SANDOZ A Novartis Division

# Improving Access to Essential and Affordable Biologic Medicines in Europe

## A SANDOZ EUROPE WHITE PAPER

Sandoz Europe

# Introduction

Biologic medicines have had a significant impact on healthcare over the past few decades as new therapies have helped save lives and significantly improve the health of patients with serious conditions such as diabetes, autoimmune disease and various types of cancer. This has also contributed to people all over Europe living longer, healthier and more productive lives.[1] However, access to biologics still varies widely across Europe and remains very limited in some countries. In addition to common access barriers such as funding issues and reimbursement restrictions, other hidden barriers can also prevent patients accessing the treatments they need.

One of the key challenges for health policymakers is ensuring more equal access to these "standard of care" therapies by making them more affordable and more broadly accessible.

The COVID pandemic is stretching healthcare systems across Europe, and the resulting impact on the economy will inevitably result in the need to be more efficient in short-term healthcare spending. The resulting crisis has also changed the way care is delivered, with an accelerated shift towards the use of telemedicine and home care. As the consequences of the COVID-19 pandemic will continue to be felt for many years, this will represent a long-term impact on public finances and will put additional pressure on healthcare budgets.

Recognizing this trend, the European Commission has initiated major reforms, with the clear objective of improving access to affordable medicines. It has been clearly recognised that greater use of biosimilars has the potential to increase access to biologic medicines for more patients across Europe. This represents a significant opportunity for patients

and there is scope for increasing the share of medicines spend on biosimilar medicines in Europe.

In Europe, Biosimilar medicines have reached €8.4 billion. They represent 9% of the total biologics market in 2020 in treatment days.[2]

If over 30% of all drug spend is on biologic medicines, only 1.5% of that total spend is on biosimilars.[3]

Although the benefits of biosimilars are recognised, significant hurdles to maximising their full potential remain. A key element of this paper will be addressing the main barriers to biosimilar use and persistent access gaps at national level.

Sandoz is one of the leaders when it comes to expertise in the development, manufacturing and delivery of biosimilars to patients and launched its first biosimilar 15 years ago. Since then, it has developed significant patient and treatment experience and has successfully launched eight products. Sandoz believes that biosimilar medicines provide a huge opportunity to deliver significantly improved access to modern therapies for millions of patients in Europe in both chronic and acute care, in areas such as cancers, diabetes, rheumatoid arthritis or other immune-related diseases. Given this heritage, Sandoz is strongly committed to continue working to ensure better access to biologic medicines for more patients and welcomes efforts to support this goal.

Consulting firm Charles River Associates (CRA) was commissioned to identify overarching developments that are likely to impact the uptake of biosimilars in Europe and to assess the potential policy challenges facing biosimilars post-COVID. With the support of CRA, Sandoz has identified policy solutions to continue to increase biosimilars usage and treatment choices, and to support the Commission's objective of delivering equal access to affordable medicines.

## Executive Sumary

The paper identifies three key areas for reform:

### 1. Improved access to biosimilars starts with improving capabilities to both diagnose and treat patients.

In countries with low pre-existing access to biologics, many different elements must come together to support this. This starts with introducing sustainable policies to improve access to biosimilars, including a favourable regulatory pathway that will facilitate a faster entry of biosimilars and seek to improve reimbursement pathways and timing to market which can vary significantly across Europe. However, other structural improvements are also needed for the sustainability of healthcare systems and to ensure that there is sufficient clinical infrastructure to identify patients and treat them as early as possible. There are systemic inefficiencies that needs to be reformed if we are to speed up the market entry of biosimilars across Central and Eastern Europe.

Policies such as *Europe's Beating Cancer plan*, the rare disease plan and other EU and national health initiatives also provide an important milestone to drive focused policy developments in areas such as cancer care and other diseases in Europe. This should focus on prevention, early detection and faster diagnosis, followed by clear treatment pathways and patient follow-up. This will not only contribute to better treatment outcomes and

improved quality of life for patients but also support the long-term sustainability of healthcare systems and bring efficiencies to healthcare budgets. In this context, biosimilars also provide some of the answers to some of the challenges experienced post-COVID. The shift seen during the pandemic may have a longer-term effect on how care will be delivered. This may trigger a shift in the way medicines (incl. biosimilars) are prescribed. Biosimilars can offer comprehensive and holistic support for patients including in-home injection support, as well as home delivery of medicines post COVID.

## 2. Smart, innovative and sustainable procurement

Given the delayed diagnosis and treatment of patients seen in some countries,[4] securing pharmaceutical supply and bolstering European manufacturing capacity are top priorities for governments, creating both risks and opportunities for biosimilars. To realise better patient access to treatment and savings, health policy makers need to facilitate the faster entry of biosimilars to the market by reducing the bureaucratic procedures that impede their launch. The European Commission "smart and innovative procurement" agenda provides an opportunity to introduce more sustainable models for biosimilars tendering, applied in the hospital setting in most EU countries.[5]

The European Commission agenda proposes improved processes that would consider additional tender award criteria beyond price, including environmental performance, device quality and/ or supply resilience. Whilst tendering practices by and large remain problematic in many countries, where they only serve cost containment objectives, policy makers should develop good practice for more innovative and sustainable procurement approaches beyond price. This will most likely require some form of decision-making process that considers multiple dimensions.

## 3. Encourage biosimilar use through incentives and utilisation support measures

This involves redesigned rules that encourage a more frequent use of biosimilars. For example, gain-sharing agreements allow cost savings generated from prescribing biosimilars to be distributed among different stakeholders, including payers, physicians, and hospitals. For example, in France, hospital prescribers can capture up to 20% of savings from the price difference between the biosimilar medicine and its reference product. Recent experiences hwave shown that incentives introduced at both the level of the hospital department and the prescriber appear to have been more efficient.

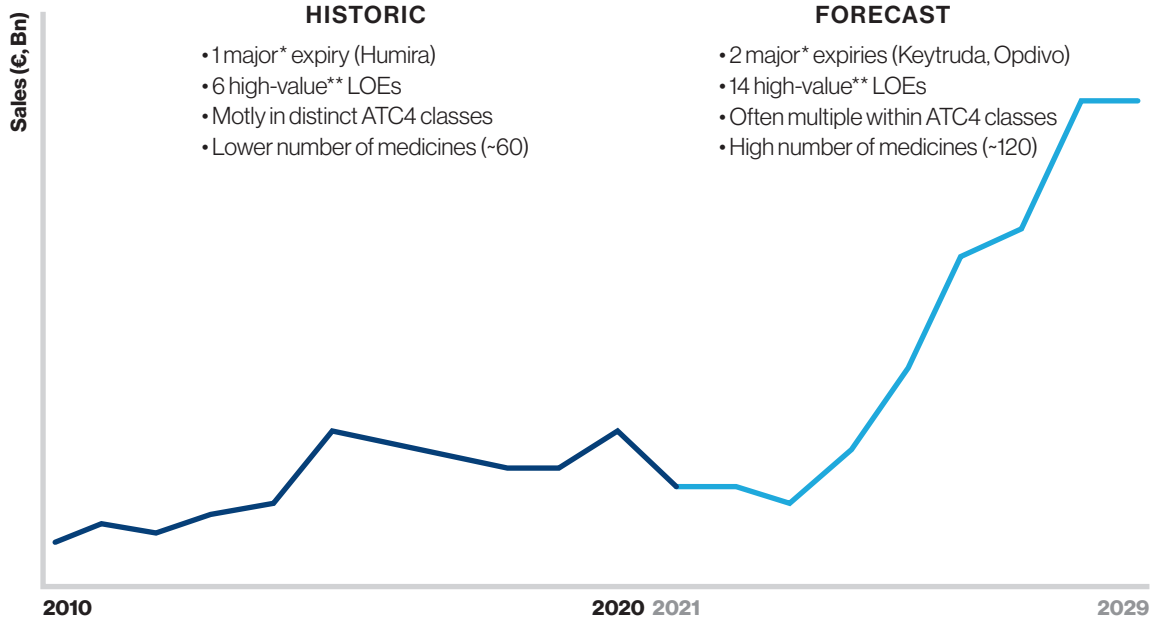
## 1. Background

Biologic medicines have had a significant impact on society, as new "standard of care" therapies have helped save lives and significantly improve the health of patients with serious diseases such as diabetes, autoimmune disease and cancer.[6]

Affordability and equal access to medicines, as well as the need to help the EU pharmaceutical industry both innovate and tackle its economic sustainability challenges is one of the key challenges health policy makers are facing in ensuring access to medicines. As the consequences of the COVID-19 pandemic will continue for many years, this will represent a longer-term impact to public finances and healthcare systems.

In this context, Sandoz firmly believes that use of biosimilars has the potential to increase access to biologic medicines for more patients and can create savings across healthcare systems, freeing up resources for new innovative medicines.

Figure 1: Loss of Exclusivity of Biological medicines (2010-2029)




Source: IQVIA MIDAS® Q4 2019 (accessed Nov 2020), IQVIA Ark Patent Intelligence, IQVIA ForecastLink for data post-2020.
Definitions: *Major molecules = sales >3Bn€ at LOE-1; **High value molecules = sales >1Bn€ at LOE-1"

In 1980, Sandoz produced one of the first recombinant proteins, an interferon alfa. After initiating the world's first biosimilar development program in 1996, Sandoz went on to receive the world's first approval of a biosimilar – somatropin – in Europe well over a decade ago. Since then, Sandoz has brought additional seven biosimilars to market across immunology, oncology and endocrinology. Our biosimilars have been used in clinical practice for 15 years (as of April 2021) and are available in 100 countries with over 730 million patient-days of experience. Sandoz continues to commit to providing high-quality, affordable medicines to patients globally.

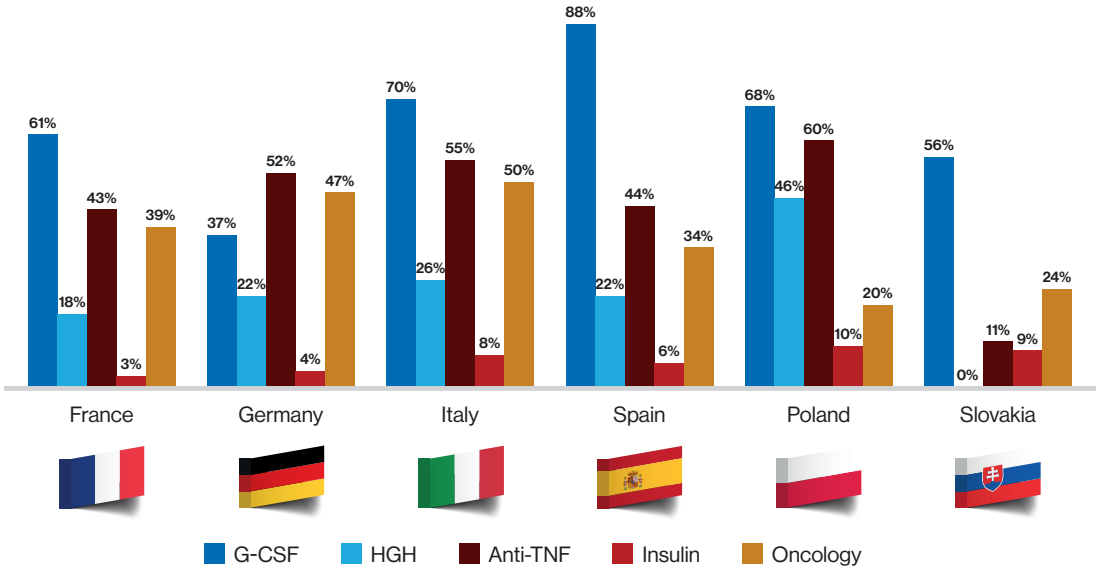
Over the next 10 years many more biological medicines are set to lose exclusivity, opening up to possible competition from biosimilar medicines.[7]

As illustrated in Figure 1, many of the opportunities generated by biosimilars have so far come from a small number of high-value biological products. In the future, much of the savings from biosimilars are likely to be driven by an increase in the number of products losing exclusivity including major loss of exclusivity for PD-1 inhibitors and much of this rise is likely to begin post 2024.[8]

Sandoz also has one of the leading biosimilars pipelines with more than 15 molecules in various stages of development. According to IQVIA, this upcoming biosimilar competition has the capacity to reduce the overall medicine expenditure in Europe significantly with total savings of up to 8% and on average 4-6% of total medicine expenditure.[9] As a result, increasing the use of biosimilar medicines can in turn improve patient access to medicines, improve healthcare budget sustainability, and fuel innovation.

The European Union was the first region to establish an approval pathway for biosimilars in October 2005. Since then, Member States have used a variety of different approaches to improve the frequent use of biosimilars, but as illustrated in Figure 2, the rate of penetration and the impact on spending varies significantly from country to country.

## Figure 2: Biosimilar penetration (Biosimilar vs Total market) – differences among molecules in selected countries in Europe




Source: IQVIA (2020), The Impact of Biosimilar Competition in Europe – MARKET SHARE TD (2020, JUNE MAT).

European countries still have plenty of challenges to address in order to continue to drive the uptake of biosimilar medicines in Europe.[10] The biosimilar manufacturers still face a number of hurdles.

- There is a lack of knowledge, education, and understanding of biosimilars among key stakeholders, which affects their uptake
- The incentives for biosimilar entrants vary significantly across Europe, have not kept up with the types of product and are not sufficiently adapted to ensure commercial rewards
- The consequences of the COVID-19 pandemic will continue to affect the biopharmaceutical industry. Biosimilars are no exception, and the effect on their uptake and adoption will be multifaceted.

## To address these issues, an unprecedented set of reforms is under way at European level as part of the European Commission's Pharmaceutical Strategy for Europe.

The European Commission is seeking to tackle the long-standing weaknesses in the medicine's regulatory framework and address Member States' concerns around access to medicines. Some weaknesses in health systems have also been exacerbated and thrown into sharp focus by the current pandemic.

This provides the European Commission with an opportunity to shake up the regulatory framework and focus on introducing structural changes via both the existing legislative measures but also the non-legislative agenda, to increase access to biologics in general and to biosimilars in particular, with a focus on affordability and equal access. The Commission also recognises that Europe urgently needs a renewed commitment to disease prevention, treatment and care that acknowledges the growing challenges experienced by healthcare systems, and the need to eradicates inequalities in access to care. The EU's cancer strategy, *Europe's Beating Cancer Plan*, is one example of this. This could represent a significant opportunity for biosimilars to contribute to achieving these goals.

Sandoz is one of the leaders when it comes to expertise in the development, manufacturing and delivery of biosimilars to the healthcare community and patients. This paper aims to set out the current challenges in biosimilar access, introduce key trends affecting future access, and highlight policy challenges and opportunities, to increase access to biologics and ensure treatment choice. This will in turn help to stimulate R&D into next-generation biologics, resulting in increased patient access to these innovative medicines.

# 2. Key trends affecting future access to biosimilars

Based on a review of the high-level trends in 2020 and their impact on the policy agenda, we have identified five overarching developments as being likely to impact the usage of biosimilars in Europe.

### *1) Discussions at EU level on simplifying and streamlining the process to expedite patient access to biosimilars*

The European Commission has adopted a communication entitled "*A Pharmaceutical Strategy for Europe*", which aims to ensure access to medicines and support innovation and sustainability in the industry. One of its goals will be to ensure that patients in Europe have access to innovative and affordable medicines. The document includes significant reforms including improving regulatory efficiency.[11] It also proposes actions for orphan medicinal products to ensure greater competition and allow generics/ biosimilars to enter the market at day-1 of the expiry of the exclusivity period.[12]

### *2) Renewed approaches to promoting competition for biologics across Europe*

Securing pharmaceutical supply and bolstering European manufacturing capacity are top priorities for governments, creating both risks and opportunities for biosimilars. The industry has long been advocating for smarter procurement and utilisation policies involving transparent decision-making processes that do not delay time to market.[13] Despite this, there has been a singular focus on price in awarding tenders, utilised in the hospital market in most EU countries.[14] This focus has hindered effective competition in the long term. There is now growing interest in re-thinking innovative procurement approaches to promote the sustainable use of more affordable medicines. The European Commission has suggested that it will review the system of incentives and facilitate more efficient market entry for generics and biosimilars, which potentially opens new opportunities for manufacturers to engage in the debate on innovative biosimilar pricing, reimbursement and tendering.

### *3) The economic impact from the COVID-19 crisis will accelerate the need for cost containment*

The COVID-19 pandemic is stretching healthcare systems across Europe, and the resulting impact on the economy will inevitably lead to cost containment, resulting in the need to be more efficient in short-term healthcare spending, which may be contrasted with greater focus on long-term investments in healthcare. It is likely that payers will look again at the biosimilar market for a new set of rules to accelerate biosimilar penetration. At the same time, there will be an increased and ongoing focus on ensuring supply continuity. Given the delayed diagnosis and treatment of patients seen in some countries, securing pharmaceutical supply and bolstering European manufacturing capacity are top priorities for governments, creating both risks and opportunities for biosimilars.

### *4) Shift in how healthcare is delivered (telehealth, home care) in a post-COVID-19 era*

The COVID-19 crisis has changed the way care is delivered, with an accelerated shift towards the use of telemedicine and home care – i.e. payer-stipulated requirements for in home-infusions beyond auto-injectors for self-administration, and other added value services.[15] The shift seen during the pandemic may have a longer-term effect on how care will be delivered post-COVID-19. This may trigger a shift in the way medicine (incl. biosimilars) are prescribed. Comprehensive and holistic support can be offered to patients including in-home injection support, as well as home delivery of medicines post-COVID-19. However, the increased use of telemedicine may also mean that prescribers could revert to their status quo therapy options and avoid switching as switching normally requires some discussions with the patient.

### *5) The EU desire to improve equal access to medicines for people across Europe*

Access to innovative biologics varies significantly across Europe and is limited in Central and Eastern European (CEE) markets. Polish patients have very restricted access to adalimumab. Recent policy trends raise concerns about the unequal access to medicines across Europe, with the European Commission stating that "patients should have equal access to safe, state-of-the-art and affordable therapies", which generic and biosimilar medicines could provide.

# 3. Policy recommendations

Based on the above trends, we have identified three key policy priorities to improve biosimilar uptake from Sandoz's perspective

### 3.1. Addressing inequalities in access to biologics across Europe

Access to biologics varies significantly from country to country. Patients can struggle to access innovation quickly in some markets, especially in Central and Eastern Europe (CEE).

Many European policymakers have recently expressed concerns that "innovative and promising therapies do not always reach the patient, and patients in the EU still have different levels of access to medicines."[16] Currently, because of budget limitations, only 1% of patients eligible for adalimumab in Poland get their therapy; and only 5% of eligible patients for adalimumab get their therapy in Slovakia or Czech Republic.[17, 18] Addressing the disparities, barriers and delays to access to medicines for patients and affordability for health systems is a goal we share with patients, clinicians, Member States and the EU institutions.[19]

Biosimilars make an important contribution to the sustainability of health systems by providing alternatives to reference biologic products once those products have lost market exclusivity. In Europe, over 30% of all drug spend is on biologic medicines and 1.5% of all drug spend is on biosimilars. This figure has increased by 3.4% over the last 5-years for all biologic medicines.[20] In contrast, biosimilar medicines represent nearly 10% of the total biologic medicines market in terms of volume.[21] Around 70% to 80% of all healthcare costs in the EU are currently spent on chronic diseases.[22]

One of the core assumptions for the impact of biosimilar competition is that 'lower prices should result in more patients treated'. However, many different elements must come together to support a market that can benefit effectively from the impact of biosimilar competition. This includes regulations and clinical guidelines, education and awareness, incentives and purchasing mechanisms.[23] The increased uptake of biosimilar medicines is one way to ensure that many patients have access to affordable treatments. However, different countries have used a variety of different approaches to benefit from biosimilars and the rate of penetration varies significantly from country to country. Often patients can only fully access the biologic medicines they need when the off-patent version is approved by the regulatory authorities (e.g. Germany) or when the biosimilar is admitted for reimbursement.

## Unequal access to biologics in Europe

Launching a biologic into a non-traditional biologic indication creates unique challenges, which must be actively overcome, and this is no exception for biosimilars which will experience similar hurdles. Without appropriate education primary care physicans may not efficiently refer patients through to the appropriate specialists who can carry out treatment.[24]

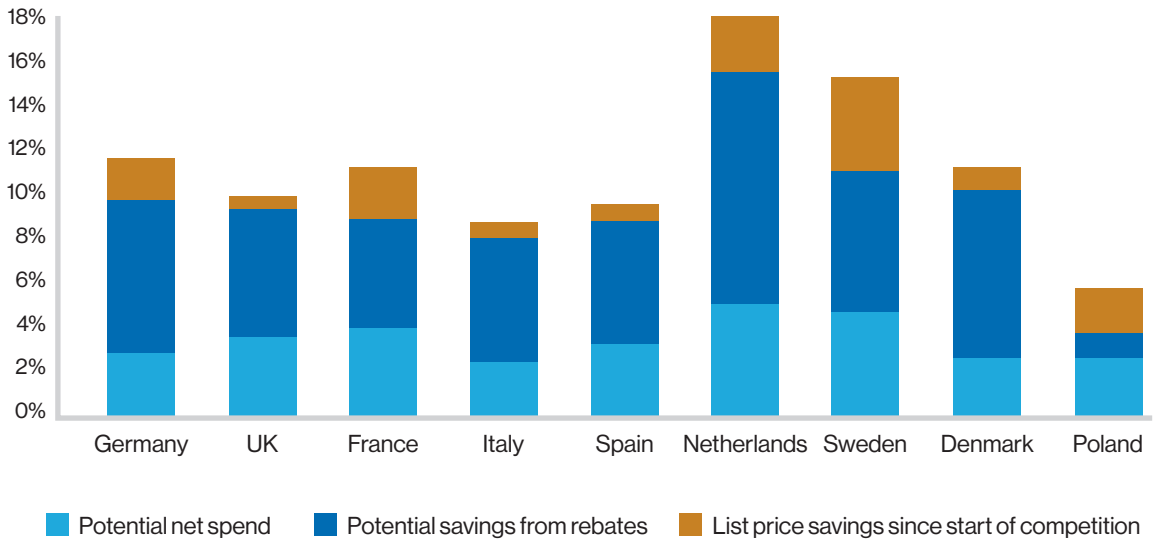
Today access to biologics in CEE countries remains very limited and in turn, this has an impact on biosimilar access. The availability of a new biologic on the national list of reimbursed medicines does not always mean full access to it. Overall access to biologics, for example disease-modifying antirheumatic drugs (DMARDs), varies widely across Europe and correlated strongly with indicators of socioeconomic health and disease activity. In total, 320 million people in the European Region (almost 40%) would have severely restricted access to DMARDs in case of rheumatoid arthritis (countries with lowest access).[25]

In addition to common access barriers such as reimbursement restrictions, restrictive clinical guidelines and high administrative burden for physicians in initiating or continuing biologics, there are also other hidden access barriers that can prevent patient access to biologics.

These include issues such as the limited number |of treatment centres, long travel times and high costs for patients in distant geographical areas. Uneven budget allocation among centres, limited capacity of nurses, and limited health literacy of patients were identified as the most relevant barriers to timely patient access in at least three countries in the CEE region.[26]

Given the low penetration of biologics in CEE markets, the opportunity for biosimilars to generate cost savings is also limited, and it's not clear how the cost savings will be reinvested. Currently, less than 10% of eligible patients are actually treated with biologics, compared to around 80% in Western Europe.[27] The amount of savings per country will vary based on the volume and list price of each country prior to biosimilar entry. IQVIA has calculated the 2019 spend at list price, and the extent to which list prices have been reduced since the introduction of biosimilars across multiple markets – and as shown in Figure 3, savings from biosimilars as a proportion of total prescription medicine spend vary significantly by country.

## Figure 3: Biologic spending and savings as a proportion of total Rx-spend (2019, %)




Source: IQVIA 2019.[28]

In order to improve access to biosimilars, there are several challenges that need to be effectively addressed in these markets:

- Switching is generally allowed, and in most countries, this is at the discretion of the physician after a clinical assessment, which helps increase biosimilar utilisation. However, complicated reimbursement paperwork and bureaucracy can sometimes deter physicians from initiating a switch to biosimilars.
- No specific criteria are applied for the pricing and reimbursement of biosimilars in selected CEE countries. The price of biosimilars is usually reduced compared with reference medicine, and specific price discounts are common.[29]
- Structural improvements are also needed to improve the sustainability of health systems and ensure that there is sufficient clinical infrastructure to identify patients and put them on treatment as early as possible.

Therefore, increasing patient access and changing the reimbursement criteria should be the key priorities to resolve the challenges and to fully utilise value brought by biosimilars. In the future, biosimilars will create opportunities within important niche areas such as treatments for rare diseases (including rare cancers) which currently form a significant part of the pharmaceutical budget. Orphan medicinal products hold unique challenges for the development of biosimilars and this is likely to exacerbate some of these challenges.

## POLICY RECOMMENDATIONS

- **Improved access to biologics, including biosimilars, starts with improving capabilities to both diagnose and put patients on treatment as soon as possible**.
  Many different elements must come together to support a market that can benefit from the impact of biosimilar competition effectively. Health systems strengthening and improving the capabilities to diagnose and treat disease can help ensure patients get better access to biologics including biosimilars. This includes regulations and clinical guidelines, education and awareness in order to build trust and confidence in biosimilar use, incentives and purchasing mechanisms amongst others. Without appropriate education these gatekeepers may not efficiently refer patients through to the appropriate specialists who can deliver treatment. Any sustainable policy framework on biosimilars should be based on a prescriber centric approach that promotes the educated decision-making process between prescribers and patients.

- **In many countries, driving access to biosimilars starts by ensuring that treatment pathways are available to prescribe biologic medicines**.
  This will become particularly important as biosimilars become available for more complex innovation such as orphan medicinal products (OMP) to treat rare diseases. Policies such as *Europe's Beating Cancer* plan, the rare disease plan and other EU and national health initiatives also provide an important milestone to drive focused policy developments in areas such as cancer care and other diseases in Europe. This should focus on prevention, early detection and faster diagnosis, followed by clear treatment pathways and patient follow up. This will not only contribute to better treatment outcomes and improved quality of life for patients but also support the long-term sustainability of health systems and bring efficiencies to healthcare budgets.

- **There are systemic inefficiencies that need to be reformed if we are to speed up the market entry of biosimilars across Central and Eastern Europe**.
  From a patient's perspective, enhancing awareness and literacy about the benefits of biologics including biosimilars on their medical conditions can help support their journey through diagnosis from the gatekeepers, referrals to specialists and receiving treatments.

- **To realise better patient access to treatment and savings, institutions such as governments and other authorities need to facilitate the faster entry of biosimilars to the market by reducing the bureaucratic procedures that impede progress. One of the areas is price and reimbursement**.
  In some countries, patients often have to wait 6 months after reimbursement approval. There is a systemic inefficiency that needs to be reformed if we are to speed up the market entry of biosimilars across Europe.

### 3.2. Smart, innovative and sustainable procurement

Access to biologic medicines (including biosimilars) across Europe is largely governed by a process of tendering conducted by health authorities. Tendering is applied to biosimilar medicines mostly in hospital markets and can happen on national, regional or hospital level across most EU markets.

As proposed in the *EU Pharmaceutical Strategy*, smart and innovative procurement procedures should be designed to foster competition and improve access e.g. by integrating issues such as security and continuity of supply.

There is a need for close cooperation and dialogue with the industry to design a more sustainable competitive frameworks.

In principle, tendering can be positive or negative for sustainable competition depending on how it is applied. There are however several factors or policies that have contributed to tenders being considered a bad practice across one or more dimension.

## Price-only and winner-take-all tenders should be avoided.

Tendering for biologics has increasingly been characterised by over-reliance on treatment costs. Although price-only and single-supplier ('winner-takes-all') tendering can generate the greatest short-term cost savings, this approach has also been shown to lead to short-term supply issues (as observed in generic tenders) and to have a negative impact on the longer-term sustainability of the biosimilar industry.[30, 31] These types of 'winner-takes all' and 'price-only' tenders are currently employed in most markets. For example, price is the main criterion for tendering in Slovakia, Poland, and Hungary.[32] Price-only and single-supplier tendering can generate the greatest short-term cost savings, but it negatively impacts the longer-term sustainability of the biosimilar industry.[33]

Biosimilar manufacturing involves high investment costs and development risks. Compressed profit margin resulting from price-only tenders may discourage participation of biosimilar companies who may decide to exit an unprofitable market but also may discourages long term investments.[34] Additional safety data and patient support program should be considered and evaluated. If innovative procurements are employed, transparency and enforcement of selected criteria should be implemented to ensure its effectiveness.

It is important that procurement bodies also understand the specificities of biologic medicines and that biosimilars are different from small-molecule generics.

The complexity of the biologic derived products means the standard generic regulatory procedure is not applicable.[35] Moreover, biosimilar manufacturing requires high technological know-how, significant capital investment, longer term development cycles, and a low geographic relocation flexibility as biosimilar production lines cannot be shifted quickly.

The unique nature of biosimilar products does not make it sustainable to continually lower price and this practice could ultimately have the consequence of manufacturers being forced to exit the market due to unsustainably low margins. Aggressive price regulation on biosimilars seen as equal to generics will adversely impact the sustainability of biosimilar supply and thus patient access to life-saving medicines.

Sandoz has been working on shaping the procurement environment for the past decade and more, but challenges remain. The European Commission has recently expressed its goal to introduce better-designed, smarter, and more innovative procurement procedures considering multiple factors, such as price conditionality, timely delivery, 'green production', or supply chain resilience will be needed. It has also stated that it wants to "encourage buyers from the health sector to cooperate in view of implementing innovative procurement approaches for the purchases of medicines that include new criteria. This will most likely require some form of decision-making process that considers multiple dimensions.

## POLICY RECOMMENDATIONS

- **'Price-only, winner-takes-all' tendering for biological medicines should be avoided**.
  The contract should be awarded to more than one manufacturer and take into account overall value (including for patients and healthcare systems). There should be a more sustainable purchasing framework also in hospital settings as well as in the retail setting.
- **Policymakers should develop good practice of innovative procurement approaches that include new criteria and will most likely require some form of decision-making process that considers multiple dimensions**.
  This could include specific tender criteria such as:
  - Environmental criteria echoing the EU Green Deal among others
  - Creating value through home care and increasing patient adherence
  - Resilient supply chain and local language helpdesk
- **Tenders and independent prescription targets/mandatory price reductions do not work together. If applied appropriately, tenders allow market forces to determine market share and also influence the price**.
  This is not compatible with the use of arbitrary prescription targets and mandatory price reduction. This will distort the tender or lead to contradictory messages being sent to clinicians.

### 3.3. Encourage biosimilar use through incentives

Policymakers and payers have taken different approaches to encourage the use of generic medicines for small molecule products, with measures ranging from information campaigns, international non-proprietary name (INN) prescribing, financial incentives, and other more interventionist measures like prescription quotas. These approaches all have varying effects on competition. Encouraging competition after loss of exclusivity in biologics markets has proven to be more complex. Payers have thus been looking for ways to encourage competition for biologics often referencing the policies used for small molecule medicines.

Although payers might be keen to generate savings, in most markets this might not resonate with physicians.[36] Offering simple price discounts does not necessarily lead to greater use of biosimilars. There remain certain rigidities such as a lack of awareness among patients as well as, in some cases, physicians.[37]

Incentives and utilisation support measures would allow reliable supply as well as efficiency gains for pharmaceutical budgets, greater access and care equity, and more patients to be treated.

In some countries like Norway and Denmark, the physician's participation within the decision-making process on biosimilar use and the development of tender practice as well as prescribing practices has helped to drive frequent use of biosimilar medicines in these countries. Thus, incentive schemes are needed to encourage stakeholders to move forward in increasing biosimilar use. Spain has piloted a hospital inventive scheme and similar scheme is also tested in France.

#### Prescribing Incentives

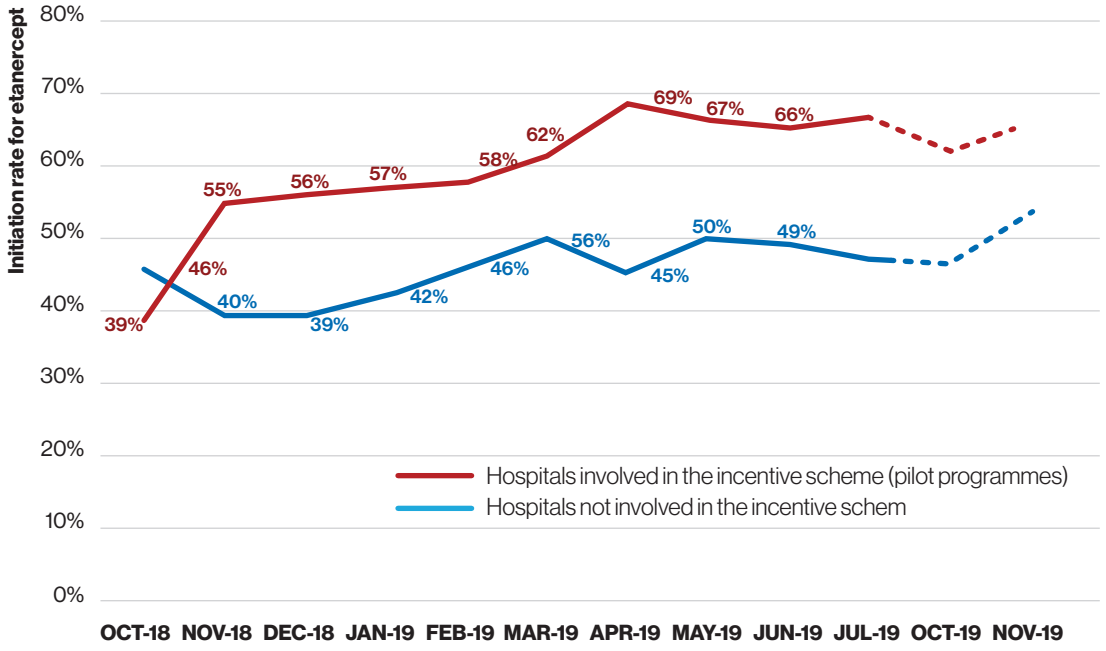
Financial incentives have been established as a mechanism to support and facilitate physician prescribing both as a means to help control costs (i.e. influencing more cost conservative prescribing), and to encourage rational use of medicines or even best clinical practice. There are different types of financial incentives, individual physician penalties for exceeding budget or rewards generating savings, versus other types of institutional (e.g. hospital) incentives.

Gain-sharing is an example of a positive incentive and it is currently implemented in the UK and Germany to encourage physicians to increase the use of biosimilars.[38]

Gain-sharing agreements allow cost savings generated from prescribing biosimilars to be distributed among different stakeholders, including payers, physicians, and hospitals.

One example of this can be observed in France, where the government has introduced a goal to reach 80% of biosimilar use by 2022 and has implemented a system to encourage the prescribing of biosimilars back in 2018. This encourages the efforts of hospitals that have signed a contract to improve the quality and efficiency of care (CAQES) who are incentivised to increase the rate of use of certain biosimilars. This includes a general incentive scheme whereby prescribers can hold on to 20% of the price difference between the biosimilar medicine and its reference product. In addition, this instruction also provided for the implementation of a reinforced experimental system with a greater direct interest in hospital services within the framework of the implementation of article 51 of the law on the financing of social security (LFSS) for 2018.[39] A few selected establishments are piloting this experimental system, which increases this incentive to 30% for a maximum period of 3 years. The impact of these pilot programmes is illustrated in Figure 4.

## Figure 4: Impact of Biosimilar prescription incentives in France – evolution of initiation rates for etanercept – comparison of hospitals with (red) and without (blue) incentives




Source: French Ministry of Health (2020) « Incitation à la prescription hospitalière de médicaments biologiques similaires Point d'étape – January 2020.[40]

In Germany, gainsharing has also been introduced at the insurer-subscriber level, which significantly supports biosimilar penetration.[41] An example is the BioLike initiative, launched by the sick fund Barmer GEK. The initiative has led to an increased use of TNF inhibitor biosimilars and has allowed for sharing the savings realized through biosimilar prescriptions between the sick fund and the physician association.[42] It has been suggested that this approach might increase the interest of physicians in the principles of cost-effective prescribing, which take advantage of the relatively high price difference between the biosimilar and the originator product. Gainsharing has shown potential to be productive if effectively communicated and monitored. This experience certainly can provide learnings for other EU markets.

## POLICY RECOMMENDATIONS

- **Switching of biologic medicines should be aligned with physician recommendations and under physician supervision**.
  Substitution or switching without a physician's involvement should be avoided.
- **The practice of switching should lie with the prescribing physician**.
- **Physicians who prescribe treatments with biologic medicinal products need to be informed on the entry and use of biosimilars in order to create trust in these products**.
  When physicians are well-informed on the treatment options, further incentives should be offered to prescribe biosimilars.
- **Gainsharing, which is here defined as an incentive where part of the savings from using biosimilars goes to the hospital or prescribing physician, is also suggested as a meaningful solution**.
  This can be used as an incentive to prescribe, dispense or use biosimilars. Recent experiences have shown that incentives introduced at both the level of the hospital department and the prescriber appear to have been more efficient.
- **Switching programs can for example be supported via insurance companies or national/regional health systems, but pharmaceutical companies could also provide supportive infrastructure, which supports pooling of data between different centres to support patient monitoring and gather medical evidence**.

# 4. Conclusion

Biosimilar medicines have been shown to deliver benefits and improved efficiency to healthcare systems and budgets. If access is accelerated and penetration increased, they have a significant potential to deliver increased healthcare systems efficiency and access to biologic medicines for more patients going forward. There are systemic inefficiencies that need to be reformed if we are to speed up the market entry of biosimilars across Europe and more specifically in some parts of Central and Eastern Europe. This will require bringing down barriers to biosimilars competition and optimizing their use so that patients can access the medicines they need.

## Improved access to biosimilars starts with improving capabilities to both diagnose and treat patients.

Structural improvements are also needed for the sustainability of healthcare systems and to ensure that there is sufficient clinical infrastructure to identify patients and treat them as early as possible. This should focus on prevention, early detection and faster diagnosis, followed by clear treatment pathways and patient follow-up. This is especially relevant for the future when biosimilars become available for treating rare diseases and these unique characteristics are likely to exacerbate some of these challenges. This will not only contribute to better treatment outcomes and improved quality of life for patients but also support the long-term sustainability of healthcare systems and bring efficiencies to healthcare budgets.

## Smart, innovative and sustainable procurement

Securing pharmaceutical supply and bolstering European manufacturing capacity are top priorities for governments, creating both risks and opportunities for biosimilars. To realise better patient access to treatment and savings, health policy makers need to facilitate the faster entry of biosimilars to the market by reducing the bureaucratic procedures that impede their launch. This includes improved processes that would consider additional tender award criteria beyond price along with some form of decision-making process that considers multiple dimensions when conducting tenders.

## Encourage biosimilar use through incentives and utilisation support measures

This involves redesigned rules that encourage a more frequent use of biosimilars. For example, gain-sharing agreements allow cost savings generated from prescribing biosimilars to be distributed among different stakeholders, including payers, physicians, and hospitals.

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