World Health Organization

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

WHO-listed authority (WLA) framework

PERFORMANCE EVALUATION SUMMARY REPORT

Medicines and Healthcare products Regulatory Agency

(MHRA)

United Kingdom of Great Britain and Northern Ireland (UK)

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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

On 19th November 2024, the National Regulatory Authority from the United Kingdom (**Medicines and Healthcare products Regulatory Agency - MHRA**), expressed interest in being designated by WHO as a WHO-Listed Authority (WLA) following the applicable WHO process and methodology, for both product streams - medicines [including multisource (generics) and new medicines (new chemical entities), biotherapeutics and similar biotherapeutic products] and vaccines - thus requesting the Performance Evaluation (PE) of concerned regulatory functions. A roadmap was drawn jointly by WHO and MHRA to reach such an objective.

The MHRA has been included in the list of transitional WLAs, being considered a Stringent Regulatory Authority (SRA) for medicines and a “highly performing Regulatory Authority” for vaccines, and therefore was deemed eligible for the abridged evaluation pathway towards listing as a WLA. Furthermore, MHRA has been included among the functional National Regulatory Authorities (NRAs) that have been benchmarked against the WHO vaccine assessment tool and announced as "functional NRAs" before the introduction of the Global Benchmarking Tool (GBT) in 2016.

Following the abridged evaluation pathway, it was concluded that the MHRA successfully met the requirements set for an authority to be designated as WLA in both fields of medicines [including multisource (generics) and new medicines (new chemical entities), biotherapeutics and similar biotherapeutic products], and vaccines, for the concerned regulatory functions.

2. INTRODUCTION AND CONTEXT

2.1. BACKGROUND

The Medicines and Healthcare products Regulatory Agency (MHRA) regulates medicines, medical devices and blood components for transfusion in the UK, operating in a statutory framework set by the Government, working within government and the wider health system to direct overall policy in the regulatory field.
It is governed by a unitary board of directors supported by three board assurance committees. The board is responsible for advising on the strategic direction of the agency, ensuring that targets set out in the business plan and agreed with ministers, are met.
The board is not involved in any regulatory decisions affecting medicines or medical devices, as these are the responsibility of the chief executive and executive committee, and are supported in this role by several independent advisory bodies.

According to its mission and vision, the main objectives of MHRA are to ensure medicines, medical devices and blood components for transfusion meet applicable standards of safety, quality and efficacy (effectiveness), secure their safe supply chain, promote international standardisation and harmonisation, educate the public and healthcare professionals about the risks and benefits of medicines, medical devices and blood components, leading to safer and more effective use, enable innovation and research and development, collaborate with

partners in the UK and internationally to enable the earliest access to safe medicines and medical devices and to protect public health.
The MHRA aims to involve patients at every step of the regulatory process to ensure that the balance of risk and benefit is considered from all perspectives.
As a Regulatory Member of ICH, as before 23 October 2015, MHRA has been included in the list of Stringent Regulatory Authorities for medicines.
Similarly, being considered by WHO as "exhibiting a high level of performance of WHO's six recommended regulatory functions and exercising full regulatory oversight of any given vaccine", MHRA has been also included in the list of "highly performing NRAs" for vaccines.
Based on the above, marketing authorization holders and manufacturers under the supervision of MHRA have so far benefited from the facilitated prequalification procedure (abridged procedure) of human medicines and vaccines.

In 2019, MHRA was listed in the time-limited "WHO Interim List of National Regulatory Authorities", as part of the planned transformation from the term Stringent Regulatory Authorities (SRAs) to WHO-Listed Authorities (WLAs). In March 2022, following the formal launching of the WLA initiative and the publication of the *Interim Operational Guidance for evaluating and publicly designating Regulatory Authorities as WHO listed authorities*, MHRA was placed on the list of transitional WLAs and considered eligible for the abridged evaluation pathway towards listing in both product streams of medicines and vaccines.

2.2. OBJECTIVES AND SCOPE

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

- Evaluate the performance of MHRA for the purpose of WLA designation as WLA for medicines, including multisource (generics) and new medicines (new chemical entities), biotherapeutics and similar biotherapeutic products, in concerned regulatory functions.
- Evaluate the performance of MHRA for the purpose of WLA designation for vaccines, in 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 abridged 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, included in a specifically designed "abridged tool" (see Annex 6 of the PE Manual); none of the PE tools are instead foreseen in the abridged pathway, as alternative evaluation mechanisms recognized by WHO already exist and provide sufficient evidence of the performance of candidate WLAs in all functions (e.g., WHO prequalified products, emergency use listing products, PIC/S membership).

2.4. PROGRAMME OF PERFORMANCE EVALUATION

The performance evaluation was conducted over the period from April 4th, 2025 to June 13th, 2025 according to the calendar of activities outlined below, which was discussed and agreed with MHRA.

PE activity	Date	Onsite/offsite
Abridged tool	04/04/25 - 13/06/2025	Desk based review of self-assessment (remote assessment)
Interview with RA representatives	14/05/2025 30/05/2025 12/06/2025	Virtual meetings (remote assessment of additional evidence)

3. PERFORMANCE EVALUATION PROCESS

3.1. GBT ML3 and ML4 mandatory sub-indicators

Pre-selected GBT sub-indicators were analyzed through a WHO desk-based review of the self-assessment report provided by MHRA.

Concerned GBT sub-indicators considered in the abridged tool are applicable and relevant for listing; therefore, even in the case of "for information only" GBT sub-indicators, additional information was requested whenever considered necessary to acquire a full picture of the regulatory practices in place.

Concerned GBT sub-indicators were satisfactorily met by MHRA in the field of medicines [including multisource (generics) and new medicines (new chemical entities), biotherapeutics and similar biotherapeutic products] and vaccines.

3.2. PE indicators

PE indicators were analyzed through a WHO desk-based review of the self-assessment provided by MHRA, followed by interviews to clarify key aspects.

As foreseen by the abridged evaluation pathway (see Annex 6 of the PE manual), all concerned PE indicators have been subject to WHO assessment, as they are considered applicable and relevant for listing.

Concerned PE indicators were found satisfactory by MHRA in both product streams

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 listing of all other functions.

3.1. PE tool for MA
NA

3.2. PE tool for VL
NA

3.3. PE tool for RI
NA

3.4. PE tool for LT
NA

3.5. PE tool for CT
NA

4. OUTCOME OF THE PERFORMANCE EVALUATION

4.1 Best practices, as applicable
The MHRA has been recognised as a highly mature regulatory authority, fully aligned with the principles of Good Regulatory Practices (GRPs). Its institutional framework is well-structured and adaptable, supported by a solid culture of continuous improvement and a strong reliance on risk-based decision-making. Regulatory actions are science-driven, transparent, and consistently communicated to both national and international stakeholders. The agency maintains close and effective relationships with other regulatory authorities, particularly in Europe, with which it shares key legislative and procedural frameworks. These strong connections ensure effective cooperation and sustained regulatory convergence at the international level.

The following best practices deserve a special mention:

a) **Regulatory Competency Frameworks**
   The MHRA has developed and implemented a comprehensive regulatory competency framework that defines core and role-specific skills, supports performance evaluation, and guides professional development, contributing to consistent regulatory capacity and staff excellence across the agency.
b) **Regulatory Transparency**

The agency sets a high standard for transparency by historically and systematically publishing its regulatory decisions, as well as the rationale and supporting information behind them, including those related to clinical trials. This longstanding commitment has positioned the agency as a global reference for openness in regulatory decision-making, fostering public trust, accountability, and alignment with international standards

c) **Emergency Preparedness and Crisis Management**
The MHRA has established clear and comprehensive written procedures for managing public health emergencies, demonstrating best practice in regulatory flexibility and preparedness planning.

d) **Lifecycle Scientific and Regulatory Advice**
A structured and responsive system for providing scientific and regulatory advice to stakeholders is well established, demonstrating a proactive regulatory engagement. Advice is available at any stage of a medicine's lifecycle — from early development to pre-submission, and even post-authorisation — including guidance on variations, pharmacovigilance, advertising, labelling, and packaging, thus improving the quality of submissions, supporting regulatory compliance, and fostering innovation through early and continuous dialogue with applicants.

e) **Laboratory Quality and Oversight**
An integrated approach is established for laboratory regulation, with well-documented activites, qualified personnel, robust quality systems, and regular participation in external quality assurance schemes, which ensures high reliability in laboratory testing function and supports regulatory decision-making.

5. CONCLUSIONS

Following the abridged performance evaluation pathway, MHRA demonstrated to comply with the requirements set for an authority to be designated as WHO-listed authority in both product streams of medicines [including multisource (generics) and new medicines (new chemical entities), biotherapeutics and similar biotherapeutic products] and 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 the TAG-WLA during its fourth meeting, held from 23 to 25 June 2025 in Geneva, Switzerland.

MHRA representatives were invited as observers, during the open session of the TAG meeting, to present the UK regulatory system.

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

A. **Medicines** (including generics and new medicines, biotherapeutics and similar biotherapeutic products), for the following regulatory functions under the overarching regulatory system (RS)**:**

1) registration and marketing authorization (MA); (2) vigilance (VL); (3) licensing establishments (LI); (4) good manufacturing practices (GMP), good storage and distribution practices (GSDP) and good clinical practices (GCP) regulatory inspections (RI); (5) laboratory testing (LT); and (6) clinical trials oversight (CT).

B. **Vaccines**, for the following regulatory functions under the overarching regulatory system (RS)**:**
   (1) registration and marketing authorization (MA); (2) vigilance (VL); (3) licensing establishments (LI); (4) good manufacturing practices (GMP), good storage and distribution practices (GSDP) and good clinical practices (GCP) regulatory inspections (RI); (5) laboratory testing (LT); (6) clinical trials oversight (CT); and (7) RA lot release (LR).