IX PAN-RUSSIAN GMP CONFERENCE

MINISTRY OF INDUSTRY AND TRADE OF RUSSIA

REGULATORY RELIANCE: CUBAN NRA EXPERIENCE.

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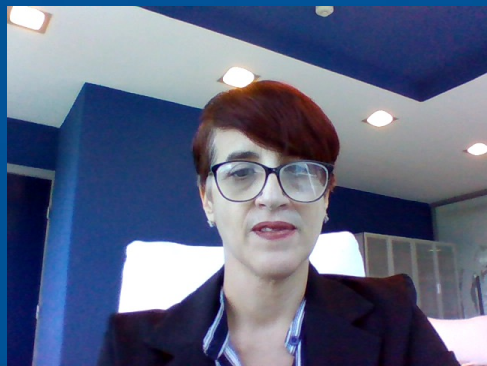
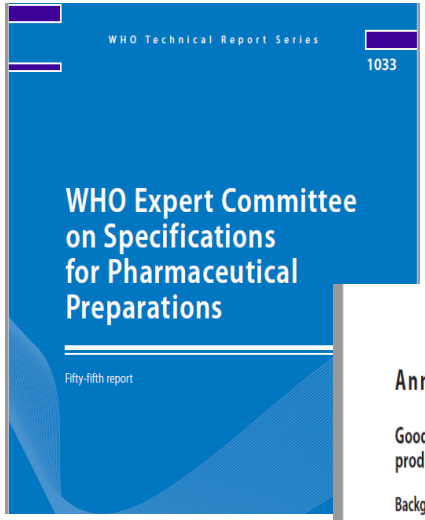
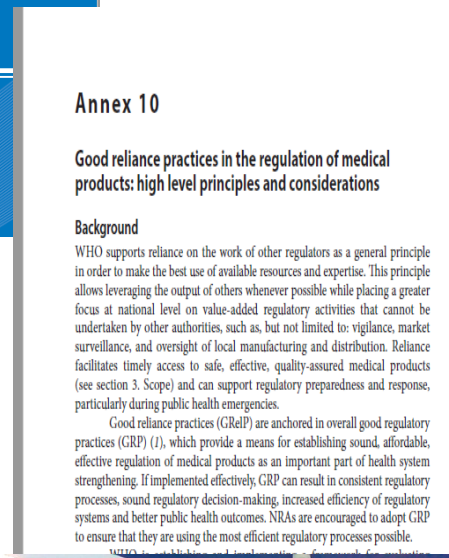
CECMED



Reliance

Reliance. The act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision. The relying authority remains independent, responsible and accountable for the decisions taken, even when it relies on the decisions, assessments and information of others




Annex 10

Good reliance practices in the regulation of medical products: high level principles and considerations

Background

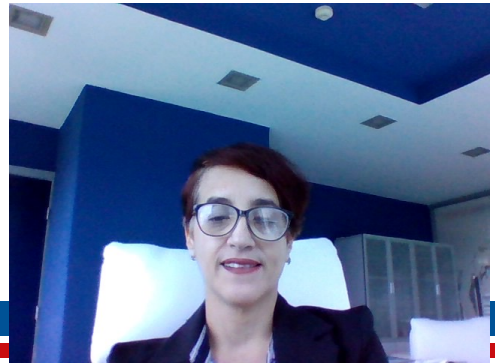
WHO supports reliance on the work of other regulators as a general principle in order to make the best use of available resources and expertise. This principle allows leveraging the output of others whenever possible while placing a greater focus at national level on value-added regulatory activities that cannot be undertaken by other authorities, such as, but not limited to: vigilance, market surveillance, and oversight of local manufacturing and distribution. Reliance facilitates timely access to safe, effective, quality-assured medical products (see section 3. Scope) and can support regulatory preparedness and response, particularly during public health emergencies.

Good reliance practices (GRelP) are anchored in overall good regulatory practices (GRP) (1), which provide a means for establishing sound, affordable, effective regulation of medical products as an important part of health system strengthening. If implemented effectively, GRP can result in consistent regulatory processes, sound regulatory decision-making, increased efficiency of regulatory systems and better public health outcomes. NRAs are encouraged to adopt GRP to ensure that they are using the most efficient regulatory processes possible.

WHO Expert Committee on Specifications for Pharmaceutical Preparations: Fifty-fifth report. Geneva: World Heal
2021 (WHO Technical Report Series, No. 1033).Licence: CC BY-NC-SA 3.0 IGO.) Annex 10 Good reliance
regulation of medical prodiucts, high level principles and consideration.

Reliance Highlights

- ✓ It is a Good Regulatory Practice complying with the principles of legality, transparency, flexibility and efficiency
- ✓ It can be use in all NRA basic function and cover the entire life cycle of the product
- ✓ Implies Regulatory sovereignty
- ✓ Risk Base approach
- ✓ Increase efficiency
- ✓ Timely Access



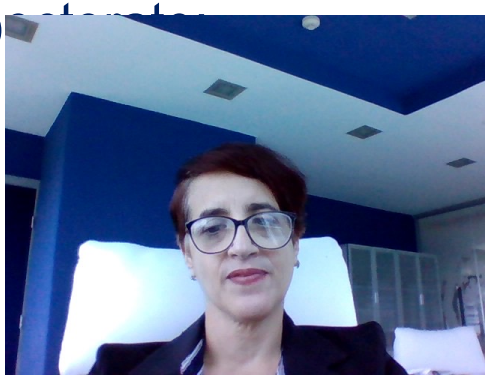
Reliance on Regulatory Inspection function

Mechanism

- ✓ Recognition: mutual or unilateral
- ✓ Work-sharing: joint inspections
- ✓ Regional or International initiatives.

International examples

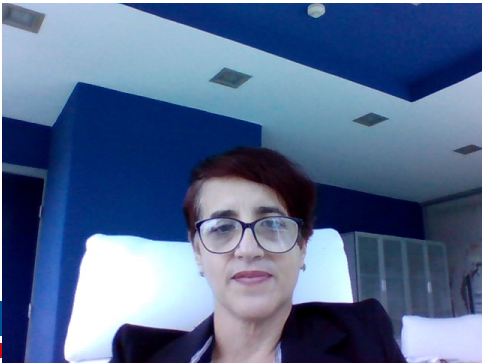
- ✓ PIC/S: ¨GMP Inspection Reliance
  https://picscheme.org/users_uploads/news_news_documents/PI_048_1_Guidance_on_GMP_Inspection_Reliance_1.pdf
- ✓ ZAZIBONA collaborative procedure for GMP inspection : https://zazibona.com/gmp-inspections/inspection-process/
- ✓ Medical Device Single Audit Program (MDSAP)
  https://www.fda.gov/medical-devices/cdrh-international-affairs/medical-device-single-audit-program-mdsap
- ✓International Pharmaceutical Insp
  GILSINP initiative



Reliance on CECMED

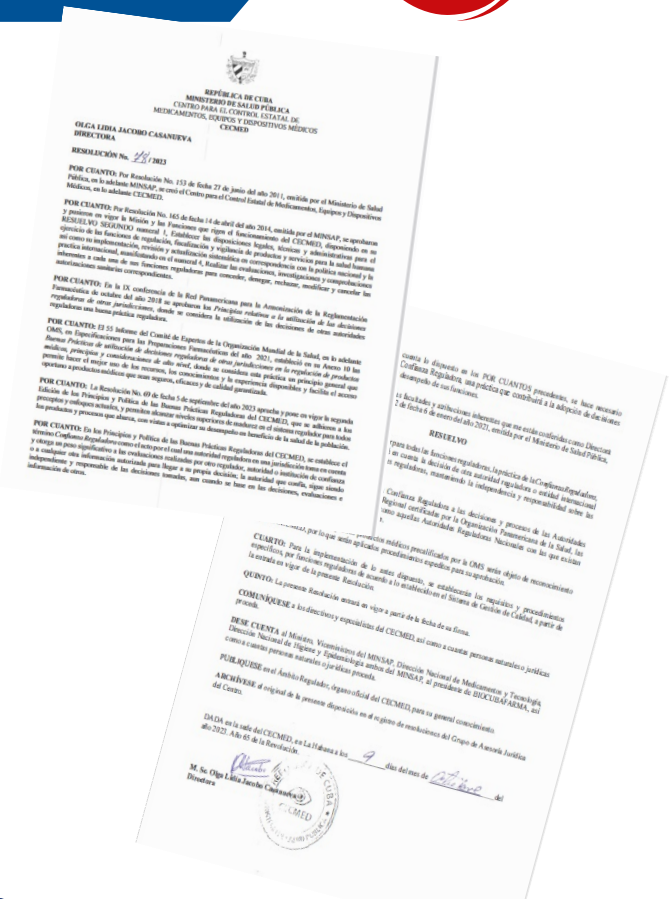
Background/Previous experience

- ✓ National Regulatory Authorities of Regional Reference in Americas Region: joint inspections and exchange of Inspection Report.
- ✓ Bilateral agreement (MoUs): Exchange of information and Inspection Reports: (ANVISA. INVIMA, ANMAT)
- ✓ Accept GMP Certification from recognizing NRA in on MA process



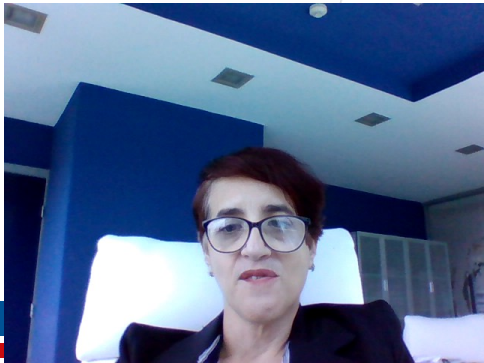
Reliance on CECMED

Resolution 78/2023: Approve and put into effect for all regulatory functions, the practice of reliance



CECMED will apply reliance to the decisions and processes of the PAHO Regional Reference Regulatory Authorities, WHO listed Authorities (WLA) and those NRA with which there are bilateral agreements that establish it

Regulatory document in process: Policy for the application of Reliance



Reliance on CECMED

THANK YOU

CECMED
CENTRO PARA EL CONTROL ESTATAL
DE LA CALIDAD DE LOS MEDICAMENTOS
Ministerio de Salud Pública de Cuba

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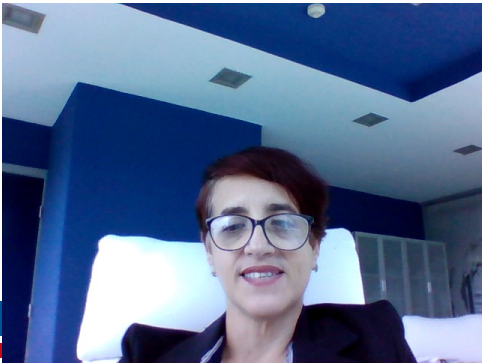

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