WTO workshop on trade and public health

How to Enhance Synergies between Public Health Objectives and Trade Agreements: Industry and Civil Society Perspective

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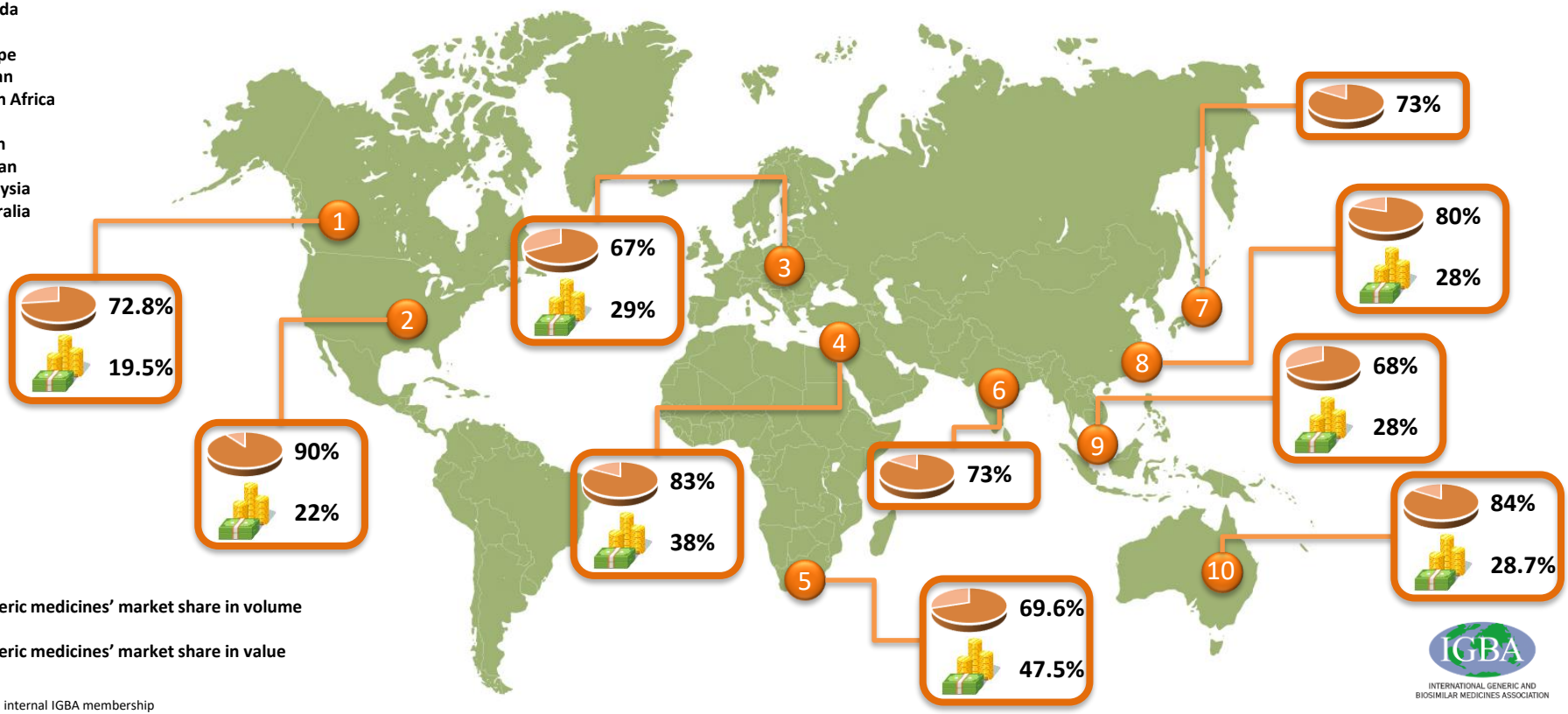
Market penetration of generic medicines

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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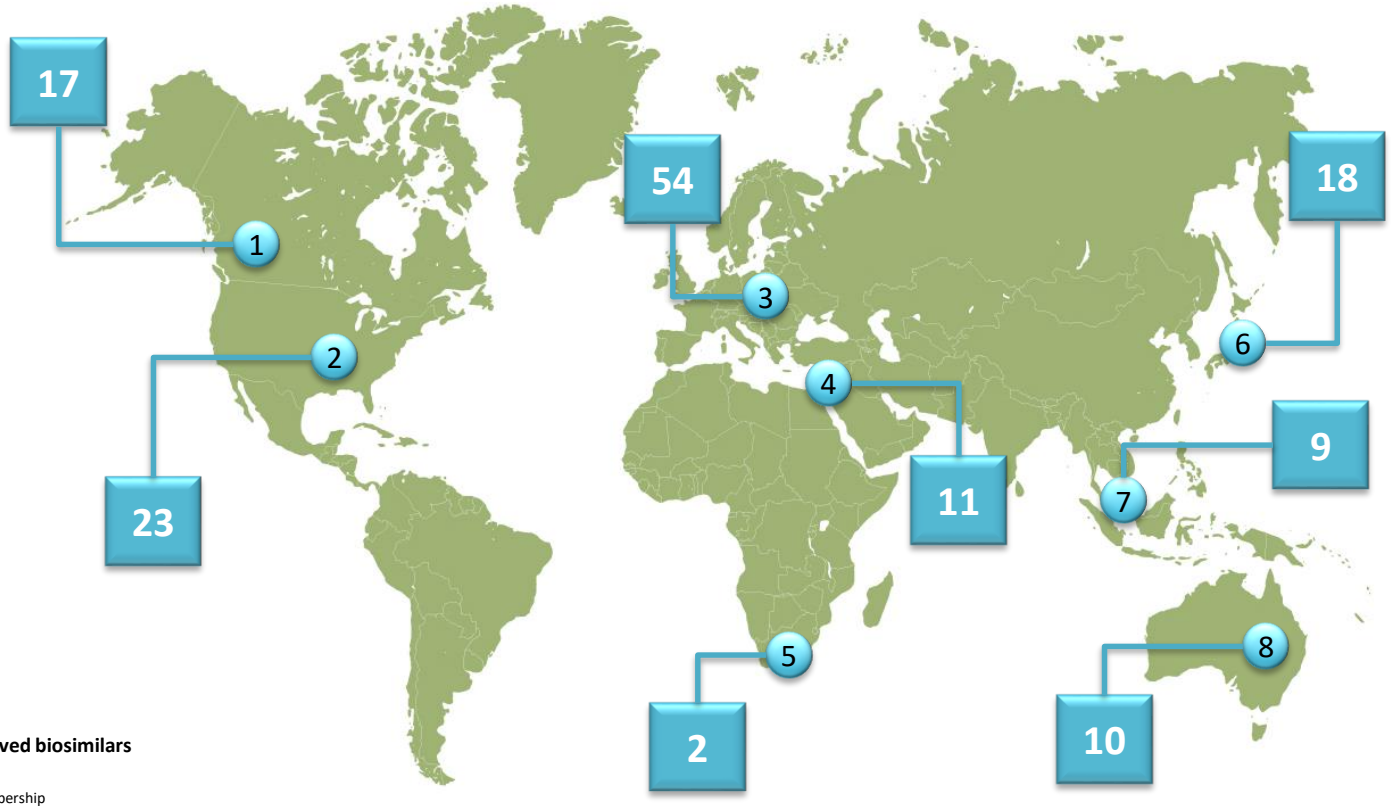
Biosimilar medicines: opportunity to generate competition in the biologics space

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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IGBA Priorities

- Impact of trade agreements on domestic legal & market access pharma rules
- Sustainability and future growth of the industry must become central focus
- Need for a new paradigm regarding pharmaceuticals and trade

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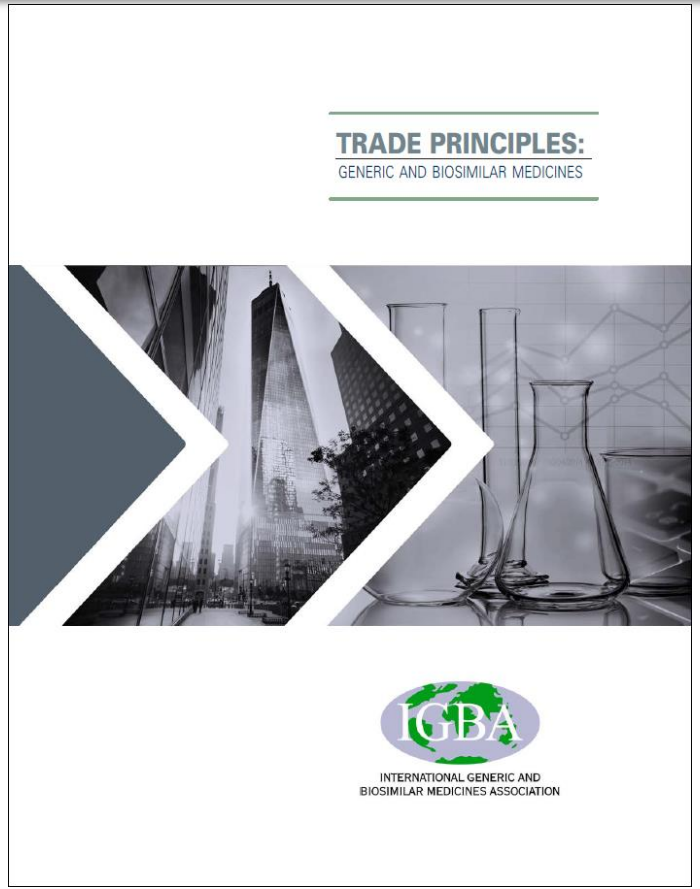
“Fostering International Trade in Generic and Biosimilar Medicines”



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The 2018 Update of the Report on Trade Principles

- Recent developments in international trade
- Recent issues of relevance to the biosimilar and generic medicines sector (*e.g.*, public health objectives & medicines shortages)
- Additional areas of trade, such as technical barriers to trade (TBT) and the issue of Good Regulatory Practices
- More recommendations for additional elements

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The Trade Principles Paper

1. Regulatory Convergence
2. Technical Barriers to Trade
3. Competition
4. Intellectual Property Rights
5. Incentives

→ Positions represent consensus position of the global industry

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1. Regulatory Convergence

1. Generic Medicines:
   - Establish regulatory frameworks for convergence on registration requirements & info sharing
   - Single Development for Complex Generic Medicines
     - Reduce: unnecessary/unethical duplicative studies + development costs (by €35m per product)
       Examples: patches, injectable products, respiratory products, etc.
   - Need for access to reference products!

2. Biosimilar Medicines
   - Cooperation as an explicit objective of every agreement
   - Single Development for Biosimilar Medicines
     - Reduce development costs (by €40 million per product)
     - Increase access to biological treatments
   - Need for access to reference products!

3. Mutual Recognition of Good Manufacturing Practice (GMP) Inspections
   - More efficient use of inspection resources: the TTIP best practice

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2. Technical Barriers to Trade

- Highly regulated sector

- Need to tackle non-tariff barriers (NTB)

→ Complement horizontal rules with adequate sector-specific commitments

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3. Intellectual Property

- TRIPs Agreement with flexibilities should be taken as the basis for negotiation of IPR Chapters in FTAs
- Provisions aimed at extending rights beyond TRIPs or undermining competition should not be included or must be mitigated
- The Chapter includes:
    1. Patents
    2. Best mode
    3. Patent Linkage
    4. Regulatory review ("*Bolar*") clause
    5. Exclusivities (Data/Market)
    6. Extension of the duration of the rights conferred by patents
    7. Enforcement of IPR (and abuses...)

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4. Competition

- Intellectual property provisions (if used for ever-greening strategies) can prevent competition & delay entry of generic & biosimilar medicines into market
- IP Protection & Competition: two tools to foster innovation
- TRIPs:
  - IP protection
  - Competition principles
- FTAs should include TRIPS provisions against misuse/abuse of IP and anticompetitive practices, in line with WTO principles and obligations
- Safeguards against abuses!
  - *e.g.*, revocability of IPR, damages, etc.

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4. Incentives

- Incentives for generic and biosimilar medicines manufacturers to enter markets

  – Encourage challenges of weak or invalid patents, stimulating competition and innovation

  – Foster the use of generic and biosimilar medicines through market access rules

→ Savings for national health care systems, increased access to medicines, reduction of shortages risks

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2030 Sustainable Development Goals – Universal Health Coverage

Australia: 84% volume - 28.7% of total cost - 10 biosimilars approved
Canada: 72.8% volume - 19.5% of total cost - 17 biosimilars approved
Europe: 67% volume - 29% of total cost - 54 biosimilars approved & +250% patient access
India: 95% volume
Japan: 73% volume - 18 biosimilars approved
Jordan: 83% volume - 38% of total cost - 11 biosimilars approved
Malaysia: 69% volume - 28% of total cost - 9 biosimilars approved
South Africa: 69.6% volume - 47.5% of total cost - 2 biosimilars approved
Taiwan: 80% volume - 28% of total cost
USA: 90% volume - 22% of total cost - 23 biosimilars approved

→ Provide **ACCESS** & support long-term **SUSTAINABILITY** of healthcare systems

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Generics, biosimilars & cost-containment

- Minimal portion of total healthcare budget (in EU: 2-3%)
- Medicines are not candies
  - Development, regulatory, quality assurance, serialization, environment risk assessment, pharmacovigilance, distribution, legal costs!
- Lack of policies to stimulate uptake
- Risk of over-reliance on 1 or 2 manufacturers/suppliers
- Business dynamic sustainability
- Increased risk of stock-outs & shortages

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Recommendations

Trade policy/FTAs should support & complement national healthcare policies, not hinder them:

- Stimulate competition via uptake measures and remove market barriers
- Balance: IP to reward innovation & regulatory/market incentives to encourage Gx/Bios entry
- Ensure stringent patent examination & quality to reduce frivolous litigation & entry barriers
- Framework for regulatory cooperation for more efficient & faster Gx/Bios access
- Not undermine the balance b/w originators and generic/biosimilars → FTA pharma provisions should NOT support originator evergreening strategies undermining access to medicines

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THANK YOU!

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