SANDOZ

Positioning paper on non-communicable diseases

Contents

Context

Sandoz is the global leader in generics and biosimilars, an industry that produces about 80% of medicines used worldwide by volume at about a third of the total cost. Our leading role in anti-infectives is balanced by an equally broad and growing portfolio targeting non-communicable diseases (NCDs). Hence Sandoz is uniquely positioned to engage governments and healthcare stakeholders on framing the solution to the global NCD burden, and to provide another perspective on efforts by originator companies to frame the solution around increasing access to innovative medicines (1).

Addressing the global health and fiscal challenge of NCDs in a sustainable manner can only be done if generic and biosimilar medicines play a large role in the treatment of those diseases.

NCDs, including cardiovascular and chronic respiratory diseases, cancer and diabetes, represent the leading causes of death, accounting for over 74% of global deaths annually (2). The economic burden is immense, estimated to reach USD 47 trillion globally by 2030 (3).

NCD prevalence can be reduced by addressing behavioral risk factors like tobacco use, physical inactivity, alcohol abuse and unhealthy diet, as well as environmental risk factors like air pollution. Metabolic risk factors such as raised blood pressure, high blood glucose levels and obesity also contribute considerably to the occurrence of NCDs (2).

As NCD onset is not entirely preventable and reversing lifestyle trends and their impact on population health is a challenging and lengthy process, access to medicines is essential for mitigating the negative impact of NCDs.

Increasingly high costs associated with innovative medicines are a source of growing concern. This is particularly the case with biologics used in cancer treatment, the largest therapy area by spending (4), as well as biologics used to treat autoimmune diseases. Addressing NCDs requires not only innovation in treatments but also sustained, affordable access to high-quality medicines. Generic and biosimilar manufacturers like Sandoz can reduce these cost barriers by improving access and thus improving the affordability of NCD-related care (5). By reducing treatment costs, generics and biosimilars free up resources for NCD prevention and screening as well as the research and development of new medicines.

The value of the generics and biosimilars industry in the NCD response

The generics and biosimilars industry enables widespread access to life-saving medications for the management of NCDs. Generic medicines typically cost 20%-80% less than the corresponding originator medicines, and biosimilars offer savings of 15%-30% depending on the market (6).
Price reductions significantly expand access to major chronic therapy areas:

- In Europe, over 10 years, generics have doubled access to medicines for major chronic diseases.
- More than 90% of the EU list of critical medicines are generics.
- Nearly nine of 10 prescriptions filled in the US today are for generics and 66% of US adults use prescription generic medicines to treat chronic conditions such as heart disease, diabetes and cancer (7).

In 2024, the lower cost of Sandoz generics and biosimilars has generated about USD 19 billion in direct savings for healthcare systems in the US and Europe alone (8).
Many Sandoz products reach patients who might otherwise have very limited access to high-quality medicines. For example, our products are available in nearly half of the world's lower middle-income countries, sometimes in countries where the reference medicines are not available.

In 2024, Sandoz delivered 902 million patient treatments and our portfolio comprises 1,300 products and 11 biosimilars in more than 100 countries (8).
Our portfolio addresses the four main types of NCDs, with our products delivering:

- 80m patient treatments for cardiovascular diseases thanks to core small-molecule medications like statins, anti-coagulants and anti-hypertensives (9)
- 72m patient treatments for respiratory illnesses, targeting key conditions such as asthma and COPDs (chronic obstructive pulmonary diseases) (9)
- 4.1m patient treatments for diabetes (9)
- 1.4m patient treatments in oncology (9)

In 2024, Sandoz provided ~1.5m patient treatments globally through biosimilars addressing some important NCDs such as multiple sclerosis, cancer, inflammatory and autoimmune disorders (9).
Moreover, our generics and biosimilars pipeline anticipates continued treatment of NCDs, with molecules used for the treatment of cancer, bone diseases and diabetes.

About one-third of our portfolio is composed of anti-infectives (9), which play an important but often under-recognized role in the management of NCDs. Anti-infectives are essential in protecting, stabilizing and improving outcomes in patients with NCDs. For instance, they are essential for treating secondary infections (e.g., pneumonia in COPD patients) or managing complications from cancer treatment and diabetic foot infections. In an era of emerging antimicrobial resistance (AMR) our hard-won advances against cancer can be threatened when infections with resistant organisms lead to higher morbidity and mortality rates, longer hospital stays and higher treatment costs.

Biologic medicines often represent the standard-of-care in the treatment of many NCDs, particularly in the fields of oncology, rheumatology, endocrinology, and others therapeutic areas. The adoption of biosimilars represents a great opportunity to reduce the budgetary pressures for payers, supporting the sustainability of healthcare systems and allowing more patients access to treatment.
Biosimilars in fact provide direct and indirect savings to healthcare systems generating an expected USD 290 billion in savings by 2027 globally (6).
Moreover, in the US biosimilars have reduced biologic prices by nearly 50% four years after their entry providing valuable savings to the American healthcare system (10).
On the other side the spending for biologics has dramatically increased over the past decade. Originators' biologics accounted for 40% of the total medicines spending in the European Union in 2023 (12). In the US branded biologics accounted for more than 50% of total medicine spending in 2024, but only for 5% of the total prescription volume (13).

Barriers and policy goals to access generics and biosimilars in the treatment of NCDs

Despite significant global progress in improving access to medicines, about one-third of the global population does not have regular access to essential medicines (WHO). The situation is even more severe in some of the lowest-income countries in Africa and Asia, where more than half of the population have no regular access to essential medicines. This persistent gap undermines efforts to control non-communicable diseases, particularly in low- and middle-income countries.

There are many challenges to increase timely access to affordable NCD treatments worldwide. Some of these barriers - such as the misuse of intellectual property, the complexity of regulatory environments, pricing and reimbursements dynamics, public procurement models and supply chain vulnerabilities - also limit the ability of the generic and biosimilar medicines industry to have a positive impact.

For Sandoz, there is value in leveraging national conversations on NCDs to highlight key changes needed to drive affordable access to high-quality generic and biosimilar medicines. Specifically, this requires reforms that ensure sustainable pricing and reimbursement systems, promote intellectual property regimes

that encourage competition, and support efficient regulatory processes that enable the rapid uptake of generic and biosimilar medicines. To overcome those shared barriers policymakers, health authorities and industry leaders must work in concert to address:

- **Biosimilars and generics adoption**
  - National NCD strategies and treatment guidelines should promote biosimilar and generic medicines as the standard of care.
  - Generic and biosimilar medicines should be included in essential medicines lists and national formularies.
  - Incentives should be created for biosimilars and generics prescribing and dispensing.
  - Education about the safety, efficacy and value of biosimilars and generics should be promoted.
- **Regulatory harmonization** and accelerated approval pathways, especially for biosimilars, can speed up access while maintaining rigorous safety standards.
- Fair competition and intellectual property laws can prevent originator companies from hindering biosimilar and generic entry.
- **Supply chain resilience** can be promoted with **value-based procurement solutions**, shifting tendering models to consider quality, reliability and long-term market sustainability, not just the lowest price.

Collaboration among regulators, manufacturers, healthcare providers and patient communities is essential to maintaining public trust in generic and biosimilar medicines and driving their uptake. Sandoz works with policymakers, trade associations and government officials to implement solutions to on-going challenges facing the generics industry with the goal of increasing patient access in the treatment of NCDs.

Sandoz and the whole generics and biosimilars industry represent an indispensable component of the global healthcare ecosystem in the fight against NCDs. By providing timely, cost-effective and high-quality medicines, Sandoz supports sustainable health systems and improves patient access worldwide. Patients should have equitable access to the therapy they need irrespective of where they live. Sandoz supports measures that drive access to more patients, today and in the future. Strengthening policy frameworks and ensuring universal access to generic and biologic medicines are vital steps in addressing the growing burden of NCDs. The continued success of our industry relies on collaboration amongst multiple stakeholders, including policymakers, healthcare providers, and patient advocacy groups. By aligning efforts toward affordability, innovation and accessibility, the global community can make meaningful progress in reducing the impact of NCDs and improving public health outcomes for all populations.

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