

Update on the Brazilian regulatory aspects on medical devices

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IMDRF Management Committee Meeting
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Basis for the regulation on medical devices

Law N. 6.360/1976 and Decree N. 79.094/1977

These norms set the basis for regulation of all products under health surveillance in Brazil, including medical devices.

They identify the need for pre and post market control of products, as well as the shared responsibility of the Federal, State and Municipality levels in the different aspects of health surveillance.

These norms organize, until today, the role of ANVISA in promoting the access by the consumers to products that proved to have quality, safety and efficacy.

Since our last meeting in
Sydney...



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Pre-market related updates

Approval of new regulation on GMP - Good Manufacturing Practices inspections for medical devices

- already approved by the Board of Directors, to be published in the next weeks
- according to the document harmonized with MERCOSUR partners
- unification of requirements for both medical devices and IVD (previously, there were separate MERCOSUR norms for these types of products)
- all companies (Brazilian and foreign) must comply with new requirements before the 6-month “adjustment period”



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Pre-market related updates

Exchange of information on GMP inspections

A mechanism that establishes the exchange of information on GMP inspections for medical devices was approved within MERCOSUR, based on the fact that there is a common legislation harmonized for GMP.

The exchange of documents among regulatory agencies aims at avoiding duplication of inspections in companies located within MERCOSUR countries' territories.

The same mechanism is under negotiation among Argentina, Brazil, Colombia, Cuba and Mexico (Reference Regulatory Agencies in the Americas, according to PAHO's classification).



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Pre-market related updates

Discussion for an updated norm for the registration of medical devices

- already under discussion with MERCOSUR partners
- will provide new logic / rationalization of the registration process, aligned with existing foreign regulations
- negotiations within MERCOSUR count with the participation of the private sector (industry associations)
- ANVISA is taking into account IMDRF discussions as input to the MERCOSUR negotiations
- public consultation to be published when negotiations reach an agreement (no timeframe established)



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Post-market related updates

Mandatory execution and report of field actions taken by the companies that hold registration of medical devices

A new legislation entered into force, based on the principle that the companies that hold registration of medical devices in Brazil, as well as other agents involved in the commercial chain share equally the responsibility for maintaining products' quality, safety and efficacy.

Reference guide on investigative inspections

Brazil is discussing within MERCOSUR the harmonization of a reference guide with a step-by-step approach on investigative inspections.

Training and information

- Further relationship with the Brazilian Technical Norms Association (ABNT) in order to produce and / or enhance norms related to medical devices
- Launching of working groups for promoting exchange of information and training activities to health surveillance authorities in the State and Municipality levels, as well as for healthcare professionals and laboratories
- Specific action with Public Health Laboratories to promote the notification of problems related to diagnostic kits
- Production of periodical Information Bulletins for the private sector and healthcare professionals



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Thank you!
Merci!
Obrigado!



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