PERÚ | Ministerio de Salud | Viceministerio de Salud Pública | Dirección General de Medicamentos, Insumos y Drogas

Regulatory Advance in Post Approval Changes of Biological Products in Peru

Pharm. Cinthia Noemi Torres Huari
Reviewer of biological products

August 6th´2024

DIGEMID

BICENTENARIO DEL PERÚ 2021 - 2024

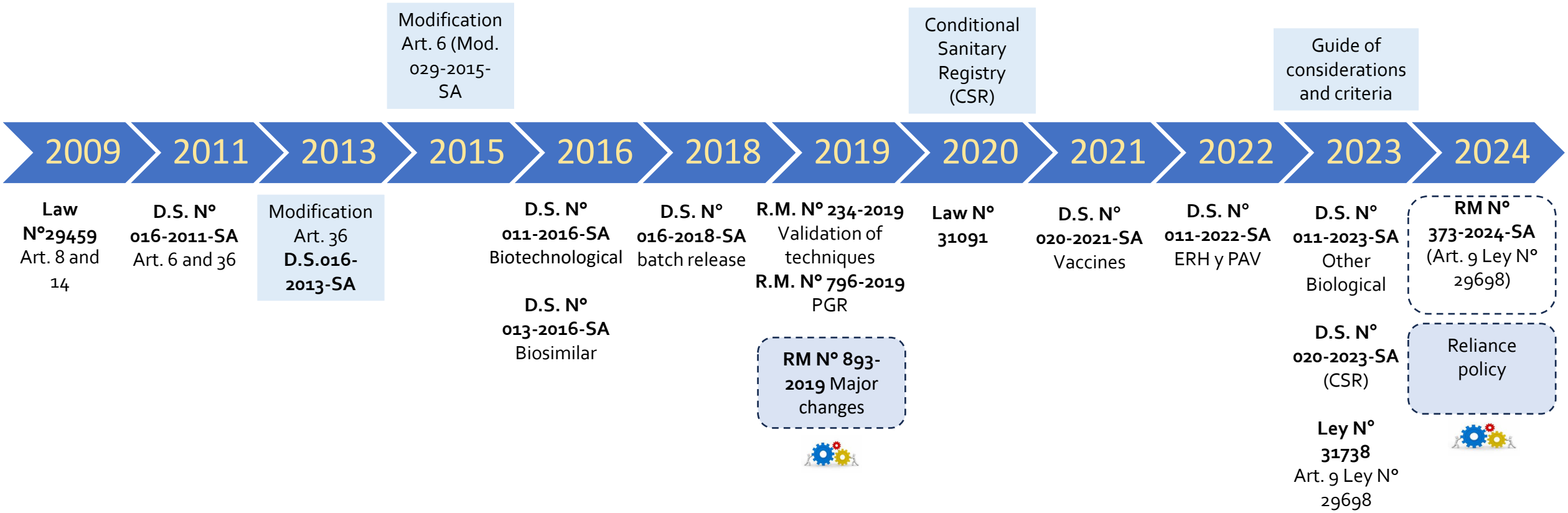
SCOPE AND ORGANIZATION

- DIGEMID
  - Pharmaceuticals products directorate
  - Medical devices and sanitary products directorate
  - Inpection and certification directorate
  - Pharmacovigilance, access and use directorate

→ Biological products team

- AIRCOPB
- AESYPGR
- ALLVDPH

ORGANIZATION OF THE REGULATORY FRAMEWORK FOR CHANGES POST APPROVAL OF BIOLOGICAL PRODUCTS



INTERNATIONAL RECOMENDATIONS

PANDRH RED PARF

World Health Organization

EUROPEAN MEDICINES AGENCY

FDA U.S. FOOD & DRUG ADMINISTRATION

Health Canada

ICH

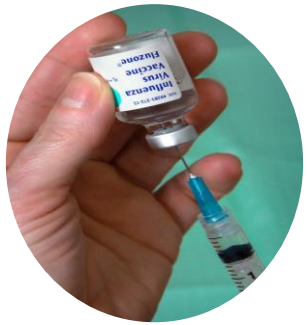
Vaccines, Biotechnological products, Biosimilar

Other biological products

BIOLOGICAL PRODUCTS

IMMUNOLOGICAL

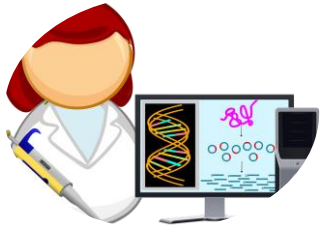
vaccines, allerges and serums



BIOTECHNOLOGICAL PRODUCTS

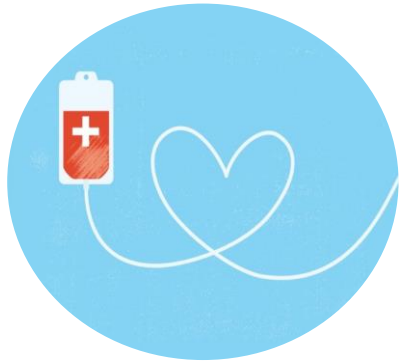
DNA Recombinant techniques

- Monoclonal antibody and hybridoma techniques
- Other methods determinate by the ANM in accordance to the advance of science



OTHER BIOLOGICAL PRODUCTS

DERIVED FROM HUMAN BLOOD AND HUMAN PLASMA



ADVANCE THERAPIES

Legal Requirements CMC of API and finished product.	RMP Preclinical and clinical studies.	CTD Format Module 3,4 and 5 in english	Biosimilar applications	International Recommendations	Reduce time evaluation for specific products approved in HSC/EMA/WHO (180 days)	Specific regulation for orphan products approved in HSC/EMA

CLASSIFICATION OF CHANGES

TYPE	DESCRIPTION	ASSESSMENT DEADLINES
Changes of minor importance	Changes that have minimal or no impact on the Quality, safety or effectiveness.	**Automatic** (*)
Changes of major importance	Changes that may have significant impacts on Quality, safety or effectiveness	**60 days**

Change of manufacturer or site of API and Finished Product (SCR)	Manufacturing process change	Change in the shelf life	Change in packaging material	Change of technical specifications	Change of labeling

Minor or major change case by case

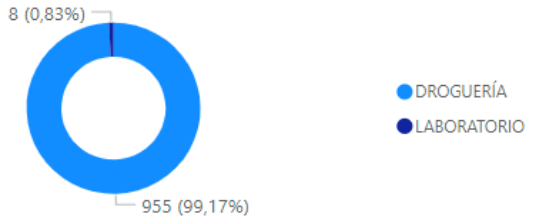
(*) Updates require evaluation

DASHBOARD OF MAJOR AND MINOR CHANGES

TOTAL EXPEDIENTES

963

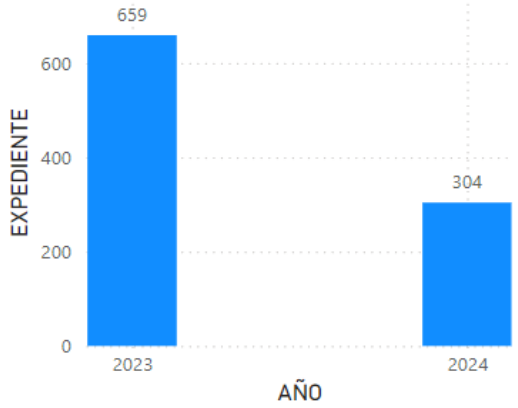
CATEGORIA ESTABLECIMIENTO



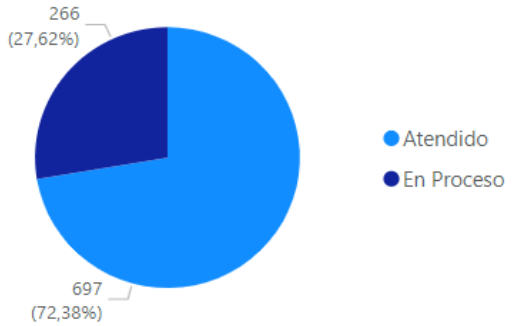
EXPEDIENTES NOTIFICADOS

170

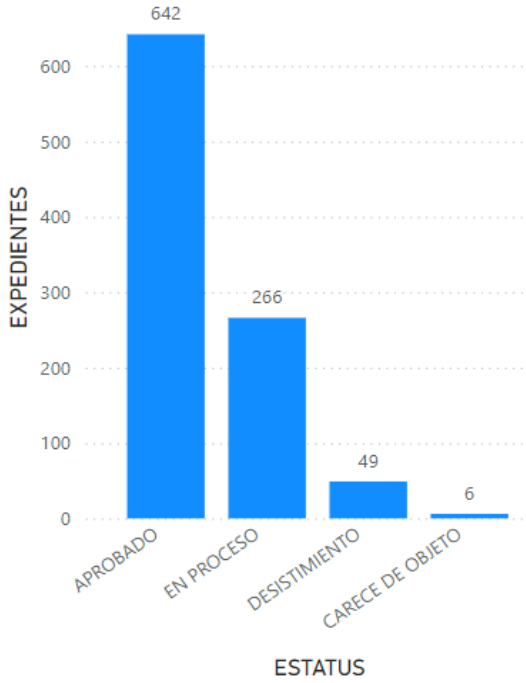
EXPEDIENTE POR AÑO



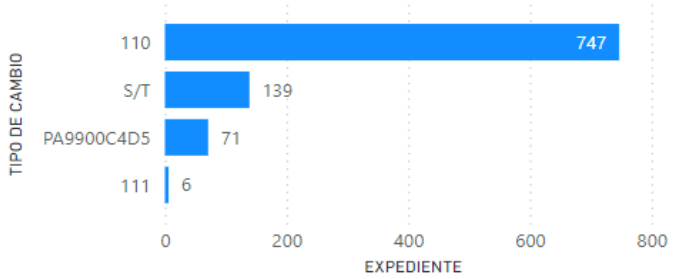
EXPEDIENTES ATENDIDOS



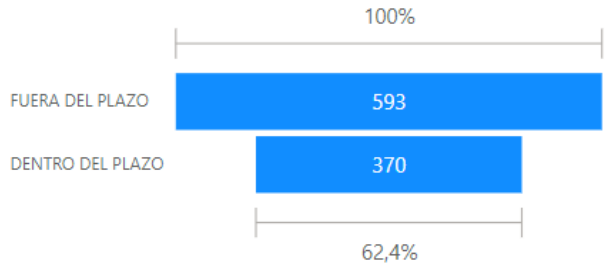
ESTATUS DE EXPEDIENTE



EXPEDIENTE POR TRÁMITE



PLAZO DE ATENCIÓN



GOOD REGULATORY CONFIDENCE PRACTICES: CURRENT APPROACH

Pre-marketing evaluation

-GMP Certificate
-CPP
-Batch Release Certificate
-Public evaluation report
-Specifications and analytical techniques
-Authorized data sheet and insert
-Biological reference product (via similarity)

Reliance unilateral HSC/EMA/OMS

-Changes in sanitary registration
-Safety alerts

post-marketing evaluation

INTERNATIONAL PARTICIPATION

Ibero-American Network of Authorities on Medicines

Pan American Network for the Harmonization of Pharmaceutical Regulation

Andean Health Organization – Convenio Hipólito Unanue (ORAS – CONHU).

Joint Commission on Narcotics and Psychotropic Substances.

Pacific Alliance - Committee on Technical Barriers to Trade

International Cooperation on the Regulation of Herbal Medicines

Red eAMI
Red de Autoridades en Medicamentos de Iberoamérica

ORGANISMO ANDINO DE SALUD - CONVENIO HIPOLITO UNANUE -

INTERNATIONAL PARTICIPATION

Andean Community of Nations (CAN)

Bilateral Working Group to Combat Smuggling with Bolivia, Ecuador and Chile, in order to combat smuggling that affects the borders

Health Technology Assessment Network of the Americas (RedETSA)

RedETSA
Red de Evaluación de Tecnologías en Salud de las Américas

WHO International Pharmacovigilance Program

REGULATORY CONFIDENCE PROJECTS - RELIANCE

ACTIVITIES

- Completion of Questionnaires
- Review of the process flow for the authorization of biotechnological products and new molecules.
- Training

PARTICIPANTS

DIGEMID

CONSULTANT:

CIRS Centre for Innovation in Regulatory Science

OBJECTIVE

- Strengthen the "reliance" in DIGEMID, for the process of granting sanitary registration of biological products and new drugs.

REGULATORY CONFIDENCE PROJECTS - RELIANCE

PERJETA 2.0 (pertuzumab)

TYPE	PARTICIPANTS	OBJECTIVE
• Changes • Collaborative regulatory procedure	World Health Organization EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH • +44 COUNTRIES	• Reducing the evaluation time from 2.5 years to 6.5 months

REGULATORY CONFIDENCE PROJECTS - RELIANCE

TYPE	PARTICIPANTS	OBJECTIVE
• Changes • Project where you will use the evaluation and approval of the EMA	EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH • +31 COUNTRIES	• 6 months for approval

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TRAINING FOR SANITARY REGISTRATION HOLDERS

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"Decenio de la Igualdad de Oportunidades para Mujeres y Hombres"
"Año del Bicentenario, de la consolidación de nuestra Independencia, y de la conmemoración de las heroicas batallas de Junín y Ayacucho"

COMUNICADO N° 019-2024

Programa de Capacitaciones en Regulación Sanitaria del Equipo de Productos Biológicos

La Dirección General de Medicamentos Insumos y Drogas -DIGEMID a través de la Dirección de Productos Farmacéuticos - DPF, invita a los administrados a participar de la segunda charla virtual que forma parte del Programa de Capacitaciones en Regulación Sanitaria del Equipo de Productos Biológicos que se llevará a cabo durante el presente año:

Tema : CAMBIOS EN EL REGISTRO SANITARIO DE PRODUCTOS BIOLÓGICOS-CLASIFICACIÓN, CASOS PRÁCTICOS Y OBSERVACIONES MÁS FRECUENTES

Día : Jueves, 18 de Julio del 2024

Hora : 10:00 am (Los participantes deberán conectarse a partir de las 9:30 am a fin de permitir el ingreso a la sala virtual).

Los participantes deben registrarse a través del link hasta el martes 16 de Julio del presente:
https://minsa-gob-pe.zoom.us/meeting/register/tZcvfuyqrj4oGteGeuGK9guy312wb8Jzsrzl

Al momento de inscribirse deben llenar el formulario consignando: apellidos y nombres (en mayúsculas), DNI, correo electrónico, teléfono, empresa (droguería/ laboratorio), cargo y consulta(s) relacionada(s) al tema

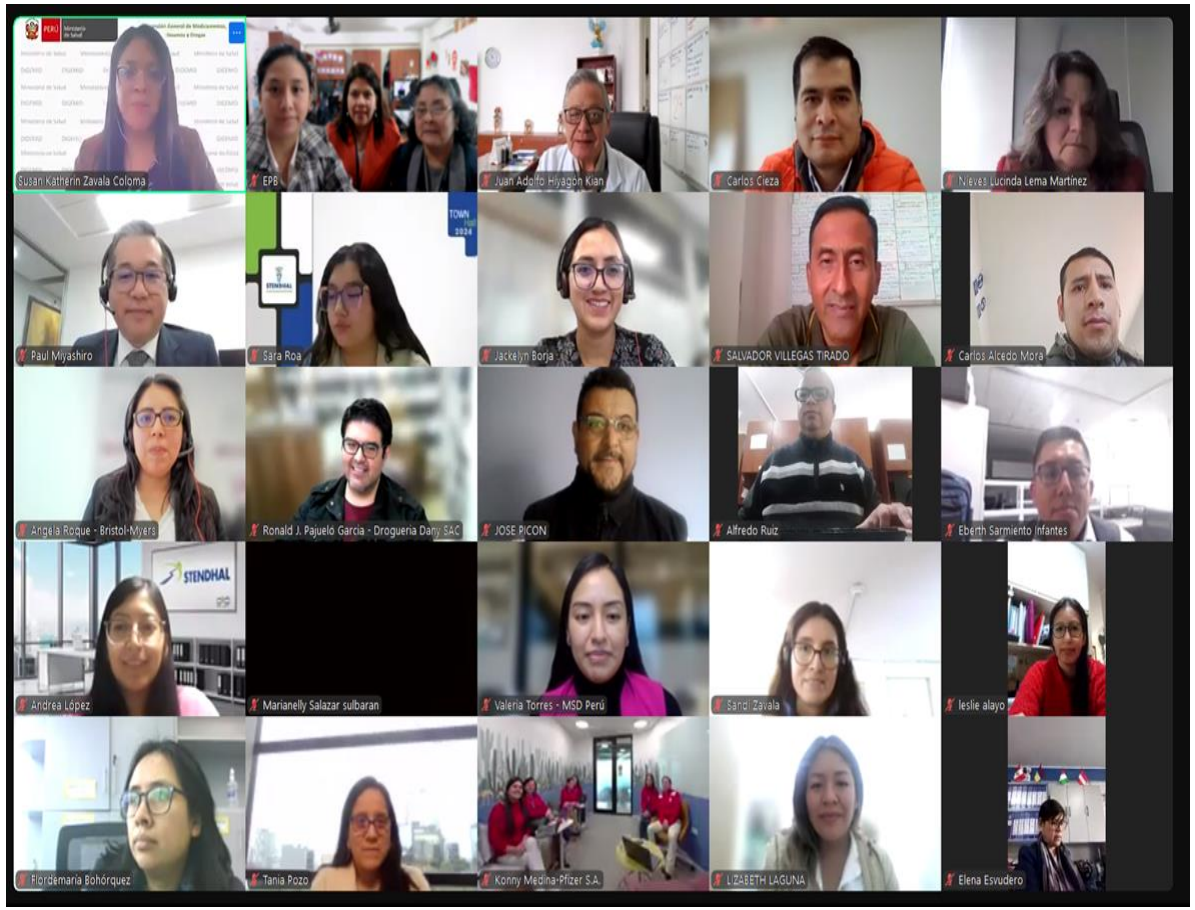
CAPACIDAD LIMITADA

San Miguel, 09 de Julio 2024

www.digemid.minsa.gob.pe
Av. Parque de las Leyendas N° 240, Urb. Pando - San Miguel, Lima 32, Perú T (511) 631-4300

BICENTENARIO DEL PERÚ 2021 - 2024

Con Punche Perú



CHALLENGES

There is no specific regulation for post-approval changes

Regulatory confidence training for reviewer

Some companies don't submit the same documentation with which the change was authorized in HSC

We are finalizing a regulatory transition that involves the registration of biological products with CTD format

Resources for reliance implementation

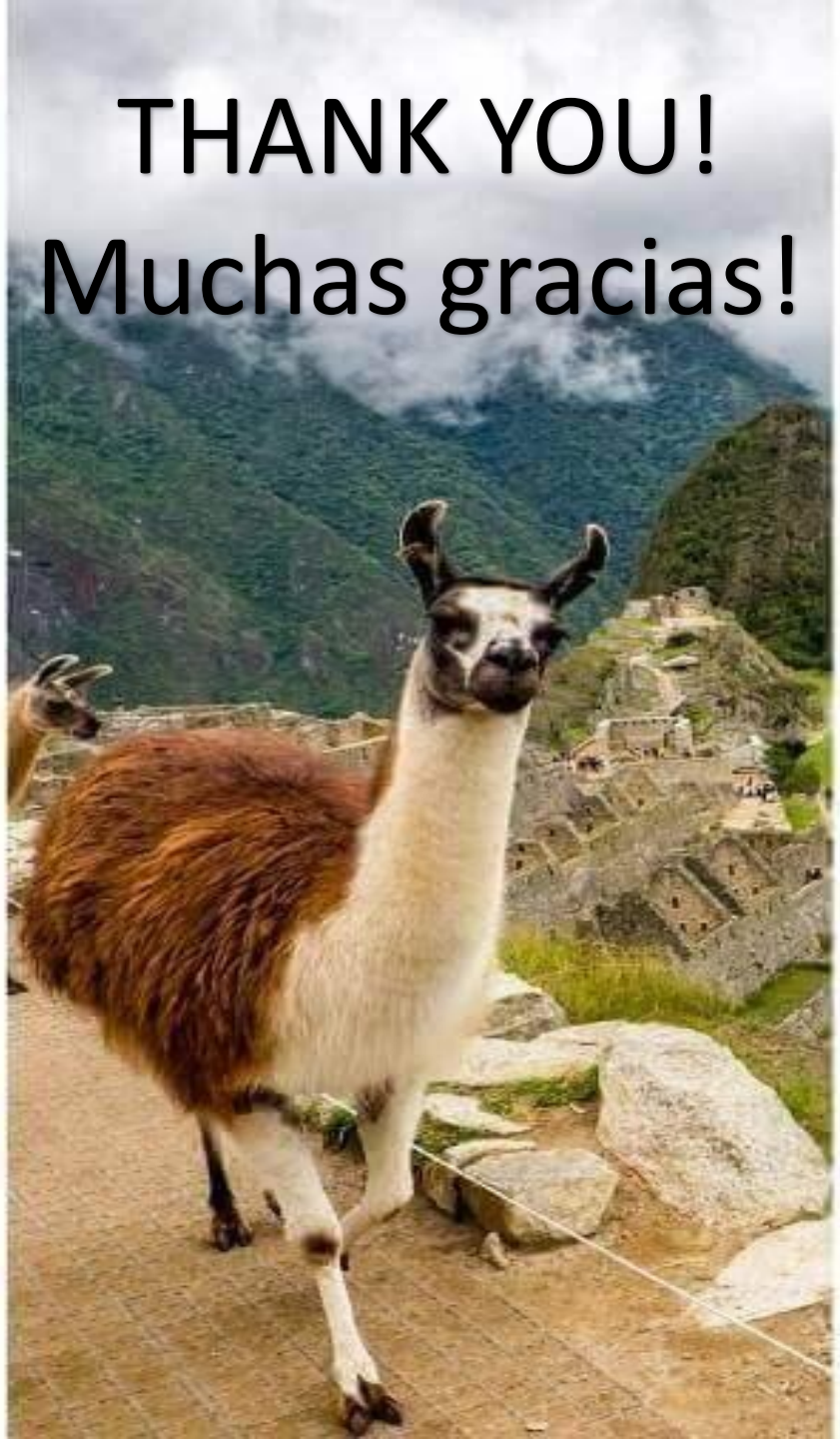
Identify which products are suitable for the application of regulatory confidence

Lack of access to full assessment reports from regulatory authorities of reference

EXPECTATIONS

- Ensuring that there are clear and consistent criteria on which products are suitable for applying regulatory confidence
- Dependency for changes after the authorization of biological products.
- Promote convergence and harmonization of requirements, standards and guidelines.
- Increase collaboration, coordination and information exchange among regulatory authorities.

THANK YOU!
Muchas gracias!



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