TESÃI HA TEKO PORÃVE Motenondeha
Ministerio de SALUD PÚBLICA Y BIENESTAR SOCIAL

TETÃ REKUÁI
GOBIERNO NACIONAL

Paraguái tetãyguára mba'e

Recent Trends in the Regulation of Biological Products in Paraguay

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Current Regulatory Framework

- **Decree N° 6611/16.**

By which Article N° 21 of Law N° 1119/97 is regulated, and specific requirements for the registration of biological medicines are established.

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Art. 4°: **Reference Regulatory Agencies**.

a) Regulatory Agencies of High Vigilance according to Law N° 3283/2007 (Alemania, Austria, Bélgica, Canadá, Dinamarca, España, EE.UU, Francia, Israel, Italia, Japón, Países Bajos, Reino Unido, Suecia y Suiza.)

b) European Medicines Agencies (EMA)

c) Regulatory Agencies of Regional Reference (Level IV, PAHO)

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Perspective

- **Regulatory Updates:**

  - Internal Procedures.
  - GMP Guideline for biological medicines (start)
  - Additional information for the Decree (draft in progress)

- **Opportunities and Challenges.**

  - Adaptation process (On going changes, Authority support)
  - Trainings (Model rol).
  - Reliance (GMP, Marketing authorization, WHO/ICH guidelines.

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Thank you!

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