Vaccine Delivery Devices

Anvisa - Brazil

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Outline

1) Current status of regulatory oversight of medical devices in Brazil;

2) Regulatory challenges regarding the new technologies in the vaccine field.

Regulatory oversight of medical devices

- If only the medical device →performed by the Office of Medical Devices – GGTPS
- Regulation:
  - RDC 185/01
  - RDC 56/01
  - RDC 24/09

Regulatory oversight of medical devices

- If the medical device is part of a biological product package → performed by the Coordination of Biologicals (CPBIH)
- Regulation:
  - RDC 55/10
  - RDC 49/11
  - RDC 50/11

Regulatory challenges

- No specific regulation/requirements for vaccine delivery devices in Brazil, that incorporate a new technology.
- They can be registered/licensed as a general device, authorized to be used with any kind of medicine, including vaccines, without the presentation of clinical data.
- Considering new devices sold separately from the vaccine: What should be assessed and how? → immunogenicity and safety of the different kinds of vaccines with the new technology in a clinical trial setting.
- Should the vaccines label change to state what kind of devices could be used for their administration?
- These points are not clear in our present regulation and should be a matter of attention.

Thank You

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