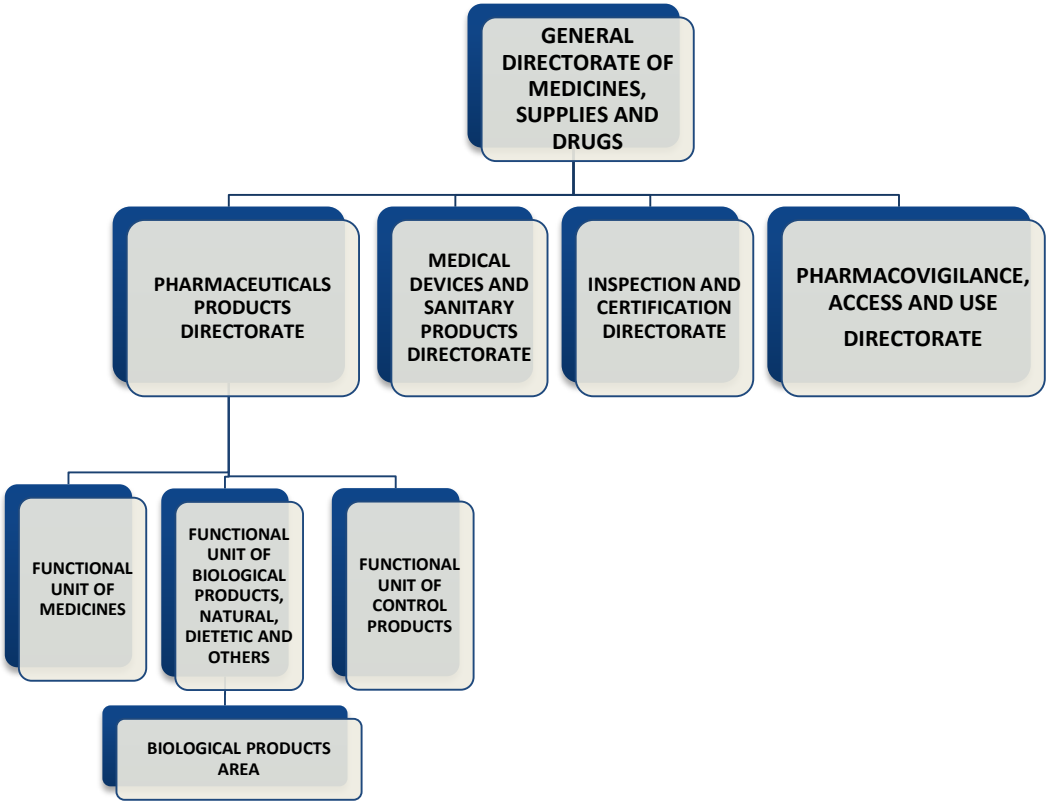
AN OVERVIEW OF THE REGULATION OF BIOLOTECHNOLOGICAL AND BIOSIMILAR PRODUCTS IN PERÚ

Susan Katherin Zavala Coloma
Area of Biological Products- UFPBNDYO
Directorate of Pharmaceutical Products
General Directorate of Medicines, Supplies and Drugs (DIGEMID)
Ministry of Health (MINSA) - Perú

OUTLINE

- Introduction of DIGEMID
- Legal Bases of Biological Products in Perú
- REGULATION OF BIOLOTECHNOLOGICAL AND BIOSIMILAR PRODUCTS
- Conclusions

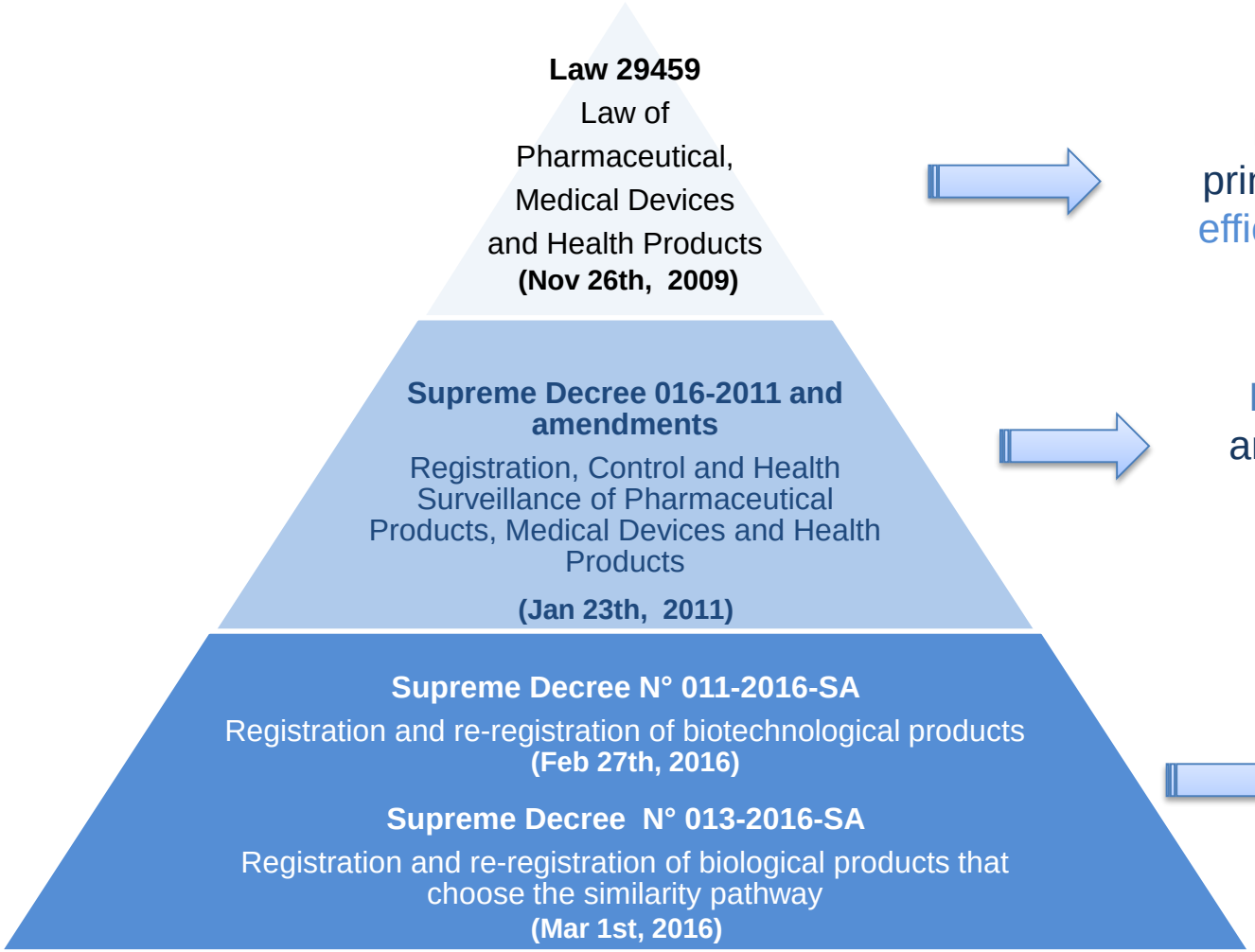
GENERAL DIRECTORATE OF MEDICINES, SUPPLIES AND DRUGS



- Created in April 18, 1990, as a line organ of the Ministry of Health.
- Located in Lima, Perú.
- Total staff: About 600 (10 in biological review).
- The main objective is to ensure access and rationally use to safe, effective and quality medicines.

Source: http://www.digemid.minsa.gob.pe/

LEGAL BASES OF BIOLOGICAL PRODUCTS



Defines basic principles of safety, efficacy and quality.

Definition, classification and general requirements for registration and re-registration

Submission and content of the documents required for the sanitary registration and re-registration

Source: http://www.digemid.minsa.gob.pe

REGULATION OF BIOLOTECHNOLOGICAL AND BIOSIMILAR PRODUCTS

- S.D. Nº 011-2016-SA took effect on Aug 25 and 2016 (for biotechnological products)
- S.D. Nº 013-2016-SA took effect on Aug 28, 2016 (for similar biological products)
- Give more specific requirements for biotechnological and similar biological products, and complement general requirements covered in Supreme Decree N° 016-2011-SA.
- The documentation should be presented according to CTD, and should comply with the recommendations of: WHO, PANDRH, ICH, EMA, Health Canada, and/or FDA.
- Quality requirements should be accompanied by a resume including information of all quality aspects emphasizing critical parameters, with an analysis that integrates quality data and preclinical and clinical data.
- In the case of biological products that choose the comparability way, the quality module should include complete data, additionally, should present the comparability exercise between SBP and RBP in terms of quality. Reduction data requirements is possible for pre-clinical and clinical aspects.
- Both regulations consider a stepwise approach to update the technical documentation of approved products.

Source: http://www.digemid.minsa.gob.pe

CONCLUSIONS

- New regulations introduce a substantial change in the regulations of Digemid.
- There are more new specific regulations to be issued: post approval changes, stability studies, vaccines, blood plasma derived products, batch release, and other biological products.
- DIGEMID is preparing to get the qualification as a reference authority for medicines and biologicals of the PAHO.
- Technicals participate in international training, workshops and virtual meetings sharing experiences with other countries and learning from other NRA with more experience.

Thank you…

Inquires/Questions: http://www.digemid.minsa.gob.pe
szavala@minsa.gob.pe