

MEDIA & INVESTOR RELEASE

Sandoz introduces Act4Biosimilars Action Plan to accelerate patient access to biosimilar medicines

- *Despite nearly 20 years of availability, biosimilars show worldwide adoption rate of only 14% in initiative-tracked countries, while reference medicines still represent 86% of biologic treatments¹*
- *Unregulated biocopies, legal and regulatory decisions, and misaligned incentives within healthcare delivery models contribute to barriers that prevent patients in the Americas from accessing biosimilars*
- *Newly launched Act4Biosimilars Action Plan identifies key challenges and provides actionable steps for countries to take to increase global biosimilar adoption by at least 30 percentage points in 30+ countries by 2030*

Basel, June 15, 2023 — Sandoz, a global leader in generic and biosimilar medicines, today announced the launch of a global roadmap to increase patient access to biologic medicines. The Act4Biosimilars Action Plan is part of the Act4Biosimilars initiative, founded by Sandoz and launched in 2022, and aims to increase global biosimilar adoption by at least 30 percentage points in 30+ countries by 2030.

Professor Emeritus Tore K. Kvien, previous Head of Department of Rheumatology, Diakonhjemmet Hospital for 25 years and a member of the Act4Biosimilars Steering Committee, said, “The time to globalize biosimilars is now, so that advanced biologic medicines are accessible to patients who need them most. Their benefits are proven, and it’s time to bring them to more patients and health systems across the world.”

The Act4Biosimilars Action Plan highlights the most critical challenges preventing patient access to biosimilar medicines, as well as actionable steps to accelerate adoption by overcoming those challenges. The Action Plan will be complemented by a series of reports which provides analysis of the key challenges by region. The first region spotlighted is the [Americas](#) and includes the following insights:

- In the **United States**, the interchangeability regulatory guidelines have caused confusion among patients and healthcare professionals.
- Due to gaps in the regulatory pathways, patients in **Colombia** and **Ecuador** can be exposed to biocopies which may not meet the rigorous international guidelines provided by the World Health Organization (WHO) for the approval of biosimilars^{2,3}.
- In **Canada**, the **U.S.** and **Brazil**, educational materials exist, however a lack of alignment across stakeholder groups on the materials has led to confusion amongst healthcare professionals and patients.
- Unsustainable procurement practices, such as single-winner tenders, are common in **Mexico** and **Brazil**, creating supply continuity risks and potential disruptions to patient care.

To address these and other challenges, the Action Plan features 12 key initiatives to accelerate biosimilar adoption across the 4As – Approvability, Acceptability, Accessibility, and Affordability. It provides actionable steps designed to help local stakeholders foster a more favorable environment for biosimilars in their country and ultimately drive global adoption.

Laura Wingate, Executive Vice President, Education, Support & Advocacy at the Crohn's & Colitis Foundation said, "Biosimilars can be life-changing for patients and their families and can play a critical role in overcoming health inequalities seen across the world. As a stakeholder-driven initiative, Act4Biosimilars aims to empower local stakeholders on the ground, who are passionate about increasing patient access to advanced medicines. We are asking them to download the Action Plan, use the information provided, and join the movement to increase biosimilar adoption."

The Steering Committee is working with local stakeholders across the Americas to implement the Action Plan and identify and address the key challenges holding back wider biosimilar adoption. The Steering Committee will turn its focus to Europe in Q4 2023, the Middle East & Africa in Q1 2024, and Asia Pacific in Q2 2024.

Arnold Vulto, Independent Consultant and Educator, VuPEC, said, "All healthcare stakeholders play an important role in improving patient access to biosimilars. So whether you're a physician, nurse, pharmacist, payer, or a patient, look for possibilities on how biosimilars can benefit your health system and patients. I encourage you to join the Act4Biosimilars movement as collaboration is the driving force behind the initiative, and those committed to the Mission should get in touch."

For nearly two decades, the introduction of biosimilars have enabled expanded or earlier patient access to biologic treatment. It is estimated that between 2023 and 2027, biosimilars could generate \$290 billion in savings globally⁴. However, biosimilars are still unavailable in most countries and there are significant challenges to expand access. As a result, their impact on patients varies widely.

Measuring Global Progress

The [Act4Biosimilars Impact Index](#) will measure and assess progress for 30 initiative-tracked countries in relation to the favorability of the local environment towards biosimilars, under each of the 4As. The Index will be updated every two years, to give local stakeholders shared visibility and understanding of the most critical issues preventing biosimilar adoption.

Act4Biosimilars aims to achieve a biosimilar adoption rate of 44% by 2030 across 30 countries in scope of tracking. This is a 30 percentage point increase on the baseline figure of 14% from 2022.¹ These figures are based on comparing the volume of biosimilars against the reference medicine for each molecule for which a biosimilar is already available or expected to be made available by 2030.

The [Action Plan](#) is available to download on the Act4Biosimilars website.

For more information, go to [Act4Biosimilars.com](#). Follow Act4Biosimilars on [LinkedIn](#). Follow Act4Biosimilars on [Twitter](#).

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About biosimilars

A biosimilar is a successor to a biological medicine (also known as "reference medicine") for which the patent has expired, and exclusivity has been lost. Biosimilars match their respective reference medicine in terms of quality, safety, and efficacy. Biosimilars are used in the treatment and prevention of many disabling and life-threatening diseases in oncology, rheumatology, dermatology and many other indications.⁵

About Act4Biosimilars

Act4Biosimilars is a global initiative aimed at increasing patient access to biologic medicines by facilitating greater Approvability, Accessibility, Acceptability and Affordability of biosimilars. Act4Biosimilars is led by a multidisciplinary Steering Committee of patient advocacy leaders, healthcare professionals, biosimilar experts, and industry leaders from around the world, with a Mission to increase the global adoption of biosimilars by at least 30 percentage points in 30+ countries by 2030. Act4Biosimilars seeks to bolster the global biosimilar movement by clearly aligning and informing action on biosimilar challenges and opportunities for patient access and sustainable healthcare and is supported by founding sponsor, Sandoz.

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References

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About Sandoz

Sandoz, a Novartis division, is a global leader in generic pharmaceuticals and biosimilars. Our purpose is to pioneer access for patients by developing and commercializing novel, affordable approaches that address unmet medical needs. Our ambition is to be the world's leading and most valued generics company. Our broad portfolio of high-quality medicines covers all major therapeutic areas.

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