



INTERNATIONAL GENERIC AND
BIOSIMILAR MEDICINES ASSOCIATION

Trilateral Symposium on The Covid 19 Pandemic: Response, Preparedness, Resilience

Convened by WHO, WIPO and WTO

16 December 2022

Geneva

IGBA detailed opening statement covering key challenges of the Covid-19 pandemic

- *The International Generic and Biosimilar Medicines Association is an international organization of national and regional associations representing manufacturers of generic and biosimilar medicines from around the world. Our industry supplies an estimated 80% of all quality-assured medicines globally and is therefore absolutely critical to ensuring safe and affordable medicines are available to patients worldwide and indispensable for achieving Universal Health Coverage.*
- *At the onset of the Covid-19 emergency and during the acute phase of the pandemic, the biggest challenges were the **demand surge**, coupled with the **closure of borders** and the **heavy-handed state interventions** undermining supply capabilities, the **lock down measures** triggering major breakdowns of the distribution supply chains, the **shutdown of commercial airlines** affecting the import and export of medicines and their components globally as well as the **dramatic increase in transportation costs**.*
- *Despite the challenges, our industry notably massively scaled up production, put in place cooperation mechanisms to tackle the colossal surge in demand for medicine, adapted workplace rules to maintain medicines manufacturing and secured import/export waivers for therapeutics, either because products were not approved (e.g. emergency use) or due to export restrictions (e.g. in India). Our industry ended up with providing the vast majority of quality-assured medicines, in particular ICU medicines.*
- *In the second phase of the pandemic with the arrival of efficacious antivirals, developed by originator companies, we have seen that the mechanism **of bilateral voluntary licensing (VL) as well as MPP licensing have worked well** with many generics' companies developing and registering the products. A timelier licensing approach should be looked at for the future. The biggest challenge now remains the **demand for COVID-19 treatments** worldwide, and especially in Low- and Medium-Income Countries (LMICs). The generic medicines industry is investing in COVID-19 treatments but there is very limited information on what the demand in LMICs is now or will be in an endemic setting, as well as on the Test & Treat policies. Some companies dropped already out of the licensing agreement due to lack of demand.*
- *It also became very clear during the pandemic that regulatory efficiencies and science-based and risk based regulatory agilities, are critical to ensuring timely access to needed medicines.*

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.



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- *The WHO Prequalification (PQ) process could also be expedited by allowing for submission while awaiting final results of stability testing (e.g. rolling stability). LMICs also tend to ask additional data to the WHO PQ results before granting national Marketing Authorization, which delays the approvals and dilutes the benefits of this procedure.*
- *In 2022, as per WHO, the number of collaborative procedures (CRP) based on approvals by Stringent Regulatory Authorities (SRAs) has increased to almost 300% when compared to all previous years and the number of participating National Regulatory Authorities (NRAs) significantly increased from 21 to 47.*
- *However, the number of countries participating in these collaborative procedures needs to increase dramatically, if we want to make quality-assured products available for every patient in the world, and meet the target of Universal Health Coverage (UHC) by 2030.*