



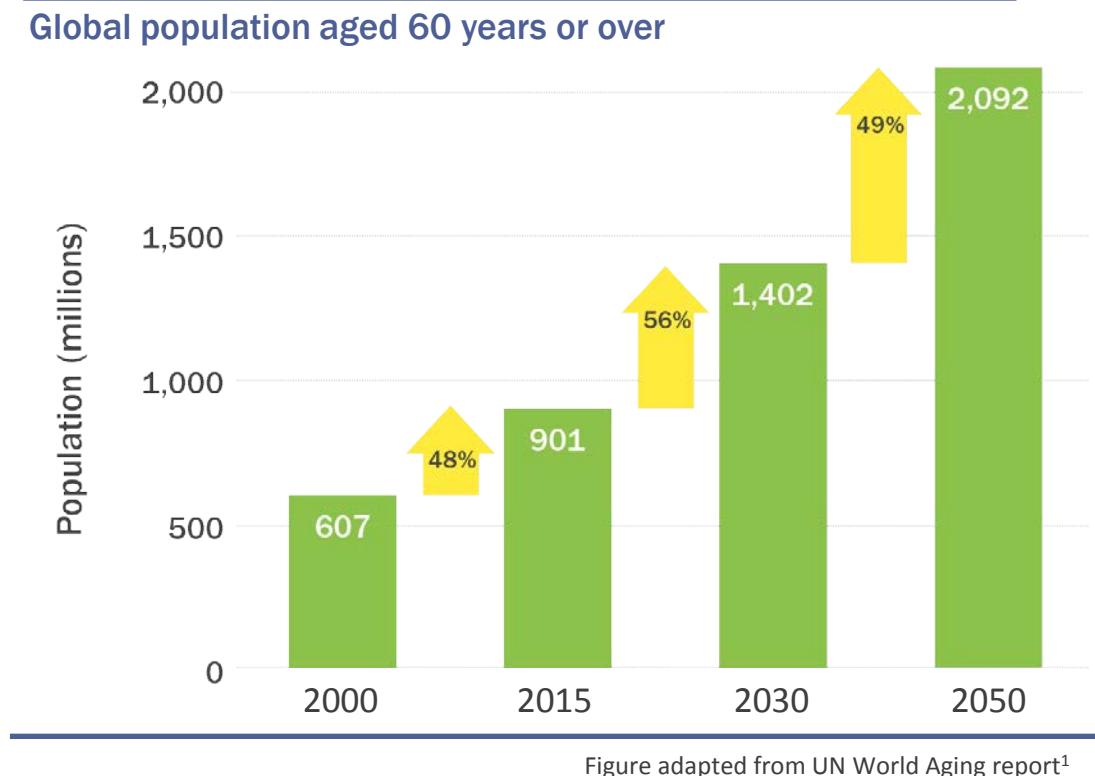
Chapter 2

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?

Population aging is increasing the pressure on health systems

- Between 2015 and 2030, the number of people in the world aged 60 years or over is projected to grow by 56%, from 0.9 billion to 1.4 billion¹
- By 2050, this population is projected to increase to nearly 2.1 billion; more than double the size it was in 2015¹



Approximately 80% of adults aged 60 years or over have at least one chronic condition²

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

In the US, chronic conditions account for:



two thirds of all healthcare costs²



and **93% of Medicare*** spending³



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

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

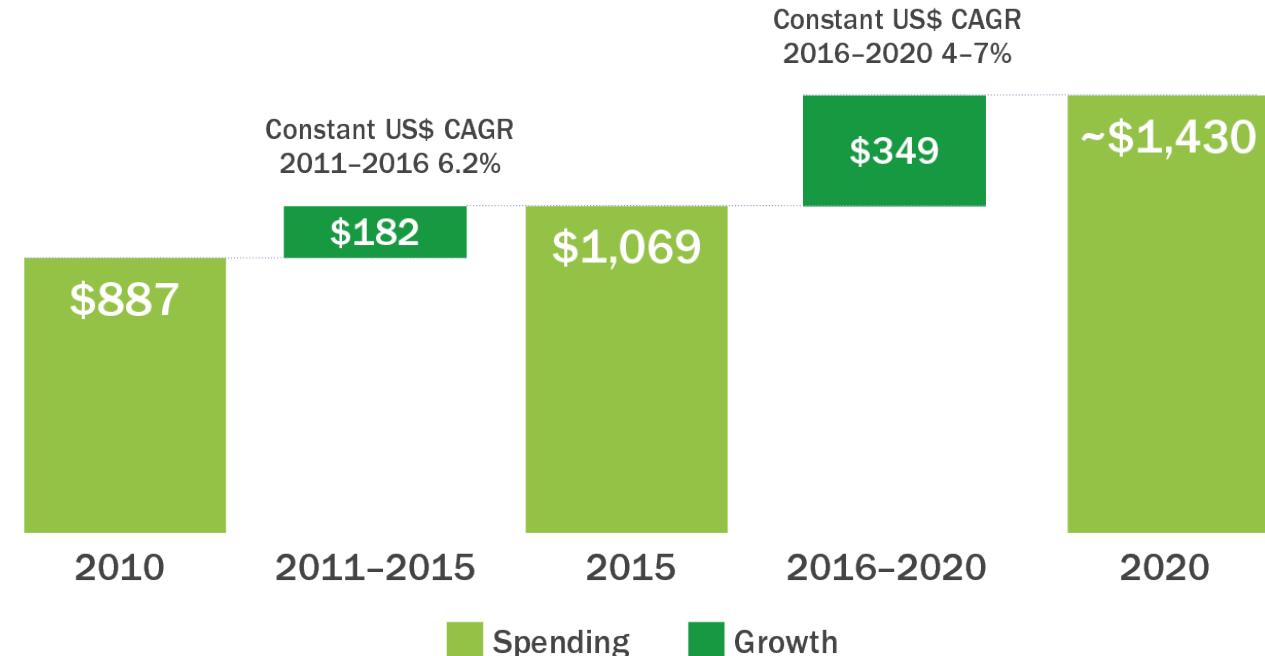
Footnotes: *Medicare is a US federal health insurance program for elderly patients.

References: 1. United Nations. World Aging Report. Available at: <http://bit.ly/1Y2LeF4>. Accessed April 2017; 2. Centers for Disease Control and Prevention. The State of Aging and Health in America 2013. Available at: <http://bit.ly/2q3y8w0>. Accessed July 2017; 3. Chronic Conditions Among Medicare Beneficiaries, Chart Book 2012. Available at: <http://go.cms.gov/2kmLP9a>. Accessed December 2017.

Progress in therapeutic options is accompanied by serious budgetary implications

- 225 new products are expected to come to market between 2016 and 2020¹
- Global spending on medicines is expected to reach 1.4 trillion USD by 2020*²

Global spending and growth (billions), 2010-2020



A large proportion of the new therapeutic options under development are biological medicines¹

Abbreviations: CAGR, compound annual growth rate.

Footnotes: *Due to exchange rate effects, growth was reduced by 100 billion USD and increased by 268 billion USD in 2011–2015 and 2016–2020, respectively.

References: 1. QuintilesIMS Institute for Healthcare Informatics. Global Medicines Use in 2020: Outlook and Implications. 2015. Available at: <http://bit.ly/1H9Nze3>. Accessed July 2017; 2. QuintilesIMS Institute for Healthcare Informatics. Delivering on the Potential of Biosimilar Medicines. 2016. Available at: <http://bit.ly/2q0bV2L>. Accessed July 2017.

The use of biological medicines continues to grow consistently each year



- **Biological medicines** are expected to account for **30%** of **new drug products** launched between 2016 and 2020¹



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



- By 2020, a number of diseases will have **new biological treatment options** available across developed markets¹



- The **constrained payer environment** is triggering a range of initiatives designed to limit growth in healthcare budgets³

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

Psoriasis

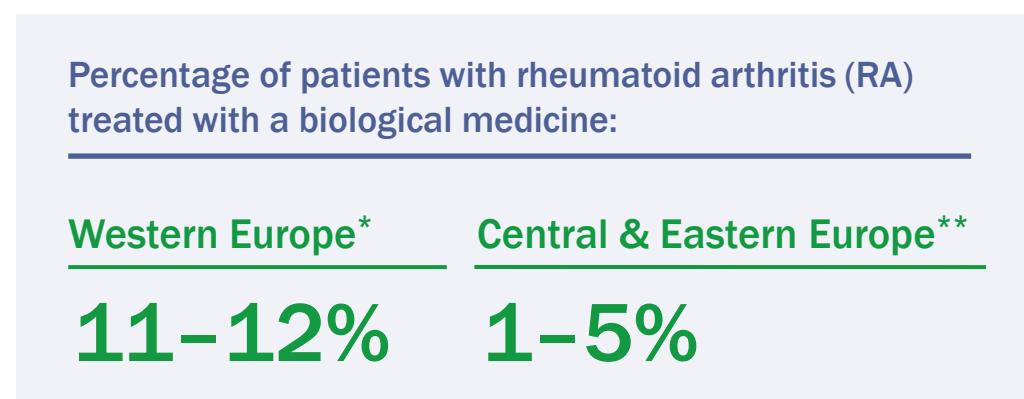
- Psoriasis affects approximately **7.4 million Americans¹**
- Access to biological medicines remains a challenge for many American patients due to factors such as **limited insurance coverage and prohibitive costs²**
- Up to 24% of dermatologists in key EU countries and Canada felt that **cost is a key barrier** to using biological medicines in psoriasis³



A number of markets, including Western markets, restrict patient access to biological medicines due to their cost⁴

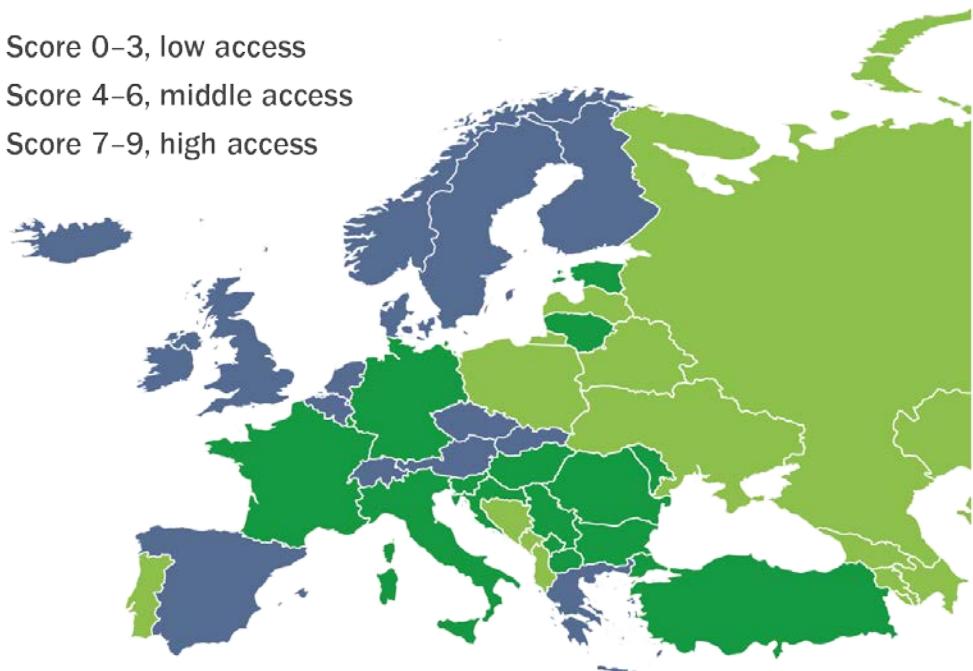
Access to biological medicines is not uniform across Europe

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



Level of access to biological treatments for RA across Europe³

- Score 0-3, low access
- Score 4-6, middle access
- Score 7-9, high access



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

Footnotes: *Based on values from 2009; **Based on values from 2011.

References: 1. Kobelt G, Kasteng F. Access to innovative treatments in rheumatoid arthritis in Europe. Available at: <http://bit.ly/Shamf8>. Accessed July 2017; 2. Orlewska L, et al. *Med Sci Monit*. 2011;17:SR1-13; 3. Putrik P, et al. *Ann Rheum Dis*. 2014;73:198–206.

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

Rheumatoid Arthritis (RA)

- There are around 1.3 million Americans living with RA, many of whom require biological medicines²
- It is estimated that the US market for RA treatment will increase from 6.4 billion USD in 2013 to 9.3 billion USD by 2020³
- On average, patients with RA can expect to pay in excess of 2,700 USD annually in co-payments for biological medicines⁴



"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

Biological medicines – the major social and economic challenges



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



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



Global spend on pharmaceutical products continues to **increase**, and is expected to reach 1.4 trillion USD in the near future³



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



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



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



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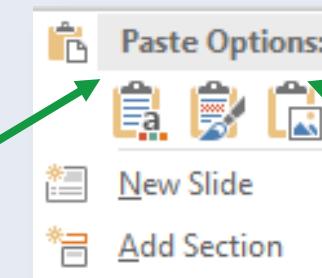
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