



IGBA's perspective on the Pandemic Accord

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June 29, 2023
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INTERNATIONAL GENERIC AND
BIOSIMILAR MEDICINES ASSOCIATION



Brief IGBA Introduction

June 2023



INTERNATIONAL GENERIC AND
BIOSIMILAR MEDICINES ASSOCIATION

About International Generic and Biosimilar Medicines Association (IGBA)

- Founded in March 1997 as the International Generic Pharmaceutical Alliance; Renamed International Generic and Biosimilar Medicines Association in September 2015; Legally incorporated in Geneva, Switzerland
- Admitted as ICH Assembly Member in 2016 and ICH Management Committee since 2017; Accredited WIPO Observer since September 2019; Got admitted as non-State actor in official relations with WHO in January 2022
- Maintains constant dialogue with the WHO, WTO, WIPO and other national, regional and international bodies



IGBA mission statement

- 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 is at the forefront of globally improving patients' access to quality-assured, safe and cost-effective medicines by preserving competition as well as 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.
- [Full IGBA profile](#)

IGBA Members

- Association for Accessible Medicines (AAM-United States)
- Canadian Generic Pharmaceutical Association (CGPA-Canada)
- Generic and Biosimilar Medicines Association of Southern Africa
- Indian Pharmaceutical Alliance (IPA-India)
- Jordanian Association of Pharmaceutical Manufacturers (JAPM-Jordan)
- Japan Generic Medicines Association (JGA-Japan)
- Medicines for Europe (Europe)
- Taiwan Generic Pharmaceutical Association (TGPA-Taiwan)

The generic and biosimilar medicines associations of Argentina, Australia, Brazil, Malaysia, the Republic of Serbia and of Montenegro are Associate Members and the Bangladesh association is Observer

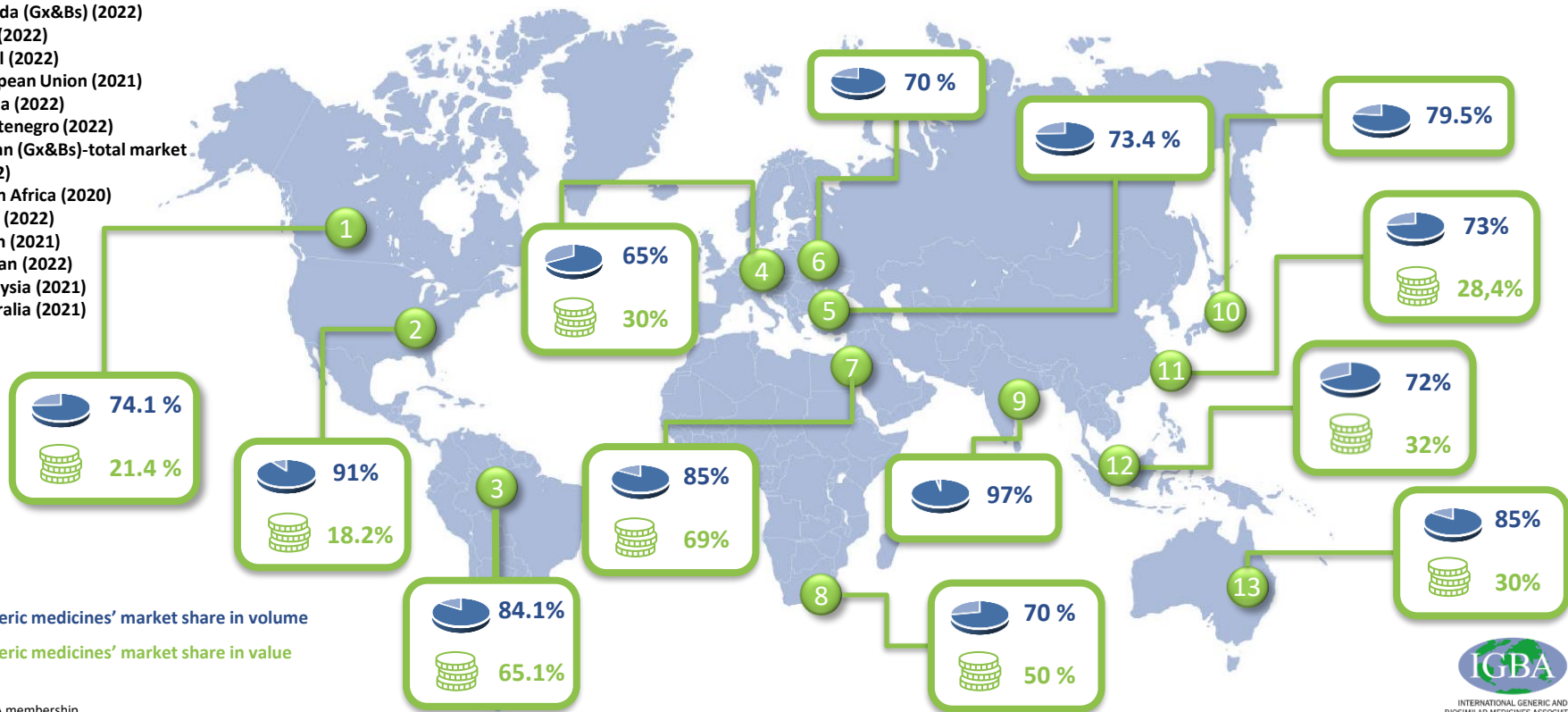
In addition, IGBA includes:

- Biosimilars Council (AAM Division)
- Biosimilars Canada
- Biosimilar Medicines Group (Medicines for Europe Sector Group)



Market Penetration of Generic Medicines

1. Canada (Gx&Bs) (2022)
2. USA (2022)
3. Brazil (2022)
4. European Union (2021)
5. Serbia (2022)
6. Montenegro (2022)
7. Jordan (Gx&Bs)-total market (2022)
8. South Africa (2020)
9. India (2022)
10. Japan (2021)
11. Taiwan (2022)
12. Malaysia (2021)
13. Australia (2021)



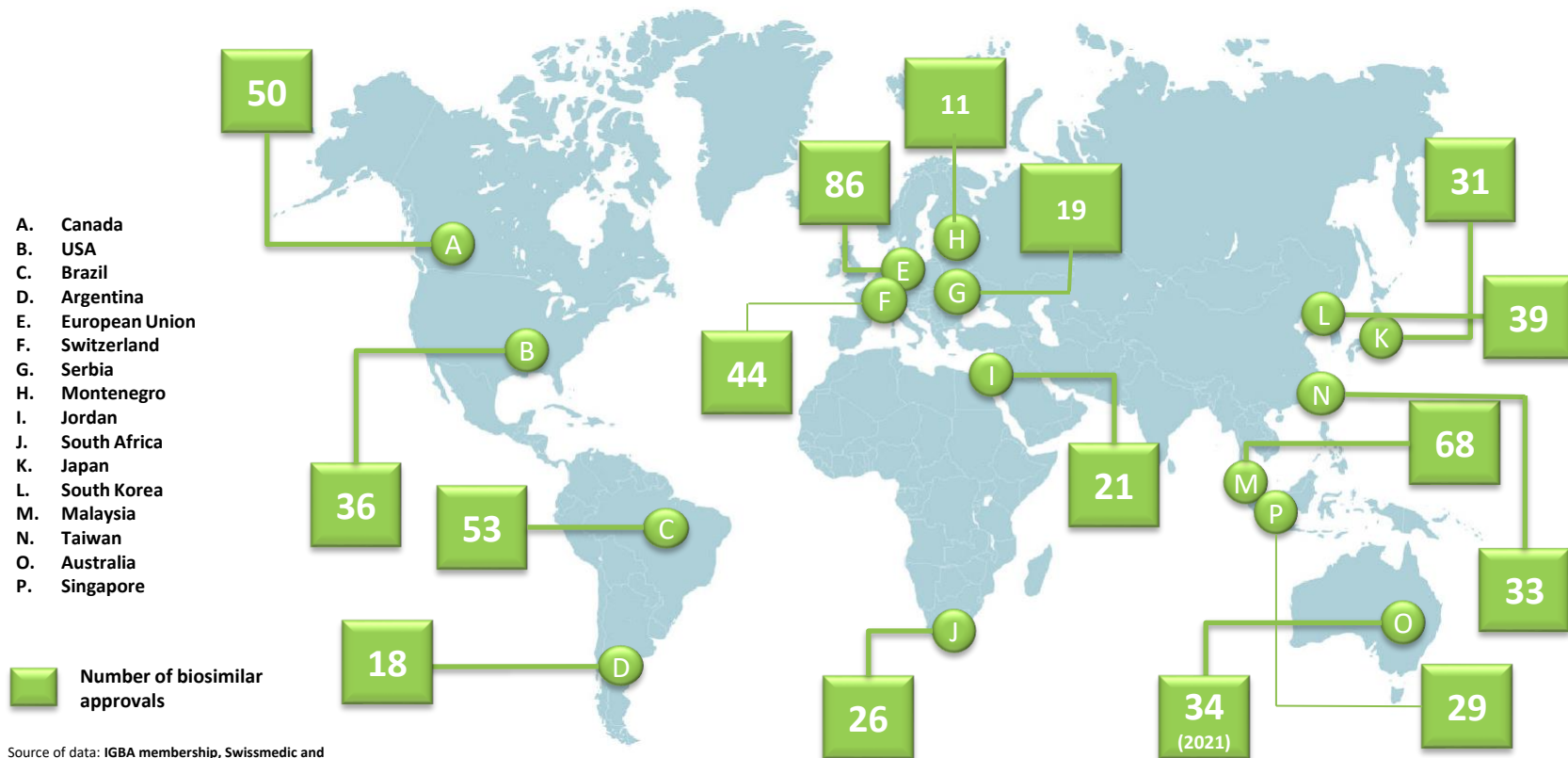
Generic medicines' market share in volume

Generic medicines' market share in value

Source: IGBA membership



Opportunity to generate competition in the biologics space with 600 biosimilar approvals covering over 10 therapeutic areas



Source of data: IGBA membership, Swissmedic and HSA Singapore

Background: Drug shortages (news 2023)



☰ The New York Times

How the Shortage of a \$15 Cancer Drug Is Upending Treatment

Older generic chemotherapy drugs remain scarce, forcing doctors to put a priority on the patients who have the best chance of survival.

🏠 > [my.europe](#) > Europe News

Brussels to present plans to avoid medicine shortages as Europe suffers from lack of supply



☰ EL UNIVERSAL SALA PLUS

+ Medicinas, el oro que escasea en América Latina

Background: Drug shortages



IGBA DRUG SHORTAGES WORKSTREAM

Report to the World Health Organization

NOVEMBER 2022

Available [here](#)

Background: Drug shortages

3.0 Factors that impact the security and supply of generic medicines.....	5
3.1 Poor procurement practices leave hospitals or regions exposed to localised shortages.....	5
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IGBA Perspectives on Pandemic Accord (Zero Draft – April 2023)

Available [here](#)

IGBA perspective on the Pandemic Accord

7. This negotiation has rightly identified the need for greater **harmonization of regulatory requirements and practices**³ to facilitate the entry of medicines into markets around the world, as well as the **harmful effects of unbalanced intellectual property rights**. Negotiators are urged to further strengthen the focus on regulatory efficiency to achieve timely, equitable access to health products, including through a recognition of the importance in advancing **single global development of generic and biosimilar medicines**.
8. The current draft negotiation document does not include reference to the importance for resilient supply chains of measures for **sustainable procurement systems for medicines**.⁴ Experience has shown that a procurement system focused only on pricing,⁵ and not on other aspects such as supply security and quality-assured products,⁶ among others, encourages the concentration of supply, driven by reaching economies of scale and the need for the lowest available raw-material and manufacturing costs. The risk that this imposes on the medicines supply chain and trade is directly counter to the intention of the Pandemic Accord to build more resilient health systems and supply chains.⁷ Negotiators are urged to consider inclusion of a recognition that procurement considering criteria beyond price is an essential component of health system resiliency.

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Key Comments and Proposals by IGBA on Selected Provisions of the Zero Draft of the Pandemic Accord May 2023

Available [here](#)



IGBA perspective on the Pandemic Accord

To amend Article 6.3 (a) as follows::

“[...] the most efficient multilateral and regional purchasing mechanisms, including pooled mechanisms and in-kind contributions, **that shall consider the market shaping impact of procurement**

criteria and incorporate sustainability of supply of quality-assured products, including award criteria beyond price and avoiding single-winner contracts, as well as promoting transparency in cost and pricing, where relevant, technically feasible and compliant with competition laws and principles; [...]

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THANK YOU!



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UN shared vision: equity of access to medicines

United Nation Sustainable Development Goals (2015):

Goal 3: **Promote health and well-being**

Shared responsibility:

- IGBA Members: key role in worldwide access to quality-assured, safe, and effective generic and biosimilar medicines
- Policy-makers at all levels: role to play in creating an environment for medicines to address inequities in health
- Regulatory authorities: central role to ensuring a sustainable environment for medicines development, approval and access



IGBA Goals

Promote regulatory cooperation and convergence of requirements for approval of generic and biosimilar medicines through international regulatory fora and trade negotiations

Promote the widest possible access of quality-assured, safe and effective medicines to patients globally

Promote balanced intellectual property regimes globally which foster innovation while supporting competition and preventing risks of IP abuses

Attract the widest assembly of members who are committed to subscribing to our standards and principles

Represent our members and support and co-operate with relevant international bodies and initiatives including the WHO, WTO, WIPO, ICH, IGDRP, IPRP, ICMRA etc

Support parties in international and regional agreement negotiations to remove barriers to and facilitate the registration and supply of generic and biosimilar medicines

Foster the sustainability of medicine manufacturers in the interests of healthcare systems and patients