Meeting of BRICS regulatory authorities for medical products

ISSUES NOTE

BRICS 2025

1. Background Information

Negotiations for a Memorandum of Understanding (MoU) between the authorities of the BRICS member countries began in 2019, during the 5th Meeting of Health Regulatory Authorities of the BRICS Countries, held in October that year in Brasília.

The Memorandum of Understanding between the BRICS regulatory authorities for medical products embodies a strategic instrument of technical cooperation for exchanging relevant information on the regulation of medical products.

The cooperation between the BRICS regulatory authorities is relevant, especially regarding the exchange of regulatory information on companies and products regulated by these authorities. Thus, exchanging information is the main concrete result to be sought, which has an immediate potential to improve the quality and agility of internal and sovereign decision-making by each regulatory authority.

Furthermore, technical cooperation between regulatory authorities plays a central role in advancing regulatory convergence and trust, which are essential for optimizing resources, processes and results, as well as access to medical products.

2. Priorities

Proposed key areas:

- Information sharing on regulatory processes, requirements and decisions to ensure safety, effectiveness and quality of medical products;
- Exchange of experience on good reliance practices, frameworks and pathways for open cooperation and better understanding of requirements for marketing authorization in BRICS countries;
- Support for ongoing BRICS initiatives in the field of safety, effectiveness and quality of medical products;
- Cooperation between the scientific community in terms of multi-country and international clinical trials;
- Collaboration in combating the circulation of substandard and falsified medical products.


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