Effective Strategies to Advance Access to Biologic Therapies for Non-Communicable Diseases

A Biosimilar medicines Access Policy Blueprint

An IGBA Biosimilars Committee White Paper

October 2021
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KEY MESSAGES

Approximately half of the world’s population is unable to access essential medicines. The large majority of these people live in poorer countries, but rising prices of new medicines are also becoming a challenge for health systems in wealthy countries.¹

The global picture on access to biologic therapies remains inconsistent between wealthy and lower-income countries, mirroring disparities in other areas such as economics, healthcare, and infrastructure. So far, the positive health outcomes delivered from biologic therapies have often been offset by their cost for healthcare systems and patients globally, as well as by the remaining presence and use of non-quality assured biologics.

Facilitating access to biologic therapies is one essential pillar in achieving Target 3.4 of the UN Sustainable Development Goals SDGs by 2030 – i.e. reduce mortality from Non-Communicable Diseases and promote mental health.

For the last 15 years, biosimilar medicines have contributed to greater and more equitable access to biologic therapies and to healthcare generally. The main driver lies in the ability of governments to reinvest savings attributable to reduced spending on biosimilar medicines, compared to innovator biologic medicines. With over 400 biosimilar approvals today in key therapeutic areas for non-communicable diseases of high prevalence, such as cancer, diabetes and rheumatoid arthritis, the biosimilar potential in supporting universal access to medicines (UN SDGs 2030) remains largely untapped with an estimated $285 billion opportunity between now and 2025.²

Along the way, a well-known set of barriers and challenges have been identified as obstructing patient access to biosimilar medicines. The wealth of global experience points to root causes stemming from the pharmaceutical policy set up (e.g. regulatory pathway, market access and competition dynamics, etc.), where regulatory experience with biosimilar medicines is more limited.

There are 4 (four) key areas of the Biosimilar medicines Access Policy Blueprint where global collaborative action can help achieve the potential of biosimilar medicines translating their use into broader, timely, stable, affordable and sustainable access to biologic therapies.

Enhancing Regulatory Efficiency For Greater Access

Increased efficiency of biosimilar regulatory frameworks is a key enabler of greater access to biologic medicines. To optimise the existing regulatory landscape for the development of biosimilar medicines, the following aspects are essential: (1) fostering global development through clinical trial tailoring; (2) converging international regulatory requirements; (3) simplifying the sourcing of comparator products; (4) facilitating reliance through training and capacity building in jurisdictions where the regulatory experience with biosimilar medicines is more limited.

Adapting Reimbursement and Co-payment Policies For Affordable Access

It is essential to consider the affordability of therapy for both the healthcare system and patients. While competition dynamics will impact overall treatment costs over time, targeted adaptation of reimbursement policies and co-payment may be required to deliver the full value of biosimilar competition.

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(2) IQVIA Global Medicine Spending and Usage Trends OUTLOOK TO 2025

EFFECTIVE STRATEGIES TO ADVANCE ACCESS TO BIOLOGIC THERAPIES FOR NCDs | A BIOSIMILAR MEDICINES ACCESS POLICY BLUEPRINT
reimbursement policy) or from a broader policy context such as, the way the healthcare system is financed, the scarcity of specialists or public transportation means. These challenges have often been further exacerbated as a result of the global COVID-19 pandemic. Deepened inequities are expected to ensue with unprecedented pressure on healthcare for years to come.

As COVID-19 shifts from pandemic to potentially endemic, reverting to a positive trend to reach the UN SDGs by 2030 remains within reach for the global stakeholder community. With a necessary renewed strategic focus on re-building efficiency in healthcare: biosimilar medicines use can act as a catalyst, bringing competition to the biologic medicines market.

A Biosimilar medicines Access Policy Blueprint can support countries around the world to effectively advance their access strategies for Non-Communicable Diseases, aiming for biosimilar use as a cornerstone to deliver more with the existing resources and to transform ‘waste’ into reinvestment in better health.

“We know how to significantly and collectively change and positively impact the lives of millions by 2030. It starts today.”

By 2025, the estimated biosimilar 5-year cumulated savings opportunity represents $285 billion.

A real and concrete impact for patients worldwide is within reach, provided stakeholders jointly recognise the strategic importance of biosimilar medicines for access to all biologic therapies, set clear objectives and a roadmap to achieve them, as well as stimulate ongoing sharing of good practices to overcome common access challenges. The IGBA sees tremendous opportunities for collaborative action by stakeholders and looks forward to partnering on a pragmatic implementation roadmap for a Biosimilar medicines Access Policy Blueprint.

INTRODUCTION

“Good health is essential to sustainable development.”

“We know how to significantly and collectively change and positively impact the lives of millions by 2030. It starts today.”

In 2000, The Millennium Development Goals (MDGs) created a blueprint to address the needs of the world’s most vulnerable people, which included tackling communicable, maternal, neonatal, and nutritional diseases. Building upon the MDGs the UN Sustainable Development Goals (UN SDGs 2030) were adopted by all United Nations Member States in 2015, with a renewed and expanded health focus: Non-Communicable Diseases (NCDs). NCDs are growing globally, and particularly quickly in Low- and Middle-Income Countries (LMICs). By 2030, U.N. SDG Target 3.4 aims to reduce, by one third, premature mortality from non-communicable diseases through prevention and treatment. While medicines comprise only one pillar of health care, biologic therapies have had transformative and far-reaching effects particularly within some of the leading NCD therapy areas: Cancer, Immunology, and Diabetes.

The positive health outcomes delivered from biologic therapies are however associated with significant societal costs. Healthcare costs, even in High-Income Countries (HICs), are increasing rapidly and straining patients, (private) insurers/payers and governments. Low- and Middle-Income countries (LMICs) often struggle with access to these critical therapies because of limited financial resources, marginal healthcare infrastructure, and lack of universal health coverage among other factors.

(3) https://www.un.org/sustainabledevelopment/health/ (ensuring healthy lives and promoting well-being for all at all ages, Goal 3)
The COVID-19 pandemic has placed global healthcare systems under extreme pressure, in some cases halting, if not reversing, the march of recent health advancements. Inequities in access to healthcare have been revealed starkly. Also concerning is the prospect of the post-pandemic health care ecosystem in which drastic cost-containment measures are expected to emerge as a tool to manage long-term budget pressures. In parallel, the consequences of delayed or disrupted treatment or diagnoses will translate to greater and more widespread incidence of chronic diseases.

The global biosimilar medicines industry has a prominent role to play in delivering on UN SDG Goal 3 (particularly but not exclusively on Target 3.4) by 2030 and in supporting pandemic mitigation initiatives for both patient care and healthcare sustainability.

Over the last 15 years — biosimilar medicines have proven how they can significantly contribute to enhancing access to biologic therapies and improving global health outcomes, directly and indirectly.

In many countries, the use of biosimilar medicine has triggered competition in the originator biologic medicines market, allowing for treatment cost-efficiency gains in the therapy areas in which they are used. In some markets, these gains have translated into more patients being treated and, clear instances show further reinvestments in healthcare. When cost savings are realized through the efficient use of biologic therapy options (both originator and biosimilar medicines), funding can be re-allocated to other areas of need such as, to finance health care staff, training, equipment, supportive care, or access to innovative treatments.

With an estimated cumulative savings of $285 billion expected over the period 2021-2025 and an average yearly savings reaching $100 billion from 2025 onwards, building and rebuilding efficient healthcare systems globally and collectively delivering on UN SDG Goal 3 (Good Health) will require concerted and collaborative efforts to include biosimilar medicines utilisation in all health policies as a key lever to improving health outcomes.

**Figure 1 Socio-economic fundamentals of demand for biosimilar medicines**

1. Based on daily consumption per capita ranging from $10 to $100 (in purchasing power parity terms)
   Source: OECD, WHO Core Health Indicators, ICP Global Results, EIU, Diabetes Research and Clinical Practice, Sung et al. (2021) CA Cancer J Clin., Thun et al. (2010) Carcinogenesis, Global Liver Institute

**THIS WHITE PAPER OUTLINES:**

> The largely unfulfilled biosimilar access opportunity.

> The known challenges and barriers to biosimilar medicines use.

> The IGBA Vision towards 2030, for the role biosimilar medicines should play in advancing access to quality-assured biologic therapies for Non-Communicable Diseases, along with a blueprint of effective strategies to achieve it.
CHAPTER 1 | Where do we stand on “universal access to affordable biologic therapies”? 

HIGHLIGHTS 

A largely unfulfilled biosimilar access opportunity

▷ Biosimilar medicines are available across key therapeutic areas for non-communicable diseases of high prevalence, such as cancer, diabetes and rheumatoid arthritis.

▷ The global picture on access to biologic therapies remains inconsistent among wealthy and lower-income countries, and it mirrors other disparities including economics, healthcare, and infrastructure.

▷ In several countries, biosimilar medicines have contributed to greater and more equitable access to biologic therapies and to healthcare more generally thanks to reinvestment of savings attributable to reduced spending on biosimilar medicines compared to innovator biologic medicines.

▷ The biosimilar potential in supporting universal access to medicines (UN SDGs 2030) remains largely untapped with an estimated $285 billion opportunity between now and 2025.

Global Access to biologic therapies - A contrasted picture

An estimated two billion people have no access to essential medicines. Meanwhile biologic medicines have transformed healthcare over the last 4 decades for those with access. Without biosimilar competition, the positive health outcomes delivered thanks to biologic therapies are associated to significant costs for society. With quality-assured biosimilar medicines, high, low- and middle-income countries can all improve patient care despite ongoing socioeconomic constraints.

The COVID-19 pandemic has halted and sometimes reversed significant progress in advancing towards better health. The pandemic has exposed and intensified inequities within and among countries. Also of great concern is the expected increased rate of debilitation for chronic diseases owing to delayed or disrupted treatment or diagnosis.

Before the pandemic, data related to the current state of access to biologic therapy was already pointing towards opportunities.

An Italian study from 2019 aimed to estimate the number of patients with rheumatoid arthritis (RA) that were eligible for therapy with biological disease-modifying antirheumatic drugs (bDMARDs). “The study findings show that 9.6% of 274,967 RA patients not currently treated with bDMARDs presented one or more criteria considered for bDMARDs eligibility”. This suggests that despite availability of biologic therapies, including alternative biosimilar options, and cost-efficiency gains from competition, not all patients could access the standard care therapy.

Today, only half of the 69 million patients (people with type 1 and 2 diabetes, 9 million and 60 million respectively) requiring insulin therapies are able to access these medicines regularly.

The number of patients living with type 2 diabetes is expected to increase by more than 20% by 2030.

By 2025, medicines to treat diabetes are anticipated to be the 3rd leading global therapy area in terms of medicines spending after oncology and immunology.

The global potential for biosimilar insulins use (incl. biosimilar insulin analogs) as a significant lever for greater access equity for patients living with diabetes remains largely untapped.

(8) L Degli Esposti et al. Assessment of Patients affected by rheumatoid arthritis eligible for biologic agents – 2019
https://doi.org/10.1016/j.jval.2019.09.192
(9) WHA Resolution on Reducing the burden of noncommunicable diseases through strengthening prevention and control of diabetes (A74/A/CONF.5/5)
Essential biosimilar medicines are already available for Non Communicable Diseases

Biosimilar medicines have been available since 2006. By 2021, over 400 biosimilar approvals were available, providing therapeutic options for many therapy areas, including the 3 leading global therapy areas in terms of medicines spending: oncology, immunology and diabetes.

Given their prominent role in treating and managing more diseases and conditions, a number of biologic medicines are now included in the WHO Essential Medicines List (EML) recognising they are increasingly the standard of care. Biosimilar options are already listed as part of the WHO EML in key non-communicable disease areas. The 2021 EML discussions highlighted that promoting their use “and supporting strategies promoting interchangeability [...] have a great potential to increase global access to effective biological medicines”.

Role of Biosimilar medicines in improving global health outcomes

The high percentage of health spending on medicines (20–60% as demonstrated in a series of studies in selected low- and middle-income countries) impedes progress for the many countries that have committed to the attainment of universal health coverage. Biosimilar medicines authorised according to the WHO regulatory requirements (or equivalent as available in WHO Listed Authorities) have greatly contributed to increasing access to key biologic therapies, “promoting more equitable access to quality, safe, efficacious and [cost-effective] medical products” in countries using them, in line with the ambition set forth in Resolution WHA 67.21.

Following biosimilar medicines availability and market entry, the onset of competition leads to treatment cost efficiency gains. Where the policy framework allows, this efficiency is further translated in:

- The expansion of the number of patients treated
  - eligible patients (according to existing treatment and/or reimbursement guidelines) within foreseen budgets
  - broader patient population after revision of relevant treatment and/or reimbursement guidelines

Source: 1. IQVIA MIDAS MAT Q2 2020; Country cohort includes 30 countries within Europe Economic Area. Biologics market by value 2. 2015: Hematopoietic Growth Hormones, Growth hormones, Sex Hormones; 2020: + osteoporosis

Figure 2 Biosimilar medicines availability by therapeutic area

(10) WHO Essential Medicines List 2021 - https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2021.01
(10b) IGBA Biosimilars communication module 3 https://www.ibgamedicines.org/doc/20201105_Module3_final.pdf
EFFECTIVE STRATEGIES TO ADVANCE ACCESS TO BIOLOGIC THERAPIES FOR NCDs

The biologic medicines industry has considerably grown over the last 40 years with recombinant biologic therapies playing a growing role in the standard of care across disease areas and a key for future pharmaceutical manufacturing focus.

By contrast, the biosimilar medicines industry officially began in 2006, with the first approval in Europe, and has been slow to develop as different countries made changes to their laws. The disparities in biosimilar use globally are significant (see Figure 4 Overview of global biologic medicines sales by region\(^{14}\)), reflecting disparities in delivering improved access and health outcomes more generally. The EU and US markets dominate use of biosimilar medicines with 90% cumulated use (by sales); other countries have yet to harness the benefit of biosimilar medicines on both health outcomes and spending.

Many innovative biologic medicines will soon lose exclusivity and likely face competition. Where this happens, “global savings from biosimilars will have a significant impact on country medicine spending through 2025, estimated at a cumulative $285 billion below estimates of spending without biosimilars”.

### Figure 3 The Biosimilar Value for Healthcare

- **Reinvestments in healthcare**
  - (staff, training, equipment, supportive care or innovative treatment)

### Most of the Global Biosimilar Opportunity is yet to be achieved

The opportunity for access to biologic therapies worldwide is immense and the direct cost of inaction is similarly high.

In the next section, the main barriers and challenges to realising the global biosimilar opportunity will be presented.

### Figure 4 Overview of global biologic medicines sales by region\(^{14}\)

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In the next section, the main barriers and challenges to realising the global biosimilar opportunity will be presented.

### Figure 4 Overview of global biologic medicines sales by region\(^{14}\)
CHAPTER 2 | What (still) stands in the way of patient access to biologic therapies?

HIGHLIGHTS

A well-known set of barriers & challenges to biosimilar access

- One size does not fit all! Policies that have worked for generic medicines do not necessarily work for biosimilar medicines; experience to date underlines that the absence of a specific policy framework correlates with slow adoption and use.

- Key barriers to equitable global access can stem from pharmaceutical policy aspects as well as from how healthcare systems are structured.

  - On the pharmaceutical policy front: inefficient regulatory approval pathways, lack of market predictability and general challenges in purchasing and procurement practices, limited or lack of use and reimbursement for the reference product along with high patient co-payments, lack of acceptance and trust in biosimilar medicines.

  - On the healthcare system front: limited or constrained healthcare budgets, underfinanced healthcare infrastructures, capped pharmaceutical spending, difficulty in accessing care specialists (scarcity, transportation means) etc.

- Deepened inequities and exacerbated pressure on healthcare and pharmaceutical budgets have resulted from the global COVID-19 pandemic and look set to continue.
Inadequacy of the ‘generic model’ to deliver the biosimilar value for healthcare

Despite the growth in biologic medicine approvals and use over the past 40 years, access to biologic therapies remains lower than it could be, according to clinical guidelines, in a vast majority of countries, despite the existing opportunity for competition since 2006.

Experience to date indicates that merely copying mechanisms that have worked for generic medicines is an unsuccessful strategy for biosimilar medicines. There are two main reasons for this:

1 – A patient needs regular clinical monitoring and check-ups when their chronic condition is managed with a biologic medicine

2 – There are vast differences in the development (incl. a thorough head-to-head comparability exercise, both analytical and with a pharmacokinetic study) and cost timelines between generic and biosimilar medicines.

This is in part due to a complex healthcare ecosystem with many stakeholders: manufacturers, regulators, payers, physicians, pharmacists, distributors, patients and policy makers.

Key barriers in pharmaceutical policy and beyond

With over 2 billion patient treatment days with biosimilar medicines in Europe alone and years of policy interventions, the key barriers to equitable global access to biosimilar medicines are well identified and fall into two main categories: those pertaining to pharmaceutical policy and those rooted in the broader healthcare system.

There are a number of other challenges including those related to the field of Intellectual Property, which are not covered in this white paper.

KEY CHALLENGES PERTAINING TO PHARMACEUTICAL POLICY (NON-EXHAUSTIVE):

- Lengthy, costly, inefficient, and divergent regulatory approval pathways limit the number of companies able to successfully bring biosimilar medicines to market in countries around the world.

- In spite of the WHO Similar Biotherapeutic Product (SBP) guideline adoption in 2009, some countries are yet to actively adopt and implement WHO-like biosimilar medicines guidelines.

(15) MIDAS MAT Q2 2020 data; rituximab and trastuzumab DDDS calculated via IQVIA Real World Data, Oncology Dynamics physician surveys on average cycles; pre-2009 analysis includes extrapolated treatment days for biosimilars launched between 2005 – 2008; country cohort includes 30 countries within Europe Economic Area https://www.medicinesforeurope.com/wp-content/uploads/2020/12/BIOS5.pdf
A number of LMICs have heterogeneous off-patent biologic medicines available, some quality-assured biosimilars as per WHO standards, some not, leading to complexity.

In the Middle East African (MEA) region, regulatory maturity varies greatly. Egypt, Israel and Saudi-Arabia can be seen as the more advanced countries of the MEA region, having biosimilar guidelines in place that follow WHO and EMA guidance, and also experience with reviewing and approving biosimilar medicines.

In most MEA, regulatory systems are still in transition and guidelines are under development, e.g. in Jordan, Lebanon, Iran, Iraq, Ethiopia, Nigeria, Ghana, Zambia. Algeria, Tunisia and Morocco remain without clear biosimilar guidance and a moderate level of off-patent biologic competition.

Lack of market predictability and general challenges in purchasing and procurement practices can especially hamper supply of biologic medicines that are complex and costly to manufacture.

In some Latin American countries, for instance, medicines first have to be listed in the national formularies before physicians can prescribe them. Even an official reimbursement status may not render a medicinal product available to a large part of the population, which does not have health insurance coverage.

Limited or lack of use and/or reimbursement for the originator biologic product along with high co-payments also hinder the use of biologic therapies for eligible patients for lack of affordability.

In the United Arab Emirates (UAE), a large part of the population is covered by private payers. The number of private payers keeps growing along with the number of health coverage plans; adding to the complexity for affordable access. In addition, the claims denial rate for biologic medicines coverage is high among all health coverage plans, basic but also enhanced, leading to challenges to access, particularly for low- and middle-income patients.

Similarly in Chile, many physicians remain loyal to originator pharmaceutical companies whose products they know and have used for years. Even when a payer adds a biosimilar medicine to its formulary, the use of biosimilar medicines remains marginal.

Lack of acceptance and trust in biosimilar medicines among providers and patients can limit use, and continued preference by healthcare stakeholders, including payers, for originator biologic medicines can challenge the viability of biosimilar competition. This is an issue where access to reliable and authoritative information from trusted sources, such as medicines regulatory agencies or governments and policy makers, is limited, lacking or difficult to obtain (e.g. language, translation, expert terminology or hard to retrieve online).

A recent peer reviewed scientific literature study underlines the continuing need for education and clear national recommendations for switching, with the involvement of the prescriber in support of the uptake of biosimilar medicines. Of note, physicians' knowledge of and attitudes towards biosimilar medicines remain varied, particularly as their immediate experience is limited.

Biologic therapy price reduction has shown to be minimally effective at increasing use when considered in isolation.

As an example, the introduction of off-patent biologic medicines in Argentina has proven difficult, and slow, with one of the main reasons being the absence of a clear national policy in a very fragmented healthcare system. This highlights that education of both physicians and payers on biosimilar medicines is equally relevant.

It has also been reported that this “knowledge gap is further exacerbated by disparagement of biosimilar [medicines] and dissemination of

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(17) IGBA Internal data
misinformation, whether intentional or otherwise). The “dissemination of disparaging, misleading, or incorrect information may lead to unwarranted concerns that patients will not attain maximal efficacy on a biosimilar or may have an adverse event that they would not have had with the reference biologic”, thereby impacting confidence and overall use.

KEY CHALLENGES IN THE HEALTHCARE SYSTEM (NON-EXHAUSTIVE):

- Silo approach to health spending can translate into capped pharmaceutical spending without consideration for the overarching healthcare & societal costs associated with suboptimal screening, diagnostics and disease management, including an increased incidence of hospitalisation rate or inability to work.
- Limited or constrained healthcare budgets and a structural lack on investment in health.
- Underfunded healthcare infrastructures and understaffed workforce translating into limited capacity, unmet need for continuous training and state-of-the-art equipment.
- Difficulty in accessing care specialists because of limited availability or because of the concentration of specialists in large cities and the inadequacy of public transportation means to reach them.

In a 2020 study on access to anti-TNF medicines used in Rheumatoid arthritis in five Central Eastern European Countries, authors identified as key hurdles for patients and mostly ‘hidden barriers to access’, the restricted rate of referral of patients to treatment centres (due to ignorance or disincentives by primary care) as well as the distant geographical areas responsible for significant travel time and cost to treatment centres.

(19) Key drivers for market penetration of biosimilars in Europe (nih.gov)
(20) Biosimilars as a sustainable option for the health system in Argentina (gabionline.net)
The global outbreak of COVID-19 suspended routine Non-Communicable Disease care in almost every country worldwide. The World Health Organisation surveyed disruptions in chronic disease care in 163 countries in May 2020 and found that:

- 53% of the countries surveyed have partially or completely disrupted services for hypertension treatment;
- 49% for treatment for diabetes and diabetes-related complications;
- 42% for cancer treatment,
- 31% for cardiovascular emergencies.

There are four main reasons for this disruption:
- Widespread and prolonged national lockdowns
- Suspension of non-urgent care

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- Healthcare professional re-deployment to manage the large numbers of COVID-19 patients,
- Limiting Intensive Care Unit (ICU) capacity in hospitals to provide for COVID-19 patients.

In Europe, the European Patients’ Forum confirmed the trend among the surveyed NCD community.

In other parts of the world, such as in Africa, the measures put in place to fight the COVID-19 pandemic have led to disruptions in the drug and equipment supply chains, the inter-tion of therapies, or the under-detection of new cases, impacting programs to fight several other infectious diseases. These indirect impacts could ultimately turn out to be much greater than the direct impacts associated with the current COVID-19 pandemic in terms of excess morbidity and mortality.

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In the next section, a Vision of the role that Biosimilar medicines can play in supporting the UN SDG Goal 3 will be outlined along with a set of recommendations and proposals on how this can concretely be achieved.

Figure 5 European Patients’ Forum survey outcome on COVID-19 impact (2021)

CHAPTER 3 | How to reshape healthcare systems and enhance access to biologic therapies for Non-Communicable Diseases?

HIGHLIGHTS

Highlights – Enhancing biosimilar use and implementing the adequate frameworks to deliver on the access promise

➤ Fostering a positive trend to reach the UN SDGs by 2030, particularly as COVID-19 shifts from pandemic to potentially endemic, requires a renewed strategic focus on efficiency in healthcare: doing more with the existing resources, transforming ‘waste’ into reinvestment in health.

➤ Biosimilar medicines are a catalyst for efficiency in healthcare systems, bringing competition to the biologic medicines market, wherever they are available.

➤ Creating a political vision for the role of biosimilar medicines in rebuilding efficient health care systems and investing in better health.

➤ Applying the wealth of global experience, good practices and lessons already learned to inform effective strategies that support access to biologic medicines for Non-Communicable Diseases.

➤ Define and tailor the policy blueprint for biosimilar medicines access to local needs.
Delivering broader, timely, stable, affordable and sustainable access to quality assured biologic therapies is at the heart of biosimilar competition and a key deliverable of the “WHO Roadmap for Access to medicines, vaccines and other health products, 2019–2023”.

When it comes to pharmaceutical expenditure, ensuring biosimilar medicine policies are included in all health policies provides a catalyst for efficient use of available biologic medicine options and an access driver through reinvestment of freed-up resources.

The cost of inaction on the progression of Non-Communicable Diseases is self-evident: the Millenium Development Goal focus on communicable disease since 2000 has seen great progress with these diseases. However there is also an inversely correlated trend in other disease areas, and most specifically the incidence of Non-Communicable Diseases. The COVID-19 pandemic has also exacerbated the pre-2020 trends.

To support countries around the globe to meet the UN SDG on health, particular attention should be paid to making the most of existing resources and tackling waste throughout the healthcare system.

Building on the vast global experience with biosimilar medicines, 3 core components have been identified as key to a functioning biosimilar policy framework capable of delivering better outcomes for all stakeholders, according to WHA Resolution 72/17, “Improving equitable access”:

**DEFINING A POLITICAL VISION ON HOW BIOSIMILAR USE WILL CONTRIBUTE TO HEALTHIER COMMUNITIES**

Governments, insurers/payers and international organisations should actively include biosimilar medicines use in all policies, particularly in recovery plans and specific targets. These can set terms of biosimilar use and how the freed-up resources will be used. Partnership with stakeholders will be essential to best match the healthcare needs.

**IMPLEMENTING MULTIPLE POLICY INTERVENTIONS (I.E. FRAMEWORK) THROUGH ROADMAPS WHILE ALLOWING TIME FOR TANGIBLE RESULTS**

Active mid-term monitoring of policy measure implementation should form an integral part of the biosimilar policy framework. Milestones can reveal new barriers to access or competition and inform policy adjustments going forward.

**ACTIVE MONITORING FOR FEEDBACK AND HORIZON SCANNING TO ADAPT TO CONTEXTUAL CHANGES**

Continuous improvement of the biosimilar policy framework, informed by current (experience and lessons learned) and future
contexts (horizon scanning), is necessary to ensure relevance and resilience of the framework and guarantee future competition.

While the above may be aspirational for a number of LIMC countries with high constraints on their healthcare budgets, these core elements are essential and complementary to efforts to ensure the quality, safety and efficacy of health products.

Delivering on the access promise: Towards a Biosimilar medicines Access Policy Blueprint

With the wealth of experience gathered since the first global biosimilar approval (2006), the elements of effective biosimilar access policy strategies have been well identified.

The industry, together with WHO and stakeholders, can benefit from jointly defining and implementing a Biosimilar medicines Access Policy Blueprint.

The long-term competitiveness of the biologic medicines market requires active policies creating a level playing field, incentivizing multiple manufacturers to supply the market – where possible – and instating competition as the main driver of treatment cost-efficiency gains and patient access development.

The challenges captured in Chapter 2 | What (still) stands in the way of patient access to biologic therapies? show that a focus on the market dynamics alone will fail to address other important hurdles. Other policy interventions, notably on the regulatory framework as well as on the stakeholder education and information front, will need to be jointly addressed and form an integral part of the Biosimilar medicines Access Policy Blueprint.

The sections below highlight 4 key areas of the Biosimilar medicines Access Policy Blueprint where global collaborative action can help achieve the potential of biosimilar medicines translating their use into broader, timely, stable, affordable and sustainable access to biologic therapies.

ENHANCING REGULATORY EFFICIENCY FOR GREATER ACCESS

Increased efficiency of biosimilar regulatory frameworks is a key enabler of greater access to quality-assured biologic medicines. To optimise the existing regulatory landscape for the development of biosimilar medicines, the following aspects are essential:

(1) fostering global development through clinical trial tailoring;
(2) converging international regulatory requirements;
(3) simplifying the sourcing of comparator products;
(4) facilitating reliance through training and capacity building in jurisdictions where the regulatory experience with biosimilar medicines is more limited.

The design and implementation of efficient and streamlined regulatory frameworks for biosimilar medicines, applying the most recent scientific advances in analytical techniques and the accumulated experience with these medicines, are key enablers of increased patient access to biologic therapies. Optimised regulatory frameworks make the development of biosimilar medicines faster and less resource intensive. Reducing the necessary investment for biosimilar medicine development programs offers greater competition, which can in turn drive access for patients.

Existing evidence supports the implementation of clinical trial (CT) tailoring, a regulatory approach that waives the default expectation for a comparative efficacy trial, provided that an in-depth laboratory-based comparability demonstration has been carried out by the biosimilar medicine manufacturer and provided a pharmacokinetic study is undertaken.\(^{(27,28)}\) The UK regulator MHRA has already adopted guidance that includes a CT tailoring approach\(^{(29)}\) and discussions are under way in other regions on how to best implement this strategy.

More generally, greater international convergence among regulators is needed to align evidence requirements and opti-mise the development timelines, as well as reduce repetitions that are currently occurring globally. Importantly, the ongoing revision of the WHO Similar Biotherapeutic Product (SBP) guideline includes considerations for streamlined biosimilar development. The future implementation of this guideline globally therefore is a key step towards earlier and broader access to biosimilar medicines worldwide.

Further regulatory optimisation needs to address the sourcing of the comparator or reference products necessary for biosimilar medicines manufacturers to demonstrate biosimilarity. Different policy interventions can support improving the availability of comparator/reference products:

- Policymakers can ensure that those making the comparator/reference products fulfil the purchase requests from biosimilar medicines developers. For example, the CREATES Act\(^{(30)}\) in the United States establishes a private right of action that allows biosimilar developers to legally challenge originator companies that refuse to sell them the necessary product samples.
- The inclusion of specific provisions in local or global guidelines, recognising the possibility of using a foreign comparator product has also proven supportive of streamlining biosimilar development, especially when it can be documented to be the same as the local reference.\(^{(30b)}\) In the

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EMEA Overarching guideline on Biosimilar medicinal products and in the UK Revised Guidance on the licensing of Biosimilar products, such provisions are already available and the evidence requirements outlined. Eventually, a global reference product should be accepted for comparability studies.

Mutual reliance between regulators, including as part of the WHO collaborative procedure, should be further deployed to leverage existing approvals by WHO Listed Authorities in support of approval in another as an efficient way to enhance the timely availability of quality assured medicines. The Caribbean Regulatory System, an initiative of the Caribbean Community and Common Market (CARICOM) represents a leading example of resource-sharing and capacity-building, in support of access to quality-assured medicines.

The acceptance of the foreign comparator product combined with global implementation of CT tailoring would reduce the amount of comparator product needed for the development of a biosimilar medicine and make them available in many more countries concurrently.

Finally, the international reliance of regulators should also be harnessed to drive the effective implementation of guidelines through the delivery of training and capacity building. The WHO, in partnership with other stakeholders, can play a key role in coordinating these efforts in countries where the biosimilar medicines regulatory framework is still new or under development, through facilitating the sharing of good practices, experience and knowledge exchange.

HOW COULD THIS BE IMPLEMENTED IN PRACTICE?

Convergence of Guideline & evidence requirements
End of local data requirements
Optimising regulatory process timelines
Global comparator product acceptance
Advancing Clinical development tailoring
Guideline Implementation (eg training)
Coordination of facility inspections
Expansion of the Pre-Qualification process to available biosimilar medicines
Progressing WHO Listed Authority approach

Improving market predictability & resilience for timely and stable access

Purchasing and procurement systems that recognise the sustained need for biosimilar competition are an important component of improving access. Policies that explicitly support biosimilar medicines and foster healthy competition between biosimilars and originator biologics may look different based on varying health system contexts, but fundamentally require a focus on removing existing barriers to biosimilar medicines use and alignment in incentives across all stakeholders to use biosimilars as an access lever. The path of least resistance in a ‘level playing field’ is to stick with the status quo (in this case, use of the original brand biologic); health systems must correct this structure to ensure long-term competition from biosimilar medicines remains viable.

Focusing on the European experience, below are some important examples of good practices in improving market predictability and resilience:

Allowing timely competition of multiple suppliers & avoiding prolongation of monopolies

In Denmark, AMGROS – responsible for procurement and supply to Danish hospitals – decided to move away from their traditional single-supplier approach and divide the country into two different regions when procuring adalimumab products after biosimilar market entry. This allowed two competitors to supply the market, reducing market concentration while maintaining fast biosimilar uptake, and helping to ensure both long-term competition and supply reliability for patients.

With similar attention to ensuring the plurality of actors in the market in Sweden, the division of the country into 10 procuring regions allows for multiple manufacturers to participate in the Swedish market at any given time.

The Italian procurement legislation was reviewed and amended to ensure tenders occur at the latest 6 months after biosimilar market entry in order to guarantee the...
market is effectively open to competition immediately on expiry of the exclusivity period of the originator biologic.

Finally, in Portugal, a specific mechanism is foreseen whereby the first biosimilar medicine available on the market triggers the re-opening of existing tenders as a means to ensure timely competition.

In order to enhance access to biologic therapies in cancer care, a reform of the purchasing of medicines took place with a focus on biosimilar medicines. A multitude of cancer clinics around Kuala Lumpur streamlined their purchasing practices and introduced a focus on ensuring multiple manufacturers would actively supply the market. This translated in better functioning competition dynamics in the market, a more resilient supply of medicines and more affordable access for patients and providers. While the change required a legislative modification to the framework to establish formularies, this turned out to be a minor step in view of the benefits for the healthcare community which are set to sustain over time.

**INCORPORATING MULTIPLE CRITERIA BEYOND PRICE**

In France, the University Hospital of Bordeaux published a tender for infliximab products with a point-based system including both therapeutic and technical factors such as packaging adaptation, readability of labelling, health traceability, support and stability data.

**TRANSLATING MAPPING INTO LONG-TERM DEMAND FORECAST**

In Denmark, market preparedness is a key feature of the procurement policy. Horizon-scanning is carried out for up to 5 years ahead of the launch of a given biosimilar medicine. This allows early engagement with potential suppliers and predictability for demand and supply aspects.

**ALIGN UTILISATION INCENTIVES ACROSS STAKEHOLDERS**

In the Westfalen-Lippe region, Germany, updated information to physicians and agreed quotas for biosimilar prescription make this region one of the top-performers in terms of biosimilar medicines use in the entire country.

France started piloting policy measures to increase biosimilar penetration in October 2018, and...
is now generalising the benefit-sharing scheme programme to all hospitals nationally. The initial pilot consisted of sharing the savings derived from biosimilar medicines prescribing in the hospital, and dispensed in the community setting, between the social insurer and the prescribing department. The latter is free to re-invest their share of the savings according to defined local needs: e.g. new equipment, staff or medicines.

Finally, in Cardiff, United Kingdom, rituximab intravenous formulation biosimilar medicines were predicted to save one hospital £300,000 -335,000 a year over the subcutaneous reference biologic. However, an additional consideration related to the duration of the treatment which could be reduced if the protocol involved subcutaneous biologic therapy (in place of intravenous). In conjunction with patients, feedback underlined that the shorter administration time of the subcutaneous administration would be a benefit, however, the overall travel times across town through large urban areas to reach the infusion centres would offset the time gains from subcutaneous administration. To ensure shared benefits for both patients and the healthcare budget, a decision was made to re-invest the financial savings from intravenous rituximab biosimilar utilisation to develop, jointly with patients and advocates, and staff, new infusion clinics closer to patients’ homes, in the city outskirts.

The various Canadian Provinces’ biosimilar transition programmes have also focused on incentivising the healthcare professionals involved in introducing biosimilar medicines and transparently indicating how the benefits of biosimilar medicines use would be translated in the healthcare system. Of particular note, the British Columbia programme, in which the re-investment of savings entailed the financing of better coverage for new treatments in diabetes and psoriatic arthritis as well as fecal calprotectin testing, a helpful diagnostic test to measure inflammation in patients living with Inflammatory Bowel Disease.

**HOW COULD THIS BE IMPLEMENTED IN PRACTICE?**

- **Reform purchasing & procurement policies**
  - Allow timely competition (multiple suppliers);
  - Avoid prolongation of monopolies

- **Tackle market barriers**
  - Consider mid- and long-term agreements
  - Incorporate multiple criteria beyond price
  - Secure global demand forecast
  - Translate mapping into long-term demand forecast
  - Align utilisation incentives across stakeholders

- **Good practice & experience sharing**
  - Market predictability
ADAPTING REIMBURSEMENT AND CO-PAYMENT POLICIES FOR AFFORDABLE ACCESS

It is essential to consider the affordability of therapy for both the healthcare system and patients. While competition dynamics will impact overall treatment costs over time, targeted adaptation of reimbursement policies and co-payment may be required to deliver the full value of biosimilar competition.

Existing reimbursement and co-payment policies applicable to a monopolistic situation (i.e. one available medicine on the market) may not be fit for purpose at the time competition starts and multiple manufacturers begin offering equivalent options for a given biologic medicine. In countries where the originator biologic product is hardly used at all, owing to capped pharmaceutical budgets or to the predominant coverage by private insurance which leads to high co-payment for patients, to ensure biosimilar medicines availability on the market, policies should reconsider public reimbursement and/or co-payment levels, particularly of biologic medicines on the WHO EML which have expired exclusivities.

In Poland, most biologic medicines are only available to patients via drug programs that are highly restrictive for prescribing physicians (i.e. capped spending), thus limiting the access to biologic treatments for patients. Upon biosimilar introduction, the lowered treatment costs resulting from competition could translate into more patients being treated and greater prescription freedom for physicians.

The availability of biosimilar medicines for adalimumab, etanercept and infliximab has led to lower overall treatment costs for rheumatoid arthritis management, allowing NICE, United Kingdom, to revise its guidelines and translate the savings from biosimilar use into broader access to biologic treatments for people with moderate rheumatoid arthritis that have not responded to conventional therapies.

The availability of GCS-F biosimilars enabled a broadening of these cancer supportive care medicines after adaptation of the guidelines in New Zealand leading to a two-third fall in the rate of Febrile Neutropenia, a severe side effect of chemotherapy, among breast cancer patients.

HOW COULD THIS BE IMPLEMENTED IN PRACTICE?

(34b) DIA US Biosimilar Conference, P Cones - Oct 2021
Regulatory agencies should be the primary source of information on biosimilar medicines. As unbiased and trusted bodies, they are most likely to be regarded as reliable sources of information by policymakers, payers, healthcare professionals and patients.

More patient and healthcare provider education is needed to improve confidence in and use of biosimilar medicines. Regulators also need to be educated about the continually evolving science of biosimilar development.

In many jurisdictions, significant efforts have already been deployed by regulators and governmental organisations to develop and distribute information materials on biosimilar medicines. These successful initiatives can be referred to as examples in support of new education initiatives in other regions. For example:

- In 2018, the Australian government awarded GBMA Education Limited a 3-year Biosimilar Education Grant as part of its investment in educating prescribers, pharmacists and consumers on the benefits of using biosimilar medicines. The purpose of the grant was to increase confidence in the use of biosimilar medicines and support a competitive market for biologic medicines via peer-to-peer health communication activities that support the increased use of biosimilar medicines. A dedicated ‘biosimilar hub’ was developed and provides extensive resources for both prescribers and consumers.35

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The EU regulator EMA, in collaboration with the European Commission, has developed two types of information material targeting healthcare professionals and patients respectively. These important resources are available in multiple languages and provide simple science-based messages reinforcing trust in the safety, efficacy, and quality of biosimilar medicines.

The Advancing Education on Biosimilars Act, which was enacted in April 2021 in the United States, directs the US FDA to create and maintain a website with information for healthcare providers, patients, and others about biosimilar medicines. Healthcare professional and patient organisations are also key players in making effective, easily understandable, and accessible information on biosimilar medicines available to patients. Indeed, healthcare professionals are always the first point of contact for patients to whom a biosimilar medicine has been prescribed. They have a responsibility to appropriately inform and empower patients in their health decisions and should aim to develop simple and effective messages. Patient organisations, on the other hand, are best placed to develop materials that specifically address patient-reported concerns and translate often complex notions on biosimilar medicines in lay terms.

Existing misconceptions on biosimilar medicines are the greatest challenge to creating and fostering trust in these therapies from both healthcare professionals and patients. A two-pronged approach is needed to overcome these:

- Perceived issues regarding the use of biosimilar medicines can be addressed with simple, and science-based arguments, addressing concerns promptly once they arise. The European Cancer Patients Coalition (ECPC) developed a unique resource for patients wanting to learn more about biosimilar medicines and how to be involved in shared decision making.

- Healthcare professionals are also key players in making effective, easily understandable, and accessible information on biosimilar medicines available to patients.

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(36) Biosimilars in the EU - Information guide for healthcare professionals
(37) Questions and answers for patients - Biosimilar medicines explained
https://ec.europa.eu/docsroom/documents/26643
(38) USA Advancing Education on Biosimilars Act 2021
Fact-based messages on the safe clinical use experience, the efficacy and quality of biosimilar medicines should also be highlighted, as done for example in a recent peer-reviewed publication showing that the introduction of biosimilar medicines did not result in an increased pharmacovigilance signal in the EU\textsuperscript{36}. This analysis by EMA regulators further shows that having a larger number of versions of a biologic medicine (i.e., more biosimilar medicines based on the same molecule) does not correlate with poorer identifiability.

The dynamic nature of the regulatory framework for the approval of biosimilar medicines also poses a challenge in the development of information on this topic. The evolution of regulatory approaches is to be expected as the analytical and scientific methods advance and accumulated experience with these medicines grow, and it is required to ensure better efficiency in the approval process. Yet, every time significant changes are implemented, it becomes necessary to update and adapt communication materials. It follows that resources allocated to the development of information resources should be complemented by a continuous investment in their maintenance and the updating and training of healthcare community stakeholders.

Finally, as biosimilar medicines become available in new therapeutic areas, it is important to ensure that existing resources and information materials are made available in a timely manner to both healthcare professionals and patients, and tailored to the needs and challenges associated with specific disease groups. Proactive communication on the importance of biosimilar medicines is also essential to achieve uptake in new indications.

These actions would support WHO’s efforts towards raising awareness and enhancing technical knowledge on the role of biosimilar medicines in access to medicines.

### HOW COULD THIS BE IMPLEMENTED IN PRACTICE?

- **SUSTAINED EDUCATIONAL EFFORTS**
  - (Co-)Design educational materials on key biologic, incl. biosimilar concepts

- **TACKLING MISLEADING INFORMATION**
  - Disseminate educational materials to all healthcare stakeholders
  - Actively tackle misrepresentations of challenging concepts towards healthcare providers and patients

- **EXPERIENCE SHARING**
  - Communicate on the cumulated global clinical experience with biologics, incl. biosimilars
  - Share regular post-approval pharmacovigilance and safety updates
  - Bring forward the unambiguous evidence on biologic switching as safe medical practice

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(39) Biosimilars E-module - ECPC - European Cancer Patient Coalition
(40) Identifiability of biologicals: an analysis using the EMA adverse drug reaction database, EudraVigilance
CONCLUSION

Facilitating access to biologic therapies is one essential pillar in achieving Target 3.4 of the UN Sustainable Development Goals SDGs by 2030 – i.e. reduce mortality from Non-Communicable Diseases and promote mental health. Experience has shown that for many patients around the world, accessing biosimilar medicines is often their first opportunity to obtain transformative biologic therapies. The global biosimilar medicines industry therefore has a prominent role to play in delivering on the timely, sustainable and affordable access promise, as captured in the WHO roadmap for access to medicines, vaccines and health products (72nd World Health Assembly in 2019 - resolution A72.17)¹.

Smart use of biosimilar medicines is also an indispensable asset in strategies aimed at mitigating the COVID-19 pandemic impact on both patient care and health care sustainability. As governments around the world set out pandemic recovery roadmaps, it is essential that efficiency in healthcare and pharmaceutical budget management be at the heart of the reflection.

With over 400 biosimilar medicines approvals to date, the opportunity to align globally on Effective Strategies to Advance Access to Biologic Therapies for Non-Communicable Diseases is starkly relevant. Many of the solutions to the current challenges are known. A wealth of experience is already available in support of setting up conducive policy frameworks. To unveil the full value of biosimilar competition for patients and healthcare systems, four (4) main areas of policy should be attended to as a matter of priority:

- greater regulatory convergence and reliance,
- efficient, timely and sustainable market competition,
- affordable patient co-payment and reimbursement policies and
- continuously growing stakeholder trust and confidence.

Collectively, the global biosimilar medicines industry, in partnership with WHO and global stakeholders, can help build and disseminate a Biosimilar medicines Access Policy Blueprint, paving the way to unlock patient access to biologic therapies.

To close the gap on access, the Biosimilar medicines Access Policy Blueprint needs to be translated into actions. A real and concrete impact for patients worldwide is within reach, provided stakeholders jointly recognise the strategic role of biosimilar medicines, set clear objectives and stimulate good practice sharing in overcoming our common access challenges.

The IGBA sees tremendous opportunities for collaborative action by stakeholders and looks forward to partnering on a pragmatic implementation roadmap for a Biosimilar medicines Access Policy Blueprint.

Achieving universal health coverage and equity in public health depends on access to essential, high-quality and affordable health related technologies for all.³
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ABOUT IGBA

The International Generic and Biosimilar medicines Association (IGBA) strengthens cooperation between associations representing manufacturers of generic and biosimilar medicines from around the world. Adopting a patient centric approach, IGBA works to improve patients’ access to quality-assured, safe and cost-effective medicines by promoting competition and enabling innovation in the pharmaceutical sector and sustainable economic contributions for all stakeholders.

INTERNATIONAL GENERIC AND BIOSIMILAR MEDICINES ASSOCIATION

For more details, regarding IGBA and its member associations, see the IGBA website at: www.igbamedicines.org

For IGBA Biosimilar resources, please see: https://www.igbamedicines.org/committees/biosimilars-committee

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