

Good Regulatory Practices: Guidelines for National Regulatory Authorities

Daniela Decina
Technical Officer
Regulatory Systems Strengthening



**World Health
Organization**

Background

- 14th WHO International Conference of Drug Regulatory Authorities (ICDRA), 2010
 - Among the outcomes: *Collect **best practices** of collaboration and cooperation between NRAs including information exchange, joint assessments and inspections and activities aimed at reducing duplication*
- Regulatory framework (WHO NRA Forum, Bangkok, May 2011)
 - Included themes on harmonization of regulatory initiatives and standards and sharing of information, as well as international and regional coordination and networking
- Feedback from assessments of National Regulatory Authorities conducted by WHO between 1997-2014
 - Request for guidance on how to develop legal frameworks, building transparency and have an efficient communication strategy
- In 2013 a guideline for GRP listed among the normative work to be developed by the WHO Department of Essential Medicines and Health Products

Drivers for Good Regulatory Practices

- A fundamental role of government is to protect and promote public health
- This objective is enabled by a system of laws, regulations and guidelines
- Degree to which the regulatory framework fulfils policy objectives depends on the quality of regulatory development and implementation process
- If consistently and effectively implemented, Good Regulatory Practices (GRP) can lead to higher quality regulation, improved regulatory decision-making, increased efficiency of regulatory systems, and better public health outcomes

What is GRP?

“Good Regulatory Practices (GRP) are internationally recognised processes, systems, tools and methods for improving the quality of regulations.

GRP systematically implements public consultation and stakeholder engagement as well as impact analysis of government proposals, before they are implemented to make sure they are fit for purpose and will deliver what they are set out to achieve.”

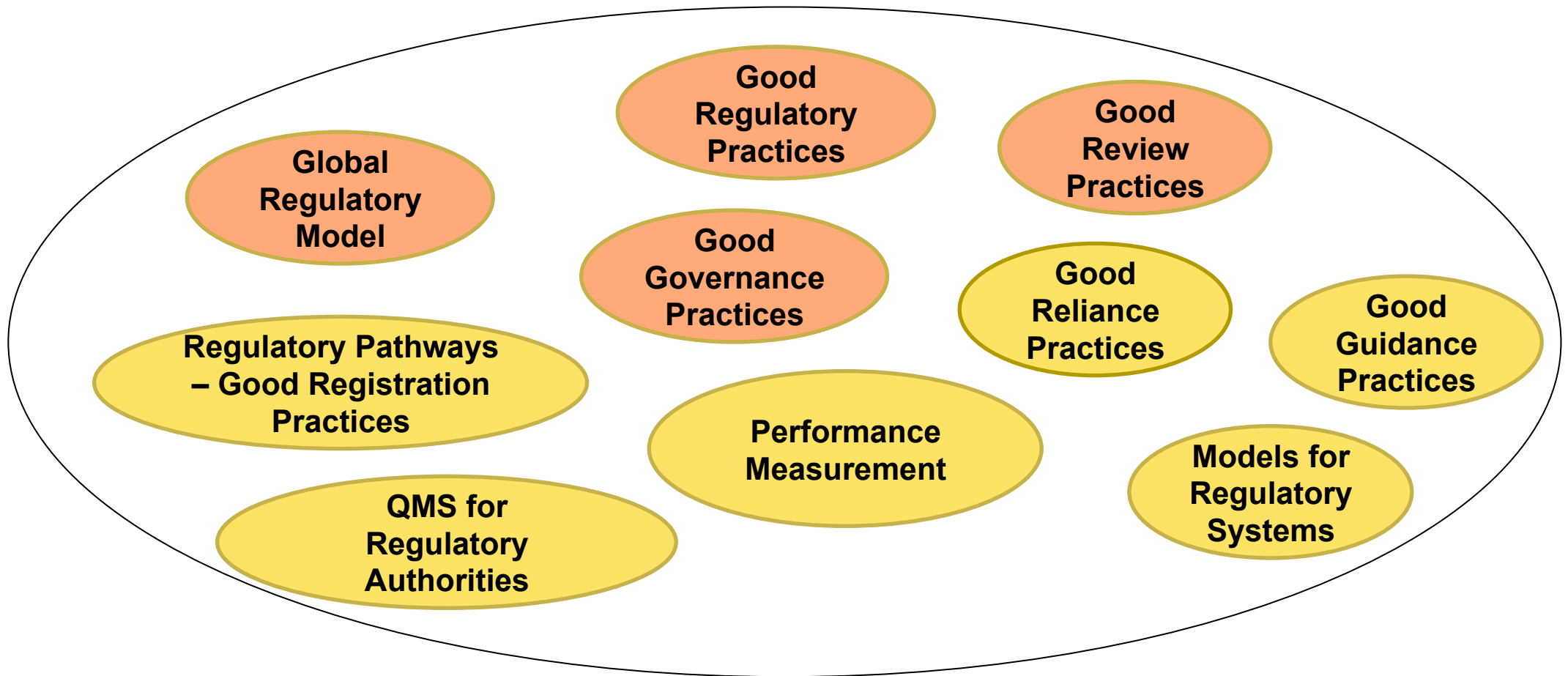
<http://www.oecd.org/gov/regulatory-policy/asean-oecd-good-regulatory-practice-conference-2015.htm>

WHO Guideline of GRP

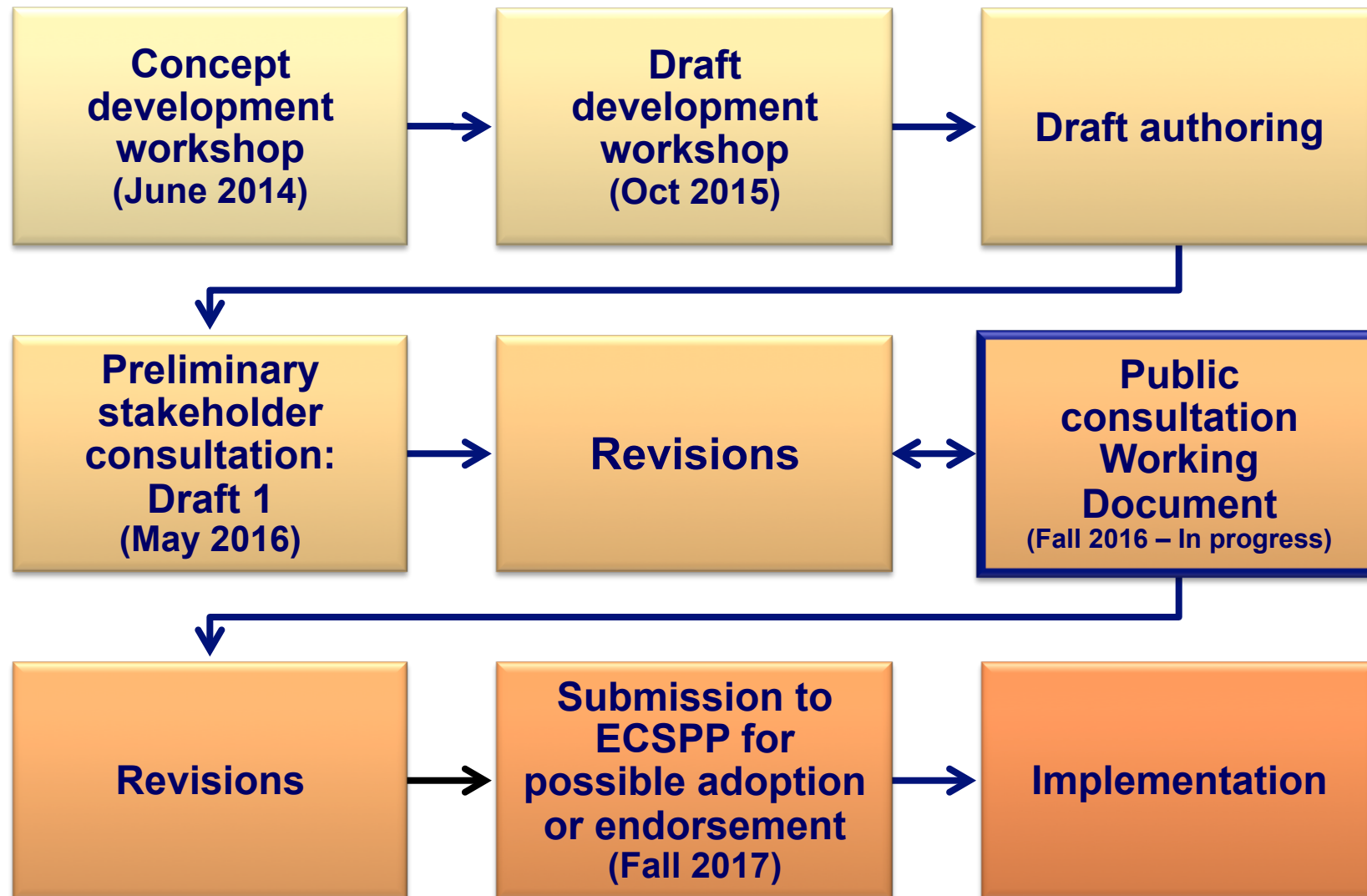
- Responds to requests from Member States for guidance on how to develop legal frameworks
- Foundational document that applies internationally accepted principles of GRP to the regulation of medical products
- Relevant to all regulators, irrespective of resources and system (centralized/decentralized/network)
- One in a series of 'best practices' guidelines

Framework of Best Practices for Regulation of Medical Products

GRP Umbrella Statement

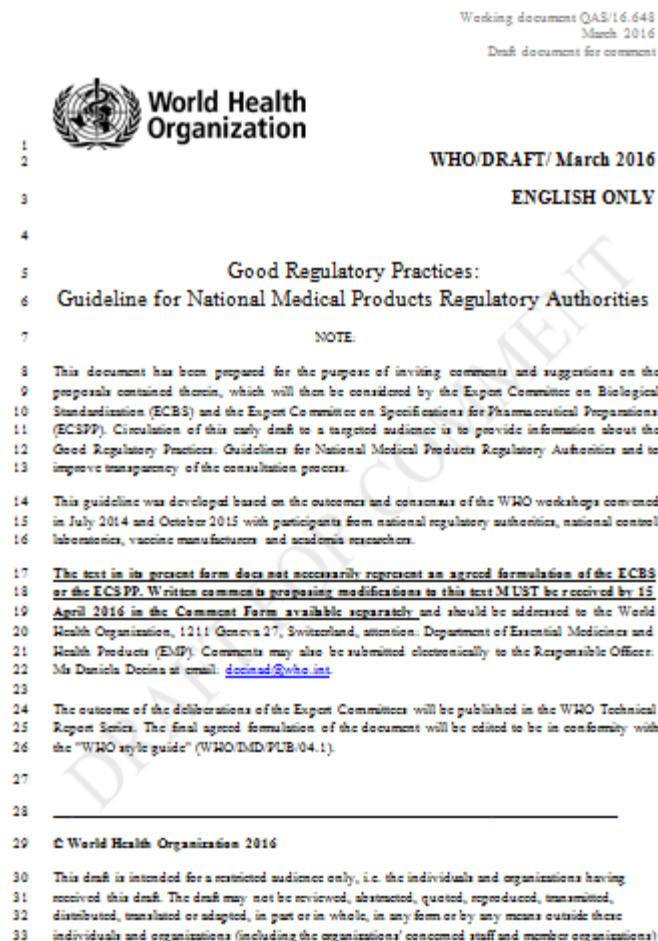


GRP Guideline Development Process



Outline of the Guideline

- Background, Introduction and Scope
- Part 1: Principles of Good Regulatory Practices
- Part 2: Implementation of regulations
 - Regulatory Impact Assessment Summary
 - Compliance and Enforcement
 - Consultation
 - Regulatory Agenda
 - Monitoring and Evaluation
 - Stock Management
- Appendices:
 - Regulatory Impact Assessment Details
 - Legal instruments and alternatives
 - International regulatory cooperation



Structure and content based on evaluation of over 600 comments

Scope

- Regulation of **medical products for human use**
- Intended for multiple audiences:
 - **senior policy-makers** responsible for the formulation of health policies, laws, regulations
 - **regulatory authorities**
 - **parties affected by or interested in regulatory frameworks**
- Equally relevant to establishing new regulatory systems and updating existing ones
- ***Does not*** explicitly cover development of laws

Part 1: Principles of GRP

Legality

Impartiality

Consistency

Proportionality

Flexibility

Effectiveness

Efficiency

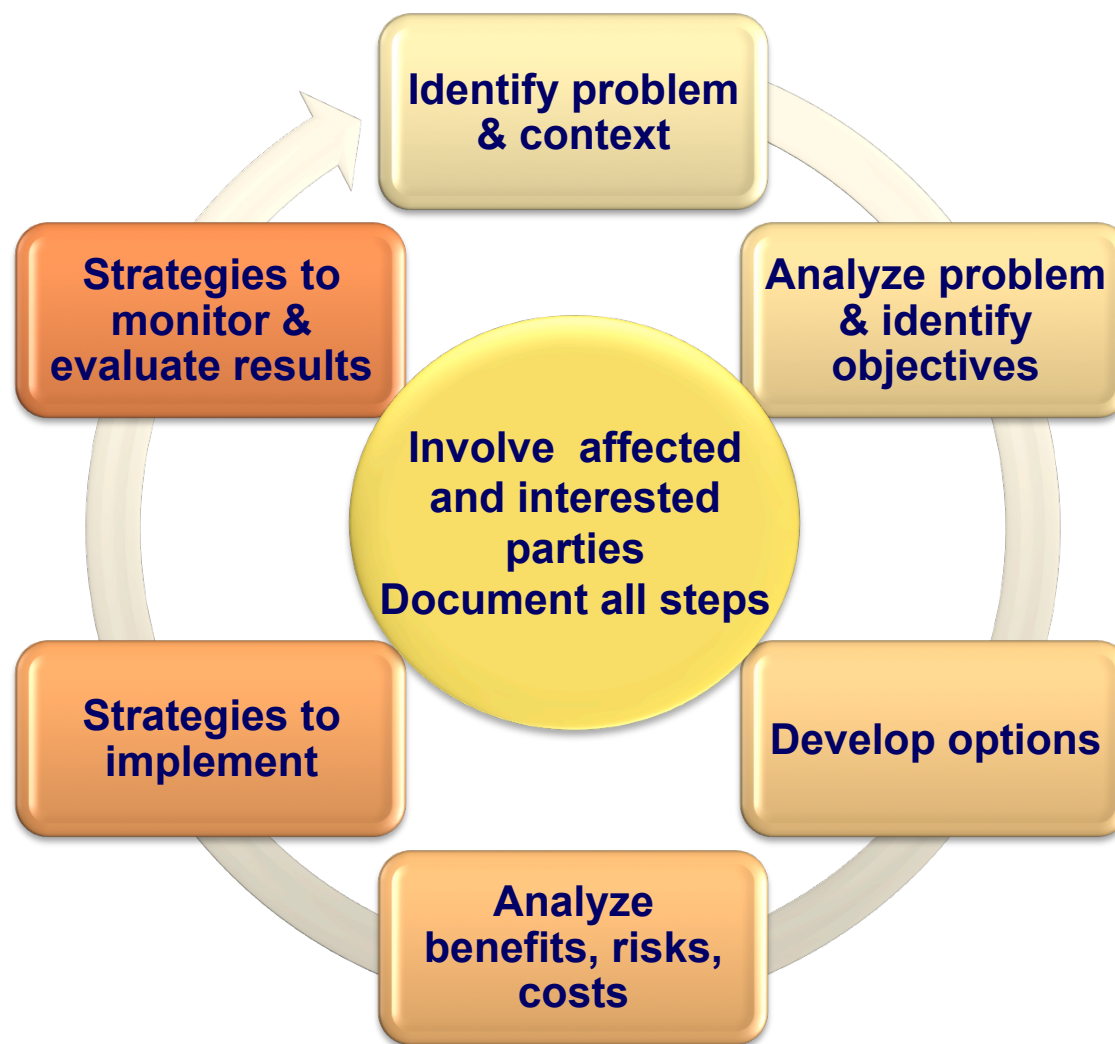
Clarity

Transparency

Part 2: Implementing GRP

Regulatory Impact Analysis (RIA)

- Outlines the major steps in developing a regulation or other regulatory instrument
- Sets out the key considerations at each step of the process
- Emphasizes importance of documenting all steps and engaging stakeholders



Implementing GRP (2)

- Compliance and enforcement: should be clear, proportionate and achievable
- Consultation: at centre of an effective regulatory system
- Forward looking regulatory agenda: identifies priorities in management of regulations
- Monitoring and evaluation: verify that regulatory intervention achieved its goal
- Management of the regulatory stock: periodic review of all regulations to mitigate redundancies, inconsistencies and outdated instruments

Glossary and Appendices

- Glossary contains definitions for a number of important terms, including *reliance*, *recognition*, *work-sharing*
- Appendix 1 – Details on the regulatory impact analysis
- Appendix 2 – Description of commonly used regulatory instruments or ‘toolbox’
- Appendix 3 - International Collaboration and Cooperation: discusses categories and considerations



Reliance and Recognition

- Often-used terms in regulatory documentation, but lack formal definition
- Proposals for consideration:
 - **Reliance:** is the act whereby a regulatory authority in one jurisdiction may take into account and give significant weight to (i.e., totally or partially rely upon) evaluations performed by another NRA or other trusted institution for reaching its own decision. The relying authority remains responsible and accountable for decisions taken, even when it relies on the decisions and information of others.
 - **Recognition:** the routine acceptance by the NRA in one jurisdiction of the regulatory decision of another NRA or other trusted institution. Recognition indicates that evidence of conformity with the regulatory requirements of country A is sufficient to meet the regulatory requirements of country B. Recognition may be unilateral or multilateral, and may be the subject of a mutual recognition agreement.

Steps toward Implementation

- Draft guideline was posted for public consultation on October 7 2016, until 15 December 2016
http://www.who.int/medicines/areas/quality_safety/quality_assurance/projects/en/
- Submission to WHO Expert Committee on Specifications for Pharmaceutical Preparations (ECSP) for possible adoption or endorsement by Fall 2017
- Communication of guideline concepts and contents at information-sharing fora:
 - Regulatory networking meetings
 - Regulatory association meetings and conferences
 - Training through Centres of Excellence
 - Regional workshops

THANK YOU

