Importance of Single Global Development to the off-patent industry

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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

Full Members

Associate Members

Observer Status

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

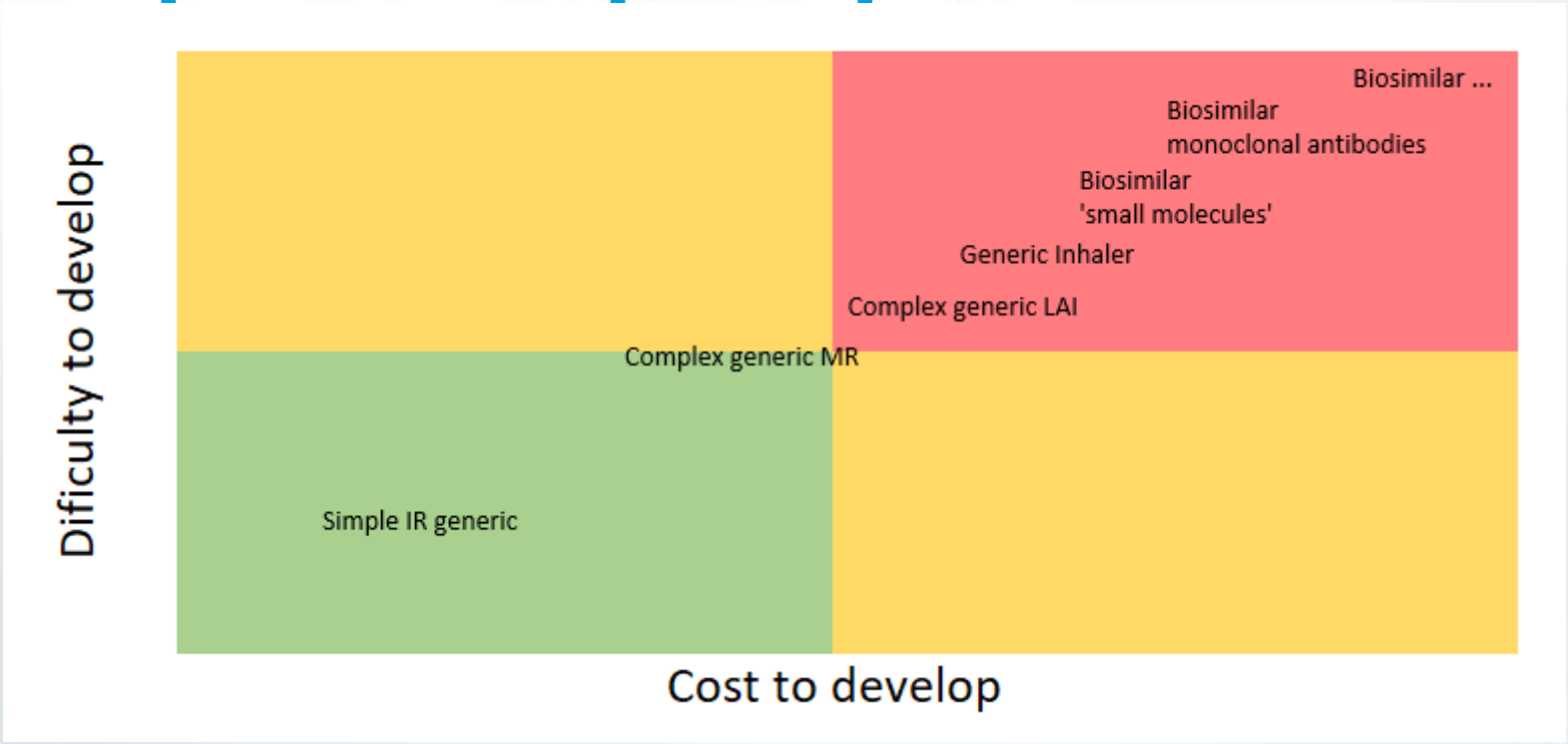
Vision for Single Global Development

- 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

Link to patient access

- 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**

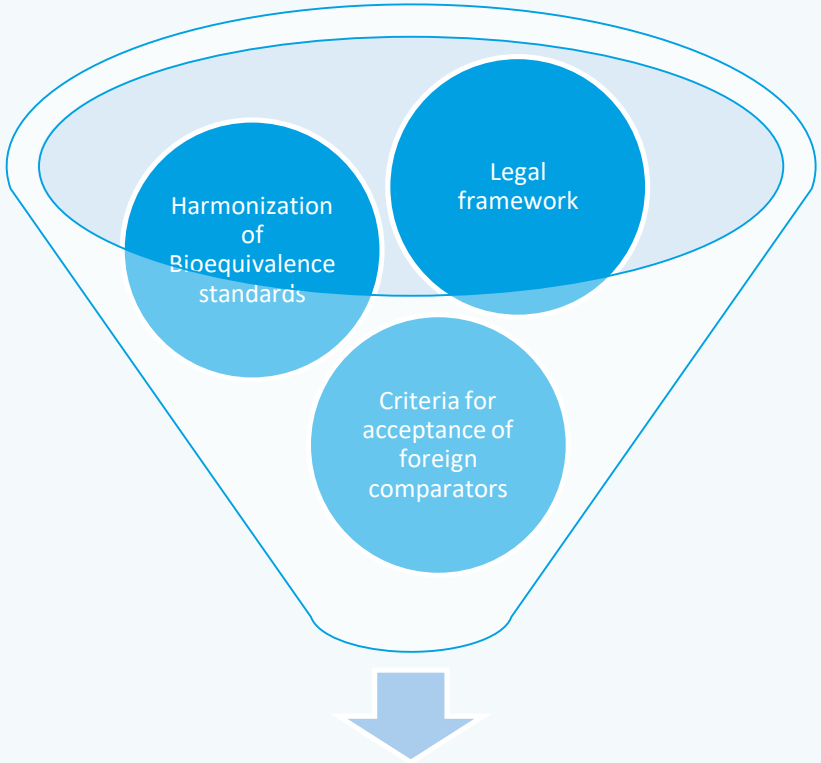
- **Streamlining product development**
- **Globally harmonized standards – international convergnce**

- **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



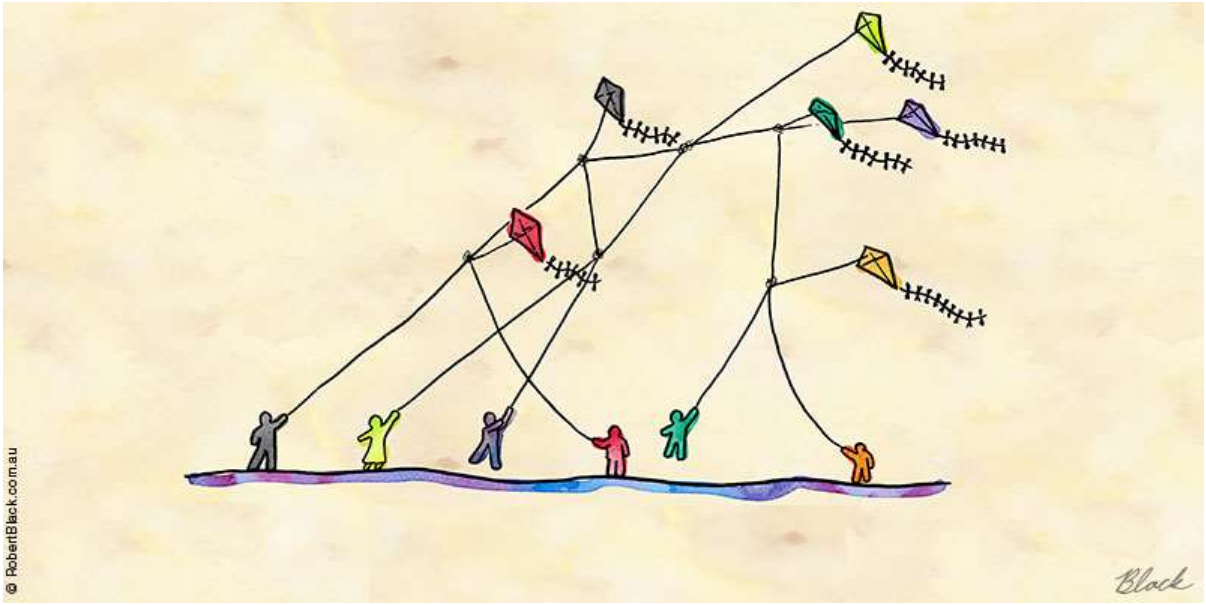
Single global development of off patent medicines

1. Harmonization of bioequivalence standards

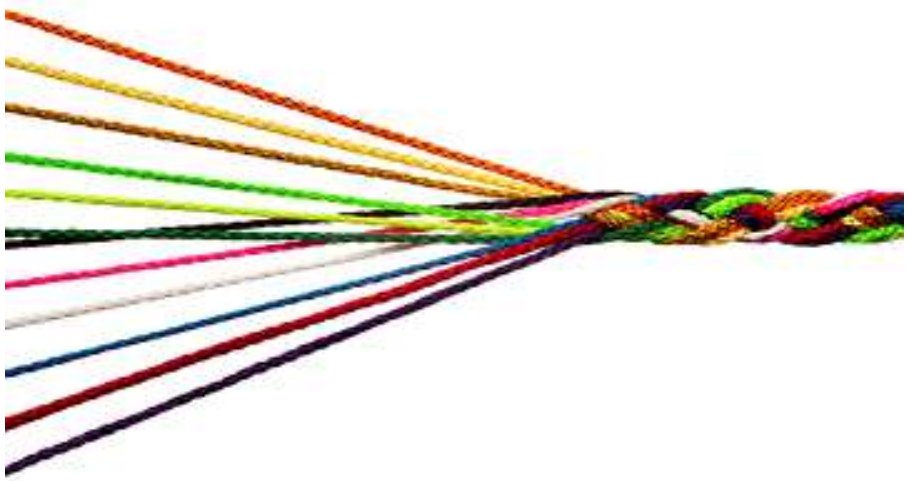
- Ongoing and advancing
- Draft of first international guideline (immediate release) released by ICH in December 2022
- M13A consultation ongoing

- Who: ICH

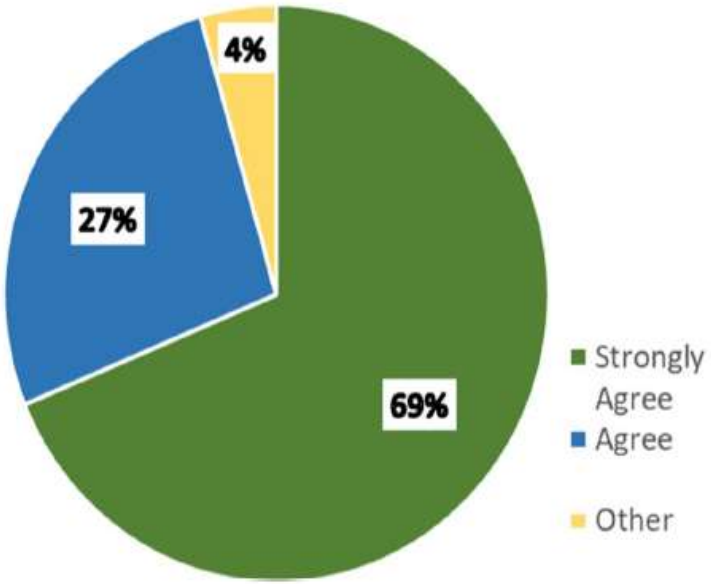
Before M13:
multiple standards (a tangled mess)



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

Stern S, Coghlan J, Krishnan V, Raney SG, Babiskin A, Jiang W, Lionberger R, Xu X, Schwendeman A, Polli JE. Research and Education Needs for Complex Generics. Pharm Res. 2021 Dec;38(12):1991-2001. doi: 10.1007/s11095-021-03149-y. Epub 2021 Dec 24. PMID: 34950975.

2. Legal framework

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

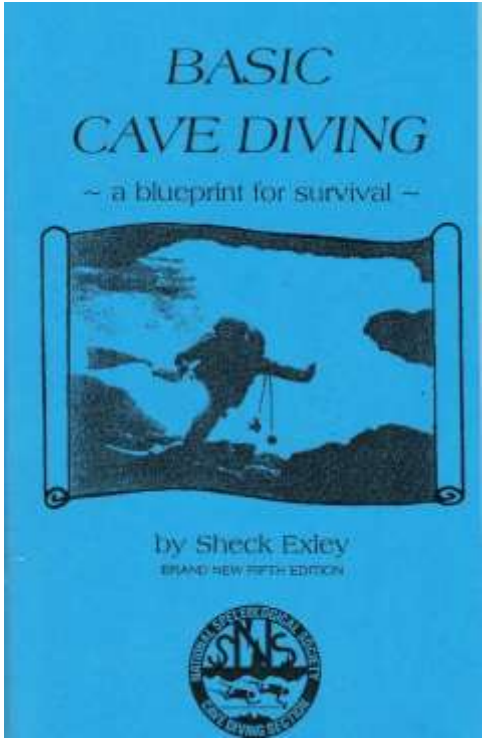
- Legislation is a key enabler of single global development

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

J Pharm Pharm Sci (www.cspsCanada.org) 22, 28 - 36, 2019

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 García-Arieta[1], Craig Simon[2], Gustavo Mendes Lima Santos[3], Iván Omar Calderón Lojero[4], Zulema Rodríguez Martínez[4], Clare Rodrigues[5], Sang Aeh Park[6], Ji Myoung Kim[6], Ryosuke Kuribayashi[7], Yusuke Okada[7], Arno Nolting[8], Chantal Pfäffli[8], Wen-Yi Hung[9], Christopher Crane[10], April C. Braddy[11], Joy van Oudtshoorn[12], Diego Gutierrez Triana[13], Mitch Clarke[14]

Comparison of Additional Restrictions for Accepting Foreign Comparator Products

Additional restrictions	Australia	Canada	New Zealand	Singapore	South Africa	Switzerland	Taiwan	United Kingdom	WHO
Drug substance properties									
NTID	Y	Y[c]	N	Y	N	N	N	Y[b]	N
Complicated PK, variable/incomplete absorption, substantial first pass metabolism	Y	Y[c]	N	N	N	N	N	Y[b]	N
Drug product properties									
Immediate-release	N	N	N	N	N	N	N	N[b]	N
Delayed-release	N	Y	N	N	N	N	N	Y	N
Sustained-release	N[b]	Y	N	N	N	N	N	Y	N

[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] Case-by-case basis
[c] Also limited to high solubility drugs

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

Comparison of the Requirement related to the Foreign Comparator Product characteristics

Comparing requirements for comparator product characteristics	Australia	Canada	New Zealand	Singapore	South Africa	Switzerland	Taiwan	United Kingdom	WHO
Qualitative comparison									(NA)
Size, weight	Y	Y	Y	N	N	Y	Y	Y	
Shape	Y	Y	Y	N	N	N	N	Y	
Colour	Y	Y	Y	N	N	N	N	N	
Scoring	Y	Y	Y	N	N	N	N	N	
Type of coating	Y	Y	Y	N	N	N	Y	Y	
Excipient composition	Y	Y	Y	Y	Y	Y	Y	Y	
Quantitative comparison	Y	Y[c]	N	N	N	N	N	Y	(NA)
Dissolution testing	Y	Y	Y[b]	Y	Y	Y	Y	Y	(NA)
Physicochemical testing other than dissolution	Y	Y	Y[b]	N	N	Y	Y	Y	(NA)

[a] Brazil, Colombia, the EU, Japan, Mexico, South Korea and US are not mentioned in this table as they ıey do not currently accept foreign comparator products.
[b] Reduced data requirements are applied to foreign comparator products sourced from Australia as describedbed 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-bioequivalencetherapeutic-equivalence-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

Way forward

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!