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?

1. 2015 WHO Global Report: Preventing chronic diseases: a vital investment
Access to cost-effective treatments increasingly important worldwide

2021 WHO World Health Statistics

- 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)
- 80% of chronic disease deaths today occur in low- and middle-income countries
- Chronic diseases accounted for a large proportion of deaths worldwide in 2019, as high as over 85% of mortality in High Income Countries

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 conditions

In the US, **chronic conditions** account for:

- **90%** of all healthcare costs

In Low and Medium Income Countries (LMICs)

- A rapid **shift** of disease burden
- Transitioning from Communicable, Maternal, Neonatal and Nutritional diseases to disease burden dominated by **chronic conditions**

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

**Footnotes:**

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

**References:**

The use of biological medicines continues to grow consistently each year

- The **global biologic medicines spending** is expected to reach $620 billion by 2026, and will account for more than one third of the global medicines spending by value\(^1\)
- In 2021, spending on specialty pharmaceuticals, including biosimilars, was **56% of total medicine spending in the U.S.**\(^2\)
- Biological medicines can cost up to **100,000 USD per year per patient**, negatively impacting on both patient choice and the healthcare system\(^3\)
- By 2025, the number of **new biological treatment** launched each year in Europe will double in key therapy areas\(^1\)
- 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 systems\(^3\)

**References:**
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.

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

Psoriasis

- Psoriasis affects more than 7.5 million Americans\(^1\)
- 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:

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 rheumatoid arthritis (RA) treated with a biological medicine: |
|---------------------------------|----------------|
| Western Europe*                 | 11–12%         |
| Central & Eastern Europe**      | 1–5%           |

This difference in access to biological medicines is largely due to general economic conditions\(^2\)

Footnotes: *Based on values from 2009; **Based on values from 2011.
A lack of treatment choice has a detrimental impact on patient care\(^1\)

Rheumatoid Arthritis (RA)

- There are around 1.5 million Americans living with RA, many of whom require biological medicines\(^2\)
- On average, patients with RA can expect to pay in excess of 3,000 USD annually in co-payments for biological medicines\(^4\)
- Nearly 10% of eligible patients in Italy are not accessing the biologic therapy they need to manage their rheumatoid arthritis\(^4\)

“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 systems\(^5\)

References:
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.

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 1.8 trillion USD in the near future\(^3\)

Biological medicines represent an important but expensive proportion of new drugs\(^4\)

Payers seek to provide and preserve access to cutting-edge medicines, but also need to ensure the long-term financial sustainability of their healthcare system\(^3\)

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 systems\(^6\)