# Making Access Happen: A Consensus Statement on Access, Generic and Biosimilar Medicines

Access to medicines is a crucial component of effective healthcare systems. For patients, timely access to affordable and appropriate medications can significantly improve health outcomes, enhance quality of life, and even mean the difference between life and death. By expanding treatment options and promoting competition, generic and biosimilar medicines can improve access, sustainability of healthcare systems, and alleviate the societal burden of untreated illnesses.



This consensus statement, developed through the Making Access Happen: Sandoz Global Access Forum 2024, brings together insights and recommended actions from patient advocates, working in patient organizations worldwide across different disease areas, on access to generic and biosimilar medicines.

# **Access to medicines: A Patient Perspective**

Access to medicines is vital for managing health conditions, prolonging life, and providing hope. Equitable and affordable access, aligned with individual needs and preferences, and supported by the right resources, empowers patients to make informed decisions, adhere to treatment plans, and achieve better health outcomes.

Access to medicines promotes health equity, supports universal health coverage, and contributes to the well-being of communities and overall productivity. Untreated conditions lead to increased healthcare costs, strain on social support systems, and lost productivity, underscoring the importance of ensuring widespread access to essential treatments. Patient engagement and education are crucial to enable patients to advocate for their rights and navigate complex healthcare systems.



# G m hi p m g a A im g fu

# The role of generic and biosimilar medicines

Generic and biosimilar medicines have a pivotal role in improving access to medicines for patients. They can reduce the financial burden on individuals and healthcare systems, making treatments more affordable and available to a wider population. Sustainable pricing models and policies that promote the use of these medicines can further enhance their impact on patient access. The availability of generics and biosimilars increases treatment options, enables earlier and broader access for patients, and promotes health equity.

Additionally, generic and biosimilar medicines increase competition, and drive innovation and financially sustainable health systems. The savings generated by generic and biosimilar medicines can be reinvested into healthcare infrastructure, funding additional patient support services, and expanding access to new therapies.

# The vital role of patient communities in improving access to medicines

Patient organizations provide a powerful voice for patients, helping policymakers understand the perspectives of the patient community as they work to implement better health policies. Patient organizations educate their communities, empower patients to make informed decisions, and play a vital role in enhancing access to medicines. Collaboration between patient organizations, healthcare providers, policymakers, pharmaceutical companies, and other stakeholders is essential for driving initiatives that improve access to medicines. Patient organizations can collaborate on a global scale to share best practices, advocate for international standards, and work towards harmonizing policies that facilitate better access to medicines across borders. To maintain credibility and effectively represent patient interests, patient organizations must operate with independence, transparency, and unbiased advocacy.

# Ensuring the sustainability of medicines

Sustainable practices in production and distribution are crucial to ensure a stable and reliable supply, directly influencing affordability and availability. Policymakers must address supply chain resilience issues while also considering the impact of pricing models and procurement practices on patient access. Strategies that balance affordability, quality and supply chain reliability should be prioritized to ensure patients receive high-quality treatment when needed. Exploring innovative pricing and procurement approaches can foster a diverse and resilient supply chain, minimizing the risk of medicine shortages. Ultimately, efforts to improve affordability and availability must not compromise the efficacy, safety, or accessibility of medicines.

# Promoting equitable access to treatments: biosimilars as part of the solution

Biosimilars play an important role in promoting equitable access to treatments by increasing affordability and availability of vital medicines. As such, advancing biosimilar adoption is essential to improve patient access and healthcare system sustainability. To effectively advance biosimilar adoption, key strategies that encompass education, digital health technologies, shared decision-making, innovative and sustainable pricing models, global collaboration, supportive regulatory and policy frameworks, and ethical practices should be considered:

- Comprehensive education initiatives targeted at healthcare providers, patients, and policymakers, with collaborative strategies to develop patient-friendly resources and online hubs for best practices. Educational materials need to be crafted in straightforward, patient-friendly language to ensure consistency across all resources.
- Leveraging digital health technologies to enhance distribution and monitoring, particularly in underserved regions.
- Promoting shared decision-making and patient involvement, which are crucial for successful adoption.
- Implementing innovative and sustainable pricing models with transparency on how savings are allocated, ensuring these savings contribute towards improving healthcare infrastructure, patient experience, and expanding access, and reducing costs for the patients.
- Harmonizing standards and fostering global collaboration among stakeholders such as regulatory bodies, healthcare providers and other stakeholders.
- Establishing supportive regulatory and policy frameworks that prioritize quality and safety, ensuring that budget-driven decisions by health authorities do not compromise these standards.



## **Key actions**

- 1. Develop and implement comprehensive **education and awareness programs** to empower patients, caregivers, and healthcare providers with knowledge about generic and biosimilar medicines, their safety, efficacy, and role in improving access to treatments. Leverage digital technologies to enhance access to information and informed decision-making.
  - Create a resource library that is accessible, patient-friendly, and covers various aspects of access to medicines.
  - Utilize diverse platforms, including social media and Al-driven tools, to disseminate educational materials and engage target audiences.
  - Develop and maintain a digital biosimilar dashboard to monitor policies, share knowledge, and facilitate collaboration among stakeholders.
- 2. Foster multi-stakeholder **collaboration** to **advocate** for **policies** that prioritize access to affordable, quality medicines and strengthen the patient voice in decision-making processes.
  - Establish partnerships between patient organizations, healthcare providers, policymakers, and the medicines industry to develop and implement patient-centric strategies.
  - Encourage patient representation in relevant decision-making bodies and policy discussions.
- 3. Work towards harmonizing **global standards** for the development, regulation, and approval of generic and biosimilar medicines.
  - Engage with regulatory agencies and international organizations to promote consistent quality, safety, and efficacy standards.
  - Advocate for streamlined approval processes that facilitate timely access to medicines across borders.
- 4. Continue a **multi-stakeholder dialogue** with best practice sharing, and collaboration to drive strategies for improving access to generic and biosimilar medicines.
  - Organize regular meetings, workshops, and conferences to foster ongoing communication and collaboration among stakeholders.
  - Develop mechanisms for tracking and reporting on the implementation and impact of access-enhancing initiatives.
- 5. Promote the implementation of transparent benefit-sharing models that allocate savings from the use of biosimilar medicines towards improving patient access and healthcare infrastructure.
  - Collaborate with healthcare systems and policymakers to design and pilot benefit-sharing initiatives.
  - Advocate for the reinvestment of savings into patient support services, education, and access-enhancing programs.
- 6. Support **research** initiatives to identify and address barriers to patient involvement in treatment decisions and biosimilar adoption.
  - Conduct studies to understand factors influencing patient, caregiver, and healthcare provider perceptions, decisions and behaviours.
  - Utilize research findings to develop targeted policy recommendations.

By taking these actions, we can impact many people's lives. Let us unite to make access happen for patients.

### **Contributors**

This consensus statement has been co-created and endorsed by the contributors in their personal capacity. The views, opinions, and recommendations expressed in this consensus statement are those of the individual contributors and do not necessarily represent the organizations they are affiliated with.

Alessandra de Souza, Brazil; Anette Meyer, Germany; Beatriz Martinez de la Cruz, Spain; Camille Lancelot, Sweden; Catalina Horta, Chile; Cecilia Rodriguez, Chile; Cheryl Koehn, Canada; Daneen Sekoni, US; Deidre Mackechnie, Australia; Dominique Grenot, France; Elsa Mateus, Portugal; Erika Vega Palavicini, Costa Rica; Federica Balzani, Italy; Ghislaine Dugoua-Jacques, France; Guillaume Molinier, France; Inna Ivanenko, Ukraine; Ivan Zelenskyi, Ukraine; Katie Joyner, Germany; Laura Wingate, US; Ljiljana Vukota, Croatia; Luis Adrián Quiroz Castillo, Mexico; Merel Hennink, Netherlands; Mike Mandelbaum, UK; Molly Murray, US; Pia Humski, Croatia; Radu Ganescu, Romania; Sergio Patricio Aravena Baeza, Chile; Tara Petch, Canada; Veronika Ivančíková, Slovakia; Zorana Maravic, Serbia