Challenges and opportunities of Regulatory convergence in Peru

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*Opinions expressed in this presentation are the sole responsability of the autor and may not coincide with those of her organization

“Effective Regulatory Systems are an essential component of Health System strengthening and contribute to better Health outcomes”

OMS- Resolutions on the strengthening of the Regulatory System for medical products -2014

Technical Barriers to Trade Agreement (TBT)– OMC

Peru signed in 1994

Main objectives of TBT:

- Member Countries don't prepare, adopt or apply technical regulations that create unnecessary obstacles to international trade.
- If necessary, Member Countries will use pertinent international standards as the basis for their regulations.

After that, **Supreme Decree Nº 014-2005-EF – regulatory provisions of TBT Agreement** was promulgated:

- Procedures or requirements that affect free internal commercialization, export or import of goods must be approved by supreme decree endorsed by Ministry of Economy and sector involved.
- Draft regulations will be published in *El Peruano* (official newspaper), without prejudice to notification to WTO and CAN

Is it contradictory for Peruvian State to commit to reducing obstacles (technical regulations) but on the other hand make approval process for new procedures more flexible?

Will all projects have been notified to the WHO and CAN? If so, how many comments or observations were adopted?

Peruvian Regulación of Medical Device

- Law 29459 (2009)- Law of Pharmaceutical Products, Medical Devices and Sanitary Products
- Supreme Decree Nº 016-2011-SA, was modified –at least- 11 times between 2012 and 2020.

We can indicate that **Regulatory framework** rules 3 aspects:

a) Criteria aplicable pre-marketing actions: obtaining a sanitary registration

b) Crireria aplicable to marketing: storage

c) Criteria aplicable to post-marketing actions: technovigilance

Challenges of Peruvian regulation

Medical devices sector

- Breach of international agreements
- Constant regulatory changes
- Inflexible procedures > excessive administrative burden
- Regulation based on device manufacturing
- Confusion with pharmaceutical product criteria
- Absence of Exchange agreements with other Regulatory Authorities

*Others: Resources, training and institutionality

Source: *Calidad Regulatoria en El Perú, Avances y Agenda Futura* (2021)

Oportunities for regulatory convergence

(Good Regulatory Practices in the regulation of medical products)

- Sign information and Exchange collaboration agreements with Regulatory Authorities within LATAM, US and EU
- Include regulatory framework for medical devices in the National Health Policy, as a tool for managing Access to technology for patiens
- Consult with stakeholders: academia, medical societies, patients associations and industry
- Establish regulations according to the Risk-Benefit of medical device
- Regulate with clear and flexible terminology, which allows an agile response to Emergency situations and the evolution of science and technology
- Measure and examine the regulatory framework holistically and constantly