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BPOM Regulation No. 7/2025 (CPOB Amendment)[P1]

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I. Introduction

It is crucial to ensure that drugs and drug ingredients available to the public meet established standards for safety, efficacy and quality. Therefore, the Indonesian National Agency of Drug and Food Control, known as *Badan Pengawas Obat dan Makanan* ("**BPOM**"), regulates the standards for good manufacturing practices for drugs.

Good Manufacturing Practices for Drugs (*Cara Pembuatan Obat Yang Baik* or "**CPOB**") provide guidelines for the production of drugs and medicinal materials, aiming to ensure that the quality of the drugs meets the required standards and their intended use. Pharmaceutical companies are obligated to comply with CPOB by obtaining a CPOB certificate, as stipulated in Article 4 of BPOM Regulation 7 of 2024 concerning Standards for Good Manufacturing Practices for Drugs.

Recently, BPOM issued Regulation Number 7 of 2025, amending Regulation Number 7 of 2024 concerning Standards for Good Manufacturing Practices for Drugs. This amendment, which was enacted on 20 March 2025, primarily updates Annex 1 regarding the manufacture of sterile products.

With the updates to BPOM Regulation Number 7 of 2025, it is anticipated that the standards for CPOB will continue to evolve and be aligned with advancements in science and technology within the pharmaceutical sector. This will help ensure that drugs available to the public maintain a higher level of quality and safety.

II. Key updates

This new BPOM regulation emphasises the importance of comprehensive control in drug production to ensure that consumers receive high quality medication. Manufacturing without proper procedures is unacceptable for products designed to save lives, restore health or maintain well-being.

It is insufficient for the finished product to simply pass a series of tests; rather, quality must be inherently integrated into the product itself. The quality of medication relies on the raw materials, packaging materials, production processes, quality control measures, facilities, equipment utilised and the personnel involved.

The new BPOM regulation offers more comprehensive and stringent guidelines for the manufacture of sterile products. This includes the principles and pharmaceutical industry quality system. The following are the key principles outlined in the new BPOM regulation:

- The production of sterile products must adhere to specific requirements to minimise the risk of microbial contamination, particulates and endotoxins/pyrogens. This measure should take into account that (i) buildings, facilities, equipment and processes must be appropriately designed, qualified or validated, and, where applicable, subjected to continuous verification, (ii) personnel should possess appropriate qualifications, relevant experience, thorough training and professional conduct, (iii) the processes and monitoring systems involved in the manufacture of sterile products should be meticulously designed, properly commissioned, thoroughly qualified, consistently monitored and subjected to regular reviews, and (iv) raw materials and packaging materials must be thoroughly controlled and tested.

- Processes, equipment, facilities and manufacturing activities must be managed in accordance with quality risk management principles to provide a framework for identifying, scientifically evaluating and proactively controlling potential risks to quality.

- A contamination control strategy ("**CCS**") should be implemented across all facilities to identify critical control points and evaluate the effectiveness of various controls (design, procedural, technical and organisational) and monitoring actions implemented to manage risks to the quality and safety of pharmaceutical products.

- Contamination control and the measures implemented to minimise the risk of contamination from microbial sources, endotoxins/pyrogens and particulates involve a sequence of interconnected events and actions.

- Developing a CCS necessitates comprehensive technical and process knowledge. Potential contamination sources include microbes and cellular debris, such as pyrogens and endotoxins, as well as particulates like glass and other visible and invisible particles. There are various elements must be considered in this regard.

- A CCS should encompass all aspects of contamination control, incorporating regular and ongoing reviews. These reviews should lead to updates in the quality systems of the pharmaceutical industry as necessary. Any modifications to existing systems should be evaluated for their impact on the CCS both before and after implementation.

- The pharmaceutical industry and manufacturers must undertake all essential measures and precautions to guarantee the sterility of products manufactured in their facilities.

Moreover, the following are the key pharmaceutical industry quality systems outlined in the new regulation:

- The production of sterile products is a complex process that demands specific controls and actions to ensure the quality of the manufactured items. Consequently, the pharmaceutical industry quality system must encompass and satisfy the particular requirements for producing sterile products, ensuring that all activities are effectively controlled to minimise the risks of microbial

contamination, particulates and endotoxins/pyrogens.

- All non-conformities, including sterility test failures, environmental monitoring excursions or deviations from established procedures, must be thoroughly investigated before batch certification or release. The investigation should assess the potential impact on the process and product quality and identify whether any other processes or batches might be affected.

III. Conclusion

As mentioned earlier, the new BPOM regulation provides more comprehensive and stringent guidelines for the manufacture of sterile products, as detailed in Annex 1 of the CPOB. Consequently, relevant business entities must ensure that their drug manufacturing activities comply with the updated CPOB, particularly concerning the production of sterile products.

Moreover, the new BPOM regulation provides that (i) pharmaceutical industries, institutions involved in drug manufacturing and institutions engaged in the production of radiopharmaceutical preparations must adhere to the provisions of the new regulation no later than 12 months from the enactment of the new regulation and (ii) if a pharmaceutical industry, drug manufacturing organisation or institution producing radiopharmaceutical preparations uses a lyophilisation process where loading or unloading is conducted without barrier technology, automation or protection by a closed barrier system, they must comply with the provisions of the new regulation within 24 months from the enactment of the new regulation.

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