Plenary 4: Transparency, responsibility and participation in processes: the interrelation of the industry with the regulator

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Pan American Health Organization
World Health Organization
Regional Office for the Americas

PAHO

Outline

- Definition
- Principles of Good Regulatory Practices
- Transparency in new or updating regulations
- Transparency on the decision making
- Public Assessment Summary Information for Biosimilar
- Benefits
- Asks

Definition

Transparency: ensuring that regulators and others involved in the regulatory process act and communicate openly, defining policies and procedures in writing and publishing the written documentation, and giving reasons for decisions to the public[1,2]

[1-] Good review practices: guidelines for national and regional regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: forty-ninth report. Geneva: World Health Organization;2015: Annex 9 (WHO Technical Report Series, No. 992), accessed- Oct 1st 2018.

2- Good Regulatory Practices: guidelines for national regulatory authorities for medical products- WHO- Draft;2016.

Principles of good regulatory practices[3]

1	Legality	Regulatory Systems should be transparent; requirements and decisions should be made known to affected parties and, where appropriate, to the public in general
2	Impartiality	
3	Consistency	
4	Proportionality	
5	Flexibility	
6	Effectiveness	
7	Efficiency	
8	Clarity	
9	Transparency	

[3] Good Regulatory Practices: guidelines for national regulatory authorities for medical products- WHO- Draft;2016.

Transparency

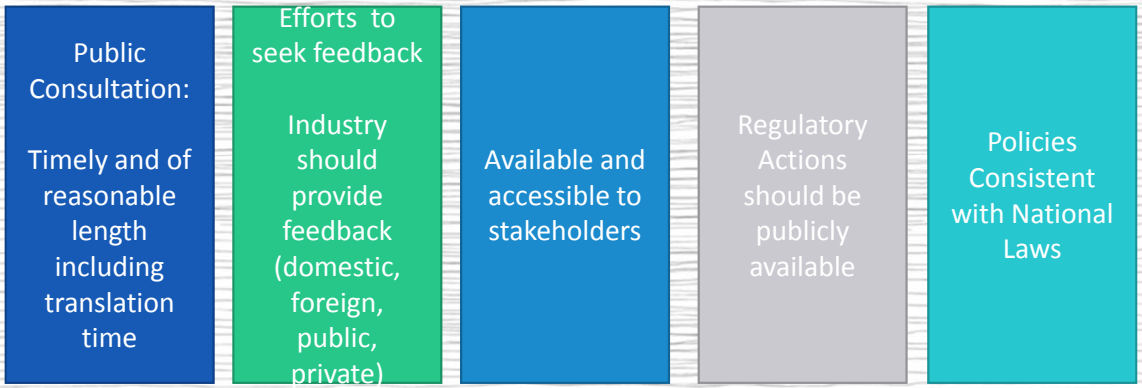
Transparency should be an integral
Part of the regulatory system

Two examples are:

When Developing New or
Updated Regulations

Regulatory Decision Making

Transparency When Developing New or Updated Regulations[4,5,6]

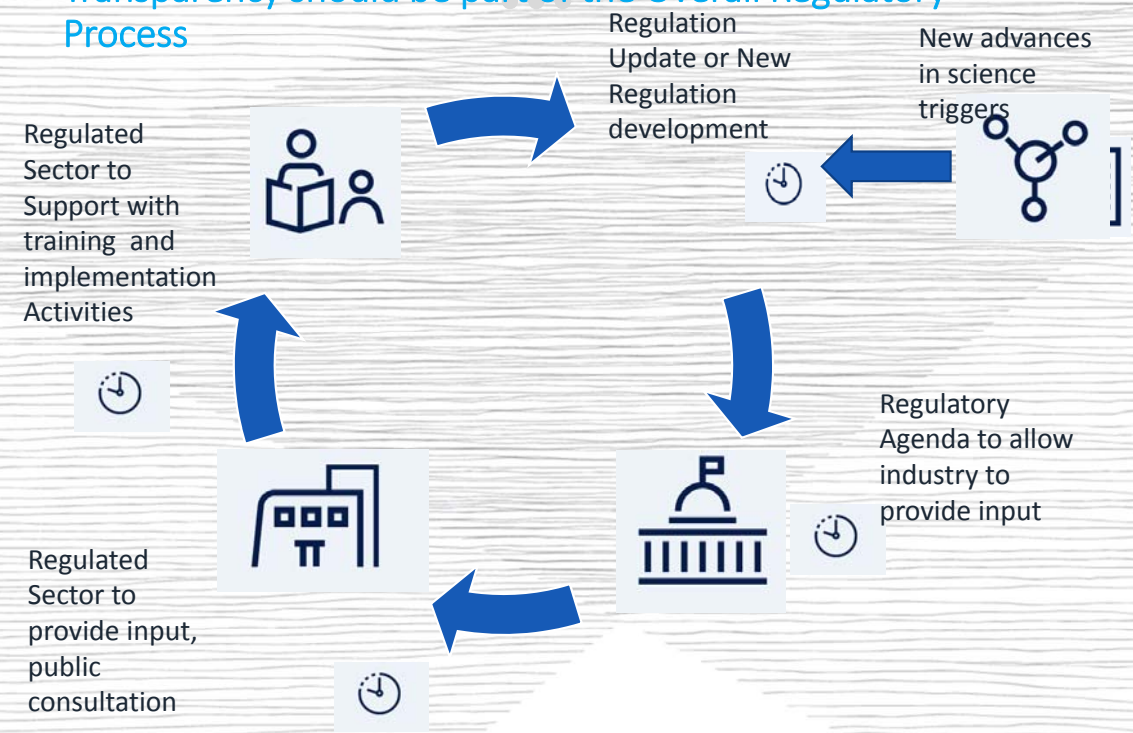


[4]Good Regulatory Practices: guidelines for national regulatory authorities for medical products- WHO- Draft; 2016.

[5] The OECD Report on Regulatory Reform Synthesis- Organisastion for Economic Co-operation and Development, Paris, 1997

[6] Regulatory policy in Latin America: An analysis of the state of play, OECD Regulatory Policy Working Papers, No. 7, OECD Publishing, Paris

Transparency should be part of the Overall Regulatory Process



Transparency on the Regulatory Decision Making[7]

"..Mechanism should exist to ensure that information on marketing authorization applications, including authorized, suspended, rejected and completed applications are published to promote transparency and information sharing amongst stakeholders"

- Website or other official publication
- Updated list of all medical products granted MA
- A summary technical evaluation report available

[7] WHO Global Benchmarking Tool (GBT) for Evaluation of National Regulatory System of Medical Products- Fact Sheets for Registration for Marketing Authorization – Draft, Dec 2017- Consulted Oct 2018

IPRP- The International Pharmaceutical Regulators Programme[8]

Launched in 2018

Regulators forum for share information, discussion issues of common concern, discuss emerging scientific areas of relevance to drug development and regulation, and work towards regulatory convergence.

ANVISA, Brazil and Health Canada- IPRP MC Chair and Vice-Chair respectively, to serve for a 1-year term

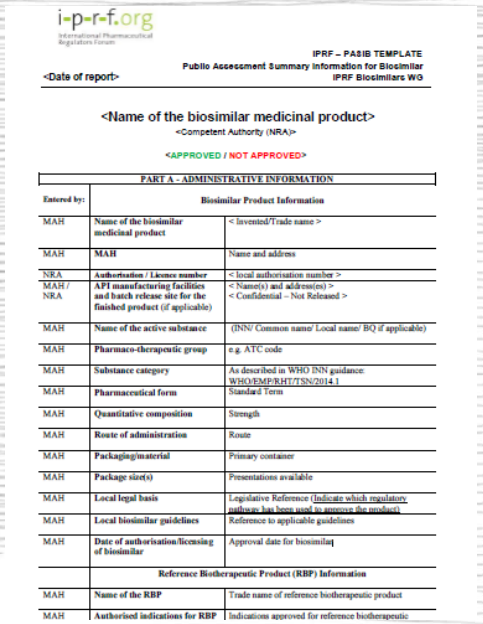
8 Working Groups:

1. Nanomedicines
2. Biosimilars
3. Gene Therapy
4. Cell Therapy
5. Identification of Medicinal Products (IDMP)
6. Quality for Generics
7. Bioequivalence
8. Information sharing for Generics

[8] www.i-p-r-f.org/ consulted Oct 2018

Public Assessment Summary Information for Biosimilar (PASIB)[9]

- The IPRP Biosimilars Working Group proposed the development of a template to assist National Regulatory Authorities (NRA) in making available a summary of the review of biosimilar applications in their country in a common language.
- The PASIB includes key information summarized details of the biosimilar review
- The template has been designed to reduce local effort.



i-p-r-f.org
International Pharmaceutical Regulators Forum

IPRF – PASIB TEMPLATE
Public Assessment Summary Information for Biosimilar
IPRF Biosimilars WG

<Date of report>

<Name of the biosimilar medicinal product>
<Competent Authority (NRA)>
<APPROVED / NOT APPROVED>

PART A - ADMINISTRATIVE INFORMATION		
Entered by:	Biosimilar Product Information	
MAH	Name of the biosimilar medicinal product	< Invented/Trade name >
MAH	MAH	Name and address
NRA	Authorisation / Licence number	< local authorisation number >
MAH / NRA	API manufacturing facilities and batch release site for the finished product (if applicable)	< Name(s) and address(es) > < Confidential – Not Released >
MAH	Name of the active substance	(INN/ Common name/ Local name/ BQ if applicable)
MAH	Pharmaco-therapeutic group	e.g. ATC code
MAH	Substance category	As described in WHO INN guidance: WHO/EMP/RHT/TSN/2014.1
MAH	Pharmaceutical form	Standard Term
MAH	Quantitative composition	Strength
MAH	Route of administration	Route
MAH	Packaging/material	Primary container
MAH	Package size(s)	Presentations available
MAH	Local legal basis	Legislative Reference (Indicate which regulatory pathway has been used to approve the product)
MAH	Local biosimilar guidelines	Reference to applicable guidelines
MAH	Date of authorisation/licensing of biosimilar	Approval date for biosimilar
	Reference Biotherapeutic Product (RBP) Information	
MAH	Name of the RBP	Trade name of reference biotherapeutic product
MAH	Authorised indications for RBP	Indications approved for reference biotherapeutic

[9] https://www.i-p-r-f.org/index.php/en/news/pasib-final/ consulted Oct 2018

Transparency on the decision making process- FIFARMA Perspective[10]

Developing and maintaining trust with stakeholders in approved medical products depends, on transparently developed regulations and on their product specific application

Making transparent what regulation is applied, what data basis is used for the assessment and what rational is behind a medical product's approval or rejection will also allow better informed decision-making at the physician and payer level

The initiative from IPRP (former IPRF) on the publication of Public Assessment Summary Information for Biosimilar (PASIB) is highly valuable and if properly implemented by regulatory agencies will significantly contribute to transparency

The availability of public assessment summary information should not be limited to Biosimilars, but should be available to any type of medical products

[10] https://fifarma.org/wp-content/uploads/2017/11/FIFARMA-Transparency-Position-Paper-final-version-FINAL.pdf consulted Oct 2018

Benefits of Transparency

PATIENTS, PHYSICIANS

Increases public awareness, provides high Level of Public Trust and Confidence in approved medical products

Allows better Informed decision-making

Allows adequate access to important medical products.

Provides input on medical needs.

REGULATORS

Builds trust in agencies capabilities approving safe and efficacious medicines

Improves efficiencies

Provides alignment in communication

Promotes regulatory convergence

Promotes inter-agency communication

Is the foundation to support the reliance pathways

Increases the understanding of challenges on the development of novel therapies

REGION

Consolidates the region in good regulatory practices.

The incorporation of good regulatory practices as foundation for the GBT and Reliance Practices.

Engage with the international community

INDUSTRY

Provides clear expectations on the regulatory processes and policies, allows faster reactions to agency requests.

Provides clear understanding of regulatory actions.

Fosters efficient medical product development

Fosters collaboration for training activities (Industry Associations)

FIFARMA Asks for PANDRH and NRAs

✓ We see encouraging examples and results incorporating the principles of good regulatory practices and transparency in the region like:

- Establishing the regulatory agenda, publishing decisions in NRA's websites, organizing workshops with the stakeholders before drafting a regulation, among others

➡ In the Latin America region there is still a need for:

- Continue the application and incorporation of the principles of Good Regulatory Practices and transparency across the regulatory system
- Understand how the Concepts from the Good Regulatory Practices and Benchmarking tool from WHO including transparency will be incorporated and measured by the regulators in the America's Region.
- How industry can support this endeavor

" Increasing our openness will help us more effectively implement our mission to promote and protect the public health"….

US FDA- Report on Good Guidance Practices- Improving Efficiency and Transparency- Dec 2011

PAHO/WHO

PAHO