



Removing access barriers

in Central and Eastern Europe

How can we ensure equitable access to
medicines for all European patients?

April 2022



1. Introduction

Equitable access to medicines and a sustainable healthcare system remain a challenge for many European governments. Multiple factors, such as a growing and ageing population, increased chronic disease burden, the increased cost of new innovative medicines, have put pressure on healthcare budgets across Europe. In this context, generic and biosimilar medicines play an essential role in promoting pharmaceutical innovation and, by introducing competition, contribute to the affordability, sustainability, and accessibility of healthcare systems. That is why the Pharmaceutical Strategy for Europe highlights the need for policies that support generic and biosimilar competition with appropriate market mechanisms, as well as the removal of barriers that delay their timely entry to market. However, in Central and Eastern Europe, underinvestment in healthcare along with inefficiencies in the way available resources are allocated, threaten the sustainability of healthcare systems and access to medicines for patients, which undermines public health. Therefore, governments should focus on measures to support the use of generic and biosimilar medicines by implementing sustainable policies with clear benefits for stakeholders.



2. Generic medicines

Uptake of generic medicines

The increased use of generic medicines presents an opportunity to improve healthcare system value, either by providing access for substantially more patients at the same spending level (higher cost-effectiveness) or by decreasing expenditure at equal treatment rates. However, not all countries in Central and Eastern Europe reach sufficient levels of generic medicine penetration (chart 1), so more can and should be done to increase the use of generic medicines and increase the efficiency of healthcare systems.

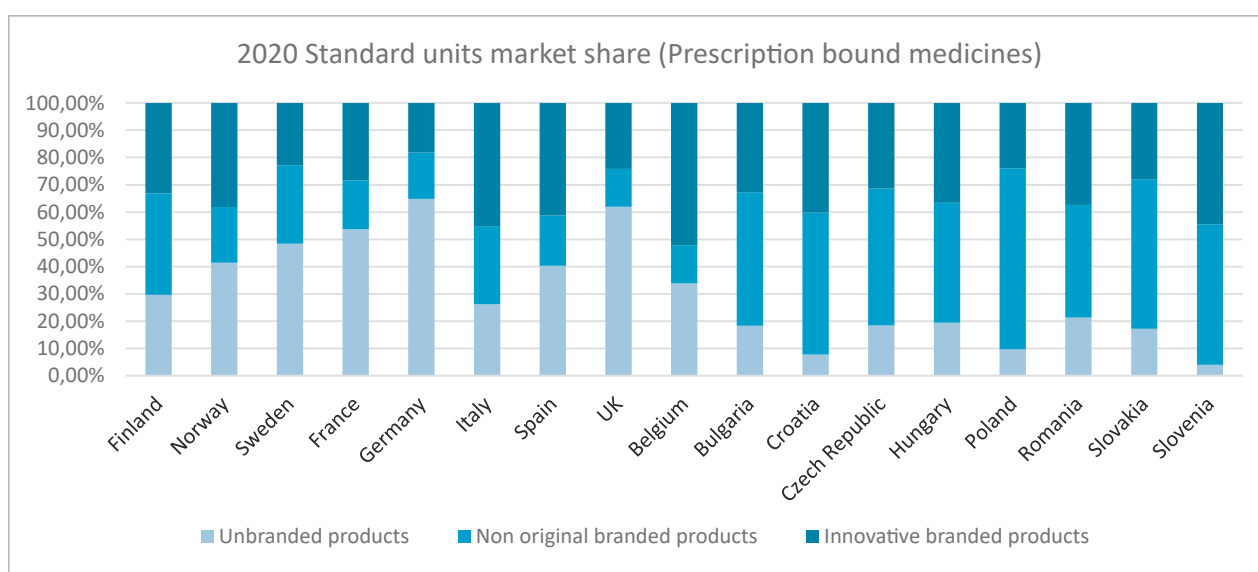


Chart 1: Standard unit market share for unbranded products, non-original branded products and innovative branded products. Source: IQVIA MIDAS MAT Q4 2020.

Pricing policies for generic medicines

Generic medicines represent almost 70% of prescribed medicines in Europe while only accounting for less than 30% of pharmaceutical expenditure. However, despite their relatively small weight on healthcare expenditure, generic medicines have frequently been subjected to short-term and drastic cost-containment measures and extreme price pressure to minimize the expenditure as much as possible, such as external reference pricing (ERP). ERP, also known as international reference pricing (IRP), is a direct price control mechanism, whereby a government considers the price of a medicine in other countries to inform or establish the price in its own country³.

Chart 2 shows the countries where the application of ERP impacts the price of generic medicines, highlighting its frequent use in Central and Eastern Europe⁴. In addition, the pricing formula of the lowest price among reference countries (Bulgaria, Poland, Romania) or the average of the lowest prices in reference countries (Czech Republic, Slovakia) is often applied in Central and Eastern Europe. This, in combination with other pricing policies, might result in artificially low prices. In some cases, the prices of generic medicines might even reach a level below which it is commercially sustainable for the pharmaceutical manufacturers.

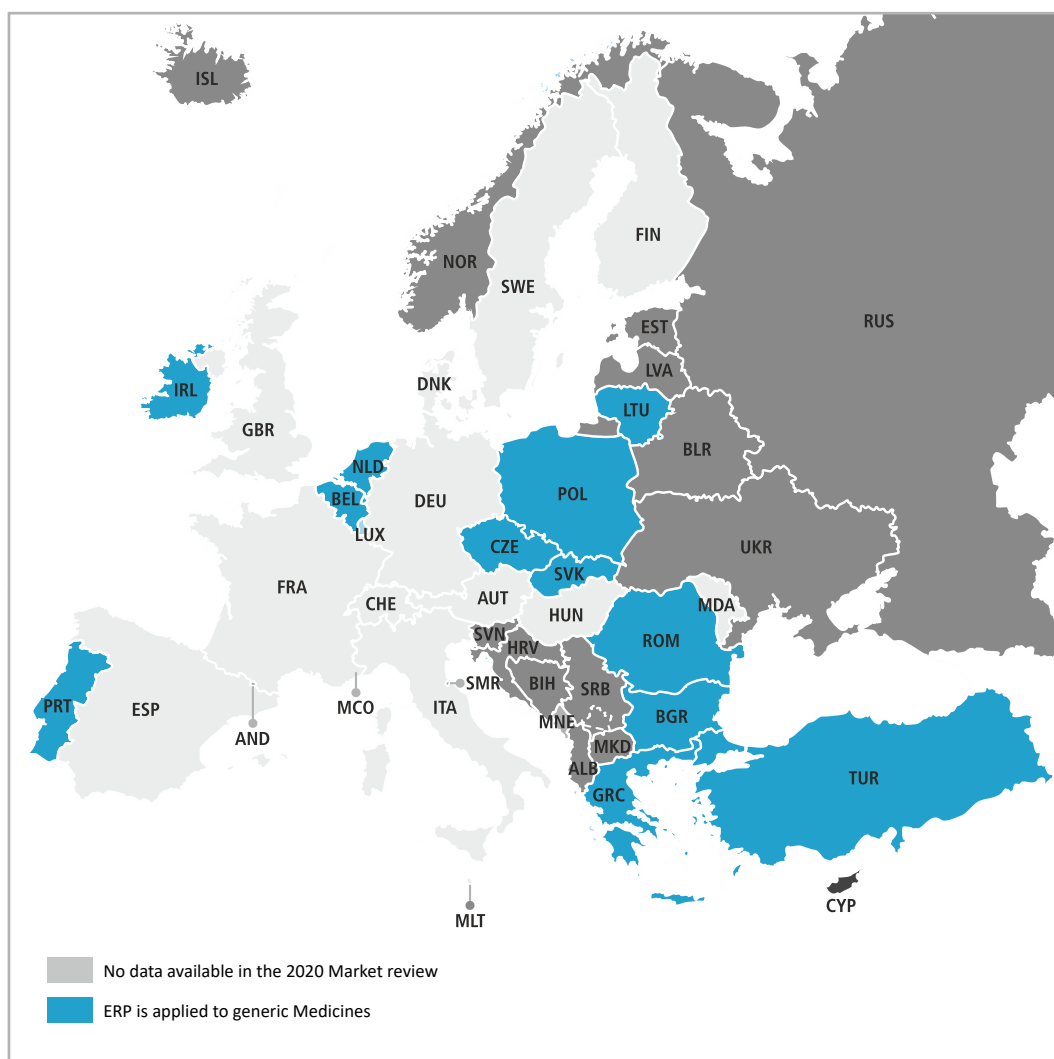


Chart 2: Application of external reference pricing to set the price of generic medicines. Countries highlighted in blue apply ERP to generic medicines. Source: 2020 Generic market review (Medicines for Europe).

In Romania, the extreme pressure on prices, set by the combination of the clawback mechanism and external reference pricing, has led to the market withdrawal of many medicines, including over 2000 generic medicines. In addition, these unsustainable pricing policies, could encourage manufacturers to not launch or to delay launching generic medicines in Romania, thereby harming access to medicines for patients.

In Bulgaria, pharmaceutical expenditure is growing rapidly due to the entry of high-cost innovative medicines. In 2017, out-of-pocket (OOP) spending was the highest in the EU (46.6 % compared with 15.8 % on average) and is mainly driven by co-payments on pharmaceuticals⁵ This causes decreased access to medicines and problems with treatment adherence for patients in Bulgaria.

In Slovakia, prices of generic medicines are set based on a combination of external reference pricing and mandatory price reductions upon the market entry of the generic medicine. These unsustainable pricing policies have led to the deregistration of many generic medicines, including first line treatments for cancer. For this reason, the Slovakian Minister of Health has published an appeal to the Market Authorisation Holders of

some common oncological treatments, namely cisplatin, fluorouracil, irinotecan, docetaxel and temozolomide, to apply for pricing and reimbursement and to ensure the availability of these medicines for patients in Slovakia⁶.

Off-patent medicines already operate in a highly competitive market environment. Therefore, external reference pricing is not a suitable price control mechanism to ensure an appropriate and competitive price environment for generic medicines. Importing prices from other EU countries distorts the competitive nature of these markets. This is of particular importance for the CEE region, where the introduction of generic medicines has significantly increased patient access to medicines. Therefore, any delayed launch or market withdrawals of generic medicine because of ERP might seriously affect the wellbeing of patients. Competitive and dynamic pricing (e.g. the ladder policy model, which allows for price adjustment when the market becomes too consolidated), combined with policies to incentivise the use of generic and biosimilar medicines (i.e. demand-side policies), would be a more sustainable pricing model benefiting patient access to affordable, high-quality and essential medicines.





3. Biosimilar medicines

Patient access to biological treatments

The experience to date shows that biosimilar medicines bring competition to the pharmaceutical market, leading to a significant increase in patient access to high quality treatments. Not only can more patients become eligible for treatment, but they can also be used earlier in the treatment course, therefore enabling a better quality of life for patients. In addition, there are invaluable opportunities for healthcare systems to significantly reduce equity gaps across Europe. Data shows that there is still an opportunity to increase patient access to biological treatments and in turn increase long-term sustainability of the healthcare system, especially in Central and Eastern Europe.

Oncology

Europe represents less than 10% of the world's population, but accounts for a quarter of all cancer cases⁷. In addition, differences in cancer survival rates across the EU exceed 25% and timely access to treatment is unequal. A growing number of new cancer therapies are biological molecules and today, the existing biosimilar competition in cancer care has led to an increase in the number of patients that healthcare systems can treat while

reducing significant equity gaps across Europe. However, there are well-identified barriers for patients' access to oncology treatment in Europe, especially in Central and Eastern Europe. For example, the number of standard units (1 standard unit equals 1 tablet/syringe)⁸ per capita for Rituximab for all Central and Eastern European countries is below the average of the Nordic countries within the scope (chart 3).

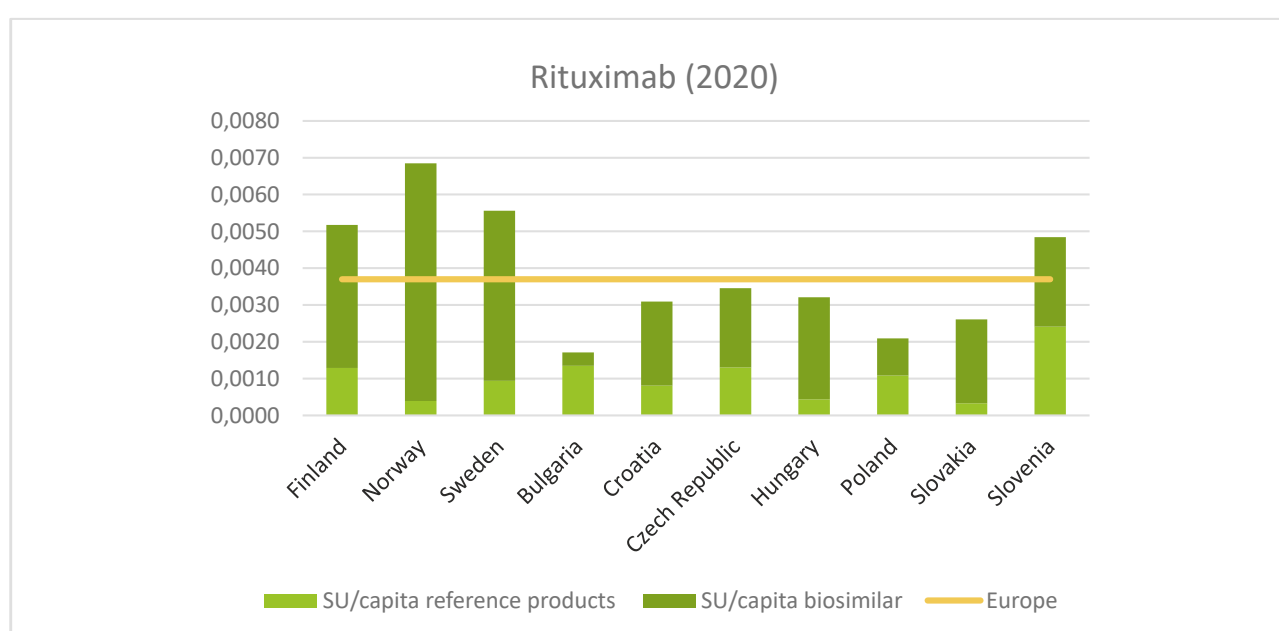


Chart 3: Number of standard units per capita for rituximab in 2020. Source: IQVIA MIDAS MAT Q4 2020.





In Romania, participation of Marketing Authorisation Holders of the biosimilar Rituximab in the national tender was blocked through extension of the ongoing tender. The Competition Council stated that the government lost around 1 million USD/month for not reopening the tender. Therefore, procurement processes should open when the medicines are about to lose their patent protection/loss of exclusivity, so that competition can start immediately after the patent/exclusivity term ends i.e, a procurement process should not run longer than the patent term of the originator⁹.

Despite the availability of biosimilar versions in several European markets and the correlated lowering of the cost of cancer treatment, not all countries are using this opportunity to increase

access to these biological treatments for patients. Frequently, patient eligibility to access biological therapies is subject to strict qualification criteria. In some countries these criteria, which were set before biosimilar competition existed, have remained unchanged and continue to limit the actual access to biological treatment, despite sizable decreases in the cost of this treatment¹⁰. These access restrictions should be lifted, in conjunction with uptake policies for biosimilar medicines.



Anti-tumour necrosis factor therapies (Anti-TNFs)

Anti-TNFs are used to treat inflammatory conditions such as Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis, Juvenile Arthritis, Crohn's Disease, Ulcerative Colitis and Psoriasis. These drugs reduce inflammation and stop disease progression. Chart 4 showcases the treatment days per capita for anti-TNFs in the different countries¹¹, indicating the lower patient access to these therapies in Central and Eastern Europe. Biosimilar medicines are central to ensure patient access without compromising healthcare budgets, by

stimulating competition in an established therapy area^{12,13}

Zooming in on etanercept and adalimumab, the following charts show the number of standard units per capita¹⁴. In Central and Eastern Europe, the use of Etanercept is not well established. However, patient access to treatment with Etanercept is clearly deficient with less than 0.0120 standard units per capita, compared to 0.0147 – 0.0499 standard units per capita in the other countries

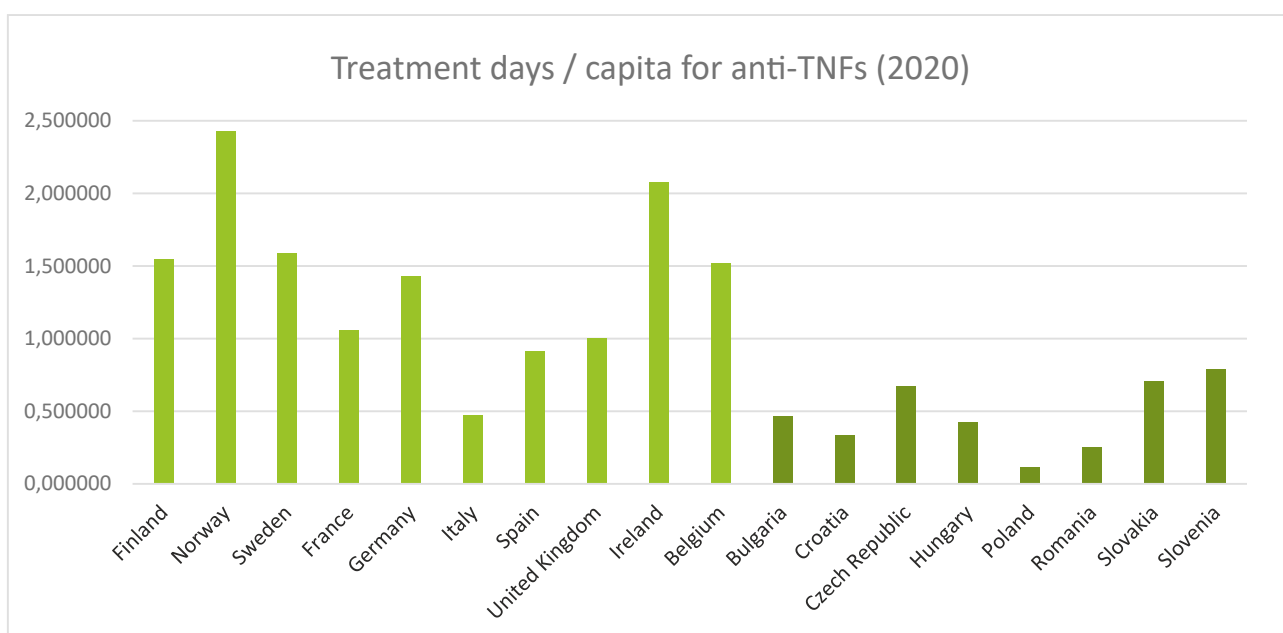


Chart 4: Treatment days per capita for Anti-TNFs. Source: IQVIA MIDAS MAT Q4 2020

within the scope (chart 5). In addition, the market share of the biosimilar medicine is low in many Central and Eastern Europe countries, highlighting the potential of biosimilar medicines to support increased access to biological treatments. Similar trends are observed for the use of adalimumab in Central and Eastern Europe (chart 6).

In Hungary, the National Health Insurance Fund waited for two years after patent expiry in

September 2018 to open the full Adalimumab market to biosimilar competition. After patent expiry, the authorities split the market into various subsegments (e.g., treatment of de-novo patients with rheumatoid arthritis) designing tenders where biosimilars could compete, while the maintenance therapy was covered by the originator exclusively. In 2021, when the full market was accessible for biosimilar medicines, patient access to treatment with Adalimumab increased significantly.

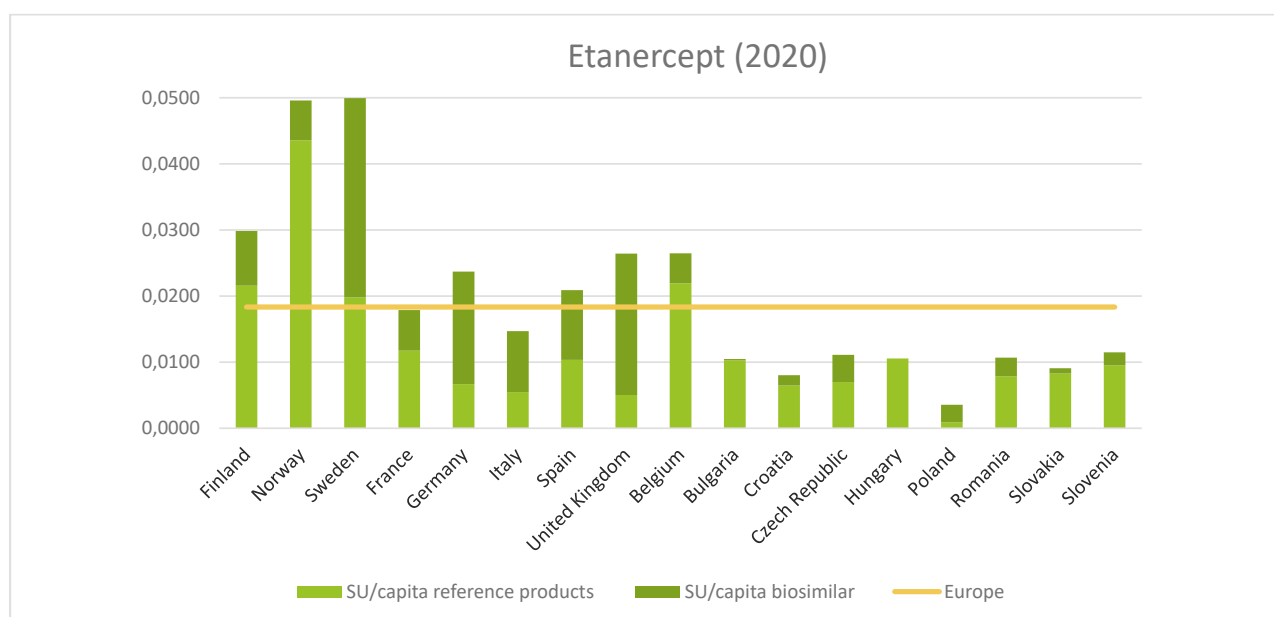


Chart 5: Number of standard units per capita for Etanercept in 2020. Source: IQVIA MIDAS MAT Q4 2020.

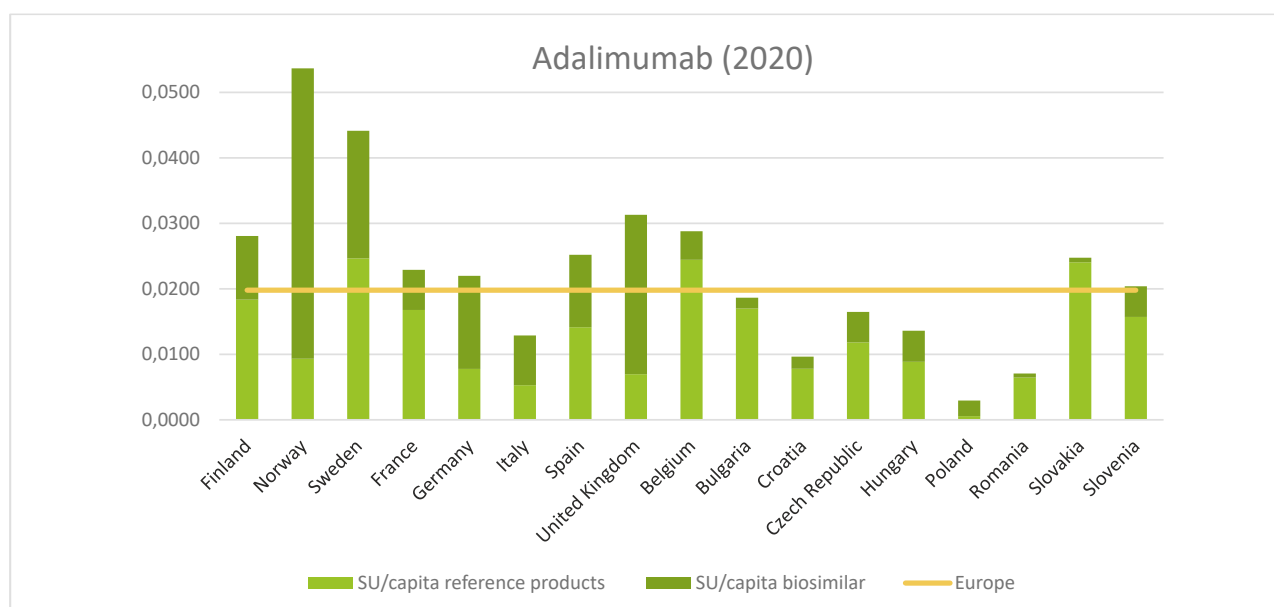


Chart 6: Number of standard units per capita for Adalimumab in 2020. Source: IQVIA MIDAS MAT Q4 2020.

In Poland, the number of treatment days per capita for anti-TNFs is the lowest of all countries within the scope of this report (chart 4). However, biosimilar penetration for adalimumab, etanercept and infliximab is higher than 70% (chart 7) and patient access has moderately improved since the

introduction of the biosimilar¹⁵. Despite this, the usage remains dramatically lower than in other European countries (0,0035 standard units/capita). Prescription guidelines are considered as the main reason for the restricted access to biological therapies.

Molecule		2020 Standard Units	Standard Units Market Share
Adalimumab	Biosimilar products	89.256	80,11%
	Biosimilar reference products	22.156	19,89%
Etanercept	Biosimilar products	100.568	74,48%
	Biosimilar reference products	34.464	25,52%
Infliximab	Biosimilar products	43.858	98,63%
	Biosimilar reference products	607	1,37%

Chart 7: Standard units and standard units market share in Poland. Source: IQVIA MIDAS MAT Q4 2020.

Conclusion

To fully realise the potential of generic and biosimilar medicines, governments in Central and Eastern Europe should invest in the off-patent pharmaceutical market. Therefore, Medicines for Europe would like to provide the following key recommendations:

- Ensure a predictable market environment by avoiding short-term cost-containment measures and extreme price pressure, such as via external reference pricing and clawback policies. Instead, focus should be on long-term sustainable policies. In addition, procurement processes should be optimised, to ensure timely access to off-patent medicines in Central and Eastern Europe (e.g. guaranteeing that the procurement processes open after the entry of the first multisource medicine and adjusting the number of procurement winners according to the market, product and country characteristics¹⁶).
- Implement clear incentives to stimulate the use of generic and biosimilar medicines by providing necessary information and creating compelling incentives for all stakeholders involved.
- Avoid restrictive prescription guidelines upon the entry of off-patent medicines that limit patient access to essential pharmaceutical treatments.

These recommendations will lead to a pharmaceutical market where payers and policy makers benefit from increased cost-efficiency, patients benefit from increased access to essential, high-quality treatments and the sustainability of the market is ensured to secure these benefits in the long-term.

References and footnotes

1. Pharmaceutical Strategy for Europe. (2020). Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Available from: https://ec.europa.eu/health/sites/default/files/human-use/docs/pharma-strategy_report_en.pdf
2. European Commission - OECD. State of Health in the EU Companion Report 2019 [Internet]. 2019. 86 p (Figure 5.1). Available from: https://ec.europa.eu/health/sites/default/files/state/docs/2019_companion_en.pdf
3. WHO. (2020). WHO Guideline on Country Pharmaceutical Pricing Policies. <https://www.who.int/publications/i/item/9789240011878>
4. Medicines for Europe – 2020 Generic market review. Available from: <https://www.medicinesforeurope.com/wp-content/uploads/2021/02/2020-Generic-Market-Review-Final.pdf>
5. State of Health in the EU – Bulgaria - Country Health Profile 2019. Available from : https://ec.europa.eu/health/sites/default/files/state/docs/2019_chp_bulgaria_english.pdf
6. <https://kategorizacia.mzsr.sk/Lieky/Common/Notices>
7. European Parliament (2020). Background note on cancer research. Available from: https://www.europarl.europa.eu/meetdocs/2014_2019/plmrep/COMMITTEES/BECA/DV/2020/11-12/2020-11-10_Backgroundnoteoncancerresearch_EN.pdf
8. A standard unit equals a tablet/syringe.
9. Medicines for Europe – position paper on best procurement practices. Available from: https://www.medicinesforeurope.com/wp-content/uploads/2019/04/M-Best-procurement-practices-position-paper_final-version.pdf
10. Modern Healthcare Institute. Dostęp do leczenia biologicznego w Polsce. 2019; Available from: <https://www.producencilekow.pl/wp-content/uploads/2019/10/raport-calosc-v2.pdf>
11. Methodology: Treatment Days are calculated based on the Defined Daily Dose (DDD) as defined by the WHO (https://www.whocc.no/atc_ddd_index/). Molecules included in the calculation: Adalimumab (DDD = 2.9mg), Certolizumab Pegol (DDD = 14mg), Etanercept (DDD = 7mg), Golimumab (DDD = 1.66mg), Infliximab (DDD = 3.75mg).

References and footnotes

- 12.** Kaló, Z., Vokó, Z., Östör, A., Clifton-Brown, E., Vasilescu, R., Battersby, A., & Gibson, E. (2017). Patient access to reimbursed biological disease-modifying antirheumatic drugs in the European region. *Journal of Market Access & Health Policy*, 5(1), 1345580.
<https://doi.org/10.1080/20016689.2017.1345580>
- 13.** IQVIA. (2021). Spotlight on Biosimilars: Optimising the sustainability of healthcare systems. Available via: <https://www.iqvia.com/en/insights/the-iqvia-institute/reports/spotlight-on-biosimilars>
- 14.** A standard unit equals a tablet/syringe.
- 15.** IQVIA. (2021). Spotlight on Biosimilars: Optimising the sustainability of healthcare systems. Available via: <https://www.iqvia.com/en/insights/the-iqvia-institute/reports/spotlight-on-biosimilars>
- 16.** Medicines for Europe – position paper on best procurement practices. Available from: https://www.medicinesforeurope.com/wp-content/uploads/2019/04/M-Best-procurement-practices-position-paper_final-version.pdf



Medicines for Europe

Rue d'Arlon 50 - 1000 Brussels - Belgium

T: +32 (0)2 736 84 11 - F: +32 (0)2 736 74 38

info@medicinesforeurope.com

www.medicinesforeurope.com



@medicinesforEU