Regulatory Systems Strengthening (RSS) Team
Regulation and Safety (REG) Unit
Regulation and Prequalification (RPQ) Department

WHO Listed Authority (WLA) Framework

PERFORMANCE EVALUATION REPORT

The Indonesian Food and Drug Authority (BPOM)

Indonesia

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Note: For a full list of abbreviations used in the following report, please refer to the *Operational guidance for evaluating and publicly designating regulatory authorities as WHO-listed authorities* and the *Manual for performance evaluation of regulatory authorities seeking designation as WHO-listed authorities.*

1. OVERALL SUMMARY

In March 2024, The Indonesian FDA (BPOM)of the Republic of Indonesia expressed interest in being designated by the WHO as a WHO-Listed Authority (WLA) following the applicable WHO process and methodology. As laid down in the Operational Guidance (OpG) for evaluating and publicly, designating Regulatory Authorities as WHO-listed authorities, the streamlined, evaluation pathway foresees (i) a self-assessment of all regulatory functions against the selected GBT sub-indicators and (ii) subsequent WHO desktop review of the self-assessment which was involved an audit against selected GBT indicators to verify the findings and (iii) WHO assessment against PE namely mandatory ML4, PE indicators and PE tools, for concerned functions except for two areas for which BPOM was recognized. These included Good Manufacturing Practices (GMP), Regulatory Inspection (RI) because of the BPOM's membership to the Pharmaceutical Inspection Co-operation Scheme (PIC/S), and Laboratory Testing (LT) for vaccines, where the National Quality Control Laboratory of The Indonesian Food and Drug Authority (BPOM) is a WHO-contracted laboratory for vaccine testing.
Several PE activities, including assessment of mandatory GBT ML4 sub-indicators and PE indicatorsand evaluation of MA applications, were conducted by WHO from August 2024 to November 2025.

At the end of the evaluation phase, it was concluded that BPOM successfully met the requirements set for an authority to be designated as WLA for the concerned regulatory functions in the product stream of vaccines..

2. INTRODUCTION AND CONTEXT

2.1. BACKGROUND

Indonesia, through The Indonesian Food and Drug Authority (BPOM), plays a vital role in the regional pharmaceutical landscape. As a major producer and exporter of WHO-prequalified vaccines, Indonesia supplies essential medical products to low-income countries via United Nations procurement agencies. The country's well-established pharmaceutical sector spans conventional and biological medicines, vaccines, medical devices, and traditional medicines. Strengthening Indonesia's regulatory system not only enhances national public health but also supports global access to safe, effective, and quality-assured medical products.

BPOM was first benchmarked by WHO in 2012, demonstrating compliance with regulatory oversight indicators for vaccines. Since then, WHO has maintained ongoing technical collaboration with BPOM, supporting institutional development and capacity-building through a structured IDP. In alignment with WHO's five-step capacity-building strategy, this collaboration has included a formal benchmarking in 2018, various training sessions, workshops, and a recent performance evaluation (PE) as part of the WLA

designation process. It should be noted that in 2019 BPOM was announced as ML3 NRA for vaccines (producing). .

In March 2024, BPOM formally began the WLA designation process by submitting an Expression of Interest (EOI) and conducting a structured self-assessment using relevant sub-indicators from the Global Benchmarking Tool (GBT). This was followed by WHO's review, off-site PE activities, and the development of a roadmap outlining the conditions for designation. Following that, several PE activities, such as the assessment of mandatory GBT ML4 sub-indicators and PE indicators, as well as the evaluation of MA application, were conducted by WHO from March 2024 to November 2025.

2.2. OBJECTIVE AND SCOPE

Based on the WLA scope applied for by BPOM, the objectives of the performance evaluation were to:

- Evaluate the performance of BPOM for the purpose of WLA designation for vaccines, in the concerned regulatory functions.

2.3. METHODOLOGY

As laid down in the Operational Guidance for evaluating and publicly designating Regulatory Authorities as WHO listed authorities, the streamlined evaluation pathway foresees a self-assessment of concerned regulatory functions by the candidate WLA and subsequent WHO desktop review against a set of pre-selected GBT sub-indicators and Performance Evaluation indicators related to Regulatory inspection (GCP), VL, CT and MA functions are prepared, organized, and conducted according to the Manual for Performance Evaluation of Regulatory Authorities seeking designation as WHO-listed authorities and follow the relevant guidelines and guidance documents available on the WHO website at the following address: https://www.who.int/initiatives/who-listed-authority-reg-authorities.

2.4. PROGRAMME OF PERFORMANCE EVALUATION

The performance evaluations were conducted from March 2024 to November 2025 according to the calendar of activities outlined below.

PE activity	Date	Onsite/offsite
Evaluation of mandatory GBT ML4 sub-indicators and PE indicators	From March to November 2024	Off-site evaluation of submitted self-evaluation
WHO PE final report	November 2024	Off-site
PE tool for Vigilance field visit	07-13 August 2025	On-site OA
WHO PE final report	September 2025	
PE tool for Regulatory inspection (GCP)	07-13 August 2025	On-site OA

WHO PE final report	07 October 2025	Off-site
PE tool of Marketing Authorization Application (MAA) assessment	From September to November 2025	Off-site evaluation of submitted self-evaluation
PE tool of Clinical trial application (CTA) assessment	From September to November 2025	Off-site evaluation of submitted self-evaluation
WHO PE final report	November 2025	Virtual meeting, remote assessment of additional evidence

3. PERFORMANCE EVALUATION PROCESS

3.1. GBT ML3 and ML4 mandatory sub-indicators

As foreseen by the streamlined evaluation pathway, pre-selected GBT sub-indicators were analyzed through a WHO desk-based review of the BPOM self-assessment report.

3.2. PE indicators

PE indicators were analyzed through a WHO desk-based review of the BPOM self-assessment. As foreseen by the streamlined evaluation pathway, concerned PE indicators have been subject to the WHO assessment, as they are considered applicable and relevant for listing.

According to the Operational guidance for evaluating and publicly designating regulatory authorities as WHO-listed authorities and the Manual for performance evaluation of regulatory authorities seeking designation as WHO-listed authorities, the following principles are recalled:

- ML3 and mandatory ML4 sub-indicators must achieve full implementation for a function to be considered for listing
- PE indicators cannot be scored as Not Implemented for a function to be considered for listing
- Full implementation of all indicators under the Regulatory System is necessary to achieve the listing of all other functions.

Evaluation of PE indicators was conducted between March and November 2025 and found satisfactory.

3.3. PE Tools:

3.3.1 PE tool for MA

The scope of the performance evaluation (PE) tool assessment for the Marketing Authorization (MA) function covered vaccines. WHO selected the list of MA applications

assessed. To facilitate the off-site evaluation, BPOM submitted a self-assessment of the PE tool, along with supporting documents and evidence, via the WHO secure SharePoint platform. The assessment was conducted in English and took place remotely from September to November 2025. The WHO team conducted a desk-based review of the submitted materials to analyze BPOM's application of the PE tool. Overall, the outcome of the evaluations was satisfactory.

3.3.2 PE tool for RI

GMP and GSDP: NA – PIC/S member

3.3.3. PE tool for LT

NA – WHO contracted laboratory

4 OUTCOME OF THE PERFORMANCE EVALUATION

4.1. BEST PRACTICES, AS APPLICABLE

The Indonesian FDA (BPOM)of the Republic of Indonesia is a mature regulatory authority, underpinned by a strong legal framework and an advanced quality and information management system. Its regulatory decisions are supported by robust internal processes and are aligned with international standards and good regulatory practices.

The following strengths deserve a special mention:

- **Strong Legal and Regulatory Framework**

BPOM operates under a clearly defined legal mandate that covers all regulatory functions. This comprehensive framework supports effective regulatory oversight.

- **Consistent quality culture across regulatory functions**

Regulatory activities are supported by a centralized, robust Quality Management System and documented, standardised processes, with mechanisms in place to monitor implementation and drive improvement.

- **Digitalization & Use of Information Systems**

BPOM has developed multiple electronic systems for regulatory functions and an informative, user-friendly website; these systems support efficiency and public trust.

- **Strong international engagement and coordination**

The authority maintains a vast network of international collaborations and information-sharing arrangements. It contributes actively to global networks, e.g., PICs, ICH, and the WHO-contracted lab for vaccines.

5. WHO CONCLUSIONS/RESULTS OF THE PE OF BPOM

Following the streamlined performance evaluation pathway, the Indonesian FDA (BPOM) of the Republic of Indonesia successfully complied with the WLA designation requirements for vaccines in the concerned regulatory functions.

6. TAG-WLA REVIEW OF THE PERFORMANCE EVALUATION RESULTS AND RECOMMENDATIONS

The WHO secretariat presented the findings of the PE, as outlined in the preceding sections, to TAG-WLA during the fifth meeting held on 02-03 December 2025, in Geneva, Switzerland.

BPOM representatives were invited to participate as observers during the TAG meeting's open session to present the Indonesian regulatory system and respond to questions from members.

Based on the performance evaluation results presented and discussed during the meeting , the TAG-WLA recommended listing the BPOM as a WHO Listed Authority for the following regulated product:

Vaccines, for the following regulatory functions under the overarching regulatory system (RS)**:**

(1)Registration and Marketing authorization (MA); (2)Licensing Establishments (LI), (3)Regulatory inspection (RI)(GMP/GSDP), (4)Laboratory testing (LT); and (5)NRA Lot Release (LR)