IMDRF International Medical Device Regulators Forum

THE REGULATION OF MEDICAL DEVICES IN MERCOSUR

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MERCOSUR

Established in 1991 by the Asunción Treaty with the purpose of promoting free trade and the free circulation of goods, people and financial assets. Currently considered a customs union and a trading bloc.

- Member States: Argentina, Brazil, Paraguay, Uruguay and Venezuela.
- Acceding member: Bolivia
- Associated members: Chile, Colombia, Ecuador, Peru and Surinam.

HARMONIZATION IN MERCOSUR

The harmonization process in MERCOSUR consists in the **negotiation of Draft Resolutions by Working Subgroups**, later submitted to the approval of the Common Market Group (executive body coordinated by the Ministries of Foreign Affairs of the Member States).

The Resolutions approved must later be "internalized" by Member States, by publishing internal norms with the exact same content of the harmonized text. Any future changes to the content of harmonized documents must be commonly agreed by all Member States, in a formal process of revision of the original Resolution.

HEALTH REGULATION IN MERCOSUR

There is an specific Working Subgroup dedicated to health-related issues (called "SGT N. 11"), inaugurated in 1998, including three Commissions which meet twice a year:

- Health Products
- Health Services
- Health Surveillance (epidemiology aspects and controls that apply to ports, airports and borders)

The Health Products' Commission already existed since 1992, within other Working Subgroup → the regulation of health products was included in the harmonization agenda of Mercosur since its establishment.

HEALTH REGULATION IN MERCOSUR

The Health Products' Commission discuss cross-cutting issues related to the regulation of products and specific themes related to the Pharmaceutical Area. Other issues are discussed within expert groups linked to the Commission, working in their specific harmonization agenda. Currently:

- Cosmetics
- Sanitizers
- Medical Devices
- Pharmacopoeia
- Pharmaceutical GMP
- Partitioning and Distribution of API
- Narcotics and Psychotropic Substances

MEDICAL DEVICES IN MERCOSUR

There are more than 120 active Resolutions harmonized by the Health Products' Commission, 10 specific to MD, including a wide range of issues:

- Pre market authorization of MD (IVD and non-IVD)
- Procedures for GMP Certification
- Requirements for licensing companies
- Training of inspectors
- Safety and efficacy of MD
- Exchange of information on adverse events
- Exchange of inspections dossiers

MEDICAL DEVICES IN MERCOSUR

- Harmonization in MERCOSUR takes into consideration existing international and foreign references ⟶ for MD, the main reference were GHTF documents.

- Most of the Resolutions about MD were harmonized before 2000, and could benefit from updates ⟶ the publication of IMDRF documents can be a valuable resource.

CURRENT MERCOSUR ACTIVITIES

- Revision of the reference document with requirements for pre market authorization of medical devices (IVD and non-IVD)
- Discussion of clinical trials guidelines (based on international and regional references, including both pharmaceutical products and medical devices) *
- Follow-up to the exchange of inspections' dossiers for GMP certification
- Internships for leveraging practices related to MD among national regulatory authorities

Next face-to-face meeting of the MD group: 11-13 April, 2016.

* cross-cutting issue being discussed within the Health Products' Commission

THANK YOU!