Medical Device Regulatory Convergence Project (MDRC)

Standard Operating Procedure (SOP) for the Draft Compilation of Regulation of the Minister of Health and Decree of the Minister of Health (Permenkes/Kepmenkes)

Preliminary Comparison of the SOP against Foundational Good Regulatory Practices (GRP)

National Regulatory Authorities (NRAs) are recommended to follow five common phases regarding GRP: Regulatory Agenda, Regulatory Impact Analysis, Regulation phase, Ex post Evaluation and finally Public Consultation Phase, which is a transverse phase applicable to all regulation /decree, consisting in the activities to be developed by the regulator in order to involve stakeholders. The table below takes into consideration these phases and relate them with the SOP.

SOP Regulation of the MoH and Decree of the MoH (Permenkes/Kepmenkes)	Good Regulatory Practices (GRP)
	O. GENERAL RECOMMENDATION
	Central Focal Point At the Ministry of Health or National Health Regulatory Authority (NRA) level, GRP requires that the health authorities establish an easily accessible focal point for external contacts on regulatory matters. As a complementary measure, at the national level, a central regulatory framework, with an appointed coordination body or structure can play an important role in promoting good regulatory practices; performing key advisory, coordination, and review functions to improve the quality of regulations; and developing improvements to the regulatory system as part of a coherent "whole-of-government" implementation of GRP. **Regulatory Forecast and National Regulatory Register** NRAs are recommended to issue a regulatory forecast and provide an accessible national regulatory register of proposed rules. To issue a regulatory forecast, there should be strategic planning and direction towards the priorities of the rule-making process within a particular timeframe. NRAs should be capable of developing a plan on what are the rules that will be created or reviewed and publish these to external stakeholders for their knowledge and preparation
	I. REGULATORY AGENDA Phase in which all projects from **(Permenkes/Kepmenkes)** are planned to be issued during the next valid period of time.
	Preparation of the regulatory agenda project It consists in preparing the planning document that contains the list of specific regulatory projects that predictably will be issued during the following year.
	Conduct a public consultation on the regulatory agenda project.
	Make adjustments to the regulatory agenda project and respond to comments from stakeholders.

	It is necessary to respond to comments and opinions provided by stakeholders.
	Publishing of the final regulatory agenda.
	II. EX ANTE REGULATORY IMPACT ANALYSIS (RIA) RIA consists in the preliminary mandatory analysis that the NRA must apply to identify the best options for the problems identified in the subject at hand.
	Define the problem and the objectives In this activity, the problem is defined and the actors and/or sectors relevant for the problem are identified. The causes and consequences of the situation are identified, using the problem tree as a tool. Additionally, definition of the objectives of the intervention to be conducted. **Use of Quality Data and Scientific Information** The activity of compiling and reviewing materials is the beginning of the regulatory process under GRP. It is necessary that the problem be **based on evidence.** It is recommended that the problem tree and the objectives tree be designed with the stakeholders.
	Check agreements, treaties, and international regulations In this activity, it is necessary to check if Indonesia has any agreements or treaties that apply international obligations that must be fulfilled and considered when identifying and selecting alternatives in relation to international standards and references. **Use of International Standards** This activity should be detailed and specified to include the use of quality data and scientific information which legitimate the objective and purpose of the prosed regulation. Additionally, NRAs should seek international standards as a basis for the draft regulation, conserving resources and as consistent with international treaty obligations and the proper legal foundations of regulations. The probability is low that there are no international standards and references that have not yet created basis for the object of the proposed regulation pertaining to medical devices. Technical regulations and conformity assessment (CA) must be in conformity with the Technical Barriers to Trade (TBT) Agreement of the WTO and related implementing measures.
	Identify alternatives This activity includes the identification of viable alternatives that can provide a solution to the stated problem so the stated objectives are met, and then evaluation and comparison of their costs and benefits, so that it can be possible to choose the alternative that generates more economic and/or social benefits.
	Check competence and legal feasibility of the alternatives.
	Analyze and evaluate alternatives. In this activity the impact analysis of each of the defined alternatives is conducted. Specific work regarding impact assessment and the assessment of the stakeholders on the draft regulation. Under GRPs, NRAs should conduct **Regulatory Analysis; Regulatory Impact**

	Assessments (RIAs); employ Risk-Based approaches; conduct Pro-Competitive Analysis and asses the International Impact of a Regulation as complimentary and necessary actions to evaluate the pertinence, efficiency and effectiveness of a regulation. NRAs conduct a regulatory analysis based on data and international references, gather inputs from external stakeholders, then evaluate impact, risk and effects on competition of the draft regulation jointly with the possible international impacts.
	Select the best alternative.
	Design the implementation and monitoring. A monitoring model must be designed to implement the alternative, so the advances made can be measured at short, medium and long term.
	Consolidate the Draft of the Project of the Complete Regulatory Impact Analysis.
	Conduct the public consultation regarding the project of the Complete Regulatory Impact Analysis Report.
	Prepare adjustments to the Complete Regulatory Impact Analysis Report.
	Publish the definitive Report of the Complete Regulatory Impact Analysis. The steps of analysis and conclusions must be published to external stakeholders.
	III. REGULATION
1. Technical directorate in the field of medical devices (Directorate)	
The Directorate drafts the Permenkes/Kepmenkes	This is a recommended step since, taking into account that the technical team is responsible for carrying out the impact analysis in the previous stage, then the technical direction is the most appropriate to start this stage, taking into account the decision chosen in the previous stage, which must be reflected in the draft.
2. The Secretary of Directorate General of Pharmaceuticals and Medical Devices (Setditjen)	
Proposal letters and draft regulations from the Directorate are submitted to the Setditjen.	
3. Legal Work Team within the Setditjen	
The Setditjen assigned the Head of the Legal Work Team to prepare the initial draft of the Permenkes/Kepmenkes	
The Legal Work Team prepared the initial draft of the Permenkes/Kepmenkes namely:	
a) Create a conceptual framework for the initial draft of the Permenkes/Kemenkes	
b) Compile and review materials	The purpose of the complied material is not clear, but if it is an input to carry out an impact analysis, it is necessary to recommend that this activity be carried out in the second stage called 'Regulatory Impact Analysis'. Therefore, the legal team,

	based on the technical decision, is in charge of giving the legal technique to the decree that incorporates the decision.
c) Correct and improve the initial draft of the Permenkes/Kemenkes	
d) Conduct a meeting to discuss the initial draft of the Permenkes/Kemenkes	When the Legal Work Team conducts meetings for discussions, it is not clear if these are internal meetings or meetings with external stakeholders. It is a fundamental pillar of GRP that full opportunity is given for **public consultation** of the draft regulation with a minimum 60-day deadline for parties to give their positions on the proposed draft – as required under the WTO TBT Agreement. Subsequently it is necessary to respond to these comments and opinions, providing stakeholders the justification and reasoning of the draft and the acceptance – or not – of the inputs provided.
e) Follow up on the results of the meeting and improve the initial draft of the Permenkes/Kemenkes	**Respond to Stakeholder Input**: These follow ups should be made in writing and be made publicly available.
f) The Setditjen approved the initial draft of the Permenkes/Kepmenkes and directed the Head of the Legal Work Team to prepare a cover letter for submission of initial draft of the Permenkes/Kepmenkes in the field of Pharmaceuticals and Medical Devices to the Legal Bureau	
g) Prepare and send a cover letter and the initial draft of the Permenkes/Kemenkes to the Legal Bureau	
h) Document all activities	
4. Legal Bureau	
The Legal Bureau conducted a review of the initial draft of the Permenkes/Kepmenkes	
Discuss the initial draft of the Permenkes/Kepmenkes	
Feasibility study with stakeholders	Conduct Regulatory Impact Assessments – See GRP on 3(d) above.
Make necessary revision and improvement	
Request approval from the technical directorate in the field of medical devices as well as the Secretariat General of Pharmaceuticals and Medical Devices for revised Permenkes/Kepmenkes	
Make a cover letter for submission of the draft of the Permenkes/Kepmenkes to the secretariat of the Minister of Health	
5. Secretariat of the Minister of Health	
Check the completeness of the draft of the Permenkes/Kemenkes	
Conduct discussions as needed	Are these internal discussions? See GRP on 3(d) above
Submit a draft of the Permenkes/Kepmenkes to be approved by the Minister of Health	
	IV. **EX POST EVALUATION** Phase applicable to regulations/decrees, from which the regulator evaluates the results of the regulation in relation to the objectives

	to be achieved, generating the recommendations to be considered in the study to conduct in the ex-ante Impact Analysis.
	After the publication of the regulation, the NRA should include its monitoring and consider the effects on the affected markets. This work will give rise to **Ex-Post assessments of the regulation** to understand its impacts and possible need for amendments. Therefore, planning on how to keep the regulation alive, relevant, effective, and not overly burdensome should be included in the regulatory framework of the authorities. It is also part of the GRP process to guarantee a secure procedure for complaints and replies from the private sector regarding regulations and CA.
	Define the scope of the evaluation In this activity, it is determined if the evaluation will be conducted on a complete set of regulations related to one single theme, a whole regulation or some articles contemplated on it.
	Identify the actors involved in the regulation Identification of actors, beneficiaries and affected actors from the intervention conducted by the entity through the implemented regulation, the groups of interest and those in charge of implementing the regulation, allows the evaluator to identify if the objectives of the regulation were met with the regulatory intervention.
	Identify information from your own or derived from the stakeholders.
	Identify the expected objectives with the regulation under analysis.
	Identify the value chain Based on the general objective and the specific objectives of the regulation, the value chain that has allowed to achieve them is constructed. It is necessary to identify the input, the activities and products generated in the implementation of the regulation. If it is possible to identify the expected result or effect with the regulation, it is included in the value chain.
	Define the questions of the evaluation.
	Select the type and evaluation method.
	Conduct a public consultation on the design of the evaluation.
	Check the international regulations and references that have been developed within the framework of the current commitments.
	Conduct the evaluation.
	Prepare the evaluation report and conclusions.
	Publish the report.

One of the key benefits of implementing GRPs is to implement them within the individual NRAs as a formally codified principles of the rulemaking process, and ideally to NRAs across the whole of government, taking international reference documents, standards and conformity assessment into consideration.