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 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 countries²

• Chronic diseases accounted for a large proportion of deaths worldwide in 2019, as high as over 85% of mortality in High Income Countries¹

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\(^1\)

In the US, chronic conditions account for:

- 90% of all healthcare costs\(^2\)

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 conditions\(^3\)

80% of Non-Communicable disease (NCD) deaths (28 million) occur in LMIC\(^4\)

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

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 value\(^1\)

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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 America\(^2\)

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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

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\(^1,2\)

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<tr>
<th>Percentage of patients with Plaque Psoriasis treated with a biological medicine(^3):</th>
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<td>European average</td>
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<td>20%</td>
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- 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 medicine\(^4\)

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

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\(^4\)

The availability of biosimilar medicines enhances competition, improves access to biological medicines, and contributes to the financial sustainability of healthcare systems\(^5\)

References:
4. ASSESSMENT OF PATIENTS AFFECTED BY RHEUMATOID ARTHRITIS ELIGIBLE FOR BIOLOGIC AGENTS Degli Esposti L et al (2019)
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.  

- 22% of global colorectal cancer cases are diagnosed at the metastatic stage, totaling roughly 400,000 patients each year worldwide.

“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 patients.”

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. 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 1,9 trillion USD by 2027\(^3\)

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

### References:

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\(^6\)