Agência Nacional de Vigilância Sanitária
ANVISA

Biologics in Brazil: overview and perspectives on harmonization

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ICH - Overview

- **In December 2015, Anvisa officially becomes an Observer in ICH**

- **In November 2016, at the Osaka meeting, ANVISA becomes a Regulatory Member of ICH**

  - Tier 1 – Immediate implementation (Q1, Q7 and E6)

  - Tier 2 – Implementation within 5 years (until November 2021)
    E2A: Clinical Safety Data management: Definitions and Standards for Expediting Reporting;
    E2B: Clinical Safety Data management: Data Elements for Transmission of Individual Case Safety Reports;
    E2D: Post-Approval Safety Data Management: Definitions and Standards for Expediting Reporting;
    M4: Common Technical Document;
    M1: MedDRA Terminology (Medical Dictionary for Regulatory Activities).

  - Tier 3 – Near Term and as soon as possible
    Adoption of the remaining guidelines. Total over the sixty Guidelines.

- **In 2019, training on ICH Q8, Q9, Q10 and Q11 guidelines at Anvisa**

Biological Products Office Activities
Backlog Reduction, Reliance and Harmonization/Convergence

- **In 2018 - Backlog Reduction (Law n. 13411/2016 – new deadlines for the conclusion of the applications)**
  - New strategies which enable to considerably reduce the timelines for assessing the applications
  - Timelines were accomplished in most cases for biologics
  - Approval before FDA and EMA in 2 cases and before EMA in 1 case (variations of new therapeutic indication)

- **OS n. 45, February of 2018 (*Orientation of Service*)**
  - Establishes an optimized review pathway for the assessment of Biologics (for Marketing Authorization and Post approval changes applications)
  - Reliance Pilot Project (duration: one year)
  - Eligibility Criteria: approved in the US FDA and EMA; same indications, posology, ARs and precautions
  - Approval reports should be provided by the applicants

- **Challenges for 2019 - Regulations under review**
  - Stability (draft almost concluded) – references: ICH guidelines, other international guides
  - Post approval changes (in progress) – same rational

- **Strengthen International Cooperation**
  - MoU with Danish Health and Medicines Authority (workshop in November 2018)

THANK YOU!

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Workshop at Anvisa with the Danish Health na Medicines Authority. November, 2018

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