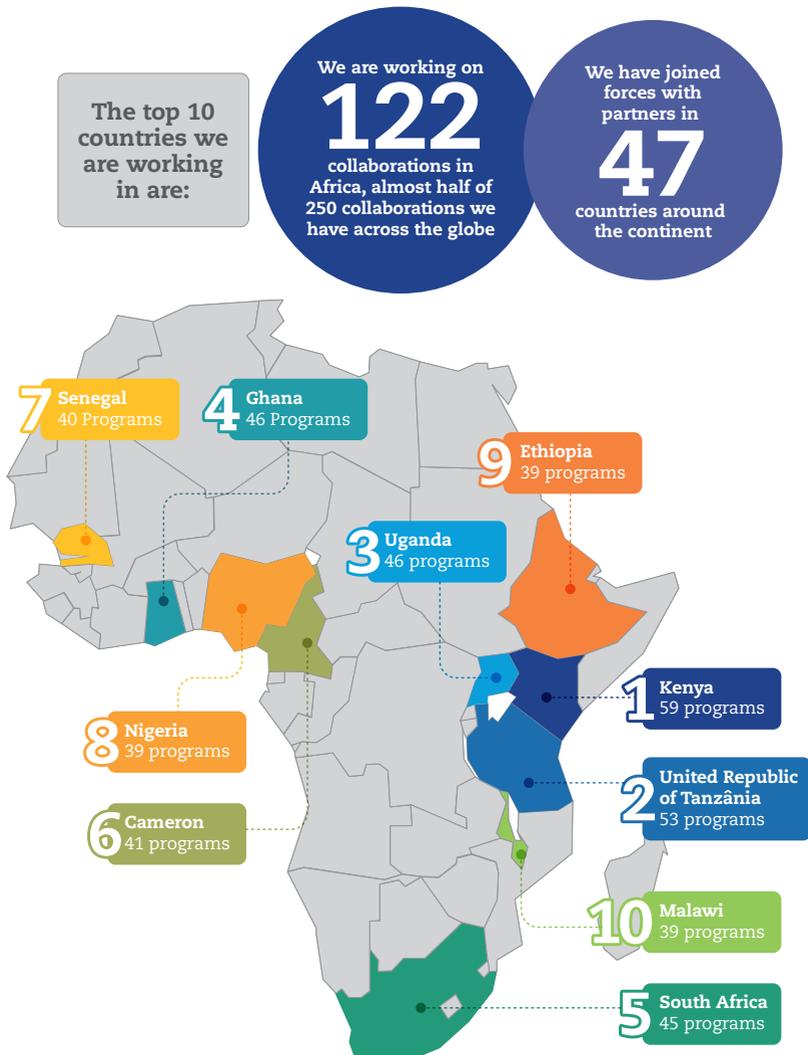


As Africa's population continues to grow, it is estimated to reach 2.5 billion people by 2050, investments in robust health systems are key to inclusive and sustainable growth. In 2019 African Union countries reiterated their pledge to allocate 15% of their annual budget to the health sector.²²⁴ The 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.

²²³ Global Health Progress (2019). Official Website: Available at: <https://globalhealthprogress.org/explore-our-collaborations/>

²²⁴ African Union. (2014). Africa Scorecard on Domestic Financing for Health. Available at: https://au.int/sites/default/files/newsevents/workingdocuments/34086-wd-au_scorecard_-_final_english.pdf

Figure 34: Collaborations in Africa Between the Innovative Biopharmaceutical Industry and its Partners to Support the SDGs²²⁵



ACCESS ACCELERATED

Launched in January 2017, Access Accelerated²²⁶ is an initiative that is implementing scalable and sustainable non-communicable disease (NCD) 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 106 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.



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 (R&D) investments, and technological capacity building. It is also a necessary foundation for the existence of the generic drug industry.

Table 10: Key Indicators of the Biopharmaceutical Industry's Economic Footprint in Europe²²⁷

	2000	2010	2015	2018
Production (EUR Million)	125,316	199,400	225,000	260,000
Exports* (EUR Million)	90,935	276,357	361,500	410,000
Imports* (EUR Million)	68,841	204,824	27,500	305,000
Trade Balance (EUR Million)	22,094	71,533	86,500	105,000
R&D Expenditure (EUR Million)	17,849	27,920	31,500	36,500
Employment (Units)	534,882	670,088	725,000	765,000
R&D Employment (Units)	88,397	117,035	118,000	115,000

**Includes Intra-EU Trade*

227 EFPIA (2019) The Pharmaceutical Industry in Figures. Brussels: European Federation of Pharmaceutical Industries and Associations, p 3 Available at: <https://www.efpia.eu/media/412931/the-pharmaceutical-industry-in-figures-2019.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 2014.²²⁸

In 2018, the biopharmaceutical industry directly added roughly the GDP of the Netherlands (USD 532 billion)²²⁹ 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.²³⁰

228 WifOR (2020). *The Global Economic Impact of the Pharmaceutical Industry*.

229 WifOR (2020). *The Global Economic Impact of the Pharmaceutical Industry*.

230 WifOR (2020). *The Global Economic Impact of the Pharmaceutical Industry*.

Figure 35: Development of the Gross Value Added and the Annual Growth Rate (Red Line) in Comparison to the Worldwide GDP (Blue Line)²³¹

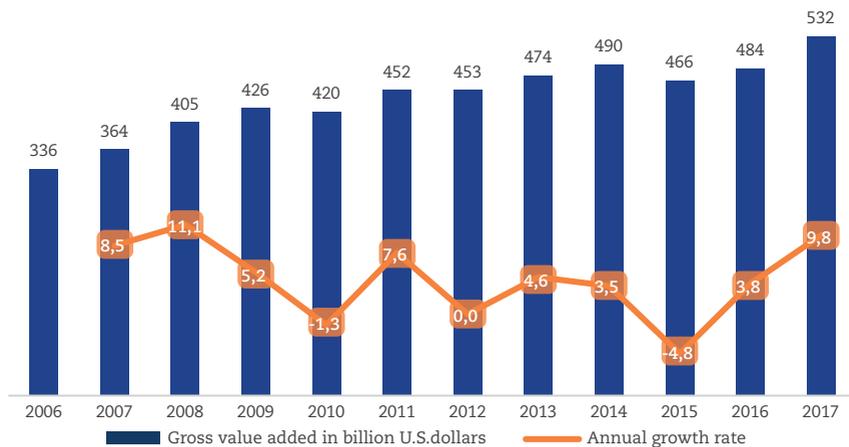
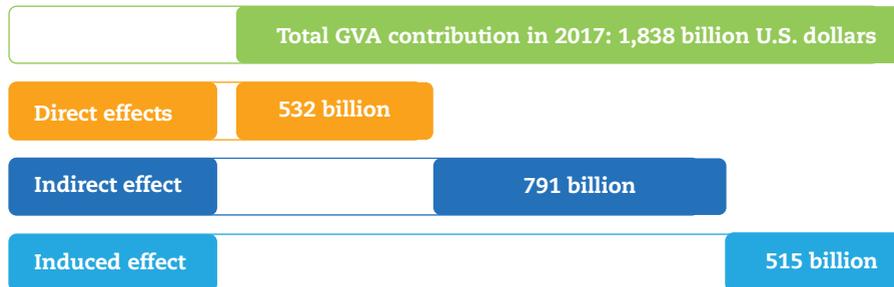


Figure 36: Direct, indirect and induced GVA effects triggered through economic activities of the global biopharmaceutical industry²³²



231 WifOR (2020). The Global Economic Impact of the Pharmaceutical Industry.

232 WifOR (2020). The Global Economic Impact of the Pharmaceutical Industry.

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.²³³ 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.²³⁴ Spending on services and supplies totaled USD 589 billion, translating into more than 4 million jobs in this country.²³⁵

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 37: Direct, Indirect and Induced Employment Effects Triggered Through Economic Activities of the Global Biopharmaceutical Industry²³⁶



233 WifOR (2020). The Global Economic Impact of the Pharmaceutical Industry.

234 Tecnomy 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>

235 Tecnomy 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>

236 WifOR (2020). The Global Economic Impact of the Pharmaceutical Industry.

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 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.²³⁷

Table 11: Selected Examples of Technology Transfer²³⁸

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

237 IFPMA (2011) Technology Transfer: A Collaborative Approach to Improve Global Health. Geneva: International Federation of Pharmaceutical Manufacturers and Associations, p. 17. Available at: http://www.ifpma.org/fileadmin/content/Publication/IFPMA_Technology_Transfer_Booklet_2011.pdf

238 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 38: Critical Factors for Creating Favorable Conditions for Biopharmaceutical Technological Transfers²³⁹



Trade in Biopharmaceuticals

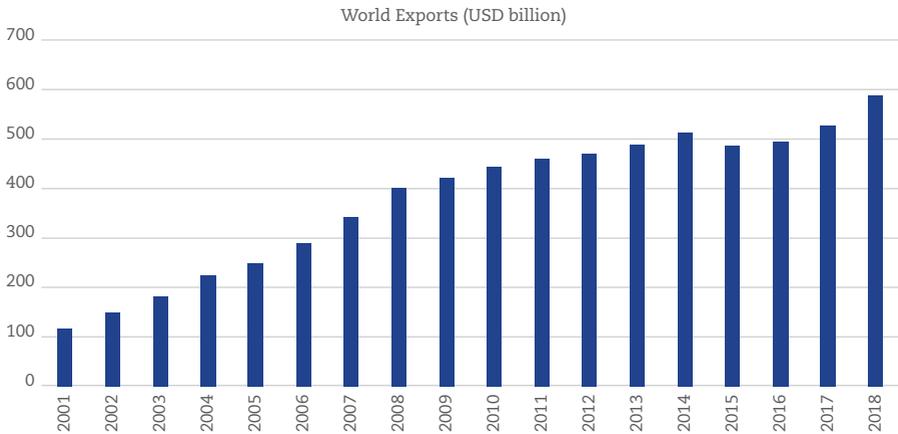
Global sales of biopharmaceutical products represent the international distribution of medical technology resulting from highly intensive R&D efforts in the exporting countries. At the same time, importing countries receive benefits through health improvements – even if they do not participate in R&D activities themselves.²⁴⁰

As medical innovation is transmitted across the world, it contributes to significant gains in average life expectancy²⁴¹ and quality of life.

239 Kiriya, N. (2011), "Trade and Innovation: Pharmaceuticals", OECD Trade Policy Papers, No. 113, OECD Publishing, Paris, Available at: <https://doi.org/10.1787/5kgdscrcv7jg-en>.

240 Kiriya, N. (2011), "Trade and Innovation: Pharmaceuticals", OECD Trade Policy Papers, No. 113, OECD Publishing, Paris, Available at: <https://doi.org/10.1787/5kgdscrcv7jg-en>.

241 Kiriya, N. (2011), "Trade and Innovation: Pharmaceuticals", OECD Trade Policy Papers, No. 113, OECD Publishing, Paris, Available at: <https://doi.org/10.1787/5kgdscrcv7jg-en>.

Figure 39: World Biopharmaceutical Products Exports 2001-2018²⁴²

The Biopharmaceutical Market of the Future

The IQVIA Institute predicts that the biopharmaceutical market will exceed USD 1.505-1.535 trillion by 2023, an increase of USD 300-330 billion from the USD 1.205 trillion recorded in 2018.²⁴³ This growth is mainly derived from market expansion in pharmerging countries²⁴⁴ and 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 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 2022.²⁴⁵

242 International Trade Center (ITC). International trade statistics 2001-2019, based on UN COMTRADE and ITC statistics. Retrieved from: Available at: <http://www.intracen.org/itc/market-info-tools/statistics-export-product-country/>

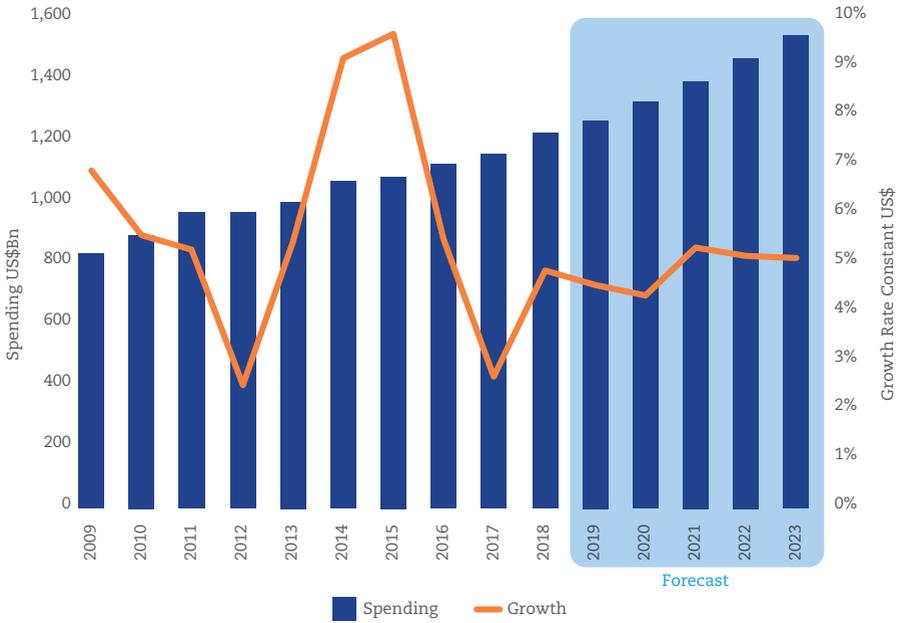
243 IQVIA Institute (2019) Global Medicines Use in 2019 and Outlook to 2023: forecasts and areas to watch. Available at: <https://www.iqvia.com/insights/the-iqvia-institute/reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023>

244 QuintilesIMS Institute (2019) Global Medicines Use in 2019 and Outlook to 2023: forecasts and areas to watch. Available at: <https://www.iqvia.com/insights/the-iqvia-institute/reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023>

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

245 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 40: Global Spending on Medicines²⁴⁶

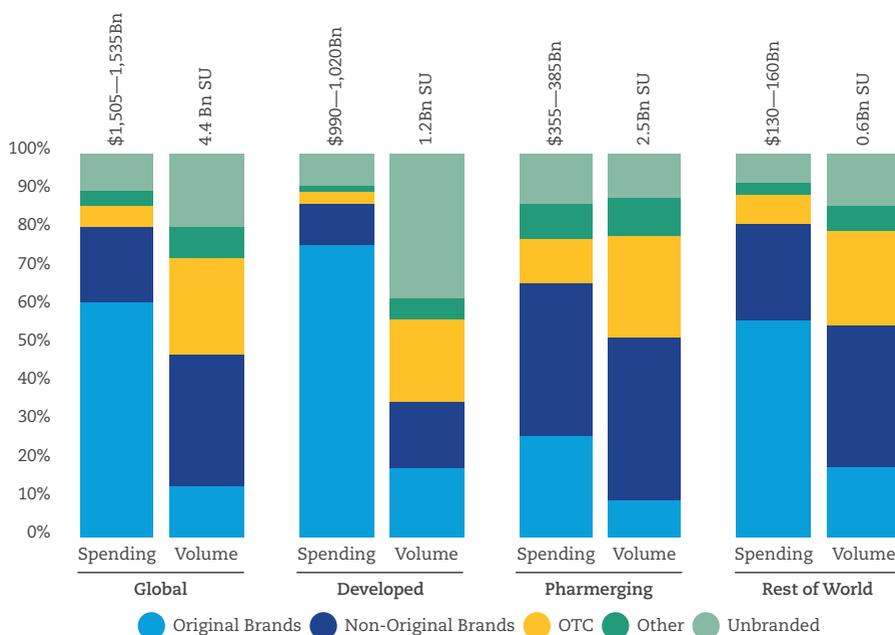


The United States share of global spending will increase from USD 485 billion in 2018 to around USD 625-655 billion in 2023, while the top 5 European countries' share of spending will grow from USD 178 billion to USD 195-225 billion. Meanwhile, pharmerging countries will spend USD 355-385 billion in 2023 from 286 in 2018.²⁴⁷ By 2022, the African continent is set to reach a total of over USD 25 billion.²⁴⁸

²⁴⁶ QuintilesIMS Institute (2019) Global Medicines Use in 2019 and: Outlook to 2023: forecasts and areas to watch. Available at: <https://www.iqvia.com/insights/the-iqvia-institute/reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023>

²⁴⁷ IQVIA Institute (2019) Global Medicines Use in 2019 and Outlook to 2023: forecasts and areas to watch. Available at: <https://www.iqvia.com/insights/the-iqvia-institute/reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023>

²⁴⁸ 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/>

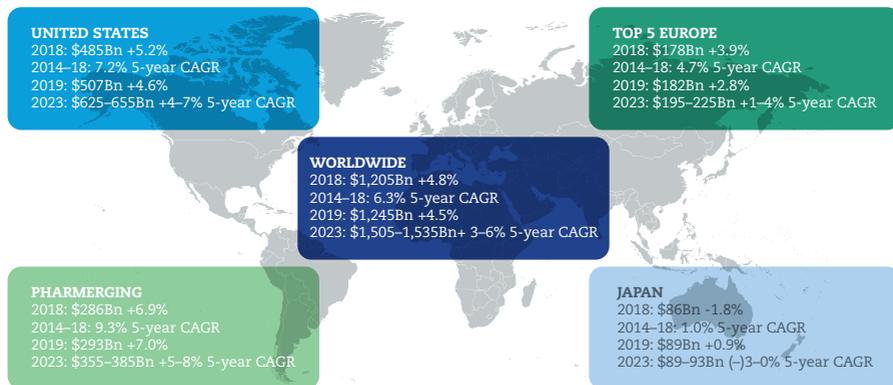
Figure 41: Spending by Geography²⁴⁹

Part of the biopharmaceutical industry's economic footprint includes branded products, which will account for over half of global biopharmaceutical growth in 2023.²⁵⁰ 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 121 billion, between 2019 and 2023. By 2023, biosimilar competition in the biologics market will be nearly three times larger than it is today, leading to consumer savings.²⁵¹ Through all these various pathways, the biopharmaceutical industry will continue to leave effective and beneficial footprints as they undertake public health challenges.

249 QuintilesIMS Institute (2019) Global Medicines Use in 2019 and: Outlook to 2023: forecasts and areas to watch. Available at: <https://www.iqvia.com/insights/the-iqvia-institute/reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023>

250 IQVIA Institute (2019) Global Medicines Use in 2019 and Outlook to 2023: forecasts and areas to watch. Available at: <https://www.iqvia.com/insights/the-iqvia-institute/reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023>

251 IQVIA Institute (2019) Global Medicines Use in 2019 and Outlook to 2023: forecasts and areas to watch. Available at: <https://www.iqvia.com/insights/the-iqvia-institute/reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023>

Figure 42: Spending by Geography, Segment and Disease Area in 2023²⁵²

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.

252 QuintilesIMS Institute (2019) Global Medicines Use in 2019 and: Outlook to 2023: forecasts and areas to watch. Available at: <https://www.iqvia.com/insights/the-iqvia-institute/reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023>

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.

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