November 1, 2023

Medical Device Regulatory Convergence Project (MDRC)

Recommendations of Implementation of Relevant International Benchmarks for Good Regulatory Practices and Medical Device Regulatory Convergence within the Indonesian Omnibus Health Law
Comments on Selected Provisions

Introduction

The MDRC translated specific articles of the new Indonesian Omnibus Health Law which may relate to the regulation of medical devices by the government authorities of Indonesia.

Per request from the Ministry of Health under the MDRC project, MDRC presents below recommendations to specific articles of the Omnibus Health Law that give space to and/or provide for the possibility of improving and developing the domestic regulation towards the implementation of and compliance with Good Regulatory Practices (GRP), as well as the establishment of a framework for application and implementation of GRP within the national regulatory authorities (NRA).

These recommendations should be taken within the context of the totality of the Omnibus Health Law, including broad provisions that are not specific to medical devices and at all times ensuring compliance with international treaty obligations that Indonesia has assumed.

Comments have been provided for articles of the Omnibus Health Law that apply to medical devices. For all articles, whether a comment has been provided or not, this document should be interpreted to recommend application of foundational GRP including but not limited to the conducting of Regulatory Impact Assessments, use of international standards and other GRP elements to ensure proper rulemaking in line with international benchmarks.

This document should be read in conjunction with two additional documents:

(i) The Preliminary Comparison of the Standard Operating Procedure (SOP) for the Draft Compilation of Regulation of the Minister of Health and Decree of the Minister of Health (Permenkes/Kepmenkes) against Foundational Good Regulatory Practices (GRP); and

(ii) The Checklists on technical regulations and conformity assessment procedures.

Selected Provisions of the Indonesian Omnibus Health Law

Article 28

(1) The Central Government and Regional Governments are obliged to provide access to Primary Health Services and Advanced Health Services throughout Indonesia.

(2) The obligation as referred to in paragraph (1) is prioritized by optimizing the role of the Regional Governments.

(3) Provision of access to Primary Health Services and Advanced Health Services as referred to in paragraph (1) may involve the public.

(4) Provision of access to Primary Health Services and Advanced Health Services as referred to in paragraph (1) includes the vulnerable in society and shall be inclusive and non-discriminatory.

(5) Provision of access to Primary Health Services and Advanced Health Services as referred to in paragraph (1) shall be conducted through:

a. construction of facilities and infrastructure for Primary Health Services Facilities and Advanced Health Services Facilities;

b. fulfillment of the needs for human resources, pharmaceutical preparations, and medical devices; and

c. improvement of the capability and scope of Health Services.

1. Comment from MDRC

Within the improvement of capability obligation provided in 28(5)b, and the general provision of health access to Indonesia28(1), the improvement of the regulatory structure within the national authority towards the transparency and application of good regulatory practices should be included.

The Indonesian Ministry of Health (MoH) is recommended to follow five common phases regarding application of GRP in the planning of regulatory instruments: Regulatory Agenda, Regulatory Impact Analysis, Regulation phase, Ex-post Evaluation and finally, Public Consultation, which is a transverse process applicable to all regulatory process stages, consisting in the activities to be developed by the regulator in order to involve stakeholders.

As a first step, it is recommended to establish: (i) who the authority is within the MoH which is responsible for creating and reviewing the regulations created therein; (ii) the internal regulation which establishes the procedures for creation and review of rules and providing guidance on how regulators must develop its work with transparency and risk-based approach, following international references and standards (named herein just as "Regulatory Procedure"); and (iii) who is the authority controlling and monitoring the compliance of the MoH authorities with the development of the Regulatory Procedure.

Public consultation should be applicable to the society as a whole with no limitation. Additionally, public consultation should be made in advance, every time a regulatory instrument is proposed or reviewed.

A Regulatory Procedure should contain an objective proposal on when the regulator must apply public consultation. Conducting public consultation should be the general rule, with some exceptions.

Public Consultation may be waived, for example, in the event of:

I - emergency; or

II - the conclusions in which the Public Consultation proves to be unproductive, considering

(a) social participation in the MoH decision-making process, as well as

(b) the principles of efficiency, administrative reasonableness and proportionality.

In these cases, a Legal Opinion should be prepared by the Legal Department at the MoH, with the technical motivation that justifies the exemption from Public Consultation.

In any case, public consultation should be published in the National Gazette and be publicly available online for broad access to all, in a specific location, with content identification for the general public.

For general public consultation, there is a procedure described below which sets the sequence of development for participation of the society.

1. The authority responsible for the regulatory instrument publishes the draft of the instrument online and in the Official Gazette.
2. The authority provides a Form for contribution from the public, online and published in the Official Gazette.
3. The technical material used as a basis for constructing the draft regulation, except documents of a confidential nature, should be made available to the society during the conduct of the Public Consultation and must contain, at a minimum, the MoH's justification for the existence of the regulation and the Regulatory Impact Assessment (RIA) report or the justification in cases where the RIA was exceptionally waived.
4. Contributions sent by the society should be made available online, in a specific location, with content identification for the general public, as soon as possible after the end of the Public Consultation period.
5. The position of MoH's authority responsible for the regulation on the inputs provided by the public should be made and duly published online and forwarded to the participants of public consultation.

MoH may also decide to conduct a public hearing to assist in the decision-making process held in a face-to-face or virtual public session, through which the oral or written expression by anyone interested in discussing proposed regulatory instruments, documents or relevant matters of interest to MoH for the final draft regulation.

6. The call for the public hearing is made available online and published in the Official Gazette.
7. The minutes of the proposed regulatory instrument, the technical material used as a basis for constructing the draft regulation, except document of a confidential nature, must be made available online to the society during the conduct of the Public Consultation and must contain, at a minimum, MoH's justification for the existence of the regulatory instrument and the RIA report or the justification in cases where the RIA was exceptionally waived. Other proposals of regulation that might exist should also be made online available.

The report of the hearing with list of participants, minutes of the meeting and summary of submissions made during the hearing should be made available online as soon as possible when the hearing is concluded.

Article 110

(1) In providing Health Services during disaster emergency response, the Central Government and Regional Governments may receive Health Resource assistance from abroad.

(2) Health Resource Assistance as referred to in paragraph (1) may be in the form of Health funding, Medical Emergency teams, donations of Medicine, and other Health Supplies.

(3) Receipt of assistance as referred to in paragraph (1) shall be conducted in a coordinated manner through the Central Government.

2. Comment from MDRC

MDRC recommends that the MoH develop a regulatory framework applied for emergency use authorization (EUA).

Article 138

(1) Pharmaceutical preparations, medical devices and Household Health Supplies must be safe, efficacious/beneficial, high quality, and affordable and meet the provisions of halal product guarantees in accordance with the laws and regulations.

(2) Every person is prohibited to procure, produce, store, promote and/or distribute pharmaceutical preparations that do not meet the standards and/or requirements for safety, efficacy/benefit, and quality.

(3) Every person is prohibited to procure, produce, store, promote, circulate and/or distribute Medical Devices that do not meet the standards and/or requirements for safety, efficacy/benefit, and quality.

(4) Procurement, production, storage, promotion, distribution and service of Pharmaceutical Preparations and Medical Devices must meet standards and requirements in accordance with the laws and regulations.

(5) Production, promotion, and distribution of Household Health Supplies must meet the standards and requirements in accordance with the laws and regulations.

(6) The Central Government and Regional Governments are obliged to develop, regulate, control, and supervise the production, procurement, storage, promotion and distribution of Pharmaceutical Preparations, Medical Devices, and Household Health Supplies in accordance with their authority.

3. Comment from MDRC

When confirming compliance with laws and regulations, the MoH must include in the Regulatory Process the obligation of the regulator to analyze and comply with the international obligations Indonesia is committed to in international treaties and also comply with international standards and references.

Check agreements, treaties, and international regulations. In this activity, it is necessary to check if Indonesia has any agreements or treaties (e.g. WTO, ASEAN, etc.) that include 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, MoH should seek international standards and references as a basis for the draft regulation, conserving resources and 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 TBT Agreement and related implementing measures.

The Regulation Procedure within the MoH should guarantee that regulations published by the authorities follow international obligations committed by Indonesia as well as it complies with international standards and references. Check the international regulations and references that have been developed already within the framework of the current commitments.

Article 140

Safeguarding of Pharmaceutical Preparations, Medical Devices and Household Health Supplies shall be conducted to protect the public from dangers caused using Pharmaceutical Preparations, Health Devices and Household Health Supplies which do not meet safety, efficacy/benefit, and quality requirements.

Article 141

(1) The use of Medicines and Natural Medicines must be conducted rationally.

(2) The use of Medical Devices must be conducted appropriately.

(3) The use of Medicines, Natural Medicines and Medical Devices as referred to in paragraph (1) and paragraph (2) must pay due attention to Patients' safety.

Article 142

(1) Pharmaceutical Preparations in the form of Medicines and Medicinal Ingredients must meet the standards and requirements of the Indonesian pharmacopoeia and/or other recognized standards.

(2) Pharmaceutical Preparations in the form of Natural Medicines must meet the standards and/or requirements, in the form of the Indonesian herbal pharmacopoeia and/or other recognized standards.

(3) Pharmaceutical Preparations in the form of health supplements and quasi-medicines must meet standards and/or requirements, in the form of Indonesian pharmacopoeia, Indonesian herbal pharmacopoeia, and/or other recognized standards.

(4) Pharmaceutical Preparations in the form of cosmetics must meet standards and/or requirements, in the form of the Indonesian cosmetic codex and/or other recognized standards.

(5) Raw materials used in Pharmaceutical Preparations in the form of Natural Medicines, health supplements, quasi-medicines and certain cosmetic preparations based on risk studies must meet quality standards and/or requirements as pharmaceutical raw materials.

(6) Medical Devices and Household Health Supplies must meet specified standards and/or requirements.

(7) Provisions regarding standards and/or requirements for Pharmaceutical Preparations and Medical Devices shall be determined by the Central Government.

(8) Standards and/or requirements for Household Health Supplies shall be implemented in accordance with the laws and regulations.

4. Comment from MDRC

(See comment number 3)

Article 143

(1) Every person who produces and/or distributes Pharmaceutical Preparations, Medical Devices, and Household Health Supplies must comply with business permits from the Central Government or Regional Governments in accordance with their authority based on nor standards, procedures, and criteria in accordance with the provisions of the laws and regulations.

(2) Every person who produces and/or distributes Pharmaceutical Preparations, Medical Devices and Household Health Supplies that has obtained a business permit, which is proven not to meet the requirements for safety, efficacy/benefits and quality shall be subject to administrative penalties in accordance with the provisions of the laws and regulations in the field of business licensing.

(3) The business licensing as referred to in paragraph (1) does not apply to herbal medicine businesses, herbal traditional medicine businesses, and production facilities for special use Medicines.

(4) Business licensing related to Pharmaceutical Preparations, Medical Devices, and Household Health Supplies as referred to in paragraph (1) and paragraph (2) shall be conducted in accordance with the provisions of the laws and regulations.

5. Comment from MDRC

In relation to the regulations applied to business permits it is GRP that the Regulatory Process include provisions on Regulatory Impact Assessment (RIA).

Whenever a RIA is conducted, MoH should identify who are the affected stakeholders to evaluate the impact the regulation may produce to them. In this case narrowing the interaction with additional formats of consultation may be advisable (such as meetings, workshops, webinars). For conducting RIA, social participation must start as soon as possible, aiming to gather information and receive subsidies and relevant information that qualifies the analysis. The authority should identify who are the affected stakeholders to evaluate the impact the regulation may produce to them. In this case, ensuring the interaction with additional formats of consultation may be advisable (such as meetings, workshops, webinars), which proceedings should be made publicly available.

Stakeholder consultation must include, whenever necessary, consultation with other entities in the National Health System. The MoH units that are affected by the regulation must also be consulted during the RIA.

Depending on the nature of the information to be obtained, consultation with the stakeholders can use different mechanisms and cover different target audiences, observing the following guidelines, nevertheless also ensuring participation of the open public:

I - clear definition of the objective and target stakeholder of the consultation;

II - use of a mechanism that facilitates the participation of the target stakeholder;

III - use of language and means of communication appropriate to the target stakeholder;

IV - in the case of mechanisms that receive contributions in writing or for a defined period, definition of an appropriate deadline for the consultation process, according to the complexity of the topic in question and requested information.

V - clear process to analyze and respond to comments

For RIA, the MoH will be responsible for deciding on:

I - exemption from RIA, expressing a statement regarding the motivation;

II - the RIA report, expressing an opinion regarding its formal adequacy and objectives intended, in order to demonstrate whether the adoption of the suggested alternatives, considering their estimated impacts, is the most appropriate to face the regulatory problem identified.

After MoH's deliberation, except for information with restriction of access, must be made available online, in a specific location, with identification of content to the general public:

I - the AIR Report or the exemption decision and

II - the reasoned decision adopting or not the AIR report, in full or partially.

There is a need to publish the output of the decision and rationale behind the decision.

Article 144

Further provisions regarding the security of Pharmaceutical Preparations, Medical Devices and Household Health Supplies shall be regulated through Government Regulations.

6. Comment from MDRC

This article provides the opportunity for the MoH to establish the Regulatory Process observing the good regulatory practices and establishing the exact procedures for development, creation, control and monitoring of regulations regarding the security of Pharmaceutical Preparations, Medical Devices and Household Health Supplies. These should be convergent and in constant dialogue with the other Regulatory Process developed by the MoH.

Article 314

(1) The Central Government and Regional Governments are responsible for the availability, equitable distribution, and affordability of Health Supplies needed to conduct Health Efforts.

(2) The responsibility for availability, equitable distribution, and affordability as referred to in paragraph (1) shall be conducted through the management of Health Supplies.

(3) Management of Health Supplies as referred to in paragraph (2) includes planning, provision. and distribution.

(4) Management of Health Supplies as referred to in paragraph (3) for Health Services shall be conducted with due attention to safety, benefits/efficacy, quality, and price.

(5) To fulfill the responsibilities as referred to in paragraph (2), the Central Government and Regional Governments can establish pharmaceutical management facilities.

(6) In an emergency, the Central Government and Regional Governments can establish and implement special policies for the procurement and utilization of Pharmaceutical Preparations, Medical Devices, and other Health Supplies.

(7) Further provisions regarding the availability, equitable distribution, and affordability of Health Supplies as referred to in paragraph (1) shall be regulated through Government Regulations.

Article 322

(1) Sources of Pharmaceutical Preparations that originate from nature and have been proven to be efficacious, meet the requirements for halal product guarantees in accordance with the laws and regulations, and are safe for use in prevention, treatment, and/or care, as well as maintenance of health must be conserved.

2) The public is given the widest possible opportunity to research, develop, produce, distribute, improve, and use Pharmaceutical Preparations and Medical Devices whose benefits and safety can be guaranteed.

3) Research, development, production, distribution, improvement and use of Pharmaceutical Preparations and Medical Devices as referred to in paragraph (2) shall be conducted in accordance with the provisions of the laws and regulations.

(4) The Central Government and Regional Governments shall guarantee the implementation of research and development of Pharmaceutical Preparations and raw materials for Medical Devices originating from nature while maintaining their sustainability.

7. Comment from MDRC

MDRC recommends that the MoH develops a proper regulatory framework for research and clinical trials for medical devices. In case a regulatory framework for clinical research already exists, then there should be a review that allows to link with the provisions of the new Health Law.

Article 323

1) The Central Government and Regional Governments shall encourage and direct research and development of Pharmaceutical Preparations and Medical Devices by utilizing available national potential.

2) Research and development of Pharmaceutical Preparations and Medical Devices shall be conducted with due attention to and maintaining environmental sustainability, natural resources, and religious and socio-cultural norms.

3) Research and development as referred to in paragraph (1) can be conducted by the Pharmaceutical Preparations industry, Medical Devices industry, research institutions, and educational institutions.

Article 326

(1) To realize the resilience of Pharmaceutical Preparations and Medical Devices, the Central Government and Regional Governments are responsible for self-reliance in the field of Pharmaceutical Preparations and Medical Devices.

(2) Self-reliance in Pharmaceutical Supplies and Medical Devices is conducted through development and strengthening of governance of the supply chain for Pharmaceutical Preparations and Medical Devices from upstream to downstream in an integrated manner by prioritizing the use and fulfillment of domestically produced Pharmaceutical Preparations and Health Devices for national health resilience and progress.

(3) Fulfillment of national health security needs as referred to in paragraph (2) shall be conducted in stages in accordance with national priorities.

(4) Development and strengthening of supply chain governance for Pharmaceutical Preparations and Medical Devices as referred to in paragraph (2) is conducted at least by:

a. issuing policies, including providing incentives to business actors who strive to achieve resilience in Pharmaceutical and Medical Devices;

b. enhancing the competitiveness of the Pharmaceutical Preparation and Medical Device industries;

c. providing support for the mastery and utilization of technology and innovation as well as research and development in the field of Pharmaceutical Preparations and Medical Devices, including through foreign cooperation, conducted by the government and/or society multilaterally, regionally, and bilaterally in accordance with the provisions of the laws and regulations;

d. producing domestic Pharmaceutical Preparations and Medical Devices to meet domestic and export needs as well as increasing industrial activities/utilization of industrial capacity;

e. ensuring the use of domestically produced Medicinal Substances and Medical Device raw materials by the domestic pharmaceutical and Medical Device industry;

f. optimizing the role of academics, business actors, the Central Government, Regional Governments, and society; and

g. guaranteeing the continuity of the supply chain through voluntary licensing, compulsory licensing, or implementation of patents by the government, especially in conditions of disaster, outbreak, or epidemic.

(5) To ensure national resilience, international non-proprietary name generic medicines marketed in Indonesia may only be made by the domestic pharmaceutical industry.

8. Comment from MDRC

Defining priorities 326(3) is a core action of a Regulatory Agenda and a good regulatory practice which the MoH should be structured to execute. The pathways for developing a Regulatory Agenda are set below.

(I) 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. The MoH should be capable of developing a plan on what are the rules that will be created or reviewed and make them publicly available to external stakeholders for their knowledge and preparation.

(II) 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 term/year. The Regulatory Agenda is made up of items prioritized by MoH, for a certain period, based on the identification of problems that indicate the need for actions to be taken by MoH, with a view to promoting transparency, planning and regulatory predictability.

(III) Conduct a public consultation on the regulatory agenda proposal. The procedure is similar of a regular public consultation.

(IV) MoH makes adjustments to the regulatory agenda proposal according to inputs received and publish them online.

(V) MoH responds to comments and opinions provided by the public and publish them online.

(VI) MoH to approve the final regulatory agenda and publish the final regulatory agenda in the Official Gazette and online.

When implementing the article towards development and strengthening of supply chain governance (reference to 326(4)) the MoH must abide to the international obligations provided in the WTO, the WHO and other international obligations as well as international standards and references.

The WTO TBT Agreement provides legal definitions of technical regulation, standards and conformity assessment procedures. These definitions should be read jointly with the definitions provided in the Indonesian law. The inclusion of definitions in the Regulatory Process should be consistent with the definitions set in the abovementioned legal instruments. In case the Regulatory Process MoH should apply the definitions consistent with all these laws and international treaties. In case it only refers to technical regulations, it could apply the TBT definition purely.

This same concern applies to the definition of "International Standards and Guidelines." The TBT agreement provides a definition of standards that should be incorporated to the definitions included by the MoH when referring to international.

WHO defines medical product as: Any product including, but not limited to, finished pharmaceutical products, medical devices including in vitro diagnostic medical vaccines. (Annex 3 WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices). We suggest that the definition within MoH follows the international reference GHTF/IMDRF.

MDRC also recommends that the current regulatory framework in clinical investigation and compulsory license be reviewed by the MoH taking into consideration the new Health Law.

Article 327

(1) The Central Government, Regional Governments, society, and Health Service Facilities must prioritize the use of domestic Pharmaceutical Preparations and Medical Devices while still paying attention to quality, safety, and usefulness.

(2) Pharmaceutical Preparations and Medical Devices as referred to in paragraph (1) that are produced by the Pharmaceutical Preparation and Medical Device industry must prioritize the use of domestically produced raw materials.

9. Comment from MDRC

MDRC refers to WTO and TBT obligations that require that rules and regulations be applied equally in relation to domestic and imported products, without discrimination. (See comment number 3)

Article 328

(1) The Central Government, Regional Governments, and Health Service Facilities, in procuring Medicines and Medical Devices, must prioritize Medicines and Medical Devices that use domestically produced raw materials.

(2) Priority to the use of domestically produced raw materials as referred to in paragraph

(1) shall be done while still paying attention to quality, safety, and benefits.

Article 329

(1) The Central Government and Regional Governments shall provide convenience in conducting downstream national research to increase the competitiveness of the Pharmaceutical Preparations and Medical Devices industries.

(2) The Central Government and Regional Governments shall develop a research ecosystem consisting of research infrastructure, ease of research licensing and research support, as well as human resources.

(3) The research infrastructure as referred to in paragraph (2) shall built by the Central Government, Regional Governments, and/or society.

(4) The Central Government and Regional Governments shall provide ease of research licensing and research support as referred to in paragraph (2) without reducing the protection of research values.

(5) The Central Government and Regional Governments may provide support for institutions and/or societies that invest in pharmaceutical and Medical Device research.

Article 330

Provisions regarding the acceleration of development and resilience of the Pharmaceutical Preparation and Medical Device industries shall be regulated through Government Regulations.

10. Comment from MDRC

This article provides the opportunity for the MoH to establish the Regulatory Process observing the good regulatory practices and establishing the exact procedures for development/update, creation, control and monitoring of regulations regarding the acceleration and resilience of the Pharmaceutical Preparation and Medical Device industries. These should be convergent and in constant dialogue with the other Regulatory Processes developed by the MoH and in full compliance with GRP obligations acquired by Indonesia through agreements, as well as attaining the recommendations of the WHO regarding Good Regulatory Practices and Good Reliance Practices.

Article 331

(1) In order to support the self-reliance of the Pharmaceutical Preparation and Medical Device industries, the Central Government shall provide incentives for the Pharmaceutical Preparation and Medical Device industries.

(2) The incentives as referred to in paragraph (1) include those given to every Pharmaceutical Preparations and Medical Devices industry that conducts research, development, and innovation activities domestically, as well as those that conduct production using domestic raw materials.

(3) The incentives as referred to in paragraph (1) and paragraph (2) shall be in fiscal and non-fiscal forms.

(4) Provision of incentives for the Pharmaceutical Preparations and Medical Devices industries shall be conducted in accordance with the laws and regulations.

Article 332

(1) The Central Government and Regional Governments shall conduct risk mitigation for Pharmaceutical Preparations, Medical Devices, and other Health Supplies needed in emergencies, disasters, outbreaks, or epidemics.

(2) In order to mitigate risks as referred to in paragraph (1), the Central Government and Regional

Governments shall establish policies, standards, systems and governance for Pharmaceutical Preparations, Medical Devices, and other Health Supplies.

11. Comment from MDRC

The establishment of policies, standards, systems and governance for Pharmaceutical Preparations, Medical Devices, and other Health Supplies aligned with good regulatory practices is a core orientation for the work that will be developed by the MoH and other governmental authorities. These must follow the international treaties and obligations, as well as international standards and references, including recommendations of WHO regarding GRP and GRelP.[1]

The development of regulatory impact assessment and regulatory result assessment are important tools for the authorities to evaluate the needs and effects of the government regulations in the affected stakeholders, which include the government authorities and the private sectors.

Article 333

Further provisions regarding standards, systems, and governance of Pharmaceutical Preparations, Medical Devices, and other Health Supplies during emergencies, disasters, outbreaks, or epidemics shall be regulated through Government Regulations.

12. Comment from MDRC

This article provides the opportunity for the MoH to establish the Regulatory Process observing the good regulatory practices and establishing the exact procedures for development/update, creation, control and monitoring of regulations on disasters, outbreaks, or epidemics. These should be convergent and in constant dialogue with the other Regulatory Process developed by the MoH.

Article 391

Health Supplies as referred to in Article 386 letter d include Medical Devices, Medicines, vaccines, consumable medical materials, and other supporting materials/equipment required for conducting vigilance activities for Outbreaks and Epidemics, handling Outbreaks and Epidemics, as well as post-Outbreaks and post-Epidemics.

Article 435

Every person who produces or distributes Pharmaceutical Preparations and/or Medical Devices that do not meet the standards and/or requirements for safety, efficacy/benefits, and quality as referred to in Article 138 paragraph (2) and paragraph (3) shall be punished by a maximum imprisonment of 12 (twelve) years or a maximum fine of IDR 5,000,000,000.00 (five billion rupiah).

13. Comment from MDRC

MDRC recommends that the MoH review its regulatory framework on post market surveillance taking into consideration the new Health Law.

[1] https://www.who.int/news/item/29-04-2021-who-publishes-new-guidance-to-promote-strong-efficient-and-sustainable-regulatory-systems