Organización Panamericana de la Salud

REUNIÓN COMITÉ DIRECTIVO, RED PANAMERICANA PARA LA ARMONIZACIÓN DE LA REGLAMENTACIÓN FARMACÉUTICA (Red PARF)
Sede de la OPS
525 23rd. St., NW Washington, DC 20037
Sala C
22 y 23 de Noviembre del 2011

the Regional Platform for Access and Innovation for Health : Regulatory Indicators for the Observatory Module

Medicines and Health Technologies
PAHO/WHO Washington DC

Contents

- ✓ CD50R9……
- ✓ National Regulatory Authority basic functions
- ✓ Framing indicators under key functions
- ✓ Data sources and post-evaluation actions

Pan American Health Organization

Mandates

June 2010 (PAHO Executive Committee)
- ✓ Members asked to discuss the initiative in the framework of PAHO's Directing Council.

October 2010 (PAHO Directing Council)
- ✓ Member States adopted by consensus the Resolution CD50.R9 "STRENGTHENING NATIONAL REGULATORY AUTHORITIES FOR MEDICINES AND BIOLOGICALS."
- – **To request the Director to:**
  - **(a) Support initiatives for the strengthening and qualification of national regulatory authorities to guarantee the quality, safety, and efficacy of medicines, biologicals, and other health technologies;**

To the Member States:

- Strengthen and evaluate their regulatory capabilities through an examination of the performance of their essential functions;
- Promote the dissemination of information on the results and processes for the regulation;
- Promote interaction and technical cooperation among countries.

Mandates

ICDRA Recommendations
Plenary 3: Improving drug regulatory as part of health systems strengthening

WHO should
- Promote collaboration and coordination to develop Medicine Regulatory Authorities capacity

Medicines regulatory authorities should
- Commit to and collaborate in prioritizing, developing and teaching regulatory science
- Work with their governments to reiterate to the WHO the importance on strengthening regulatory capacity and cooperation

PAHO Region NRA Assessment Process

- ***Pre-assessment***
  - – Preliminary evaluation, based on the activities documented.
- ***Assessment***
  - – visit to the NMRA and all other institutions directly or indirectly related to it;
  - – ***Follow up*** of the institutional development plan (IDP).
- ***Re-Assessment (every 3 years)***

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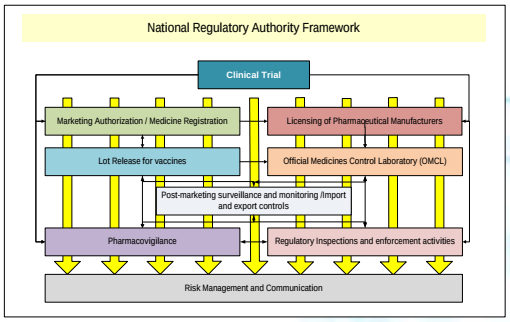
WHO essential functions of a Regulatory System for Medicines and Biologicals

Source: regulation of vaccines: building on existing drug regulatory authorities [WHO/V&B/99.18]

Key regulatory functions relationship



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Pilot Countries – Working Group

Argentina, Dominican Republic, Colombia and Panama

Information Hub - Regulatory indicators

N#	Access	Level	Clas.
20	Open access	Basic	Yes/No
~ 200	Restricted access among NRA	Advanced	N.I.: Not implemented I.I.: In implementation P.I.: Partially implemented I.: Implemented

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Information sources

PAHO/WHO Pharmaceutical Country Profile (*145 indicators*)

Process:
PAHO evaluation and Pilot Countries validation by selection of the minimum and open access indicators that reflect the essential regulatory functions

20 Basic regulatory Indicators

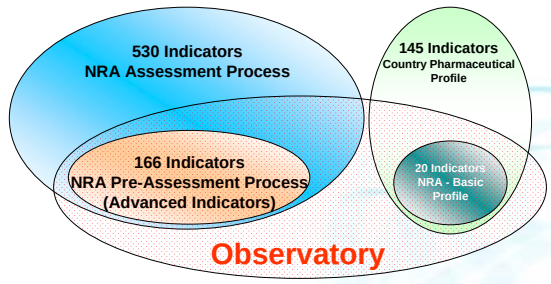
Data collection tool used in the procedure for the qualification of National Regulatory Authorities of Medicines and Biologicals

(*530 indicators*)

Process:
leading indicators that reflect key regulatory functions
- PAHO evaluation
- Pilot Countries validation
- PANDRH Steering Committee

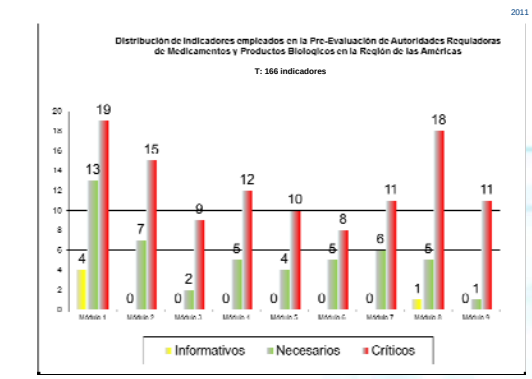
166 Advanced regulatory Indicators

Information Hub - Regulations



Regulatory functions correlations

Essential Functions (WHO)	Key Functions (PAHO Region)	Regulatory Indicators at the Collection tool
Licensing (of products and manufacturers)	National Regulatory Authority Framework	36
	Marketing Authorization / Medicine Registration	22
	Licensing of Pharmaceutical Manufacturers	11
Surveillance of medicines	Post-marketing surveillance and monitoring / Import and export controls	17
	Pharmacovigilance	17
System of lot release	Lot Release for vaccines	12
Laboratory access	Official Medicines Control Laboratory (OMCL)	24
inspections of manufacturers (GMP)	Regulatory Inspections and enforcement activities	17
Clinical trials	Clinical Trials	17



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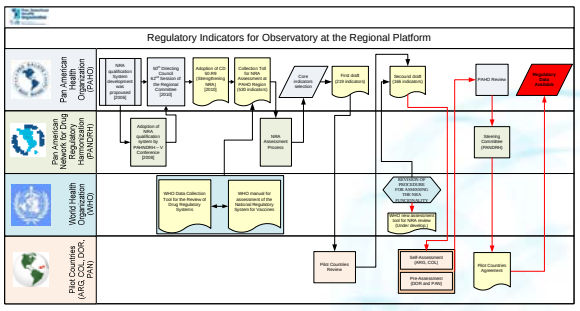
Regulatory Indicators development flow



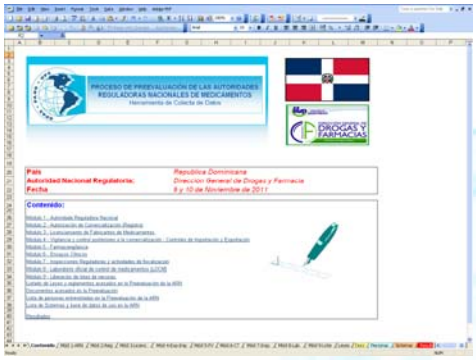
Indicadores Básicos para la Plataforma
Fuente: Perfil Farmacéutico

5.08.02	¿Existen disposiciones legales que exigen el visto bueno de un **comité de ética (comité ético de investigación clínica)** antes de iniciar un ensayo clínico?	Si ☒ No ☐	2008	Resolución 2378 de 2008. Resolución 8430 de 1993

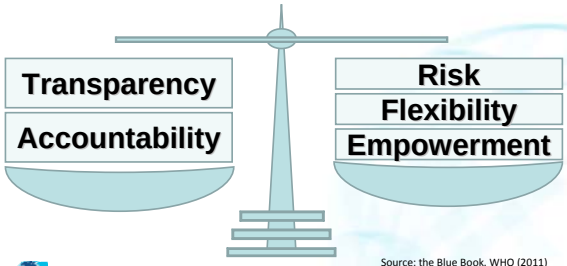
Basic regulatory Indicators for the Observatory

Regulatory Framework	Are legal provisions that establish the functions and responsibilities of the NRA?
	Does the NRA have an own Website?
	Does the NRA participate in harmonization or collaboration initiatives?
	Does the NRA use a digital information system management to keep and recover all information relative to product licensing, registration, inspections, etc.?
	Legal provision require a marketing authorization (registration) for all pharmaceutical products on the market
Marketing Authorization	Legal provisions require the NRA to make publicly available the registered pharmaceutical products with defined periodicity
	Legal provisions require to publish the Summary Product Characteristics (SPCs) of the pharmaceuticals registered
	Legal provisions exist permitting inspectors to inspect premises where pharmaceutical activities are performed
Regulatory Inspections	Local manufacturers are inspected to supervise the implementation of adequate GMP
	Legal provisions exist requiring authorization to import medicines
Import control ad licensing	legal provisions exist allowing the sampling of imported products for testing
	Legal provisions exist requiring manufacturers to be licensed. If yes please attach document or provide URL
	Legal provisions for controlling the pharmaceutical market
Quality control	Does a Laboratory exist in the country for quality control testing?
	Legal provisions exist requiring NRA authorization for conducting Clinical Trials
Clinical Trials	Legal provisions exist requiring the agreement by an ethics committee/institutional review board of the Clinical Trial to be performed
	Legal provisions require sponsor, investigator to comply with Good Clinical Practices (GCP)
	There are legal provisions in the Medicines Act that provide for pharmacovigilance activities as part of the NRA mandate
Pharamacovigilance	A national Adverse Drug Reactions database exists in the country
	A routine and crisis communication strategy exists

Advanced Indicators Data Tool



Good Regulatory Practice: The Regulatory Balance



Source: the Blue Book. WHO (2011)

2011

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Thank you

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