AFIDRO

Asociación de Laboratorios Farmacéuticos de Investigación y Desarrollo

POLICY BRIEF

COLOMBIA'S DRAFT DECREE AMENDING DECREE 677 OF 1995: IMPLICATIONS FOR TRADE, INNOVATION AND REGULATORY CONVERGENCE

Executive Summary

- Colombia's draft decree amending and repealing Decree 677 of 1995 seeks to modernize the pharmaceutical regulatory framework. While the proposal incorporates internationally recognized concepts, including regulatory reliance, AFIDRO's assessment indicates that, in its current form, the draft falls short of enabling meaningful regulatory convergence, trade facilitation and investment certainty, particularly when compared with recent reforms adopted across Latin America.
- Several provisions risk introducing new regulatory and commercial barriers, increasing uncertainty for investors and delaying patient access to innovative medicines.

Regional and International Context

- Over the past decade, Brazil, Mexico, Peru, Ecuador, Chile and Central American markets have implemented regulatory reforms aligned with OECD principles of good regulatory practices, emphasizing:

1. Risk-based regulation,
2. Operational reliance on trusted reference authorities,
3. Predictable and shortened regulatory timelines, and
4. Reduced friction for cross-border pharmaceutical trade.

- These reforms have strengthened regulatory efficiency while improving access to innovation. Against this backdrop, Colombia's draft decree represents a critical opportunity to reinforce its position as a competitive and predictable market. However, several design choices diverge from emerging regional and OECD-aligned approaches.

Key Policy Issues

1 Reliance: Legal recognition without operational impact (Arts. 20–21)

Articles 20 and 21 introduce regulatory reliance into Colombia's legal framework, broadly reflecting WHO guidance. Nevertheless, the proposed implementation does not reflect international reliance practices and limits its effectiveness as a trade-facilitating instrument.

Key concerns include:

- Operational requirements that are difficult to implement in practice, such as mandatory access to full confidential assessment reports or reliance on formal confidentiality agreements, which are not standard practice in OECD jurisdictions.
- The restriction of reliance to "ordinary" approvals, excluding accelerated, conditional or priority pathways, despite these being core components of reliance-based models in reference agencies.
- The absence of clearly differentiated binding timelines for reliance-based procedures, undermining predictability and efficiency.

As drafted, reliance risks becoming a formal concept without material regulatory or commercial effect.

2 Marketing authorization requirements and regulatory proportionality (Arts. 4.1 and 6.2)

Article 4.1 introduces duplicative documentation and requirements that are misaligned with risk-based regulatory approaches, increasing compliance costs without proportional public-health benefits.
In parallel, Article 6, paragraph 2, mandating the registration of all indications approved by reference authorities:
·Creates automatic dependence on third-country regulatory decisions

- Imposes continuous administrative obligations with limited local relevance, and
- Distorts commercialization strategies for innovative products.

These provisions depart from OECD principles of regulatory proportionality, coherence and flexibility.

3 Regulatory timelines and separation of regulatory functions (Art. 9 and Art. 72)

Article 9 does not resolve longstanding inefficiencies in regulatory review timelines, as it fails to:

- Establish a single, transparent regulatory clock,
- Reduce timelines for innovative products, or
- Operationalize differentiated pathways for reliance-based applications.

Moreover, the linkage between marketing authorization and therapeutic value or pricing assessments (Art. 9 in connection with Art. 72) blurs the separation between sanitary regulation and economic policy, introducing legal uncertainty and potential market access conditioning inconsistent with OECD good regulatory practices.

4 Supply management and potential technical barriers to trade (Arts. 63, 66, 68, 69, 71–72)

The draft adopts a predominantly punitive approach to supply management, including:

- The transfer of global supply chain risks to marketing authorization holders,
- Disproportionate sanctions for administrative non-compliance, and
- Limited recognition of systemic, logistical or economic drivers of supply disruptions.

Such measures functioning as technical barriers to trade, discouraging market participation and negatively affecting the availability of innovative medicines.

5 Transitional arrangements and regulatory certainty (Art. 101)

Article 101 establishes a prolonged transition period heavily dependent on the future issuance of multiple technical guidelines, without defined timelines or clear alignment criteria.

This approach:

- Prolongs regulatory uncertainty,
- Increases operational risk for long-term investment and launch planning, and
- Places significant demands on regulatory capacity.

From an OECD perspective, excessive reliance on future secondary regulation undermines predictability and legal certainty.

Implications for Trade and Investment

In its current form, the draft decree may:

- Reduce Colombia's relative attractiveness for pharmaceutical investment,
- Introduce regulatory uncertainty affecting trade and market entry decisions,
- Delay access to innovative medicines, and
- Weaken Colombia's alignment with regional and OECD regulatory convergence efforts.

AFIDRO Policy Position

AFIDRO supports a targeted revision of the draft decree to:

- Establish a fully operational reliance framework with clear scope and differentiated timelines,
- Ensure proportional, risk-based marketing authorization requirements,
- Preserve the separation between sanitary regulation and economic policy decisions,
- Adopt a preventive and collaborative approach to supply management, and
- Provide clear, time-bound transitional arrangements aligned with international standards.

These adjustments would strengthen Colombia's regulatory governance, enhance trade facilitation, and reinforce the country's position as a predictable and competitive destination for pharmaceutical innovation and investment.