Turning Complex Post-Approval Changes in Biological Products into Actionable Regulatory Insight

A global analysis of alignment of country-based regulations and guidelines with WHO guideline for Post-Approval Changes (PAC) in biological products.

Background

The International Federation of Pharmaceutical Manufacturers & Associations, or IFPMA, represents the innovative, research-based pharmaceutical industry and serves as a critical bridge between the biopharmaceutical sector, governments, and global organizations. Through its engagement with organizations including the United Nations, WHO, WIPO, and WTO, IFPMA helps advance policies that support innovation, access to medicines, pandemic preparedness, and better health outcomes worldwide.

As part of its commitment to strengthening global regulatory systems, IFPMA identified regulatory convergence as a key enabler of regulatory reliance. To support this priority, Clarivate was engaged to assess how Post-Approval Changes, or PACs, guidelines for biological products align across selected markets and how those requirements compare with existing WHO guidance for biologics.

Clarivate

Challenge

Post-Approval Changes for biological products are complex, with requirements that can vary significantly across markets. IFPMA needed a clear, evidence-based framework to compare PAC legislation and guidance across 22 selected markets in the EU, MEA, LATAM, and APAC, while also benchmarking those requirements against WHO guidelines.

The goal was to create actionable intelligence that could help stakeholders better understand where regulatory approaches are aligned, where gaps remain, and how greater convergence could support more consistent, efficient post-approval change management for biological products.

Solution

Clarivate's regulatory and clinical consulting team developed a standardized, market-by-market comparison of PAC requirements using a structured Q&A format and visual heatmaps. This approach enabled complex regulatory differences to be translated into clear, accessible insights that stakeholders could use to evaluate convergence across markets.

The team also established criteria to assess convergence levels across selected PAC changes, analyzing alignment between individual market requirements and WHO guidelines across change categorization, submission requirements, and review timeframes.

The full article is available here:

Global regulatory approaches to post-approval changes in biotherapeutic products

Insights & Impact

The analysis revealed meaningful variation in how markets manage PACs for biological products. Specific guidance for biotherapeutics was available in only 59% of markets assessed, while broader guidance covering other modalities was included in 86% of markets. CTD submission formats were required or accepted in 86% of markets, with several also accepting eCTD submissions.

The review also found that risk categorization and timelines were established across all 22 markets, and 95% allowed grouping of changes. However, scientific advice was available in only 55% of markets, and reliance pathways for PACs were available in only 50%, highlighting opportunities to further strengthen regulatory convergence.

By combining deep regulatory expertise with a structured, visual approach, Clarivate helped IFPMA transform complex market-level guidance into practical, decision-ready intelligence. The work provided a clearer view of global alignment on PAC requirements and helped support broader conversations on regulatory convergence for biological products.

As IFPMA noted, Clarivate's expertise was essential in interpreting and comparing complex guidelines, while the visual output helped communicate key references and the importance of regulatory convergence more clearly. IFPMA also highlighted Clarivate's flexibility in adapting the project as new insights emerged, ensuring the final output was accurate, fit for purpose, and appropriately detailed.

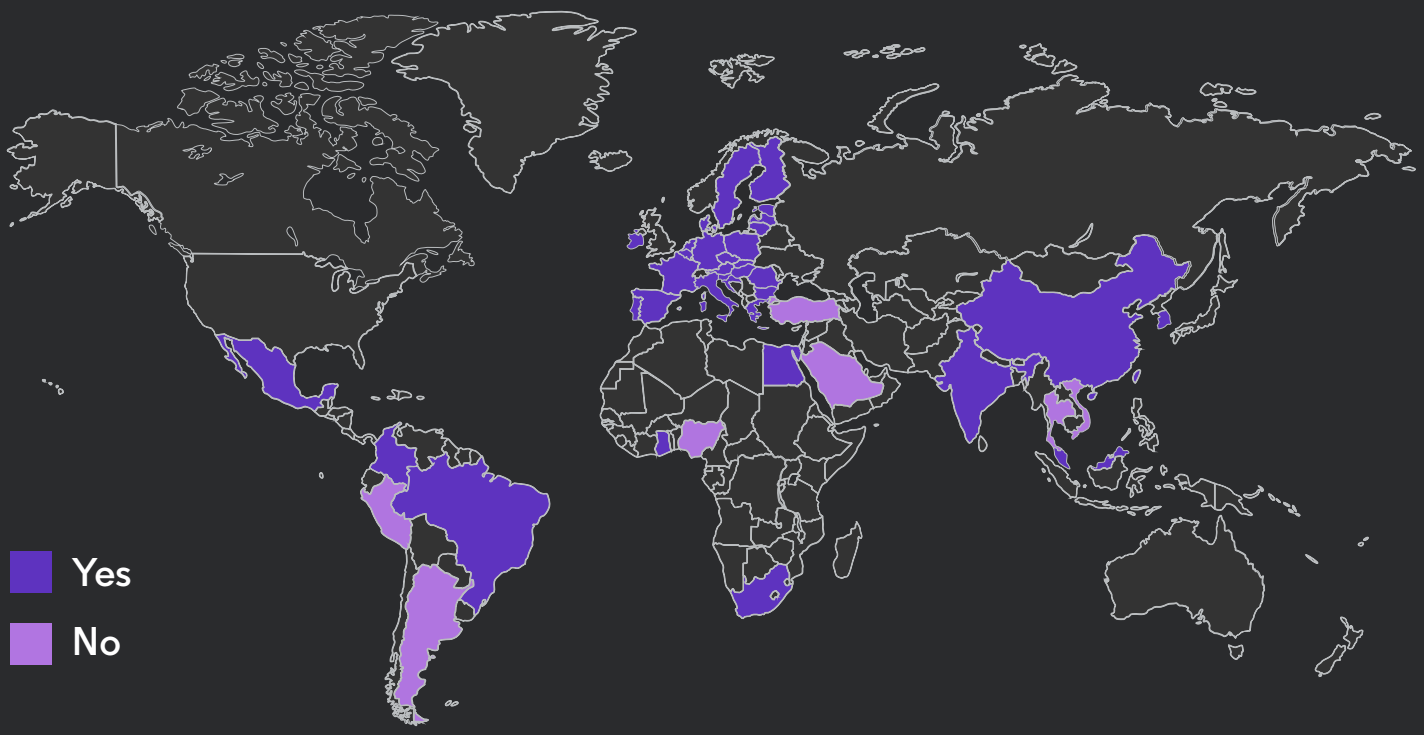
Clarivate's expertise was essential in interpreting and comparing the guidelines, which is a complex task. The results were also translated into a visual output, which was very useful for presenting key references and clearly communicating the importance of regulatory convergence.

Clarivate was flexible in building and adapting the project as new insights emerged, ensuring the final output was fit for purpose, accurate, and had the right level of detail.

Sérgio Cavalheiro Filho,
IFPMA Regulatory Affairs Manager

Figure 1

Is there any specific guideline on variations for biotherapeutics?



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This project was developed through a collaborative effort between Clarivate and International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) subject matter experts and was funded by IFPMA. The analysis and conclusions presented are based exclusively on publicly available information relating to the assessed PACs and reflect the regulatory landscape and evidence available at the time of the review, completed in October 2025. While every effort has been made to ensure the accuracy and completeness of the information presented, regulatory requirements may evolve over time. Accordingly, the findings should be interpreted within the context of the review period and are intended for informational purposes only.

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