Biologics in Brazil: Overview and perspectives

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Perspectives and Challenges

**Harmonization**

WHO: Regulations for biological and biosimilar products are aligned with WHO recommendations;

PAHO: Anvisa attends PAHO meetings involving regulatory authorities from Latin America in order to discuss harmonization of regulations

Strengthen international cooperation

**ICH membership - guidelines**

As observer, ANVISA started to attend ICH meetings (Dec/15) - Biologics - Q12 group;

As a member (Nov/16): in 5 yrs (adoption of E2A, E2B, E2D, M4 and M1 guidelines)

**Breakthrough therapies**

RDC 55: Acceptance of Phase II (completed) and Phase III (in progress) for serious or life threatening diseases/ Indication of efficacy + no alternative therapy or drug

Priorities: system of points (for rare/neglected/emerging/re-emerging diseases)

New regulation: shorter deadlines compared to regular evaluations and to priorities

**Biosimilars**

During the development: the companies may request meetings to discuss next steps

Thematic meetings: Package insert texts (TN on website); interchangeability and extrapolation of indications (to be scheduled in 2017)

Challenges: interchangeability, INN and extrapolation of indications

**Improve the transparency of the acts**

Pre-submission meetings, Public Consultations, Drug Approval and Refusal Letters
THANK YOU

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