

Chapter 2

Biological medicines — the major social and economic challenges

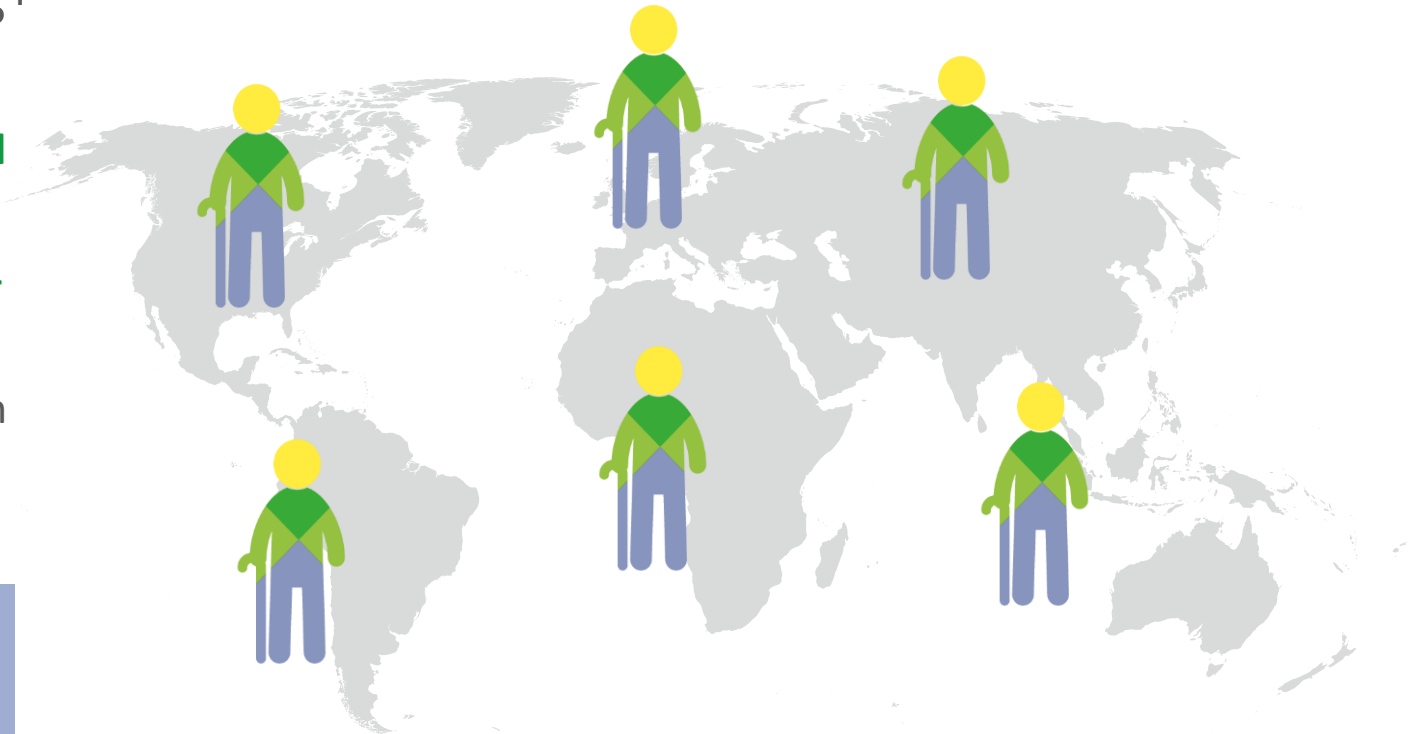
The global spend on pharmaceuticals continues to increase. The use of biological medicines offers new treatment choices to patients, but at a high financial cost. What are the challenges faced by payers and physicians in preserving access to biological medicines within a financially constrained healthcare system?

Access to cost-effective treatments increasingly important worldwide

2021 WHO World Health Statistics¹

- Globally, 7 of 10 leading causes of deaths in 2019 were **chronic diseases**, accounting for **73.6% of all deaths in 2019** (rising from 60.8% in 2000)¹
- **80%** of chronic disease deaths today occur in **low- and middle-income countries**²
- Chronic diseases accounted for a large proportion of deaths worldwide in 2019, as high as over **85% of mortality in High Income Countries**¹

With the global prevalence of age-related chronic diseases rising, **access to cost-effective medical treatment** will become increasingly important over the next decades worldwide



Health systems must adapt to meet the growing demand for the treatment of chronic conditions¹

In the US,
chronic conditions account for:

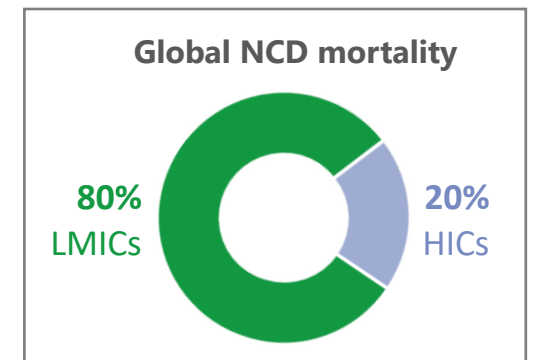


90% of all healthcare costs²

In Low- and Middle-Income Countries (LMICs)

Overall disease burden has transitioned from Communicable, Maternal, Neonatal and Nutritional diseases to **disease burden dominated by chronic conditions³**

80% of Non-Communicable disease (**NCD**) **deaths** (28 million) **occur in LMIC⁴**



Access to cost-effective treatment is paramount for the short, medium, and long-term sustainability of healthcare systems¹

Footnotes: *Medicare is a US federal health insurance program for elderly patients.

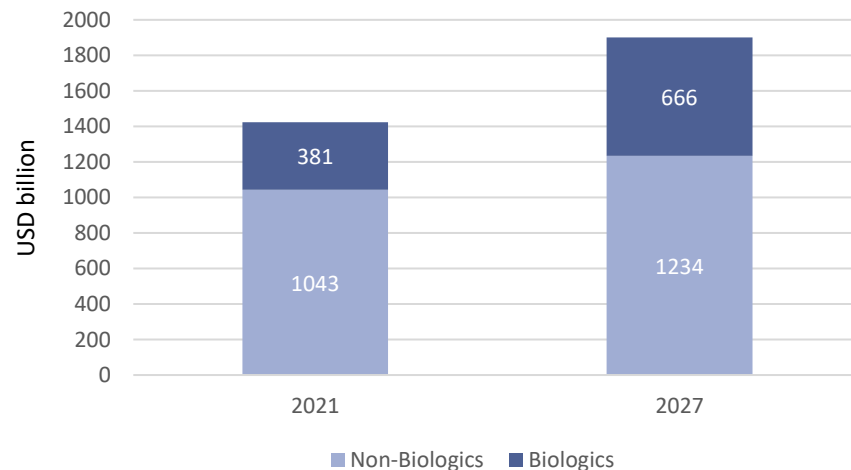
References: **1.** United Nations. World Aging Report. Available at: <http://bit.ly/1Y2LeF4>. Accessed March 2020; **2.** Centers for Disease Control and Prevention. Health and Economic Costs of Chronic Diseases. Available at <https://www.cdc.gov/chronicdisease/about/costs/index.htm>. Accessed June 2022; **3.** Global Burden of Disease Study 2019 - Viewpoint [Vol. 396, Issue 10258](#), p1135-1159, October 17, 2020, Accessed August 2021. **4.** Noncommunicable Diseases Prevention In Low- and Middle-Income Countries: An Overview of Health in All Policies (HiAP) 2021

doi: [10.1177/0046958020927885](https://doi.org/10.1177/0046958020927885) accessed Sept 2023.

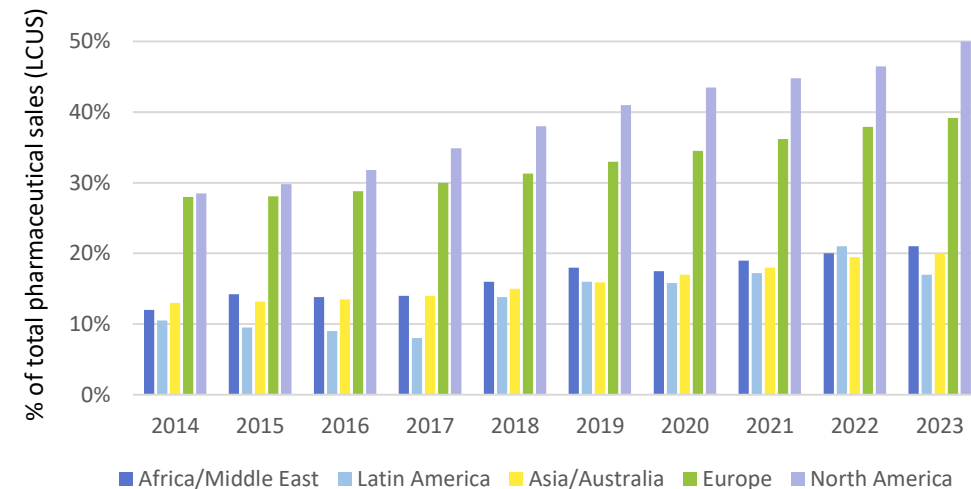
The use of biological medicines continues to grow consistently each year

- The **global biologic medicines spending** is expected to reach \$666 billion by 2027, and will account for **more than one third** of the **global medicines spending** by value¹

Global Pharmaceutical Market Size 2020 - 2027



Global biologics sales (by region, 2014-2023)



Inequitable access to biologic therapies is unequivocal: Europe and North America remain the predominant user of biologic medicines with 4 times as much spending as in Africa, Asia or Latin America²

The use of biological medicines continues to grow consistently each year



- In 2021, spending on specialty pharmaceuticals, including biosimilars, was **56% of total medicine spending in the U.S.**¹



- Biological medicines can cost up to **100,000 USD per year per patient**, negatively impacting on both patient choice and the healthcare system²



- The key growth area for medicines in the next five years is biotech (incl. novel medicines), which will represent **35% of global** spending³



- The **constrained payer environment** is triggering a range of initiatives designed to limit growth in healthcare budgets

Payers seek to provide and preserve access to cutting-edge medicines, but also need to ensure the long-term financial sustainability of their healthcare systems³

References: 1. The Use of Medicines in the U.S. 2022: Usage and Spending Trends and Outlook to 2026. Available at <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-use-of-medicines-in-the-us-2022/iqvia-institute-the-use-of-medicines-in-the-us-2022.pdf>. Accessed June 2022; 2. QuintilesIMS Institute for Healthcare Informatics. Delivering on the Potential of Biosimilar Medicines. 2016. Available at: <http://bit.ly/2q0bV2L>. Accessed July 2017. 3. IQVIA: The Global Use of Medicines 2023, Outlook to 2027. Available at <https://www.iqvia.com/events/2023/01/the-global-use-of-medicines-2023>. Accessed Sept 2023;

The long-term potential of biological medicines is hampered by their high cost

Cancer

- Cancer is the **second leading cause of death globally**, representing one in six deaths in 2020.
- Large numbers of cancer patients globally do not have access to timely quality diagnosis and treatment.
- In countries where health systems are strong, survival rates of many types of cancers are improving thanks to accessible early detection, quality treatment and survivorship care.¹



*In 2020, it has been estimated that the top 3 medicines used for cancer in Europe account for 15% of all cancer medicines sales and that the biosimilar options could bring a **cost reduction of EUR 2.4 billion in Europe per year.**²*

With more biological therapies used to treat cancer set to lose their market exclusivities in the next 5 years, countries will enjoy even greater opportunities to increase patient access to cancer treatment

Reference: 1. WHO, Available at: <https://www.who.int/news-room/fact-sheets/detail/cancer>, accessed June 2022.

2. Chapman, S., Paris, V., & Lopert, R. (2020). *Challenges in access to oncology medicines*. 123. <https://doi.org/10.1787/4b2e9cb9-en>.

The long-term potential of biological medicines is hampered by their high cost

Psoriasis

- Psoriasis affects more than 7.5 million Americans¹
- Access to biological medicines remains a challenge for many American patients due to factors such as **limited insurance coverage** and **prohibitive costs**²



A number of markets, including in High Income countries, restrict patient access to biological medicines due to their **cost** and **impact on pharmaceutical & healthcare budgets**³

References:

1. Psoriasis Prevalence in Adults in the United States *AMA Dermatol.* 2021;157(8):940-946. doi:10.1001/jamadermatol.2021.2007. Accessed October 2021;
2. Kamangar F, et al. *J Dermatolog Treat* 2013;24:13–24;
3. Putrik P, et al. *Ann Rheum Dis.* 2014;73:198–206.

The long-term potential of biological medicines is hampered by their high cost



Diabetes

- Worldwide, **more than 420 million adults** live with diabetes. This number is estimated to rise to 578 million by 2030 and to **700 million by 2045**.
- Diabetes, **can be treated with off-patent medicines** included in WHO's Model List of Essential Medicines (EML).
- Today, **only half of the 69 million patients** requiring insulin therapies **are able to access these medicines regularly**



The global potential for biosimilar insulins and analogs' use as a significant lever for greater access equity for patients living with diabetes remains largely untapped

Access to biological medicines is not uniform across Europe

- Compared with Western Europe, Central and Eastern Europe have experienced reduced access to biological medicines^{1,2}

Percentage of patients with Plaque Psoriasis treated with a biological medicine³:

European average

20%

Poland

1%

- Eligible patients continue facing **delays in accessing biologic therapies**⁴



Out of nearly **237.000 (100%)** diagnosed **Italian IBD patients**

- > 25.000 (11%)** are eligible for biologic therapies yet **remain untreated** (no medicine)⁴
- >42.000 (17.8%)** are eligible and not yet treated with a biological medicine⁴

This difference in access to biological medicines is largely due to general economic conditions²

A lack of treatment choice has a detrimental impact on patient care¹

Rheumatoid Arthritis (RA)

- There are around 1.5 million Americans living with RA, many of whom require biological medicines²
- On average, patients with RA can expect to pay in excess of 3,000 USD annually in co-payments for biological medicines⁴
- Nearly 10% of eligible patients in Italy are not accessing the biologic therapy they need to manage their rheumatoid arthritis⁴



“I use Enbrel. I couldn’t walk without it, and when I lost my healthcare insurance it was \$1,800 per box. I sold my car to pay for the Enbrel”⁵

**Mika Collins, Michigan
Patient with RA**

The availability of biosimilar medicines enhances competition, improves access to biological medicines, and contributes to the financial sustainability of healthcare systems⁵

References: 1. QuintilesIMS Institute for Healthcare Informatics. Delivering on the Potential of Biosimilar Medicines. 2016 ; 2. Arthritis by the Numbers Book of Trusted Facts & Figures 2020. Available at: <https://www.arthritis.org/getmedia/73a9f02d-7f91-4084-91c3-0ed0b11c5814/abtn-2020-final.pdf>. Accessed June 2022; 3. Jennifer Freeman, MD. RA Costs: What are Payment Options for Treating Rheumatoid Arthritis? Available at: <https://www.rheumatoidarthritis.org/treatment/costs/paying-for-treatment/> Accessed October 2020. 4. ASSESSMENT OF PATIENTS AFFECTED BY RHEUMATOID ARTHRITIS ELIGIBLE FOR BIOLOGIC AGENTS Degli Esposti L et al (2019) 5. Healthline: Rheumatoid arthritis patients bear heavy cost burden for biologic drugs. Available at: <http://bit.ly/2pQ63J9>. Accessed March 2020.;

Covid-19 pandemic disruption to cancer care exacerbated disparities, further delaying access to life-saving therapies

- In Europe, only 15% of patients are diagnosed at stage I, when they have a chance of survival of 90% and more.¹
- **22%** of global colorectal cancer cases are diagnosed at the **metastatic stage**, totaling roughly 400,000 patients each year worldwide²

“Approximately 50% of patients from Eastern Europe had to wait longer than a month to receive treatment, in contrast to ~30% from other European countries. All groups emphasised the unmet need for support from psychologists and other patients³”

Mortality in patients living with cancers is expected to increase over the next few years as a direct consequence of delays in screening, diagnosis and access to first line biologic therapy.⁴ Use of available biosimilar medicines will contribute to ensuring accessibility and sustainability.

1. DiCE <https://digestivecancers.eu/dice-releases-the-crc-screening-roadmap/>; 2. Thierry A.R. et al. *JAMA Netw Open*. 2021;4(9):e2124483. doi:10.1001/jamanetworkopen.2021.24483 3. DiCE interview Cancer World <https://cancerworld.net/covid-19-is-delaying-diagnosis-but-getting-back-to-normal-is-not-what-we-need/> 3. Maravic Z, Rawicka I, Benedict A, et al **A European survey on the insights of patients living with metastatic colorectal cancer: the patient journey before, during and after diagnosis - an Eastern European perspective** *ESMO Open* 2020;5:e000850. doi: 10.1136/esmoopen-2020-000850; 4. The BMJ Visual Abstracts Mortality due to cancer treatment delays <http://bit.ly/BMJctd>

Biological medicines — the major social and economic challenges



Population ageing and the rising prevalence of **chronic conditions** is increasing the pressure on health systems^{1,2}



Global spend on pharmaceutical products continues to **increase**, and is expected to reach 1,9 trillion USD by 2027³



Biological medicines represent an **important but expensive** proportion of new drugs⁴



Payers seek to provide and preserve access to cutting-edge medicines, but also need to **ensure the long-term financial sustainability** of their healthcare system³



Access to biological medicines is not uniform, and is **often restricted** by their high cost^{4,5}



The **availability** of biosimilar medicines enhances competition, improves access to biological medicines, and contributes to the financial sustainability of healthcare systems⁶

References: 1. United Nations. World Aging Report. Available at: <http://bit.ly/1Y2LeF4>. Accessed March 2020; 2015 WHO Global Report: Preventing chronic diseases: a vital investment https://www.who.int/chp/chronic_disease_report/presentation/en/ Accessed October 2020; 2. CDC - Healthy Aging: Promoting Well-being in Older Adults Available at: <https://www.cdc.gov/grand-rounds/pp/2017/20170919-senior-aging.html>; 3. . IQVIA: The Global Use of Medicines 2023, Outlook to 2027. Available at <https://www.iqvia.com/events/2023/01/the-global-use-of-medicines-2023>. Accessed Sept 2023; 4. QuintilesIMS Institute for Healthcare Informatics. Global Medicines Use in 2020: Outlook and Implications. 2015. Available at: <http://bit.ly/1H9Nze3>. Accessed March 2020; 5. Orlewska L, et al. *Med Sci Monit*. 2011;17:SR1-13; 6. European Commission – [What you need to know about biosimilar medicinal products](#). Accessed October 2021