WTO workshop on trade and public health

Engaging in the Production of Generic Medicines Under the Paragraph 6 System

Sergio Napolitano

13 November, 2019 - WTO, Geneva

IGBA

INTERNATIONAL GENERIC AND BIOSIMILAR MEDICINES ASSOCIATION

About the 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** in 2018
- Accredited **WIPO Observer** since September 2019
- **WHO signed a MoU with IGBA to promote access** in October 2019
- Maintains constant dialogue with the WHO, WTO, WIPO and other national, regional and international bodies
- Open to national and regional associations

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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 high quality, safe and effective medicines to patients globally
- Promote generic and biosimilar friendly 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, IPRF, 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

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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 Australia, Brazil, Malaysia, Mexico and Saudi Arabia are Associate Members.

In addition, IGBA includes:

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

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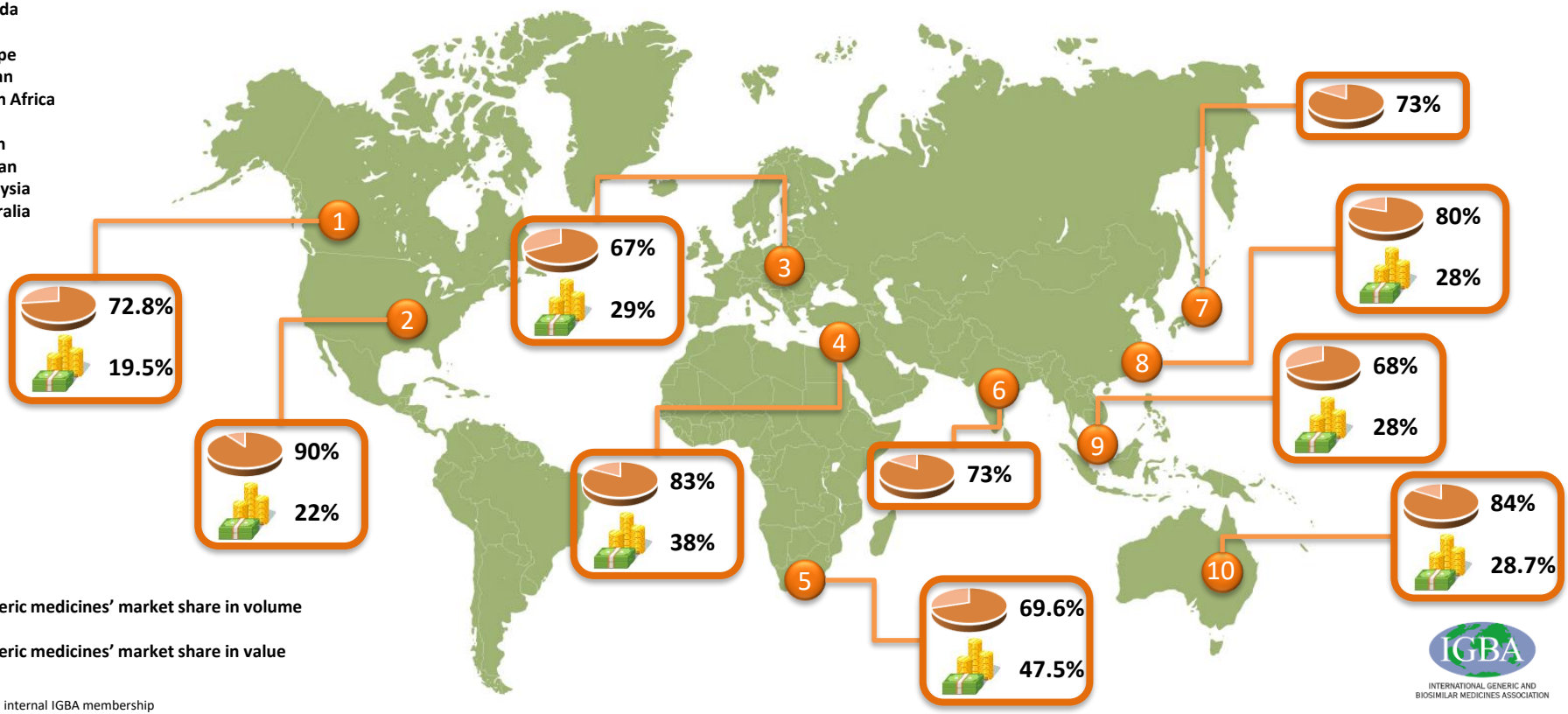
Market penetration of generic medicines

1. Canada
2. USA
3. Europe
4. Jordan
5. South Africa
6. India
7. Japan
8. Taiwan
9. Malaysia
10. Australia



Generic medicines' market share in volume

Generic medicines' market share in value

Source of data: internal IGBA membership

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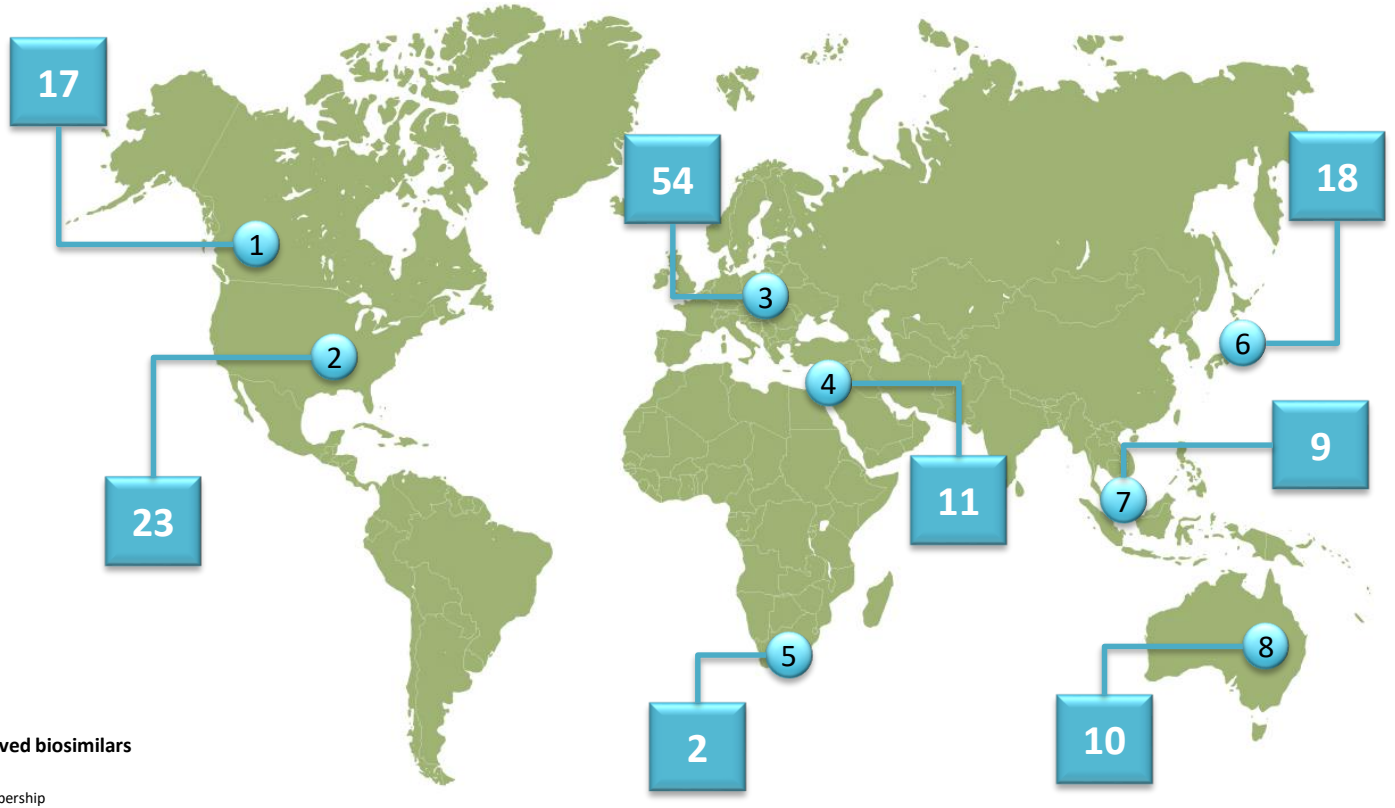
Biosimilar medicines: opportunity to generate competition in the biologics space

1. Canada
2. USA
3. Europe
4. Jordan
5. South Africa
6. Japan
7. Malaysia
8. Australia



17 Number of approved biosimilars

Source of data: internal IGBA membership

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Compulsory License (CL) - Scope

- Strict conditions for its application
- Scope:

  ✓ specific product concerned;

  ✓ relevant patents/SPCs;

  ✓ specific quantity to be produced;

  ✓ predetermined duration of the CL;

  ✓ specific importing country(s).

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An Industry Assessment of the Current System

- Very limited use of the “Paragraph 6 System” so far
- Highly regulated and science-based sector
- The process for obtaining a CL is rather complex and burdensome
  - Several actors involved (*ie.*, importing country, exporting country, patent owner, manufacturer)
  - Negotiations take time
  - Unpredictable results
- The CL mechanism has a very targeted scope
  - Specific product
  - Duration of supply
  - Quantity of production
  - Export country/region

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Stimulating export

- Viability, sustainability and predictability are crucial

- Predictable tools to spur export of generic medicines
  (*e.g.* export exception to patent extensions)

  – Broad geographical scope

  – Permanent tool

  – Impact on LDCs considering limited number of patent extension countries (EU, US, JP)

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Stimulating access

- Ensure access to essential medicines to avoid health risks
  - Shortages of essential medicines
  - Pricing policies
  - Ensure stability

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THANK-YOU!

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