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:
  o RDC 185/01
  o RDC 56/01
  o 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:
  o RDC 55/10
  o RDC 49/11
  o 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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