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Brazil – Updates on the Partnerships for Productive Development (PDPs)

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Brazil's long-running effort to internalize drug manufacture through state-backed technology transfer agreements continues to face scrutiny. On May 7, 2025, the country's Government Accountability Office (GAO) upheld its prior recommendation that the Ministry of Health (MOH) refrain from initiating new Partnerships for Productive Development (*Parcerias para o Desenvolvimento Produtivo* – PDPs) until it can demonstrate that the program is effective.

Launched more than a decade ago, the PDP program was intended to reduce Brazil's reliance on imported pharmaceuticals by enabling local production of drugs deemed strategic to the Unified Healthcare System (*Sistema Único de Saúde* – SUS). Under these agreements, a private company (domestic or foreign) commits to transferring manufacturing technology to a government-owned producer, which then becomes responsible for local production. In exchange, the MOH agrees to purchase the medicine, often under exclusive terms, for up to ten years.

Despite its promise to lower costs, improve access, and boost domestic capabilities, the PDP program has long been criticized for lacking transparency, clear performance metrics, and safeguards to ensure value for public spending. The PDPs have also become subject to patent infringement.

Audit Findings and GAO Rulings

In 2017, a GAO audit identified serious structural flaws in the PDP program. Chief among them was the absence of any reliable mechanisms to verify whether technology had actually been transferred and absorbed. The audit also found no established methodology to determine the actual value of the know-how. As a result, several PDP agreements were suspended or terminated.

In October 2023, the MOH asked the GAO to reconsider its previous decision, arguing that uniform pricing models were unworkable due to the wide variability in technologies and agreements. The ministry also hoped to lift the recommendation that prevented new PDPs from being signed, noting its intention to revive the program under a new legal and regulatory framework (later published as Ordinance No. 4,472/2024).

However, the GAO dismissed the request, stating that the ministry had failed to address the concerns raised in the 2017 audit. While acknowledging that a single pricing formula might be impractical, the GAO emphasized that this did not exempt the government from establishing

general pricing principles to ensure transparency, accountability, and fiscal responsibility. In other words, the problem isn't the complexity of pricing; it's the absence of a system to make pricing decisions accountable.

The GAO further stressed that the value of know-how should be assessed based on its strategic worth to the SUS, not merely on the cost of transferring it. This principle was deemed key to determining whether a PDP delivers value for the public healthcare system.

In response to MOH concerns that factoring in technology value could lead to inflated product prices, the GAO pointed out that acquisition costs should reflect the full cycle of product development and technology absorption, not just the market cost of the medicine. It further clarified that excessive pricing would still be constrained by the requirement that final prices remain compatible with those practiced within the SUS.

Another major sticking point was the MOH's claim that much of the data necessary for valuation is either incomplete or confidential. The GAO rebutted by noting that lack of information cannot be equated with commercial secrecy, and that no requirement has been made to publicly disclose proprietary information.

No Ban, But Clear Warning

The GAO observed that its recommendation does not amount to a ban on new PDPs. Instead, it is a precautionary measure advising institutional reform before expanding a program still plagued by opaque processes and unclear results.

To support its recommendation that the MOH hold off on new agreements until proper oversight mechanisms are in place, the GAO referenced Decree No. 2,903/2017. Enacted during President Michel Temer's administration, it establishes governance guidelines for federal programs. These include mandates for transparency and measurable performance indicators, which are applicable to the PDP initiative.

The New PDP Framework and Ongoing Concerns

While the new PDP framework under Ordinance No. 4,472/2024 has not yet been formally evaluated by the GAO, early analysis suggests it only partially addresses the concerns raised. Previously, PDPs had drawn criticism and even legal challenges for allowing up to 10 years of exclusivity in government procurement, sometimes in conflict with existing patents. The new ordinance now requires parties to disclose patent protections, bars proposals tied to active patents with more than three years left in their terms, and demands an IP compliance update demonstrating lack of constraints before the government can initiate product acquisition (Phase III).

Nonetheless, major concerns remain, especially around the program's ability to demonstrate that its goals are being met. Although the new framework mandates evaluation reports and assessments by technical committees, no objective parameters have been defined for verifying whether the technology has been successfully absorbed and whether the project delivers public value.

Pricing provisions are also vague. The ordinance allows adjustments in exceptional circumstances and requires committee review before entering Phase III, but it fails to articulate any pricing principles or criteria that could guide price-setting and prevent abuses.

Conclusion

Despite GAO's recommendations, the MOH has already authorized two new PDPs in 2025. It will now be required to demonstrate compliance with the standing ruling.

Although the GAO's recommendations are non-binding, continued noncompliance could lead to legal consequences. Should the ministry fail to establish adequate pricing and evaluation mechanisms, the GAO may conclude that public funds have been misused, potentially triggering penalties such as fines, dismissal of public officials, or disqualification of private entities from entering into public contracts.

While the MOH remains committed to reviving the PDP program, the GAO has made it clear that reform must come first. Without strong safeguards, evaluation criteria, and pricing systems, Brazil's ambitions for pharmaceutical self-reliance risk continuing under a veil of inefficiency and poor accountability.

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