



INTERNATIONAL GENERIC AND
BIOSIMILAR MEDICINES ASSOCIATION

Aligned Regulations. Faster Access.

The same medicine,
proven the same way,
once and not differently,
in every market.

Core Proposition

Meaningful regulatory harmonisation aligns the technical and scientific requirements used to assess generic and biosimilar medicines across markets.

It reduces unnecessary duplication and enables manufacturers to use a more consistent evidence package to support filings in multiple markets, while maintaining robust standards for quality, safety and efficacy.

Why it Matters

Generic and biosimilar medicines may be required to prove equivalence differently across markets through study designs, clinical evidence requirements and local comparator product rules that vary by jurisdiction and product type.

This can force companies to repeat studies and create market-specific development programmes, adding time and cost without necessarily improving safety or scientific confidence.

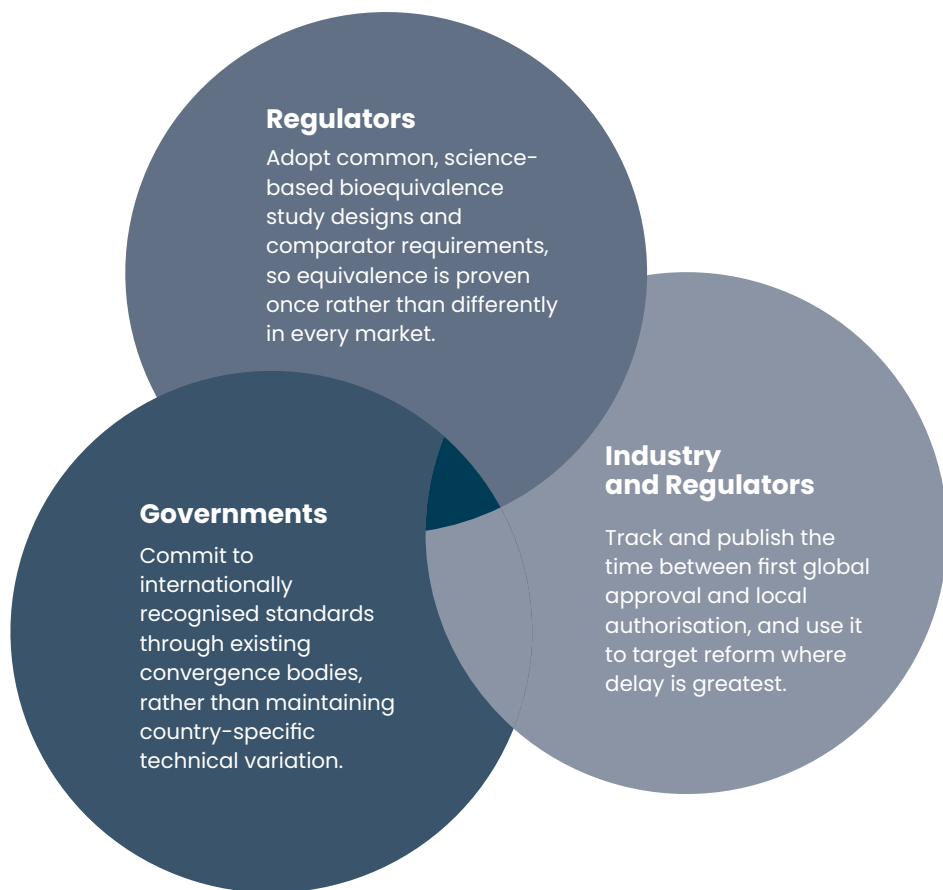
The consequence can be later filing, later market entry or a decision not to enter some markets at all. Harmonised, science-based requirements can reduce duplicated development and support earlier, broader access to quality-assured medicines.

6x

Higher Reported Study Costs

Duplicated equivalence studies can cost around US\$1.5 million under EU requirements, compared with US\$250,000 in some other jurisdictions.

What Regulatory Harmonisation Requires



Shared Outcome
Earlier, broader access.

Less duplicated development, earlier filing in more markets and broader patient access to quality-assured medicines.

WHY HARMONISATION MATTERS

The Cost of Fragmented Regulatory Requirements

Similar scientific questions can require different evidence in different markets, adding cost and delaying entry.

Generic and biosimilar medicines can face different study designs, comparator requirements or market-specific development programmes. This duplication adds time and cost and can lead to staggered filings, with some markets reached later or not at all.

With greater harmonisation, one aligned evidence package could support filings in multiple markets, enabling earlier, broader entry without lowering regulatory standards.

Conclusion

Aligned, science-based requirements can reduce unnecessary duplication and improve the case for entering more markets sooner.

US\$1.5m

Reported cost of bioequivalence studies conducted to meet EU regulatory requirement

US\$250k

Reported cost in some other jurisdictions for similar protocols

A six-fold difference in reported cost



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igbamedicines.org

Source

Rodríguez A et al. Importance of Single Global Regulatory Standards for the Assessment of Generic and Biosimilar Medicines to Advance Patient Access. The AAPS Journal. 2026.



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IGBA and its members remain committed to partnering with governments, international organisations, civil society, and industry stakeholders to improve patients' access to quality-assured, safe and cost-effective medicines.