External Stakeholders Session - IACRC

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Agência Nacional de Vigilância Sanitária

Anvisa's Reliance on Pre-Market Authorizations

IN n. 290/2024, In force since June 6, 2024, brought reliance practices to non IVD and IVD medical devices Pre-Market Authorizations

- Product registration certificates from Equivalent Foreign Regulatory Authorities (EFRAs, *AREE*s) may now be used for abbreviated analysis

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INSTRUÇÃO NORMATIVA - IN N° 290, DE 4 DE ABRIL DE 2024

Estabelece, nos termos da Resolução da Diretoria Colegiada - RDC nº 741, de 10 de agosto de 2022, procedimento otimizado para fins de análise e decisão de petições de registro de dispositivos médicos, por meio do aproveitamento de análises realizadas por Autoridade Reguladora Estrangeira Equivalente (AREE).

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- Initially defined EFRAs are the MDSAP founding members.
  - Australia Therapeutic Goods Administration (TGA) - Australian Register of Therapeutic Goods (ARTG)
  - Health Canada (HC) - Medical Device Licence
  - US Food and Drug Administration (US FDA) - 510(k) Clearance, Premarket Approval (PMA), 513(f)(2) "De Novo"
  - Japan Ministry of Health, Labour and Welfare (MHLW) - Pre-market approval (Shonin)

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Santé Canada Health Canada

FDA U.S. FOOD & DRUG ADMINISTRATION

MHLW
Ministry of Health, Labour and Welfare of Japan

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- Class III and IV Medical Devices (as defined on RDC 751/2022 and RDC 830/2023
- The product must be essentially identical
  - *" the documentation that proves the registration or authorization issued by the AREE must refer to a medical device essentially identical to the one intended to be registered with Anvisa, and must include information regarding the indication(s) of use/intended use and manufacturer(s)"*

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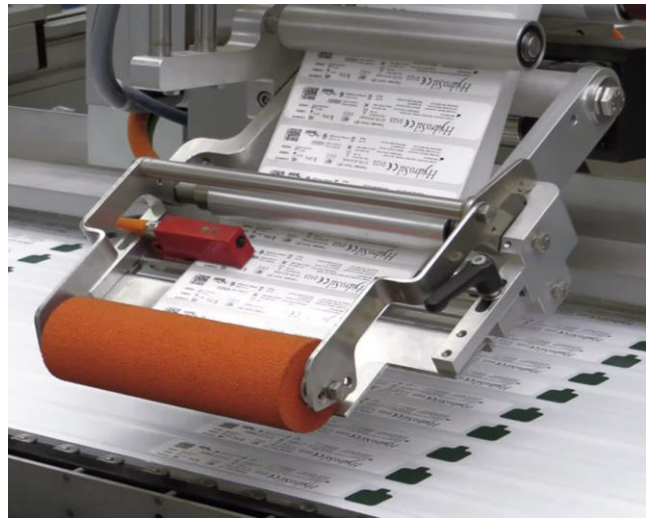
To enable this assessment, it requires that companies submit the following documentation in addition to the registration process:

- Proof of approval in the reference NRA.
- The original instructions for use, presented and approved in the reference NRA
- Declaration by the manufacturer regarding the equivalence of the products and the absence of circulation restrictions due to safety and performance issues.
- Specific requeriments for labeling.



Differences between products that are considered 'essentially identical' cannot impact performance or quality. A common example is changing the power plug of equipment, since the standard is different between countries.

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Brazilian labeling and specific requirements must be met:

- *The information shown in labels and instructions for use must be in Portuguese.*
- *The DM that are subjects of compulsory certification must meet the requirements of specific regulations.*

Anvisa may choose, at any time, to carry out the full assessment of the tech dossier or may ask for clarifications on the documents submitted for analysis

Reliance on MD Pre-Market Authorizations

Challenges NRAs are facing to verify the "Sameness of products":

- Difficulty in identifying the models and components of the equipment family in the register. We did not find a description of the equipment models and modules. In this case, we had to analyze it through the ordinary path.
- Proof of registration or authorization issued by an Equivalent Foreign Regulatory Authority (AREE), not apostilled in the country of origin.
- The GMP certificate does not cover the product risk class.
- We did not find all the components (in the product sistem) in the CLC issued by the country.

Reliance on MD Pre-Market Authorizations

How can official medical device databases contribute to reliance?

There is currently no standardization in the type of information disclosed in the NRA databases. This makes it difficult to identify products registered in different countries.

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