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Administración Nacional de Medicamentos, Alimentos y Tecnología Médica

Ministerio de Salud
Presidencia de la Nación

BIOSIMILAR CLINICAL EVALUATION: ANMAT PROCESS AND PERSPECTIVE

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January 30th, 2018

ANMAT DEFINITIONS

- ANMAT Regulation 7075/2011 (Biological products)
  - Derived from living material (natural sources or genetic engineering)
  - Used in humans for diagnosis, prevention or treatment
- ANMAT REGULATION 7729/2011 (Biosimilar products)
  - Biologic product that demonstrated to be highly similar to a previously approved one based on Quality, Efficacy & Safety
  - Has no clinically meaningful differences in terms of composition, indication and propose route of administration

FOR BOTH A RISK MANAGEMENT PLAN IS REQUIRED

ANMAT REQUIREMENTS

- PD/PK: comparing a proposed product to the reference product , in a population where the possible differences can best be observed
- In certain circumstances, human PK and PD data may provide sufficient clinical data to support a demonstration of biosimilarity
- Efficacy & safety: well designed clinical trials are required
- Post approval safety: close monitoring must be continued post approval (RMP)

BIOSIMILAR CHALLENGES

- **Immunogenicity**
  - There shouldn't be clinically meaningful differences in immune response between the proposed product and the reference one
  - Antibodies are a potential source of lack of efficacy or safety issues (hypersensitivity)
- **Extrapolation**
  - Use in an indication held by the reference product but not directly studied in a comparative clinical trial
  - Possible but must be justified
  - Share the MOA
- **Interchangeability**
  - The product may be substituted for the reference product, but not automatically

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Muchas gracias

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