Agência Nacional de Vigilância Sanitária
ANVISA

Biologics in Brazil: overview and perspectives

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Biological Products Office Activities

- **Biological Products Office**
  - Marketing authorization and post approval change applications (CMC, pre-clinical and clinical studies)
  - Includes: biotechnological products; vaccines; hyperimmune sera; blood products; medicines obtained from biological fluids or animal-originated tissue; medicines containing live, attenuated or dead microorganisms; probiotics; and allergens.

- **Backlog Reduction - Law n. 13411/2016**
  - Shorter deadlines for the conclusion of the applications.
    - Marketing authorization:
      - Ordinary category: 365 days* (max. 487 days)
      - Priority category: 120 days* (max. 160 days)
    - Post-approval changes:
      - Ordinary category: 180 days* (max. 240 days)
      - Priority category: 60 days* (max. 80 days)
  - Timelines were accomplished in most cases for biologics
    - Eg. Biosimilars (PK comparative studies are evaluated by a different office)
  - New strategies which enable to considerably reduce the timelines for assessing the applications

* An extension of 1/3 of the time can be granted, under justification

Biological Products Office Activities
- Reliance Project

- **OS n. 45, February of 2018 (*Orientation of Service*)**
  - Reliance Pilot Project
  - Establishes an alternative review pathway for the assessment of Biologics (for Marketing Authorization and Post approval changes applications)
  - Anvisa performs an optimized review (focusing on critical documents) and an assessment of the decision of US FDA and/or EMA (it is not a mutual recognition)
  - Eligibility Criteria: approved in the US FDA and EMA (MAA); same indications, posology, ARs and precautions
  - Approval reports should be provided by the applicants (MAA)
  - Only 20 applications used this pathway (out of 837 potential applications)
  - Conditions are under review in order to increase the number of applications

Biological Products Office Activities
- Harmonization/Convergence

- **ICH activities**
  - 2016 - ANVISA became a Regulatory Member of ICH
  - Implementation of tier 1 and 2 guidelines
    - 2019 - ANVISA published CTD guideline and are already receiving dossiers using CTD format

- **In 2019 - Regulations under review**
  - Stability – references: Alignment with ICH guidelines, and other complementary international guides
    - 237 contributions received, under evaluation
  - Post approval changes – Alignment with WHO guideline for changes to approved biotherapeutic products, and other complementary guidelines
    - 502 contributions received, under evaluation

- **Strengthen International Cooperations**
  - MoU with Danish Health and Medicines Authority
    - Course - Faculty of Health and Medical Sciences – University of Copenhagen
  - USFDA – Orbis (concurrent submission and review of oncology products among international partners)
    - Starting to discuss this project

THANK YOU!

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Backup

Accelerated Pathways of Approval

RDC 204/2017 – Priority Review Pathway

- Eligibility criteria: Emergent or neglected disease – significant improvement in treatment; vaccines for National Immunization Program; new or innovative drug product, for pediatrics; API manufactured in Brazil; Public Health Emergencies and shortages; first generic
- Timelines:
  - Marketing Authorization: 120 calendar days (CD) Agency time/clock stops (vs. 365 CD regular pathway)
  - Variations / Post-approval changes: 60 CD Agency time/clock stops (vs. 180 CD regular pathway)

RDC 205/2017 - Special Procedure - rare diseases (MA, clinical trial and GMP applications)

- More flexible technical requests (since the applications in Brazil are part of the first wave)
  - On-going stability studies
  - Finished Phase II + on-going Phase III clinical studies or no Phase III (if not feasible)
- Timelines:
  - Marketing Authorization : 60 CD first evaluation + 30 CD sponsor's response + 30 CD final decision
- Submission format:
  - CTD format (M4) and submission of the Approval Reports from the other authorities (if available)
  - Encourages submission of the same dossier in different regions
- Sponsor's responsibility: Pre-submission meeting to be scheduled