



INTERNATIONAL GENERIC AND
BIOSIMILAR MEDICINES ASSOCIATION

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IGBA taking action to tackle shortages of antibiotic medicines

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For immediate release

The global generic medicines industry supplies most of the world's antibiotic medicine and is aware of the current surge in demand of these products that is leading to shortages. The surge is driven by an unusually high rate of respiratory conditions and infections that are occurring as we exit the most acute phase of the Covid-19 pandemic and, in many countries, an unusually high rate of respiratory conditions and infections among children. Demand has also increased due to changes in prescribing protocols, leading to a much higher number of prescriptions being issued for certain antibiotic medicines.

Our industry is working hard to increase production to meet this demand surge and are fully engaged to overcome these challenges and serve patients in need. Our manufacturers are in discussions with regulatory agencies like the FDA, the EMA and the WHO among many others to find solutions to meet the demand in the most efficient way possible. Our member trade associations are also mobilised at global, regional and national level to help address this demand surge.

We encourage governments and healthcare stakeholders to help mitigate this shortage by implementing the following recommendations.

- Governments should share epidemiological assessments of the estimated number of patients and the rates of growth of the diseases with the pharmaceutical industry. WHO, regional entities like the EU and governments could then provide the pharmaceutical industry with some expectations of demand, which will facilitate allocation to patients. We are especially concerned about the growth rates in paediatric populations as these patients often rely on a different pharmaceutical form or delivery than the adult population.
- Medical professionals must strictly follow antibiotic prescribing and dispensing guidelines to ensure that these critical medicines serve the patients with bacterial infections. This will mediate the demand surge and contribute to the fight against antimicrobial resistance (AMR). Important changes to prescribing guidelines that could increase or decrease prescribing volumes should be rapidly communicated to manufacturers to enable adequate adaptation of supply.
- Distribution chain actors (wholesalers, pharmacies, hospitals) should avoid stockpiling antibiotic medicines at this time as it is critical to allocate to meet patient need. Governments should engage in dialogue with these stakeholders.
- Trade facilitation measures should be utilised to accelerate the global delivery of medications.

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

- Regulatory authorities should authorise greater flexibility on packaging and leaflet requirements in the context of this demand surge. This should be automatic for hospital products and considered with appropriate safeguards for community products. Where possible, authorities could reuse the exceptional change management process (ECMP) that was successfully used to manage demand surges during the Covid-19 Pandemic. (see enclosed EU [guidelines](#) related to ECMP and to packaging/labelling as a reference)
- In the mid-term, we strongly encourage governments to rethink the functioning of antibiotic medicines markets to ensure greater availability and security of the supply of medicines. The current policy models are not conducive to investment in sustainable production for the future.

Richard Saynor, Chair of the IGBA CEO Advisory Committee and Chief Executive Officer of Sandoz, stated: *“I am deeply concerned about the high number of patients, including many children, contracting infections requiring antibiotic treatment. IGBA members are highly engaged to mitigate shortages caused by these surges and are willing to work closely with authorities to ensure that patients get access to the medicines they need”.*

Vivian Frittelli, Chair of the IGBA Management Committee and Chief Executive of the Generic and Biosimilar Medicines of Southern Africa Association, added: *“The IGBA is engaged with its member associations to prevent and to mitigate medicine shortages. The Covid-19 pandemic and its aftermath have increased the risk of demand surge shortages which require rapid response. We continue to encourage a patient-centric, proactive dialogue to address the root causes of medicine shortages and improve mitigation efforts. This dialogue should involve all stakeholders: patients, payers, healthcare professionals, regulators and supply chain participants to achieve the most benefit. Together, we can move more quickly to treat patients in need”.*