Importance of Single Global Development to the off-patent industry

Susana Almeida, PhD
Secretary General, IGBA
About IGBA

- Founded in March 1997 as the International Generic Pharmaceutical Alliance (IGPA)
- Renamed International Generic and Biosimilar Medicines Association (IGBA) 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
- Non-State actor in official relations with WHO since January 2022
- Maintains constant dialogue with the WHO, WTO, WIPO and other national, regional and international bodies
Recent developments

- May 2025 – CEO Advisory Committee met in Vienna
Recent developments

- IGBA reelected to the Management Committee of ICH
Current status

- Currently, generic and biosimilar medicines are not able to use a single data package for registration in most countries.

- Many jurisdictions enforce local requirements for these off-patent medicines.
Single Global Development
Vision for Single Global Development

- Enabling off-patent medicines to prepare a single data package globally, acceptable in all jurisdictions, would support more timely and equitable access to affordable therapies.
Landscape

- More complex products
  - Increasingly complex development programs - further increasing the cost of duplicating trials
- Niche therapeutics and orphan products
- Personalized medicine
- Risk of fewer, or no, off-patent competitors for higher priced innovative medicines
  - Single global development is essential for competition and patient access to complex products
- Fundamentally, duplicating clinical trials is unethical as it involves superfluous experimenting in human subjects with no added benefit (Declaration of Helsinki)
Development of off-patent products

IR - immediate release; LAI - long acting injectable, MR - modified release
Regulatory processes and requirements influence development timelines and the resources involved.

Disparate requirements between countries delay or inhibit patient access to medicines:

- ↑ development timelines
- ↑ resources needed
Role of SGD on supply chains and emergencies

• SGD reinforces the agility and robustness of supply chains of quality-assured medicines

• Different regulatory requirements limit or restrict patient access to critical medicines during crises and public health emergencies and ability of the industry to prevent and mitigate supply disruptions, including drug shortages
Rationale

Timely access to affordable therapies is more important than ever:

- the number of patients requiring treatments is increasing
- health budgets face greater constraints
  - Streamlining product development
  - Globally harmonized standards – international convergence
- Standard approach for originator development

= increase patient access to more affordable quality assured medicines
Regulatory convergence
3 Pillars of Single Global Development that must advance simultaneously

- Harmonization of Bioequivalence standards
- Legal framework
- Criteria for acceptance of foreign comparators

Single global development of off patent medicines
1. Harmonization of bioequivalence standards

- Ongoing and advancing
- Draft of first international guideline (immediate release) released by ICH in December 2022
- M13A consultation ongoing

- Who: ICH
Before M13: multiple standards (a tangled mess)
After M13: Harmonization and convergence
Harmonization of BE: does it matter?

- It matters A LOT!
- Recent international survey on complex generics:
  - 96% Agree or Strongly Agree on the importance of a harmonized international approach for complex generics

2. Legal framework

• It is necessary to assess legal frameworks and address any possible barriers
• Predictability is important!

• Legislation is a key enabler of single global development
3. Which foreign comparators are acceptable?

- A guideline is needed!
- Scientific criteria and the conditions of acceptability of foreign comparators for bioequivalence

Who:
Local competent authorities (or jointly, or together with more regions)
Learning from those with experience
IPRP: Mapping the barriers to FRPs

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A Survey of the Regulatory Requirements for the Acceptance of Foreign Comparator Products by Participating Regulators and Organizations of the International Generic Drug Regulators Programme

Alfredo Garcia-Arieta¹, Craig Simon², Gustavo Mendes Lima Santos³, Iván Omar Calderón Lojero⁴, Zulema Rodríguez Martínez⁴, Clare Rodrigues⁵, Sang Aeh Park⁶, Ji Myoung Kim⁶, Ryosuke Kuribayashi⁷, Yusuke Okada⁷, Arno Nolting⁸, Chantal Pfäffli⁸, Wen-Yi Hung⁹, Christopher Crane¹⁰, April C. Braddy¹¹, Joy van Oudtshoorn¹², Diego Gutierrez Triana¹³, Mitch Clarke¹⁴
Comparison of Additional Restrictions for Accepting Foreign Comparator Products

Note: MHRA requirements added after publication
https://www.gov.uk/guidance/comparator-products-in-bioequivalencetherapeutic-equivalence-studies

<table>
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<tr>
<th>Additional restrictions</th>
<th>Australia</th>
<th>Canada</th>
<th>New Zealand</th>
<th>Singapore</th>
<th>South Africa</th>
<th>Switzerland</th>
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<td>Y&lt;sup&gt;c&lt;/sup&gt;</td>
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<td>Y</td>
<td>N</td>
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<td>N</td>
<td>Y&lt;sup&gt;b&lt;/sup&gt;</td>
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<sup>a</sup> Brazil, Colombia, the EU, Japan, Mexico, South Korea and US are not mentioned in this table as they do not currently accept foreign comparator products.

<sup>b</sup> Case-by-case basis

<sup>c</sup> Also limited to high solubility drugs
Comparison of the Requirement related to the Foreign Comparator Product characteristics

<table>
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<tr>
<th>Comparing requirements for comparator product characteristics</th>
<th>Australia</th>
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</tbody>
</table>

\[^a\] Brazil, Colombia, the EU, Japan, Mexico, South Korea and US are not mentioned in this table as they do not currently accept foreign comparator products. 

\[^b\] Reduced data requirements are applied to foreign comparator products sourced from Australia as described in the text.

\[^c\] Only for suspensions, or powders for inhalation.

Note: MHRA requirements added after publication
https://www.gov.uk/guidance/comparator-products-in-bioequivalencetherapeuticequivalence-studies
Swiss example

- Guidance document
- Authorisation of human medicinal product with known active pharmaceutical substance (v5.1, 2024)
- Comparability of a foreign comparator product with the Swiss reference product (pharmaceutical bridging)
Importance of single global development

• Avoids redundant (hence unethical) clinical trials
• Helps increase patient access to generic medicines (orphan drugs or complex generics)
• Contributes to competition, therefore increases access (resilience of supply chains)
• Leverages the benefits of harmonizing BE standards
• Helps to overcome challenges on sourcing of the comparator products, in some regions
• Enables regulatory reliance and mutual recognition agreements
Internationally:
• Advancing harmonization, dialogue and international convergence

Locally or jointly:
• Regions/countries to assess their legal frameworks:
  – Move forward if there are no legal barriers!
  – Address any potential legal barriers

• Define (ideally common) criteria for acceptance of foreign comparators in guidelines
Thank You!