Manual for benchmarking of the national regulatory system of medical products and formulation of institutional development plans

Version 1, February 2021
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Foreword

This manual was developed to provide clear operational guidance on the benchmarking of regulatory systems for medical products and the development of institutional development plans to address areas for improvement.

The manual is integral to the structured and evidence-based approach of the World Health Organization (WHO) to regulatory systems strengthening as mandated by the World Health Assembly resolution (WHA) 67.20. The manual serves to ensure a proper understanding of the global benchmarking tool (GBT), the processes and principles that govern its use, the expectations of individuals and institutions involved, and the information management systems that underpin the collection, analysis and management of data and the generation of knowledge.

The manual, together with supplementary procedures and detailed guidance referenced herein, constitutes a comprehensive body of work that defines the end to end regulatory strengthening process and the quality management system (QMS) under which it operates.

Just as the benchmarking tools used to evaluate regulatory systems have evolved since the inception of the regulatory systems strengthening (RSS) programme, so too have the corresponding manuals that govern their application. This document builds upon previous manuals describing the planning, conducting, follow-up and management of benchmarking activities, the roles and responsibilities of WHO team members, and the principles which guide the overall process. It also embodies the distillation of recommendations from international consultations and workshops on benchmarking policy, tools, methodology and procedures, as well as the collective experience of regulatory authorities world-wide and the WHO with the five-step model for strengthening regulatory systems.

Importantly, this manual consolidates, updates and elaborates material from previous manuals and introduces important concepts related to regulatory maturity level and their assignment, transparency, and good regulatory and reliance practices.

This manual will continue to evolve to reflect experience gained, best practices and a process of continuous improvement. Looking ahead, the manual will be updated to take account of the policy and operating guidance for evaluating and designating regulatory authorities as WHO listed authorities (WLAs); the WHO Competency Framework for Regulatory Professionals; and a framework for collaboration with external entities through the Coalition of Interested Parties (CIP) Regulatory System Strengthening Network.

The WHO would like to thank all those who supported the WHO RSS programme and contributed to the development of the GBT and this manual.
### Acronyms and abbreviations

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Full form</th>
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<tbody>
<tr>
<td>AB</td>
<td>approval of blood and blood components, including plasma for fractionation</td>
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<td>BEMA</td>
<td>benchmarking of European medicines agencies</td>
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<td>ECBS</td>
<td>Expert Committee on Biological Standardization</td>
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<td>ECSPP</td>
<td>Expert Committee on Specifications for Pharmaceutical Preparations</td>
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<td>EPI</td>
<td>Expanded programme on immunization</td>
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<tr>
<td>cGBT</td>
<td>computerized global benchmarking tool</td>
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<td>CIP</td>
<td>coalition of interested parties</td>
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<td>CO</td>
<td>WHO Country Office</td>
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<td>CT</td>
<td>clinical trials oversight</td>
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<td>DOI</td>
<td>declaration of interests</td>
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<td>GBT</td>
<td>global benchmarking tool</td>
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<td>GBTQI</td>
<td>global benchmarking tool quantitative indicators</td>
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<td>GCP</td>
<td>good clinical practice</td>
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<td>GDP</td>
<td>good distribution practices</td>
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<td>GMP</td>
<td>good manufacturing practice</td>
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<td>GRP</td>
<td>good regulatory practice</td>
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<td>HQ</td>
<td>WHO headquarters</td>
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<td>I</td>
<td>fully implemented</td>
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<tr>
<td>IDP</td>
<td>institutional development plan</td>
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<td>iIDP</td>
<td>initial institutional development plan</td>
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<td>ISO</td>
<td>International Organization for Standardization</td>
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<td>IT</td>
<td>information technology</td>
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<td>LI</td>
<td>licensing establishments</td>
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<td>LR</td>
<td>national lot release</td>
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<td>LT</td>
<td>laboratory testing</td>
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<td>MA</td>
<td>marketing authorization and registration</td>
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<td>MC</td>
<td>market surveillance and control</td>
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<td>ML</td>
<td>maturity level</td>
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<td>MS</td>
<td>Member State</td>
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<td>MOH</td>
<td>Ministry of Health</td>
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<tr>
<td>NA</td>
<td>not applicable</td>
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<tr>
<td>NCL</td>
<td>national control laboratory</td>
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<tr>
<td>NI</td>
<td>not implemented</td>
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<td>NRA</td>
<td>national regulatory authority</td>
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<td>OI</td>
<td>ongoing implementation</td>
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<tr>
<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>PDMP</td>
<td>plasma-derived medical products</td>
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<td>PI</td>
<td>partially implemented</td>
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<td>PIC/S</td>
<td>Pharmaceutical Inspection Co-operation Scheme</td>
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<td>PQT</td>
<td>prequalification team</td>
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<td>RI</td>
<td>regulatory inspection</td>
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<td>RM</td>
<td>regulatory oversight of blood products associated substances and medical devices</td>
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<td>RO</td>
<td>WHO Regional Office</td>
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<td>RS</td>
<td>national regulatory system</td>
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<td>RSS</td>
<td>regulatory systems strengthening</td>
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<td>SOP</td>
<td>standard operating procedures</td>
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<td>TOR</td>
<td>term of reference</td>
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<td>UN</td>
<td>United Nations</td>
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<td>VL</td>
<td>vigilance</td>
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<td>WCO</td>
<td>WHO country office</td>
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<td>WHA</td>
<td>World Health Assembly</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<td>WIMS</td>
<td>WHO identity management system</td>
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<td>WLA</td>
<td>WHO listed authority</td>
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<td>WR</td>
<td>WHO Representative</td>
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1 Introduction

The benchmarking of regulatory systems referred to in resolution WHA 67.20 implies a structured and documented process by which Member States (MSs) can identify and address gaps with the goal of reaching a level of regulatory oversight commensurate with a stable, well-functioning and integrated regulatory system.

The use of the WHO global benchmarking tool is the primary means by which WHO assesses regulatory systems for the regulation of medical products. The tool and benchmarking methodology enable WHO and regulatory authorities to identify areas of strength as well as areas for improvement; facilitate the formulation of an institutional development plan (IDP) to build upon strengths and address identified gaps; to aid in the prioritization of investments in IDP implementation; and to help monitor progress.

The WHO began assessing regulatory systems in 1997 using a set of indicators designed to assess the regulatory programme for vaccines. Since that time, several tools and revisions have been introduced, and the regulatory systems of over 150 countries have been benchmarked.

The development of a unified WHO GBT for the assessment of medicines and vaccines programmes began in 2013, following a mapping of benchmarking tools internal and external to WHO with a view to ensuring policy coherence, maximizing regulatory outcomes and reducing burden on regulatory authorities1.

This manual is structured in a way to help in understanding the context of benchmarking activities along with in-depth understanding of the GBT as well as the processes and procedures related to planning and scheduling, preparation, conduct and reporting of benchmarking activities.

It is well acknowledged that the size of the manual is big, so it is strongly advised to use the table of contents (TOC) of the document to navigate through it and review the section(s) targeted by the reader/user. Furthermore, this manual is not a standalone document. Rather, it is complemented with other relevant manuals and procedures. Whenever needed, the users of the manual are advised to refer to other document(s) which may benefit better understanding and suitable implementation of the relevant processes.

Finally, in case of any queries related to this manual or associated documents, including queries related to GBT, it should be addressed to WHO regulatory systems strengthening (RSS) team at nra_admin@who.int.

1 At the time of publication, the tool for the benchmarking of blood and blood products has also been incorporated within the GBT, while the tool for benchmarking medical devices (including in vitro diagnostics) is nearing completion. These developments now provide for a single consolidated tool with flexibility to assess different product related regulatory programmes.
2 Objective

The objectives of this manual are to:

- familiarize WHO staff, experts and consultants, national regulatory authorities (NRAs) and other parties (e.g., national control laboratories (NCLs), the expanded programme on immunization (EPI), ethics committees, ministries of health (MOHs) with the overall benchmarking process by highlighting the relevance of the GBT for: a) identifying the strengths and gaps of regulatory systems, b) demonstrating the need to formulate IDPs, c) monitoring the implementation of IDPs as part of the regulatory systems strengthening (RSS), and d) documenting how expected outcomes were achieved.

- provide the users with guidance on all aspects of the WHO benchmarking process through a self-benchmarking, an assisted self-benchmarking, or a formal benchmarking of the regulatory system. The manual also provides detailed guidance on the formal benchmarking activities including the procedures and timelines for planning, conducting, following up and documenting the benchmarking of regulatory systems based on the WHO GBT. The manual also defines the composition of benchmarking teams as well as the required competencies, roles and responsibilities of team members. Furthermore, the manual describes the roles and responsibilities of the three levels of WHO headquarters (HQ); Regional offices (ROs); and Country offices (COs) in the benchmarking of national regulatory systems and the formulation of IDPs.

This manual should be read in conjunction with other relevant manuals, standard operating procedures (SOPs) and work instructions\(^2\). Furthermore, training materials on the use of the tool and the conduct of benchmarking activities are being developed to complement this manual.

This manual is subject to a periodic review and revision as part of the quality system approach applied by WHO (see Section 5.4 for more details).

3 WHO RSS programme

The objectives of the WHO RSS programme are to:

- promote regulatory cooperation, convergence and transparency through networking, work-sharing, and reliance
- build regulatory capacity in MSs consistent with good regulatory practices (GRPs).

Towards this end, WHO has over the last three decades established, implemented and refined a five-step model for strengthening regulatory systems (see Figure 1):

1. Development and maintenance of a benchmarking tool (i.e., the GBT) for assessing national regulatory systems.
2. Benchmarking of the regulatory system.
3. Formulation of an institutional development plan for continuous improvement.
4. Capacity building through technical support, training and networking.
5. Continuous monitoring and documentation of programme outcomes and impact.

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\(^2\) This manual is complemented by other documents including manuals and SOPs as listed in annex 1.
The WHO GBT consists of a well-structured hierarchy of indicators, sub-indicators and accompanying factsheets and can be accessed at the following WHO webpage:

https://www.who.int/medicines/regulation/benchmarking_tool/en/

The GBT also incorporates the concept of maturity levels (MLs), adapted from the international standard, ISO 9004:2018. This concept is not new within the context of regulatory systems benchmarking and has been implemented since 2004\(^3\) through the benchmarking of the European medicines agencies (BEMA). The concept has also been extensively discussed within WHO and in international consultations organized by WHO in January and December 2015.

By applying the concept of MLs according to a well-defined algorithm, regulatory authorities can ascertain their level of development or “regulatory maturity”. The ML classification additionally allows for the identification of more advanced systems that in turn should facilitate reliance and greater regulatory cooperation.

Maturity of regulatory systems is divided into four levels characterized as follows:

- **ML1**: regulatory systems in which some elements of regulatory systems exist; corresponds to “no formal approach” (ISO 9004:2018);
- **ML2**: evolving national regulatory systems that partially perform essential regulatory functions; corresponds to “reactive approach” (ISO 9004:2018);
- **ML3**: stable, well-functioning and integrated regulatory systems; corresponds to “stable formal system approach” (ISO 9004:2018); and
- **ML4**: regulatory systems operating at advanced level of performance and continuous improvement; corresponds to “continual improvement emphasized” (ISO 9004:2018).

The goal of RSS work is to help ensure the availability of safe, effective and quality medical products by assisting countries reach and sustain a level of regulatory oversight that is effective, efficient and transparent. This equates with MLs 3 and 4 (see Figure 2).

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\(^3\) https://www.hma.eu/bema.html
WHO recognizes that it may not be realistic for the body(ies) charged with regulatory oversight in some MSs to achieve ML3, for example, in the case of low resourced MSs. In such situations, efforts should be focused on establishing basic, value-added regulatory functions (e.g., product registration, licensing of establishments involved with manufacture, importation, storage, and distribution of medical products, medical products vigilance, or market surveillance and control) while relying on other advanced regulatory authorities, international organizations or regulatory networks to provide assurance of the quality and safety of supplied medical products. This also includes reliance on the WHO prequalification programme for products that address priority public health diseases such as malaria, tuberculosis and HIV/AIDS. (See also Section 6.11 Customization: Benchmarking of regulatory functions in different regulatory settings.)

![WHO GBT Performance Maturity Levels](image)

**Figure 2: Maturity levels as defined by WHO**

### 4 Country requests and prioritization model for RSS

Resolution WHA 67.20 stresses the importance of providing support in RSS "particularly for developing countries" upon MS request. The same resolution expresses concern regarding “the impact on patients of medical products of compromised quality, safety and efficacy, in terms of poisoning, inadequate or no treatment, contributions to drug resistance, the related economic burden, and erosion of public trust in the health system”.

The formal benchmarking may be requested by the country most commonly for one of two reasons: 1) to provide a detailed picture of the maturity, strengths and areas for improvement of the system, thereby serving as a roadmap for RSS, or 2) to provide support for the official recognition by WHO in the context of achieving ML3 or for a public designation as a WHO listed authority (WLA).
When determining the response to requests from MSs for capacity building and RSS, WHO acknowledges that it serves as a secretariat to MSs and must consider all received requests. However, the RSS programme must also consider the impact on access to safe and quality assured medical products when prioritizing its efforts and investments, given limited resources and growing demand.

The following considerations should be considered in prioritizing country requests for capacity building to strengthen regulatory systems. The list is not meant to be inclusive or mutually exclusive, nor is it ranked in terms of priority. The relative weighting and translation of these considerations into regional work plans will take place through a joint country support planning process involving the three levels of WHO (HQ, ROs, and COs). Plans and activities are dependent on the availability of resources and may be subject to change, including urgent or unforeseen requests.

Considerations in prioritizing country requests to strengthen their regulatory systems include:

- Low- and middle-income countries with significant capacity for the production and export of medical products or with the potential to develop such capacity. Within this category, further priority is given to countries that are a source of prequalified medical products and active pharmaceutical ingredients.
- Countries transitioning from United Nations (UN) or other global procurement models to self-procurement, taking into consideration the associated risks to the continued supply of quality-assured medical products (notably, prequalified medical products).
- Countries that are serving, or that have good potential to serve, as regional or international reference authorities, including those regulatory authorities that are seeking to be recognized as WLAs.
- Countries for which benchmarking and capacity building would be geared towards regulatory harmonization, reliance and work-sharing through regulatory networks.
- Countries that are prone to or severely affected by public health emergencies (e.g., pandemics or shortages) or that have vulnerable public health systems, and thus have a need to prepare for rapid action, including access to required medical products.
- Low income countries with either a weak regulatory system or no regulatory system for medical products.
- Countries and regions supported by other development agencies where a Coalition of Interested Parties approach may be adopted, or where collaboration with public health programmes can advance comprehensive, coordinated RSS efforts.

Underpinning all considerations is evidence of strong and sustained commitment of the government to make the necessary investments in its regulatory system, to adopt international standards and best regulatory practices, and to practice good governance. The latter considerations should serve as eligibility, rather than prioritization, criteria for WHO when planning for and deciding on responses to requests for RSS and MS capacity building.

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4 Member States, in WHO consultations on the introduction of the WLA framework, noted the need for clear prioritization of efforts and for dedicated, supplemental funding. They also agreed that the low regulatory performance of a majority of WHO Member States constitutes a global public health risk and underscored the need to maintain RSS in these countries as a priority.

5 CIP is a new, collaborative model for RSS with a view to optimizing regulatory outcomes by coordinating the efforts of development organizations (including mature regulatory authorities) and donors interested in promoting access to safe, effective and assured quality medical products in a targeted country or region. The first pilot of CIP was conducted (and continues) in Bangladesh, beginning in 2017. Additional CIP approaches have been launched since that time that will inform the operation of a WHO led, network-based approach to RSS. Anticipated benefits include a more efficient use of overall resources, greater consistency in standards and approach, improved outcomes and impact, and less burdensome interventions for regulatory authorities.
5 GBT

The GBT serves as the instrument by which WHO assesses regulatory systems for medical products in MSs. Increasingly, other organizations and NRAs are using the GBT and this manual for the same purpose.

WHO defines a national regulatory system in terms of the enabling legal system and infrastructure, common regulatory functions, and non-common regulatory functions (see Figure 3).

Seven common functions apply to the regulation of all medical products:

- registration and marketing authorization (MA),
- vigilance (VL),
- market surveillance and control (MC),
- licensing establishments (LI),
- regulatory inspection (RI),
- laboratory testing (LT), and
- clinical trials oversight (CT).

In addition, a number of functions apply only to certain medical products. These non-common functions include:

- NRA lot release (LR) for vaccines, plasma derived medicinal products (PDMPs) and blood related in-vitro diagnostics;
- approval of blood and blood components, including plasma for fractionation (product and/or process approval) (AB); and
- regulatory oversight of blood products associated substances and medical devices including in vitro diagnostics (RM).

The following figure illustrates the above listed regulatory functions and their application across the medical product life cycle.
Figure 3: Common and non-common regulatory functions across product life cycle for medicines, vaccines and blood/blood products

These functions may be undertaken by one or more institutions reporting to the same or different senior official(s). When functions are distributed across institutions, the degree to which these institutions communicate and to which they have mandates clearly defined in law, determines in large part how well the designated regulatory bodies perform as an integrated system.

It is important here to distinguish between terms commonly in use as they have direct implications on benchmarking.

The body legally mandated to regulate the functions listed above is commonly known as the regulatory authority (RA) or national regulatory authority (NRA)\(^6\). These terms imply that a single organization is responsible for all regulatory functions. As mentioned above, this is often not the case. Furthermore, depending on the product type, different bodies may be legally responsible, for example, for the regulation of medicines and vaccines as compared to medical devices.

Even when one body is responsible for all regulatory functions being examined, some aspects critical to certain functions may lay outside the authority. For example, those functions performed by pharmacovigilance centres that have a formal relationship with the authority to collect adverse event reports. This could also include immunization programs for vaccines in low- and middle-income countries. Certain regulatory functions may also be undertaken by third parties, as in the case of auditing organizations that perform some functions related to medical devices.

A further consideration relates to the fact that an increasing number of regulatory authorities practice reliance, namely, the act whereby the NRA in one jurisdiction may take into account and give

\(^6\) Other used terms include national drug authority (NDA), national medicine authority (NMA), national medicine regulatory authority (NMRA) and Drug Regulatory Authority (DRA). RA or NRA are the preferred terms for the purposes of benchmarking given their applicability to all medical products.
significant weight to assessments performed by another NRA or trusted institution, or to any other authoritative information in reaching its own decision. The relying authority remains independent, responsible and accountable regarding the decisions taken, even when it relies on the decisions and information of others. In some cases, this could also take the form of reliance on supranational entities or other regulatory systems.

Given these considerations, the term *regulatory system* is used to describe the combination of the institutions, processes, regulatory framework and resources which, taken together, are integral to the effective regulatory oversight of medical products in a given country or multi-country jurisdiction. GRPs should be considered and applied for the whole regulatory system. Patients, consumers and the general public make no distinction among the various elements of a regulatory system, provided the overall system works well.

### 5.1 Scope of the WHO GBT

With respect to the products covered, the scope of the current GBT (revision VI) has been developed for use in benchmarking regulatory systems for:

1. medicines;
2. vaccines; and
3. blood products including whole blood, blood components, plasma for fractionation, PDMPs, and blood associated substances and medical devices including in-vitro diagnostics.

With respect to the institutions covered, the GBT is intended for use in benchmarking national and sub-national (e.g., federal, provincial or state levels) regulatory systems. The GBT is not currently designed or intended for use in the benchmarking of supranational (e.g., regional) regulatory systems. The GBT is designed to assess the inputs (e.g., legal framework, organizational structure and available resources), processes and intended outputs in determining the maturity of regulatory systems. GBT indicators stipulate that the staff of the regulatory system should possess the necessary competencies to perform respective duties; however, the GBT does not generally define nor directly assess expected competencies. Instead, these are assessed indirectly through regulatory outputs, or directly through observed audits of regulatory inspections or vigilance field visits.

### 5.2 Structure of the tool

The GBT is structured into four levels (see Figure 4):

1. national regulatory system and regulatory functions,
2. indicators,
3. sub-indicators, and
4. fact sheets as well as questionnaires for other products and activities.
Sub-indicators and accompanying fact sheets represent the basic blocks of the tool. Each regulatory function is assessed through a set of sub-indicators. Sub-indicators are grouped under a parent indicator that aids data compilation and analysis.

The GBT also groups indicators into nine categories:
1. Legal provisions, regulations and guidelines
2. Organization and governance
3. Policy and strategic planning
4. Leadership and crisis management
5. Transparency, accountability and communication
6. Quality and risk management system
7. Regulatory process
8. Resources (human, financial infrastructure, equipment and information management systems)
9. Monitoring progress and assessing impact

These categories provide options to assess regulatory systems transversely (i.e., cross-cutting themes) across some or all regulatory functions, for example, legal provisions and resources.

Fact sheets were developed to provide guidance to assessors in assessing compliance with indicators and sub-indicators. An example is provided below related to the overarching regulatory system.

**01- NATIONAL REGULATORY SYSTEM (RS)**

The national regulatory system provides the framework that supports the World Health Organization (WHO) recommended regulatory functions. The national regulatory authority (NRA) is the institution in charge of assuring the quality, safety, and efficacy of medical products as well as ensuring the relevance and accuracy of product information. A sustainable, well-functioning regulatory system will ensure an independent and competent oversight of medical products.

**Indicator:** RS02 Arrangement for effective organization and good governance.

**Objective:**
The objective of this indicator is to ensure that arrangements for effective organization and good governance are in place. Good governance is an essential factor for economic growth and sustainable development at all levels and within all sectors of society. The term good governance is increasingly used to emphasize the need for governance to operate with due regard for the rule of law and especially in a manner that is free of corruption. There is also growing consensus on the major characteristics of good governance. Good governance is participatory, consensus-oriented, accountable, transparent, responsive, effective, efficient, equitable, inclusive, and follows the rule of law.

**Category:** 02. Organization and governance

**Sub-indicator:** RS02.04: Independence of NRA from researchers, manufacturers, distributors and wholesalers, as well as from the procurement system.

**Maturity Level:** 2

**Scope:**
1. Medicines
2. Vaccines
3. Blood Products (whole blood, blood components and PDMPs)

**Description:**
The assessor should identify documented evidence that demonstrates the independence of NRA decision-making from researchers, manufacturers, distributors, wholesalers as well as from procurement institutions involved in acquiring different medical products. For example, the control laboratory of a manufacturer must not perform the quality testing on behalf of the NRA when quality testing is deemed necessary by the NRA (e.g., for the purpose of post-marketing surveillance or NRA lot release, if applicable). Another example is that the decision-making bodies should not include or be influenced by experts who represent institutions interested in marketing of medical products. If the Ministry of Health or other governmental authority is responsible for procuring medical products in the country, documented evidence should be provided that NRA decision-making is independent from the organization or office that is responsible for procuring the products.

Aspects to consider when assessing whether the objectives of the indicator have been met:
1. Determine whether the duties assigned to the NRA include research, manufacture, or distribution of medical products.
2. Examine the hierarchical level of the NRA and verify that the NRA is independent of those involved in research, manufacturing, and distribution of product.

**Objective:**
The objective of this indicator is to ensure that, consistently over time, the NRA operates independently of researchers, producers, distributors and other regulated parties. In order to discharge its duties fairly, the NRA must be independent of those regulated entities. Thus, the NRA may not be engaged in the activities that it regulates and may not be at a hierarchical level that is subordinate to those institutions that perform regulated activities. In some countries, the NRA historically has been responsible for manufacturing vaccines, which placed the NRA in the position of being judge and party to the matters before it, and thus compromising its independence and impartiality. Independence of the NRA decision-making process from influence by institutions, societies, and industries which may have direct or indirect interest in the NRA decisions is one of the key elements regarding the safe use of medical products and protection of public health.

**Requirement:** Independence of the NRA

**Evidence to review:**
The assessor should request for and review:
1. Organizational chart of the national regulatory system.
2. Functioning organizational chart of the NRA.
3. Documents defining mission and functions of the organizations within the national regulatory system.

References:


Framework: Structure/Foundation/Input

Rating Scale:

⇒ NOT IMPLEMENTED (NI): There is no evidence that the NRA is independent from researchers, manufacturers, distributors and wholesalers, as well as from the procurement system.
⇒ ONGOING IMPLEMENTATION (OI): There is no evidence that the NRA is independent from researchers, manufacturers, distributors and wholesalers, as well as from the procurement system; however, demonstrable steps toward this have been taken.
⇒ PARTIALLY IMPLEMENTED (PI): There is evidence that some steps have been taken to establish the independence of NRA from researchers, manufacturers, distributors and wholesalers, as well as the procurement system, but it is not yet implemented.
⇒ IMPLEMENTED (I): There is documented evidence that the NRA is independent from researchers, manufacturers, distributors and wholesalers, as well as from the procurement system.

Limitations and remarks:

• In case the manufacturer is part of the structure of the national regulatory system, this must be taken into consideration when evaluating the independency.
• It is important to maintain good collaboration and communication between industry and academia while maintaining the independence of the regulatory system. Regulatory authorities (including national control laboratories) may be involved in scientific research activities. However, these research activities should not entail any conflict of interest with respect to regulatory oversight. Internal researchers with no conflicts of interest are not meant to be addressed by this sub-indicator and scoring the sub-indicator as "not implemented" should be excluded (unless justified for some other reason). On the other hand, if the regulatory authority is involved in research activities which conflict with the mandate to regulate medical products, the sub-indicator should be scored as “not implemented".
Scoring this sub-indicator as "not applicable" (NA) is excluded (i.e., this sub-indicator will always apply for all benchmarked NRAs).

The GBT is supported by a computerized platform known as the computerized GBT (cGBT). The cGBT facilitates the benchmarking process (including the calculation of MLs) and helps manage the information collected. The cGBT is the tool used in the actual benchmarking and self-benchmarking process.

For more information on cGBT, please refer to Section 11 (Information management system).

5.3 Scoring and the algorithm used for determining ML

Scoring the findings of the assessment and using the algorithm for determining the ML, are two important and interlinked benchmarking concepts. Scoring refers to the assessment of the level of implementation for each sub-indicator, while the algorithm refers to the tool used to consider the cumulative implementation of sub-indicators to determine the ML of each regulatory function and the overall maturity of the regulatory system.

As part of the benchmarking exercise, assessors (as well as self-assessors) are requested to score each sub-indicator. The options for scoring of the sub-indicators are listed below with a short description of the same. Detailed guidance on the scoring of each sub-indicator is provided in the respective fact sheet.

1. Not implemented (NI): no evidence is provided to demonstrate any degree of implementation of the sub-indicator. One or more IDP activities related to the sub-indicator should be reflected in the GBT. ‘Not implemented’ is scored as zero out of one (i.e., 0% as a percentage).

2. Ongoing implementation (OI): some actions/steps/activities are taken towards the implementation of the concerned sub-indicator, however, the sub-indicator is not yet implemented in full. OI may also entail implementation of some but not all components of the concerned sub-indicator. Subsequently, one or more IDP activity of the relevant sub-indicator should be reflected in the GBT to contribute to the full implementation of the sub-indicator. For mathematical scoring, ‘ongoing implementation’ is scored as 0.25 out of one (i.e., 25% as a percentage).

7 A greater level of flexibility was introduced into the GBT Revision VI compared to previous versions to allow for better adaptation to various regulatory situations while maintaining the robustness of benchmarking measurement and the assignment of ML. Flexibility is provided through a variety of measures including the ML algorithm, application of not applicable indicators and customization of the GBT, as described in this manual.

8 Depending on the objective and context of the benchmarking related activity, apart from formal benchmarking, it is at the discretion of the WHO Responsible Officer to communicate or not to communicate the overall ML of the regulatory system to the benchmarked entity(ies). For example, for capacity building and RSS purposes, the WHO Responsible Officer may wish not to communicate the overall ML as part of a self-benchmarking or assisted self-benchmarking exercise in order to avoid any potential discouragement particularly in the case of less mature systems. On the other hand, also for the purpose of RRS, WHO Responsible Officer may wish to communicate the overall maturity as well as detailed scores and maturity of different regulatory functions in order to channel a message about prioritization and stepwise approach of strengthening and support of specific regulatory functions, themes, or activities. In all cases, in association with formal benchmarking, the overall ML shall be clearly communicated to the relevant entity(ies) once the activity is concluded.
3. **Partially implemented (PI):** some actions/activities are showing the full implementation of the sub-indicator; however, such full implementation is recent or relatively new with little cumulative data for consistent implementation. Supporting documented evidence is expected to be provided to show the recent full implementation of the concerned sub-indicator. Subsequently, one or more IDP activity of the relevant sub-indicator should be reflected in the GBT to ensure consistent implementation and to address any area of improvement. For mathematical scoring, ‘partially implemented’ is scored as 0.75 out of one (i.e., 75% as a percentage).

4. **Fully implemented (I):** some actions/activities demonstrate the consistent and full implementation of the sub-indicator over a period of time. Supporting evidence is expected to be provided that demonstrates the full, consistent implementation of the sub-indicator (i.e., demonstrated over time and/or through repetition of the process and outcome). One or more IDP activities of the sub-indicator may or may not be reflected in the GBT to address any identified area for improvement. ‘Fully implemented’ is scored as one out of one (i.e., 100% as a percentage).

5. **No data available (Not available):** no data is provided regarding the level of implementation of the sub-indicator. ‘Not available’ is a temporary option which should exist only prior to the self-benchmarking exercise, i.e., when the empty tool is provided to the NRA and no data are yet available. Once the self-benchmarking exercise is concluded, ‘not available’ should not be recorded against any sub-indicator. ‘Not available’ is scored as zero out of one (i.e., 0% as a percentage).

6. **Not applicable (NA):** the sub-indicator does not apply to the regulatory system in question. The non-applicability of any sub-indicator should be supported with a justification that also supports how its exclusion does not pose any adverse or unwanted effect on the relevant regulatory function. Scoring as NA could be an option for some (but never all) sub-indicators under a specific regulatory function. In general, NA is not an option for scoring the sub-indicator unless otherwise indicated in its fact sheets (i.e., in the limitation section). For the purpose of scoring, NA eliminates the sub-indicator. In other words, each time NA is scored for a sub-indicator under a defined function, the total number of sub-indicators required to be met is reduced by one (i.e., the denominator is reduced by one).

The algorithm, as noted, is used to determine the ML of each regulatory function based on the cumulative scoring of the sub-indicators under that function. The below table, explanatory notes and examples illustrate how the ML algorithm operates.

Each sub-indicator under each regulatory function is linked to a particular ML (i.e., ML1, ML2, ML3 or ML4) as indicated in the corresponding fact sheet of the GBT. For a regulatory function to reach a certain ML, a specified percentage of sub-indicators must be scored as ‘fully implemented’, while others may be scored according to the below table.
<table>
<thead>
<tr>
<th>ML</th>
<th>Percentage of implementation of sub-indicators attained</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>% of implemented sub-indicators</td>
</tr>
<tr>
<td>1</td>
<td>Up to 100% of ML1</td>
</tr>
<tr>
<td>2</td>
<td>95% of ML1+ML2</td>
</tr>
<tr>
<td>3</td>
<td>100% of ML1+ ML2 and 90% of ML3</td>
</tr>
<tr>
<td>4</td>
<td>100% of ML1+ ML2+ML3 and 80% of ML4</td>
</tr>
</tbody>
</table>

Explanatory Notes:

1. MLs are built on each other, i.e., reaching a certain level (ML2 to ML4) for a function is not possible unless the lower ML(s) are met for that function or, in other words, unless all sub-indicators linked to lower MLs are fully implemented. By definition, a regulatory function cannot be scored less than ML1.

2. The overall maturity of the regulatory system is a function of the maturity of individual functions subject to the benchmarking process. More specifically, the overall maturity of the regulatory system is equal to the lowest ML of any function subject to benchmarking.

Examples of how the algorithm works in determining the ML of regulatory functions:

Example 1: The number of sub-indicators linked to ML1 and ML2 under registration and marketing authorization function is six and two sub-indicators respectively (i.e., total of 8 sub-indicators). Thus, 5% is equal to 0.4 sub-indicators and this is rounded up to one sub-indicator. If a regulatory system is found to have one sub-indicator linked to ML1 or ML2 under registration and marketing authorization function which is scored as ‘not implemented’, the ML for the function will be ML1 as 0% of ML1 and ML2 sub-indicators should be scored as ‘not implemented’.

On the other hand, if the regulatory system is found to have one sub-indicator linked to ML1 or ML2 which is scored as ‘ongoing implementation’, the ML of the registration

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9 In case the percentage is less than or equal to 1 sub-indicator for a particular function, it should be rounded up to 1 sub-indicator for that function provided that the total percentage across all functions does not exceed the stated one, as explained in the examples below.
and marketing authorization function will be ML2 (i.e., if all other sub-indicators linked to ML1 and ML2 are scored as ‘implemented’) because the algorithm allows 5% of ML1 and ML2 sub-indicators to be scored as 'partial' or ‘ongoing implementation’. However, this is also conditional on a second requirement, namely, that the number of sub-indicators linked to ML1 and ML2 which are scored as 'partial implementation’ or ‘ongoing implementation’ across all regulatory functions is less than 5% of the total number.

Example 2: The number of sub-indicators linked to ML1, ML2, ML3 and ML4 under the national regulatory system function are four, seven, 27 and 22 sub-indicators, respectively. As with the previous example, if a regulatory system is found to have one regulatory system sub-indicator linked to ML1 or ML2 which is scored as ‘not implemented’, the ML for regulatory system will be ML1. On the hand, if the regulatory system is found to have one sub-indicator linked to ML1 or ML2 which is scored as ‘ongoing implementation’, the ML assigned to the regulatory system will be ML2. Furthermore, if the regulatory system is found to have two sub-indicators linked to ML3 which are scored as ‘ongoing implementation’ or ‘partial implementation’, the maturity of the regulatory system will be ML3 as 10% of ML3 sub-indicators is equal to 2.2 sub-indicators (i.e., rounded to two sub-indicators).

While the algorithm may initially seem complex, users are not required to perform the calculations as the algorithm is built into the software of the cGBT. Consequently, the ML assigned for the benchmarked functions is automatically calculated and displayed to the user following the scoring of the relevant functions.

5.4 Maintenance and revision of the tool

The GBT is revised on a periodic basis to: (i) reflect experience in use; (ii) consider feedback from the users; (iii) ensure continuous monitoring and improvement of the tool’s capability to benchmark regulatory legality, independence, impartiality, proportionality, clarity, flexibility, responsiveness, consistency, effectiveness, efficiency and transparency; and (iv) align with updated WHO guidelines and with advancements in the regulatory sciences field.

In order to ensure the tool continues to be fit for purpose, several approaches may be considered including, for example, formal and informal consultations with national and regional regulatory experts, related technical agencies, other partners or, when necessary, public consultations.

The GBT must comply with current WHO guidelines for assuring the quality, safety and efficacy of medical products as endorsed by the WHO Expert Committee on Specifications for Pharmaceuticals Preparation (ECSPP) and the WHO Expert Committee on Biological Standardization (ECBS); with WHO prequalification requirements; and with any relevant international standards or guidelines consistent with WHO policy for strengthening regulatory system capacity (e.g., ISO standards, International Conference on Harmonization, and Pharmaceutical Inspection Co-operation Scheme (PIC/S) guidelines).

For the purpose of change control and management, WHO GBT is subject to strict rules for nomenclature as below indicated:

- GBT name reflects a two-tier control system that consists of revision and version level designations, for example, GBT rev. VI, ver. 1. As noted, revision and version are shortened as rev. and ver. respectively.
The revision number, expressed in Roman numerals (beginning with I), denotes the control of the GBT functions, indicators and sub-indicators. Any change to these GBT components results in a change of the GBT revision number.

The version number, expressed in Arabic numbers (beginning with 1), denotes the control of the GBT fact sheets in the absence of changes to the above-mentioned components (i.e., functions, indicators and sub-indicators). Any change in the GBT fact sheets would result in a change of the GBT version number.

Whenever a new revision is introduced, the version number is reset to one (1).

Only the latest revision and version of the GBT will be available on the WHO web site in PDF format. No other software format (e.g., Word or Excel) is considered valid.

In order to ensure accessibility to the GBT, WHO is constantly working on translation and publication of the GBT in several languages, mainly UN ones. For example, the GBT currently is available in English, French and Spanish languages (see the GBT page on the WHO website: https://www.who.int/medicines/legislation/consent_tool/en/).

Further details on the control of the GBT including revisions, versions, format, content and registration of changes are provided in the SOP on GBT change control.

6 Overview of the benchmarking process

This manual provides high-level guidance on the GBT and the overall benchmarking process. The manual is complemented by a set of SOPs, manuals and other references.

For the purpose of this manual, the term “benchmarking” represents the end to end benchmarking process, comprised of the following activities:
1. Planning and scheduling
2. Desk-based screening
3. Introductory visit
4. Self-benchmarking
5. Verification of self-benchmarking
6. Pre-benchmarking visit
7. Formal benchmarking
8. Enhanced performance assessment of specific regulatory functions, for example:
   - Observed audit for evaluation of good manufacturing practice (GMP) regulatory inspection function.
   - Field visit for assessment of vigilance function.
9. IDP
10. Follow up and monitoring
11. Re-benchmarking

The following points are essential for a proper understanding of the benchmarking process:

- The overall benchmarking process can be considered an ongoing, long-term process which requires full commitment and cooperation among parties involved, including WHO and the institution(s) forming and contributing to the regulatory system (e.g., NRA, NCL, research ethics committees, institutional review boards, pharmacovigilance centre(s), and EPI). The

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10 This manual is complemented with two other documents including manuals and SOPs as listed in annex 1.
11 Assessment of regulatory performance will be expanded under the WLA framework.
existence of political will and the availability of resources are also key for successful benchmarking processes.

- The benchmarking process may not necessarily cover all activities mentioned in the GBT, depending on the status of the regulatory system that is the subject of benchmarking and on mutual agreements reached among WHO, the country and other relevant partners.
- The sequence of steps may not follow the exact order listed above, for example, the timing of any enhanced performance assessments may vary.
- Customized benchmarking activities as described below in Section 6.11 may also be conducted as part of the overall benchmarking process, including a ‘rapid’ (or abridged) benchmarking exercise for the purpose of providing a preliminary and partial understanding of the maturity of the regulatory system. Such customized activities could also include the assessment of specific aspects of the regulatory system, notably those functions undertaken at the state or provincial level; these would be conducted using a customized GBT developed for this purpose.
- The IDP is a dynamic plan that is updated and implemented in parallel with the benchmarking of the regulatory system.

Figure 5 is a high-level visual representation of the different steps of the WHO benchmarking process including WHO pre-visit, self-benchmarking, verification of the self-benchmarking, formal benchmarking, and finally monitoring of progress made. Figure 6 provides a detailed flowchart of the same process.

**Figure 5: High-level overview of the benchmarking process**
*(refer to the flowchart in Figure 6 for more detail)*
Figure 6: Flowchart of benchmarking process
6.1 Planning and scheduling

The work planning process ensures the involvement, based upon agreed work plans, of the three levels of WHO – headquarters, regional offices and country offices (HQ, ROs and COs) on all aspects related to benchmarking activities.

Work plans should be reviewed at least once a year, in light of country’s requests and in agreement with ROs and COs, as changes may occur in the dates, team composition and specific objectives of benchmarking activities (e.g., introductory, self-benchmarking, pre-benchmarking and formal benchmarking missions). For further details on the coordination between HQ, ROs and COs, please refer to Section 7 on Roles and Responsibilities.

Terms of Reference (TORs) to be sent to the country: TORs should be drafted once an activity is confirmed with the counterparts in the concerned MS following the applicable WHO procedures, and as soon as a visit is scheduled and agreed to with the respective RO and CO. The TORs should specify objectives, proposed dates for the benchmarking activity, a tentative agenda and the composition of the team. The proposed TORs should then be shared with the concerned NRA through the official communication channels for agreement and concurrence.

Selection of WHO staff and external assessors: Benchmarking activities are conducted by a team of qualified subject matter experts. Except for formal benchmarking missions, the team may be composed of WHO staff, WHO consultants, external experts, or a combination thereof. Formal benchmarking, on the other hand, are always conducted by a team composed of WHO staff and non-WHO expert assessors. In all cases, activities are conducted under the direction of WHO.

External assessors should be selected from the database of qualified subject matter experts or from other sources as required and are chosen based on the specific areas of expertise required for the activity. External experts are regulatory experts from NRAs that are not the subject of the benchmarking activity (i.e., free from any potential bias). In addition, the selected assessors, as part of their qualification, should complete any essential training on GBT and cGBT. Other considerations in selection of benchmarking team members include avoidance of language barriers, as well as ability to handle more than one function (i.e., to maintain a team of appropriate size).

It is strongly advised that each team include senior assessors who have prior experience with the regulatory system benchmarking process and who are able to serve as mentors to new assessors or observers. Further details on the criteria for qualification and competence of the assessors can be found in Section 8 and in the respective procedure for establishment and maintenance of the roster of qualified GBT assessors.

Before a regulatory system benchmarking, a list of team members, along with the curriculum vitae of non-WHO assessors, is conveyed to the NRA for information, comment, and government clearance. The NRA has the right to request, subject to proper justification, a replacement for any team member who is not a WHO staff. Once the team composition is endorsed by the NRA, invitation letters should be sent to the home institutions of the selected team members to obtain clearance.

In the case of formal benchmarking or re-benchmarking activities, team size and composition should reflect the scope of the visit, as well as the size and complexity of the regulatory system and the targeted regulatory functions that are to be assessed. For follow-up visits, a smaller team is normally adequate in view of the objective and scope of the visit.
6.2 Desk-based screening

Desk-based screening is most effective in the case of countries with well-documented regulatory activities, accessible online resources (e.g., web pages), or other published documents. Many NRAs are linked to other governing bodies that can also provide valuable information, such as the MOH.

Desk-based screening might also be performed when data on an earlier benchmarking, assessment or audit exists for one or more product streams (i.e., if earlier assessment was done by WHO or other well recognized entities, such as BEMA, PIC/S, the European Directorate for the Quality of Medicines, the Official Medicines Control Laboratories, or ISO). In this case, existing data should be imported, when possible, or input into the latest version of the GBT with the assistance of WHO RSS information technology (IT) specialists.

Desk-based screening can provide relevant information on almost all regulatory system functions. It can also reduce costs and time spent in country. For a pre-screened regulatory system, the duration of a formal benchmarking can be reduced from five days to three to four days if the requested documentation has been received in sufficient time for advance review.

Further details on the desk-based screening process are described in the respective SOP (currently under development).

6.3 Introductory visit

The introductory visit serves to explain the WHO RSS programme and ensure the NRA understands the objectives, policies, terms, and methodology of the programme, as well as the overall benchmarking process. In addition, as part of the introductory visit, WHO can confirm the political will to proceed with the benchmarking process.

Specifically, the primary goals of the introductory meeting are to:

- help the NRA understand the type of information required and identify documents for translation, if any;
- confirm commitment and cooperation among parties involved in the benchmarking process;
- develop a roadmap for the benchmarking including the planning for the steps that lead up to the formal benchmarking, such as self-benchmarking, observed audits and vigilance system field visits;
- clarify the obligations of the parties;
- respond to questions and clear up any misunderstandings;
- ensure a more effective and efficient benchmarking process, especially when coupled with the screening activity mentioned above. The benchmarking manual should be provided to the NRA at this time, together with an explanation of how and where to access all relevant documents for the benchmarking; and
- map the regulatory system in the country. The mapping process involves discussions around who is responsible for different regulatory functions in the country and, if more than one entity is involved, how they collaborate and coordinate with one another. In addition, the mapping process helps to understand how the regulator is interacting with different stakeholders.

Other relevant concepts and principles, when necessary, may be addressed during the introductory visit (e.g., WLA, GRPs, and the roadmap for prequalification of vaccines) based on prior discussions and agreements with the NRA; such details should be reflected in the relevant TORs.
The introductory meeting may be conducted virtually, for example, when the NRA already has some familiarity with the benchmarking process. The meeting can also be held in conjunction with a self-benchmarking workshop involving a number of countries.

When the introductory visit is not performed, the responsible WHO officer must ensure that all relevant explanations and clarifications are provided to the NRA prior to any planned WHO visits (e.g., self-benchmarking, observed audit, benchmarking, and follow up visits).

### 6.4 Self-benchmarking

The regulatory authority and affiliated entities should perform a self-benchmarking using the current version of the GBT in order to ensure the quality and efficiency of the formal benchmarking process. Assigned staff of each affected department or unit within the regulatory system should:

- self-score each GBT sub-indicator;
- provide input to justify the scoring;
- provide links to publicly available evidence or upload relevant documented evidence to the WHO NRA information sharing platform (see Section 11 for further details); and
- propose input to the initial institutional development plan (iIDP) as deemed necessary.\(^\text{12}\)

WHO may assist the NRA in the self-benchmarking by organizing a self-benchmarking workshop. The workshop serves to explain the tool, the importance of accurate assessment, and the expected outcomes of the exercise. The workshop also provides an opportunity for WHO to respond to questions and address potential misunderstandings regarding the information sought in the tool.

One of the expected outcomes of the self-benchmarking exercise is to discuss and to reach agreement on sub-indicators that can justifiably be scored by the NRA as ‘NA’ (See Section 5.3). This determination is critical, considering the impact of scoring of each sub-indicator on the ML of respective functions and on the overall ML assigned to the regulatory system. In addition, having a mutual understanding and agreement between the NRA and WHO on these sub-indicators is essential to avoid time-consuming debates during subsequent activities. However, NRA staff and WHO experts should keep in mind that discussions on non-applicable sub-indicators during the self-benchmarking are preliminary. Further confirmation and agreement on the applicability of these sub-indicators is expected during the subsequent step (i.e., verification of the self-benchmarking).

The results of the self-benchmarking, including the draft iIDP produced by the NRA and affiliated institutions, will be used as a basis for the formal benchmarking. Once verified by WHO (as explained in the next step), the draft iIDP will be provided to the assessors prior to benchmarking. The scoring justification and supporting evidence from the self-benchmarking exercise should be provided to WHO in the form of a completed GBT, with supporting evidence uploaded to the WHO information sharing platform (i.e., by an agreed upon date).

Refer to the self-benchmarking manual including generic TORs for further guidance on the self-benchmarking workshop.

### 6.5 Verification of self-benchmarking

The verification step is meant to assess the completeness and quality of self-benchmarking results. WHO (or a designated expert on behalf of WHO) reviews and verifies the information generated

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\(^{12}\) The NRA updates information prepopulated by WHO based on the desk-based screening.
from the self-benchmarking exercise in order to confirm that: i) all relevant regulatory functions and sub-indicators have been addressed; ii) scoring appears to be justified on the basis of information provided; iii) the information provided is indeed relevant, adequate and, when necessary, supported by documented evidence.

As highlighted in the preceding section, further discussion and agreement on non-applicable indicators should take place during the verification of self-benchmarking results. Towards this end, WHO may seek further clarifications and justifications from the NRA. Discussions on non-applicable sub-indicators are not expected to be repeated during the formal benchmarking unless relevant new evidence emerges. In the latter case, the benchmarking WHO Team Leader should be notified by the assessor and the issue brought to the attention of the WHO formal benchmarking team for the appropriate decision (i.e., to maintain or change the original scoring of the respective sub-indicator).

The NRA shall be given a clear timeline to amend its scoring and inputs to the GBT and upload the completed tool along with supporting evidence and documents to the WHO information sharing platform. WHO (or an expert on behalf of WHO) shall verify the submitted information no later than one month from the date of submission (i.e., uploading) of the amended self-benchmarking report.

Following the verification of self-benchmarking results and supporting evidence, an amended and completed self-benchmarking report should be uploaded by the NRA onto the WHO NRA information sharing platform. The report should include all details related to the self-benchmarking including background, activities performed (e.g., self-benchmarking workshop), preliminary outputs, outcome verifications, proposed iIDP and the path forward (i.e., next steps and timelines).

### 6.6 Pre-benchmarking visit

When necessary, the responsible WHO officer (or a delegate) may perform a pre-benchmarking visit a few weeks prior to the formal benchmarking to confirm the readiness of the NRA for the formal benchmarking. During the visit, detailed discussions should be held, and agreements should be reached on the agenda and on the activities planned for the formal benchmarking. In addition, a final check should be performed with respect to documents that require translation, documented evidence that must be uploaded to the information sharing platform, and any other steps that must be performed in preparation for the formal benchmarking. As appropriate, a virtual meeting can replace the visit.

Moreover, the NRA may be asked to fill in the GBT quantitative indicators (GBTQI) and share it with WHO at least 14 calendar days before the formal benchmarking. For this purpose, the latest version of the GBTQI template should be provided to the NRA by the WHO officer. The WHO officer is responsible for providing clarifications on the content and the completion of the GBTQI (see Annex 5).

The WHO officer should convey the following facts to the NRA:

- Filling out the GBTQI template is optional and does not represent an essential part of the GBT.
- Although optional, the GBTQI does contribute to the quality of the formal benchmarking process and outcomes.

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13 Keeping in mind the limited number of sub-indicators that can justifiably be scored as not applicable.
• GBTQI are not subject to any scoring and hence do not have an impact on the assignment of ML to the regulatory system.

In all cases, the NRA should provide WHO with the filled cGBT, along with the relevant documented evidence (e.g., through the information sharing platform), well in advance of the formal benchmarking, but not later than 14 calendar days prior to the formal benchmarking visit. Note that the GBTQI should be provided if completed. A minimum of 14 days is needed so that the benchmarking team has sufficient time to prepare for the benchmarking visit.

6.7 Formal benchmarking

Description of the process:
The formal benchmarking is meant to provide an objective assessment of the enabling regulatory system and the regulatory functions under review, based on agreements reached at the start of the overall benchmarking process. Furthermore, as noted elsewhere, the final list of assessors is confirmed following review and endorsement by the NRA.

Most commonly, the formal benchmarking is requested by the country for one of two reasons: 1) to provide a detailed picture of the maturity, strengths and areas for improvement of the system, thereby serving as a roadmap for RSS, and 2) to lead to official recognition by WHO in the context of achieving ML3 or to a public designation as a WLA.

Pre-benchmarking steps and activities that are undertaken with the NRA and that lead up to the formal benchmarking serve to ensure, to the extent possible, that the authority and affiliated institutions are prepared for formal benchmarking. However, it is important that senior NRA officials are aware from the start of the process that the outcomes of the formal benchmarking can differ from the outcomes of the self-benchmarking exercise.

TORs: Once the objectives, dates and other details of the formal benchmarking are agreed upon, the Responsible Officer or the designated Team Leader should arrange for drafting of TORs for the formal benchmarking as per the relevant template (see Annex 2).

The TORs should include the following:

• background and rationale for the formal benchmarking mission;
• scope, objectives, expected outcomes and deliverables for the mission;
• dates, locations and institutions to be visited;
• WHO benchmarking team members and lead (see Section 7 on roles and responsibilities of team members);
• assignment of assessors to the different regulatory functions (i.e., benchmarking streams) along with tentative benchmarking schedule; and
• documents to be ready in sufficient time before benchmarking, including those available through the WHO secure information sharing platform.

In addition, the TORs may include details related to complementary activities required to assess the level of performance of the regulatory system (e.g., an observed audit of regulatory inspection or vigilance field visit) which may precede the formal benchmarking.

The TOR to be used for the formal benchmarking should be available and distributed to all participants 60 calendar days before the visit, including relevant NRA staff, the WHO benchmarking team, and responsible staff of WHO RO and CO. As previously noted, the TORs should consequently be shared with the concerned NRA through official communication channels for agreement and concurrence.
The list of assessors and observers should be shared with the NRA at least 30 working days prior to the benchmarking visit. Should the country have concerns over the list of non-WHO assessors due to a perceived conflict of interest, this concern should be communicated at least 20 working days before the benchmarking. A decision to consider such concerns will be made by WHO on a case by case basis in consultation with the NRA.

**Briefing of benchmarking team:** The WHO benchmarking team must be thoroughly briefed on the principles described in this manual prior to the start of the formal benchmarking visit. The Team Leader will brief all team members virtually (e.g., videoconference, teleconference, and email) with respect to:

- the methodology of the benchmarking;
- the availability of required documents;
- the use of the cGBT;
- the roles and responsibilities of different team members, including the specific area(s) of the benchmarking process to which they have been assigned; and
- the logistical arrangements.

When necessary, this briefing may be repeated between two to three times to cover all team members. Concerns or issues raised by the WHO benchmarking assessors may also be discussed at this time.

Each team member, no matter how experienced, will need to spend the necessary time preparing for the benchmarking, reading background documents, and becoming familiar with the latest version of the GBT and cGBT.

**Onsite preparatory meeting:** A short meeting should be organized by the Team Leader the day before the official meetings start or upon arrival of all benchmarking team members. During this meeting, the Team Leader will review the programme and update team members on the latest information, benchmarking agenda and schedules. Therefore, travel schedules for team members should be arranged to ensure arrival in country by early afternoon (at the latest) of the day before the start of formal benchmarking.

**Opening meeting with NRA:** During the opening meeting on the morning of the first day of the visit, the WHO benchmarking team must present and explain the objectives and expected outcomes, as well as the methodology and tools to be used for conducting the benchmarking. Key decision makers and/or top managers representing the relevant institutions involved in the national regulatory system must attend this meeting. This includes NRA staff, NCL staff, staff from allied institutions (e.g., representatives of the immunization programme in charge of adverse events following immunization and top management of the national vigilance centre) and CO staff including the WHO Representative (WR) or a delegate 14.

A WHO presentation during this opening meeting should use the relevant slides prepared prior to the visit. The presentation should include the following slides: 1) title of the visit, 2) outline of presentation, 3) objectives of the benchmarking, 4) expected outcomes, 5) WHO benchmarking team, 6) proposed programme, 7) list of institutions to be visited, and 8) methodology of work.

The meeting should begin with the NRA and the MOH delivering opening remarks and introducing officials. The Team Leader should then introduce team members and their responsibilities and present, for discussion and agreement, the objectives and the agenda for the visit. During the meeting, appointments with key staff should be confirmed and the list of documents to be provided to team members during the benchmarking should be reviewed. The NRA is typically invited to present an overview of the regulatory system during the meeting.

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14 Whenever possible, the WR should participate in the opening and closing sessions of a benchmarking mission and a subsequent debrief.
Points related to the actual benchmarking process:

a) As reflected in the final TORs for the formal benchmarking visit, the team should split into benchmarking streams assigned, based on expertise, to one or more regulatory functions. This approach also provides for a more focused and efficient process (see also Section 7, Roles and responsibilities of the Team Leader).

b) In addition to the documented evidence available on the information sharing platform and through links included in the cGBT, supplementary documents may be requested during the benchmarking visit, if necessary, because each indicator and sub-indicator score must be supported by documentation. Before placing such requests, the assessor should first collect all official documents or working papers that can be used as evidence. These documents are usually provided to the team prior to the formal benchmarking through the WHO information sharing platform, during the first day or when conducting interviews. However, some documents may not be provided on time, may be incomplete or may not yet be translated. In such cases, the team should conduct interviews with the concerned NRA staff to clarify the details of these documents.

c) In some cases, the team may need to ask for assistance from an external translator. Usually the Team Leader has the responsibility to arranging this with the relevant WHO officials in advance of the visit. The NRA may also arrange for translation (i.e., typically through the international regulatory affairs unit).

d) WHO benchmarking team members are expected to record their input and scoring for each indicator and sub-indicator in a clear and transparent manner following the necessary discussions. Assessors must also ensure that, for all sub-indicators which are not fully implemented, recommendations to address the gaps are included in the proposed IDP.

e) The scoring and the recommendations from the benchmarking assessors are based on a review of NRA input and documented evidence and on further clarifications provided by the relevant NRA staff.

f) The score to be attributed to each indicator should be suggested by the relevant team members and, when necessary, discussed among the WHO benchmarking team in the daily wrap up session in order to obtain consensus, particularly in case of dissenting opinions. Once agreement is reached, the WHO benchmarking team should explain the findings to the institution being benchmarked. Before the final report is submitted, it is important that the team of assessors obtain feedback and explain the score. During the scoring process, the Team Leader and team members should keep in mind that the scoring should be openly discussed with the NRA staff interviewed and that, as much as possible, a consensus is reached (see below). This means that the finalization of scores should first occur among the WHO benchmarking team and, subsequently, with NRA staff, with possible adjustment of scores and recommendations based on NRA staff suggestions.

g) Dissenting opinions:

a. Dissenting opinions internal to the WHO team: If dissenting opinions arise among assessors during the scoring process, they should be addressed and resolved within the team so that there is one consistent message from WHO.

b. Dissenting opinions between WHO team and the NRA: Some sub-indicators may not be sensitive enough to provide an accurate benchmarking finding and score and therefore could easily be challenged by the NRA. In these and other situations where the score is challenged, it is important to explain the scoring process, to receive and discuss feedback on the challenged indicators and to obtain a consensus on the score obtained. If this is not possible, the WHO team should explain to the NRA why the score cannot be amended to reflect its views or concerns.
h) A daily wrap up session among the WHO benchmarking team should be held to update each member of the team on progress made, to discuss any issues raised, and, if necessary, to adjust the benchmarking agenda.

i) A closed wrap up session among all members of the WHO benchmarking team should be conducted one day before the end of the formal benchmarking visit to share information and documents collected by the different team members and to agree on the benchmarking draft report, including proposed scoring and IDP recommendations. Consensus should be sought among team members; however, the final decision, in the case of disagreement, is the responsibility of the WHO Team Leader. The closed wrap up session also serves to ensure that strengths and gaps as well as recommendations (i.e., proposed IDP activities) for related indicators are clear and consistent across regulatory functions, and that the designated assessors are prepared adequately for the presentation of findings and recommendations to the NRA.

**Technical debrief meeting:** Findings and recommendations made by the WHO team should always be shared and discussed with senior NRA officials before they are presented to a larger audience in order to avoid surprises or delicate situations that could offend the NRA. A technical debriefing should therefore be organised a day before the closeout meeting to provide detailed feedback on observations and identified gaps. The technical debriefing should be used as a further opportunity for the NRA to provide additional information and to resolve any misunderstandings between the NRA and the WHO benchmarking team.

**Closeout meeting:** A closeout meeting is organized on the last day of the formal benchmarking visit. Ideally, the closeout meeting should be attended by the same participants as the opening meeting (i.e., high-ranking officers, key personnel, and top management of the NRA and MOH).

The WHO Team Leader should make a presentation covering the benchmarking visit. The presentation should include a recap of objectives, expected outcomes, and team members, as well as the overall findings (i.e., ML and underlying scoring) and recommendations (i.e., IDP activities) related to the regulatory system and the individual regulatory functions. The presentation should also include a tentative roadmap (i.e., next steps with associated timelines) and possible opportunities for the NRA to consider when implementing the IDP. Designated assessors should present findings and recommendations related to their area of review.

The presentation generated by the WHO cGBT from the team’s input can be used for this purpose "as is" or after appropriate amendment. The cGBT will automatically assign and display the level of maturity for each regulatory function.

It is essential to highlight and build on the strengths of the NRA in order to encourage further progress and ongoing commitment and to avoid undermining the work done by the NRA. Comparisons with other NRAs should be avoided.

The presentation should be distributed to participants at the closeout meeting and uploaded to the relevant WHO NRA information sharing platform. With the agreement of WHO, the presentation may subsequently be amended to its final version to reflect comments and corrections requested by the NRA.

**Preliminary draft benchmarking report:** The preliminary draft benchmarking report should also be distributed at the closeout meeting and uploaded to the relevant information sharing platform. As with the exit presentation, the draft report should be created from the cGBT that was used during the benchmarking visit and should include WHO assessors’ comments, scoring and IDP activities, if any, for each sub-indicator. The report should also include a tentative roadmap with next steps. Comments from the meeting should also be incorporated, as appropriate, into the preliminary benchmarking report.
The Team Leader subsequently compiles the different parts of the report written by team members, along with a narrative section, and forwards it to the designated Responsible Officer for review not later than two weeks following the visit. The preliminary report should be uploaded to the information sharing platform soon thereafter.

The preliminary draft report may be amended according to comments and corrections requested by the NRA or by members of the WHO benchmarking team (see below).

**NRA feedback on the preliminary draft benchmarking report:** Upon notification by WHO, the NRA should download the preliminary draft WHO report for thorough review and analysis. The NRA should provide comments, if any, to WHO within 20 working days after receipt of the WHO draft report. NRA comments should be supported, as appropriate, with supplementary documented evidence. This evidence should be uploaded to the information sharing platform. Ideally, the NRA may provide a corrective and preventive action plan. The NRA should notify WHO once all comments have been compiled and supporting evidence has been uploaded to the information sharing platform.

NRA comments along with the documented evidence should be downloaded by WHO/RSS and shared, as necessary, with each WHO assessor, because additional facts and evidence may be available which could result in a change in benchmarking results. This evidence could include further documentation, explanations or evidence of activities that address one or more of the gaps found during the benchmarking visit. While this may delay the issuance of the final report, it should not delay the implementation of the IDP, provided that the activities had been agreed upon during the closeout meeting.

**Final benchmarking report:** Any comments or corrections received from the NRA and team members are collected for consideration in the final report by the designated Responsible Officer. After all comments from the NRA are resolved, or if no comments are received from the NRA, WHO will issue the final report and inform the country that the report is issued as “an endorsed report”.

The final benchmarking report should be uploaded to the respective section of the relevant WHO NRA information sharing platform within 180 calendar days of the benchmarking mission. The NRA should be officially notified (e.g., through e-mail or other reliable means) when this occurs.

**WHO master file:** The WHO Team Leader is responsible for the collection of all electronic documents related to the benchmarking process in order to build a WHO master file to be archived on the NRA information sharing platform. The master file should be ready by the end of the benchmarking visit. Updates to the master file will continue to take place; these may include comments, suggested revisions and evidence submitted by the NRA, as well as the finalized benchmarking report.

Electronic documents may be posted immediately on the information sharing platform server. See Section 11.2 for further detail.
Issuance of a WHO official letter: A WHO official letter indicating the ML of the overall system and individual regulatory functions will be issued for a regulatory system that has reached ML3 or 4, as documented by WHO following a formal benchmarking and resolution of all (major) outstanding issues. The letter should be signed by the appropriate WHO official as per WHO internal procedures. An official ceremony may be requested by the country and organized locally with the WR presenting the WHO official letter. If requested by the NRA, WHO may also issue an official public statement or press release following the review and concurrence by the relevant WHO communications unit.

Once in place, the public designation of WLAs will be governed by the policy and operational guidance.

6.8 Institutional development plan

The IDP is the work plan prepared by the NRA and the WHO team of assessors listing proposed activities to be undertaken for a regulatory function, normally within a timeframe of two to three years. It represents the key output of the benchmarking process and serves as the basis for improvement and for monitoring progress.

The IDP includes the proposed activities for each recommendation together with associated milestones or deadlines and responsible institutions and officers. The IDP also identifies the additional support required to implement recommendations, the approximate amount of funding required, and the potential sources of funding.

As previously noted, a high-level roadmap (i.e., next steps with associated timelines) is also helpful in guiding the implementation of IDPs and subsequent benchmarking activities. The roadmap may cover a longer time frame (e.g., five years) and include interim benchmarking when resolution of outstanding gaps is not realistic within a shorter period.

Each assessor is responsible for proposing at least one recommendation for sub-indicators that were not fully implemented. The proposed IDP must be discussed with the institutions being benchmarked before the team completes the visit. The IDP should be discussed and agreement should be reached between the benchmarked regulatory system and WHO before the finalization and official endorsement of the benchmarking report.

Considering the global demand for RSS, several factors may be considered by WHO when addressing country requests for implementation of IDP activities. These include, but are not limited to, resources required for implementation versus resources available, impact of the implementation at the country, regional and international levels, existing capabilities that can be used, involvement of other partners at country level and beyond, and the NRA’s contribution to and commitment for the IDP.

The IDP is a living document that is meant to be updated by the NRA as measures are implemented to address recommendations. The ‘ownership’ of the IDP resides with the NRA and must be understood as such by the country. The implementation of the IDP is therefore the responsibility of the NRA. Successful implementation of the IDP will require the full commitment of the country, including assurance of the necessary human and financial resources.

Notwithstanding the above, most countries will require additional support. WHO plays a critical role in this regard, either by providing or trying to secure the necessary technical support, for example, through the CIP, centres of excellence, or identified subject matter experts. Different mechanisms might be considered in addressing gaps and building capacity, such as in-country, regional or virtual

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15 Subject to available resources and ability to execute recommendations, especially when they relate to legislation, structural changes or increases in staffing.
training, use of consultants, twinning between NRAs, study tours, placement of NRA regulators into advanced NRAs or WHO (e.g., prequalification team (PQT), pharmacovigilance team, or RSS team). To the extent possible, efforts should be made to identify possible sources of funding to support implementation of the IDP beyond the resources available or anticipated at the country level, including support from the donor community. It is also important to confirm resources available within WHO at the country, regional and headquarters level. Ideally, this should be confirmed prior to the benchmarking visit as part of the joint country support planning process.

6.9 Follow-up visit

“Follow-up visit” is a generic term used to describe visits to the NRA that may occur at any time during the country RSS programme and that are not part of other visits described above.

The overall objective of follow-up visits is to maintain close contact and coordination with the NRA in relation to the overall RSS programme. Follow-up visits may therefore serve a variety of purposes, including, for example, supporting the NRA’s preparation for formal benchmarking; monitoring progress made since the last WHO visit (including IDP implementation or updating the IDP for future implementation); and providing additional support to the NRA. The same benchmarking tool and IDP should be used and updated in all follow-up visits to reflect progress or areas for either further improvement or new recommendations. On a case by case basis, agreement should be reached on other objectives of a follow-up visit.

Follow-up visits can be requested by the NRA, the CO or the RO. In some cases, an urgent follow-up visit can be suggested within 90 to 180 calendar days or as needed to finalize the benchmarking process (e.g., for benchmarking associated with prequalification).

6.10 Re-benchmarking

Benchmarking performed in the context of regulatory system recognition (e.g., as required for prequalification of vaccine manufacturers or in relation to a WLA designation), requires periodic confirmation of performance and ML. The term, “recognition”, refers to regulatory systems that have achieved at least ML3, a level that represents a stable, well-functioning regulatory system.

The “re-benchmarking” is performed typically every three to seven years using a risk-based approach. Re-benchmarking may be conducted onsite or offsite through desk review. The frequency of re-benchmarking may be subject to revision based on the introduction of the WLA framework.

In the event of a major change that may represent a potential risk to regulatory oversight, such as a change in legislation, a re-organization, or incidents that might call into question the status of regulatory system, a follow-up visit or re-benchmarking activity should be scheduled to assess potential impact on the regulatory system.

6.11 Customization

The context and objective of benchmarking may differ from one country to another. Therefore, it is essential that the benchmarking methodology and tools are sufficiently flexible to fit the targeted country and purpose. Customization is the means by which the benchmarking methodology and tool are adjusted to meet the pre-set expectations and agreements between the MS and WHO. Nevertheless, customization does not alter or negatively impact the benchmarking process or tool. Rather, customization is meant to utilize the essential and applicable parts of the benchmarking process and tool.
The following examples of customization of the standard benchmarking process provide additional elaboration. The benchmarking process is intended to meet specific objectives and ensure the best use of resources. Benchmarking customization should not, by any means, compromise the assurance of the ML of the benchmarked regulatory system. Any proposed customization should be discussed, and agreement should be reached between the MS and WHO well in advance of the benchmarking process; discussions should be based on mapping of regulatory system and functions. Ideally, regulatory system and functions mapping should be part of the introductory visit or the self-benchmarking exercises.

6.11.1 Benchmarking of regulatory functions in different regulatory settings

The GBT is designed to be used across the spectrum of regulatory models and levels of sophistication, as well as across categories of medical products. Adaptation to the specific country context does not alter the GBT application or methodology, but rather has an impact on which regulatory functions, indicators, sub-indicators, and fact sheets are appropriate for the particular regulatory system and its current circumstances. The ability to adapt or ‘customize’ the GBT in this way is a strength of the tool and its associated methodology, as illustrated below and reflected in the TORs for a given benchmarking activity.

Adjustments are subject to discussion with the country. Examples of such adjustments include but are not limited to the following:

<table>
<thead>
<tr>
<th>Example situation</th>
<th>Suggested adjustment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Country requests benchmarking of medicines only.</td>
<td>Non-common regulatory functions (e.g., lot release) would not be included in the scope of the benchmarking.</td>
</tr>
<tr>
<td>Country does not conduct domestic or overseas GMP inspections (e.g., if no medical products are domestically manufactured and no overseas inspections are conducted because the reliance model is applied to ensure compliance with GMP for imported medical products).</td>
<td>The GMP part of the regulatory inspection (RI) function would be excluded from the scope of benchmarking. Nevertheless, good distribution practices (GDP) and good clinical practices (GCP) regulatory inspections would still apply as appropriate.</td>
</tr>
<tr>
<td>Country requests benchmarking of vaccines only while securing its vaccines through UN supply. As per WHO recommendations, the importing country would not conduct testing and lot release for WHO prequalified vaccines; instead, these two functions would be undertaken by the vaccine producing country.</td>
<td>NRA lot release (LR) and laboratory testing (LT) would be excluded from the scope of benchmarking.</td>
</tr>
<tr>
<td>Country requests benchmarking of whole blood and blood components only.</td>
<td>Registration and marketing authorization (MA) and NRA lot release (LR), as well as other sub-indicators that do not address whole blood or blood components (as indicated under the scope section in the fact sheets), should be excluded from the scope of the benchmarking process.</td>
</tr>
</tbody>
</table>
6.11.2 Rapid benchmarking

The “rapid (or abridged) benchmarking” programme is appropriate for use where the capacities of the regulatory system or functions are already well known. For example, the GBT may be used for benchmarking of the relevant regulatory system, within the context of self-benchmarking, facilitated self-benchmarking or formal benchmarking, up to a certain level of maturity for all or some regulatory functions. In practice, this means that the tool will be customised for the benchmarking of indicators and sub-indicators related to ML1 and ML2 for the regulatory system (and for certain other regulatory functions), while potentially benchmarking up to ML3 for certain other functions.

Similarly, rapid benchmarking may ignore some regulatory functions altogether if there is agreement with the relevant NRA and if this is compatible with the objectives of the rapid benchmarking exercise. For example, rapid benchmarking within the context of harmonization of registration requirements and processes for generic medicines would ignore non-bio-equivalence clinical trial studies, which may not be required for generic medicines.

In this latter example for generic medicines, the rapid benchmarking programme will focus on the following areas of the various regulatory functions:

   a) The existing policy, legal framework and organization.
   b) The human resource capacity to handle its mandate in terms of qualification, competencies, skills and experience of staff, and in terms of the number of staff.
   c) The authorities in charge of implementing medicine regulation as well as the institutional arrangements and collaborative mechanisms in place.
   d) The available infrastructure in terms of space and equipment, including vehicles, general equipment and information systems.
   e) Availability of a monitoring and assessment system or framework.
   f) Availability of systems for quick response in the event of public health threats and existence of systems or processes for risk management.
   g) The existing procedures for documentation, including a review of how the documents are managed, implemented and lead to the expected results by the NRA.
   h) The financial resources and the sustainability of the NRA.
   i) The extent to which any existing review and/or ongoing plans might already address the gaps or deficiencies identified above.

6.11.3 Decentralized regulatory system

Customization of the tool and related process may also occur when benchmarking a decentralized regulatory system where responsibilities for various functions are performed either at the central (or national) or state (or provincial) level. Prior mapping of different regulatory functions is essential to identify the institutions and levels of government responsible for different functions.

In this case, the tool may be customized to assess only those functions performed by state (or provincial) authorities, simplifying the self-benchmarking/benchmarking process. Similarly, regulatory functions performed by the central authorities would be benchmarked at the central level.

The scenario varies significantly from one country to another. Therefore, prior agreement between the relevant NRA and WHO is essential.

6.12 Other activities conducted for further measurement of regulatory performance

The vigilance field visit and observed audit of regulatory inspection are complementary to the formal WHO benchmarking activity. While the GBT remains the foundation for assessing regulatory inputs, processes, outputs and outcomes, the activities described below are meant to provide a more detailed picture of how certain regulatory functions operate through an expanded performance assessment
process. It is the intention of WHO to extend performance assessment activities within the context of the WLA framework.

6.12.1 Vigilance field visit

A field visit might be warranted prior to the formal benchmarking in order to document the performance of haemovigilance and medicine and vaccine vigilance programmes. Information and evidence collected through the field visit will be documented and used for the relevant sub-indicators of the vigilance regulatory function.

Further details can be found in the respective manual which summarizes different activities for preparing, conducting and reporting the vigilance field visit.

6.12.2 Observed audit of regulatory inspection

The observed audit aims to assess the performance of the regulatory inspection function with an emphasis on inspection activities and inspectors’ competency and attitude. The observed audit is normally conducted a few months to weeks prior to the formal benchmarking. Outcomes of the observed audit are documented and used for the relevant sub-indicators of the regulatory inspection function.

Further details can be found in the respective manual which summarizes different activities for preparing, conducting and reporting the WHO observed audit.

7. Roles and Responsibilities

7.1 National regulatory system (Authority)

WHO benchmarking is a voluntary process which is based on a country’s request. Consequently, the entity(ies) in charge of the national regulatory system is a main contributor to the benchmarking process and to its outcomes.

The entity(ies) in charge of the national regulatory system of medical products is responsible for:

- Expressing interest and communicating a request for WHO benchmarking, either for capacity building and RSS or for the purpose of recognition as a WLA. Countries request should follow the applicable WHO rules and procedures (e.g., channel the request through the CO).
- Allocating the necessary resources (e.g., human, financial, equipment and information management systems) to manage and support the benchmarking process.
- Assigning a multi-disciplinary team consisting of a sufficient number of staff from the applicable regulatory system and functions
- Assigning one (or a few) focal points for contact with WHO on benchmarking related subjects including access to the WHO information sharing platform.
- Following the roadmap and adhering to agree upon timelines for benchmarking related activities (e.g., introductory visit, self-benchmarking, and corrective and preventive action plan).
- Filling in the cGBT along with the relevant documented evidence and uploading this evidence into the WHO information sharing platform.
- Contributing to attainment of any necessary national clearances for benchmarking related activities.
• Interacting openly and constructively with WHO staff, consultants, and advisers including the benchmarking team during all benchmarking related activities.

If necessary, in order to ensure smooth and secure sharing of benchmarking related information which may be deemed confidential, the benchmarked NRA and WHO may engage in a Confidential Disclosure Agreement. Annex 4 of this manual can be used for this purpose.

7.2 WHO headquarters

WHO HQ (RSS team), in collaboration with six WHO ROs as well as relevant COs, is responsible for:

• Global Public Health Good\textsuperscript{16}: benchmarking policy, tools, databases, training (of ROs and partners on GBT-related aspects) and ensuring consistency in quality and in approach (as part of quality management approach);
• leading the benchmarking of regulatory systems seeking ML3 or ML4 status;
• leading the benchmarking of regulatory systems seeking to become a WLA
• leading the benchmarking of regulatory systems in vaccine producing countries
• assisting ROs, as requested, in the provision of specialized technical assistance; and
• development and maintenance of global regulatory databases and IT systems, including data management, data analysis, and regulatory intelligence.

WHO HQ, ROs and COs contribute to IDP implementation and to the monitoring of progress, as agreed upon between the three levels of WHO and made possible through available resources. These activities also include coordination of external support through the CIP. Whenever possible, coordination and monitoring of IDP implementation should be led by a designated resource at the country level.

7.3 WHO regional offices

Other than the activities listed above to which ROs contribute, ROs assume primary responsibility for:

• benchmarking and strengthening of regulatory systems at ML1 and ML2 and of regulatory systems seeking regional recognition\textsuperscript{17}; these activities are supported by HQ as necessary;
• providing oversight of and assistance to the processes of IDP implementation and monitoring of follow up;
• coordinating all activities and meetings with the NRA that involve the three levels of WHO; and
• acting as the official contact point with WRs on benchmarking activities.

ROs should also report to HQ any changes in the status of regulatory systems, given that the RSS team has the responsibility to maintain up-to-date global databases on the status of national regulatory systems.

\textsuperscript{16} Includes the maintenance and improvement of the GBT, this manual, associated SOPs and manuals and other guiding documents; establishment and maintenance of a roster of qualified assessors; and development of training materials for GBT assessors.

\textsuperscript{17} For example, NRAs of regional reference (NRAr) in WHO/AMR (PAHO).
7.4 WHO Country Office\textsuperscript{18}

The CO should be involved in all RSS activities, including benchmarking and capacity building, and should provide the necessary administrative and technical support to the benchmarking team. An example of administrative support which should be provided by CO includes, but is not limited to, serving as the liaison with the NRA and MOH.

As noted, coordination and monitoring of IDP implementation should be led, whenever possible, by a designated resource at the country level.

In all cases, WHO internal policies and procedures on engagement with countries should be respected and followed\textsuperscript{18}.

7.5 Responsible Officer

The designated Responsible Officer\textsuperscript{19} in HQ or in the RO is responsible for overseeing the planning and execution of regulatory system benchmarking and its follow up activities.

The responsibilities of the Responsible Officer are listed below\textsuperscript{20}:

a) Plan, schedule, and organize the regulatory system benchmarking (including pre-benchmarking steps), follow-up visits and re-benchmarking.

b) Coordinate with other WHO teams and specifically with the WHO PQT for the benchmarking of regulatory systems that oversee medical products that are prequalified or that are proposed for prequalification.

c) Ensure that the country’s invitation to undertake the benchmarking is received by WHO before the visit.

d) Commission a desk-based screening of regulatory system functions, if the regulatory system information is accessible through internet or any official published documentation.

e) Conduct or commission an introductory visit to the NRA prior to the benchmarking visit to explain the benchmarking tool and process, to determine the data that are available to WHO, to identify the additional data that are needed, and to initiate or plan a self-benchmarking process.

f) Provide support, if needed, to assist the NRA to perform the self-benchmarking, including, for example, the organization of the self-benchmarking workshop.

g) Approve candidate assessors for the regulatory system benchmarking, follow-up visits and re-benchmarking, determine their availability, provide their profiles to the country, and secure country clearance for their participation.

h) As required, brief new assessors and WHO staff on the purpose of the benchmarking and on the benchmarking tool and process and provide the assessors with access to the information sharing platform server and all relevant documents.

i) Assess understanding and secure agreement of the qualified GBT assessors by completing and signing confidentiality and conflict of interest forms prior to a visit.

\textsuperscript{18} Guidelines for working with WHO offices in countries, territories and areas, 8 October 2012.

\textsuperscript{19} It is the responsibility of the relevant leadership at HQ or ROs to designate the Responsible Officer according to the applicable rules and procedures. At WHO/HQ, the designated Responsible Officer is usually the RSS Team Lead.

\textsuperscript{20} The Responsible Officer assumes ultimate responsibility for ensuring that these steps are undertaken for each country engagement. The actual execution of many of these tasks, however, would normally be undertaken by the Team Leader or other designated WHO official with the exception of a), b), j) (review and sign-off), l), m), and n).
j) Prepare (or commission) and review documentation for each NRA visit, including the TORs and slide presentation to be used.

k) Ensure that an IDP is submitted to the benchmarked NRA following the formal benchmarking.

l) Ensure timeliness of all benchmarking related activities.

m) Initiate the process of IDP implementation whenever possible through sharing the IDP, including training needs, with the relevant WHO officers and discussing proposed training activities or requested technical support. Another approach (or possibly a complementary approach) is to utilize the resources of the CIP based on defined roles and responsibilities; when used, this approach is led by WHO.

n) Ensure that all relevant WHO staff at different organizational levels of HQ, RO and CO are kept informed of benchmarking visits and outcomes. This may also extend to external WHO parties, for example, engaged CIP participants.

7.6 Benchmarking team

This section focuses specifically on roles and responsibilities of the team members assigned for formal benchmarking.

The benchmarking team should be composed of qualified benchmarking assessors who are competent in their respective field of regulatory oversight. All invited regulatory assessors are selected based on their qualifications (as described under Section 8) and track record in regulatory excellence.

7.6.1 Team Leader

The Team Leader of each benchmarking is assigned by the designated Responsible Officer in charge of the regulatory strengthening programme and should be a WHO staff member.

The benchmarking Team Leader has the primary operational responsibility for planning and conducting the regulatory system benchmarking, and therefore the responsibility for ensuring that all assessors and the NRA staff are familiar with the benchmarking methodology. The Team Leader should also oversee the proper and timely development, distribution and archiving of the benchmarking report as per the relevant methodology and procedures included in this manual. The designated Responsible Officer, as noted above, has overall oversight responsibility for all steps involved in strengthening a given regulatory system.

The following responsibilities are assigned to the Team Leader:

a) Assemble the benchmarking team.

b) Prepare documentation for each NRA visit, including the TOR and the slide presentation to be used.

c) Meet and brief team members prior to the benchmarking; discuss the TOR, the agenda and the plans for the visit.

d) Divide team members into groups according to their experience and the expertise needed for the regulatory functions to be benchmarked. The number of assessors varies according to the size of the NRA and the country and complexity of the system and functions undergoing assessment. For more complex benchmarking activities, as in the case where the regulatory system is scattered over several institutions or levels (e.g., central and state or provincial levels), the WHO Responsible Officer may assign two assessors to each regulatory function in order to provide for a peer-validated assessment. Such decisions are made in agreement with the benchmarking Team Leader and are based on their understanding of the context and complexity of the relevant regulatory system. When used, paired assessors may be assigned.
more than one regulatory function. In less complex situations, one assessor per function may suffice.

e) Assign and clearly communicate roles, responsibilities and reporting hierarchy to every member of the team; this is especially important when multiple assessors are assigned to the same or similar functions (i.e., paired assessors).

f) Distribute an electronic copy of the cGBT to each team member to use when assessing the assigned function(s) according to the team member’s TOR for the visit.

g) Serve as the expert on the benchmarking process and on quality assurance.

h) Conduct the initial briefing meeting held at the beginning of the visit to present the objectives and expected outcomes of the visit and to reach formal agreement with the NRA on the agenda.

i) At the end of each day, meet with all team members to receive and discuss feedback, findings and recommendations from the different groups, and to share information and documents collected by team members (i.e., daily wrap-up session).

j) Chair and lead the discussion among the benchmarking team during the closed wrap up session conducted one day before the end of the benchmarking visit. The closed session is restricted to assessors and WHO staff, and the purpose is to present, defend and modify findings, observations, scores and recommended actions to address gaps.

k) Collect benchmarking data, including recommendations from all team members to be discussed at the debriefing meeting, and prepare the preliminary draft of the regulatory system benchmarking report (See Section 6.7, under preliminary draft report); this should include the first draft of the IDP. The Team Leader should copy and send the preliminary regulatory system benchmarking report to all team members.

l) Serve as the lead when presenting draft findings and recommendations to senior NRA officials and representatives of related institutions during the technical debriefing meeting and correct or amend the report as necessary based on further information and clarifications; the goal is to reach consensus (whenever possible) before presentation at the closeout meeting on the final day of the visit.

m) Anticipate and take the lead in resolving any potential issues that may arise. (See Section 6.7, under Dissenting opinions).

n) Conduct the closeout meeting held at the end of the benchmarking visit with the concerned authorities and staff. The Team Leader presents and explains draft findings, recommendations and the IDP, responds to questions or concerns, and explains subsequent steps and timeframes, including timeframe for resolution of critical deficiencies. Electronic copies of the presentation made at this meeting are provided to the NRA and to the relevant WHO RO and CO representatives.

o) Prepare the final report, and, following review by the designated Responsible Officer, post it on the information sharing platform server within the timelines stated above.

p) Ensure that all data entries relevant to the benchmarking are completed within the indicated timeframes, and, for benchmarking linked to prequalification of vaccines, ensure that the PQT Unit Head has received a copy of the report.

q) When necessary, coordinate with PQT and other relevant WHO teams, and convene an ad-hoc advisory committee to review the outcome of the benchmarking.

r) Ensure continuing follow-up of implementation of the IDP, including, when indicated, follow-up visits or re-benchmarking within the agreed timeframes.

### 7.6.2 Team members

Team members should be selected from the roster of qualified GBT assessors. The Responsible Officer, in discussion and agreement with the assigned Team Leader, will designate the proposed assessors.
The responsibilities of the team members include the following:

a) Review and sign the relevant administrative documents including invitation letter, confidentiality agreement, and declaration of interests (DOI).

b) Make necessary travel arrangements (e.g., book flights and obtain visa) as described in the invitation letter.

c) Create a user account and confirm access to the NRA information sharing platform site that is used to share reference documents and all visit information.

d) Read the TORs and the attached programme for the visit.

e) Read the WHO manual for benchmarking of the national regulatory system of medical products.

f) Read the benchmarking indicators and sub indicators, including relevant fact sheets, for assigned regulatory functions and the regulatory system. In case of any ambiguity, clarification should be sought from the Team Leader before benchmarking. The global benchmarking tool, including the fact sheets, is available at http://www.who.int/medicines/regulation/benchmarking_tool/en/.

g) Take and pass the necessary benchmarking training (see next section).

h) Ensure the ability to work on the cGBT, including, for example, the availability of a computing device with suitable configuration. Each team member should ensure that their laptop has updated antivirus software and that it has been scanned for any possible viruses or malware immediately before starting their benchmarking activities. Team members are requested not to create or use any hard copies. All related documents should be scanned and attached in electronic format.

i) Prior to the benchmarking visit read the self-benchmarking report prepared by the NRA, validated by WHO and uploaded to the information sharing platform.

j) Participate in all briefing sessions in preparation for the benchmarking visit and all group meetings during the visit.

k) Perform the benchmarking of assigned regulatory functions. If more than one person is assigned to the same function, team members should split the work among themselves so that the related function can be benchmarked in more detail; however, each assessor should consider the necessity of cross-referencing one another’s assessments. Proposed scores and recommendations should be discussed among assessors as well with the benchmarking team and with NRA staff for input and consensus building.

l) Deliver the following materials in a timely manner to the Team Leader:

   a) PowerPoint presentations using the WHO templates provided.

   b) An electronic folder with all documents reviewed; these should be numbered and named to match the indicators benchmarked (i.e., if not already available on the information sharing platform).

   c) The completed benchmarking tool software (cGBT).

m) Present and explain findings on behalf of the team assigned to a designated regulatory functions or system. Each team should select the best communicator.

n) Review comments provided by NRA on preliminary draft benchmarking report while respecting the relevant timelines.

o) When visiting facilities, team members should comply with the immunization requirements and bring with them a copy of their immunization certificates; there should be no waiver for any WHO team member, including WHO staff, for compliance with the established immunization requirements.

p) Obtain vaccinations or medicines that may be necessary to ensure health and safety of the team member during the visit.
It is essential that all team members are familiar with all documents described above and come fully prepared for the visit.

7.6.3 Observers

WHO may invite other participants as observers to benchmarking visits, including, for example, candidate assessors as noted above, regulators preparing for benchmarking in their countries, technical or development partners contributing to RSS under the CIP, and WHO staff working in other departments or units and whose work might be related to RSS.

As previously noted, a list of proposed benchmarking team members and observers, along with their curriculum vitae, is conveyed to the NRA for information and comment and to obtain government clearance for non-WHO assessors and observers.

No specific roles and responsibilities are assigned to the observers; however, similar to team members, observers should consider the following:

a) Review and sign the relevant administrative documents including invitation letter, confidentiality agreement, and DOI.

b) Make necessary travel arrangements (e.g., book flights and obtain visa) as described in the invitation letter.

c) When visiting facilities, observers should comply with the immunization requirements and bring with them a copy of their immunization certificates.

d) Obtain vaccinations or medicines which may be necessary to ensure health and safety of the team member during the visit.

e) Respect all applicable protocols and codes of ethics and conduct.

f) Observe one or more team members during the benchmarking activity; observers may seek some clarifications from the team members provided that the observers do not negatively impact the work of the team members.

g) Report back to their institutions about the benchmarking visit so that the objectives of the observation of the formal benchmarking are met.

In all cases, observers should not be actively involved in the benchmarking process (i.e., refrain from performing any assessment or interview).

8. Team members competencies and training

The expected competencies of assessors must be evaluated prior to selection to ensure high quality output from the benchmarking team and consistency in benchmarking visits.

A multi-disciplinary team will be assembled with the necessary experience, skills and abilities in dealing with the relevant regulatory functions, working effectively as a team, respecting diversity and exercising tact, diplomacy, performance under pressure, good judgment, and communication skills.

The scope of benchmarking should be considered when selecting assessors with the required expertise. For example, if the purpose of benchmarking is related to medicine or vaccine regulation, assessors with knowledge and experience in this field should be selected. In all cases, assessors should have adequate scientific and technical knowledge and experience to assess the assigned regulatory functions and product categories using GBT indicators.

A roster of qualified international experts eligible for benchmarking regulatory systems has been established and is maintained and regularly updated by WHO headquarters. This roster can be
utilized by WHO at all levels for the purpose of benchmarking related activities. Information available at regional levels will be used to develop and update the global roster of experts. In addition, ROs and COs could provide feedback to complete or update the global roster when needed, for example, when new personnel with required expertise are available, or when a former expert is no longer employed by an NRA. Further details on the procedure of establishment and maintenance of a roster of qualified GBT assessors, including their selection, qualification, competence and evaluation, can be found in the respective SOP (currently under development).

Before undertaking their duties as part of the benchmarking team, assessors must also successfully complete the necessary training on WHO benchmarking methodology and the use of the cGBT. Training on the use of the tool is available online (see figure below). The certificates issued following successful completion of the training are valid for two years.

The training on the conduct of benchmarking activities is being developed to complement this manual.

Training of junior assessors is also acquired from preparatory briefing sessions prior to the visit, from a system of mentorship provided by senior assessors, and from pairing with other assessors during activities.

![Global Benchmarking tool online training](image)

*Figure 7: GBT online training platform*

### 9. Code of conduct for benchmarking team, conflicts of interest and confidentiality

WHO values and relies upon the technical advice provided by leading subject matter experts in the context of its advisory and technical committees, meetings and other activities. Such advice contributes to the formulation of public health policies and norms that are promulgated by WHO for the benefit of MSs.

To ensure the integrity of such processes, it is critical that WHO staff and assessors appointed by WHO to benchmark regulatory systems:
a) fully and honestly disclose, in the DOI form, all relevant interests and biases that may give rise to real or perceived conflicts of interest;
b) spontaneously report, on an on-going basis, any material changes to their disclosed interests during the period in which the assessor serves WHO;
c) respect the confidential nature of the advisory function assigned by WHO and make no public statements regarding the assessor’s advice without prior consent from WHO;
d) refrain from engaging in any activity that may bring reputational harm to the WHO benchmarking process;
e) represent their views in a personal and individual capacity, keeping in mind the best interest of WHO as opposed to the views of their employers or other institutions or governments;
f) respect cultural differences and dress codes of the host country. Team members are advised to wear official attire for opening and closing meetings.

To reduce any potential conflicts of interest, team members, including WHO staff, should not be part of the formal benchmarking team if they have been involved in providing technical support, capacity building, advice or similar support to the NRA under assessment.

**Code of conduct during benchmarking activities:** The benchmarking team is led by a WHO Team Leader. The team members should respect the communication hierarchy established by the NRA and by the WHO Team Leader. Team members are expected to treat the NRA staff members with respect and exercise tact, diplomacy and good judgement. This is particularly important in instances when the NRA staff may be apprehensive about the outcomes of the benchmarking. It is important that the NRA staff feel comfortable when being interviewed.

Team members are to observe, collect and assess information and to formulate draft findings and recommendations. Team members should not simply communicate gaps or be perceived to be lecturing or in any way imposing their own way of undertaking regulatory activities.

The WHO team should not enter any premises without being invited by the relevant entity’s representative and should always be accompanied by an official representative of the NRA.

No document should be collected or copied without consultation with the Team Leader and prior authorization from the NRA, as the document may serve as official evidence of findings. Furthermore, benchmarking visits are generally “paper free” (i.e., paper copies are not normally collected as part of the benchmarking exercise).

**Confidentiality:** All documentation and information related to the benchmarking that are not in the public domain or that are not designated as non-confidential by the national authorities, must be considered by all benchmarking assessors and observers as strictly confidential. No report or benchmarking outcome shall be disclosed to any external parties unless disclosure has been approved by the relevant benchmarked authorities; in such instances, disclosure would be through designated WHO channels.

Prior to the benchmarking visit, the confidentiality agreement and DOI forms must be signed by all non-WHO team members. Completed and signed confidentiality and DOI forms should be checked and archived by WHO Team Leader and Responsible Officer prior to the benchmarking visit. The signed forms will be available at WHO and may be shared with the relevant authorities, if required. WHO staff are similarly bound by confidentiality provisions as stated in the WHO code of conduct.

The WHO team should never mention the findings from other benchmarking visits as this information is strictly confidential.

This section will be updated with the introduction of the WLA framework.
10. Complaints management (appeal process)

In the event that the NRA disagrees with the findings and assigned maturity rating from a formal benchmarking activity, and if the benchmarking activities were led by HQ, a formal appeal of the findings may be submitted to WHO through the CO. The relevant WHO Director shall reply to such appeals within 60 calendar days. The appeal process may involve an ad hoc committee to advise on the submitted appeal. For activities led by the RO, the complaint and appeal process should be managed according to the respective RO arrangements and procedures.

Further details on the appeal process can be found in the respective SOP (currently under development).

11. Information management systems

11.1 Computerized benchmarking tool

The benchmarking process is an information intensive exercise that involves the collecting, sharing, processing, analysing and storing of large amounts of information, much of which is of a confidential nature. The cGBT is an electronic means to facilitate and manage the aforementioned activities during the benchmarking process. The cGBT contributes to resource-saving for the NRA as well as for WHO within the context of the benchmarking (i.e., more efficient use of NRA staff, WHO staff and external assessors).

The cGBT facilitates all steps of the benchmarking process, including advance preparation, conduct, conclusions and automated report preparation. Also, the cGBT facilitates information-sharing and transparency.

The latest version of the cGBT, the cGBT manual and an online training module are available to NRAs on the secure WHO RSS information sharing platform (link: https://worldhealthorg.sharepoint.com/sites/ws-att/RSS_Benchmarkingtool/Forms/AllItems.aspx) and can also be requested by other interested stakeholders through the designated Responsible Officer.

The cGBT is a desktop application, which is available on Windows and macOS. The minimum system requirements to run the application are stated below:

**Windows version**
- Processor: 64-bit (x64) processor
- RAM: 2 GB minimum (4 GB recommended)
- Operating Systems: 64- bit (x64) Windows 7 or later

**Mac version**
- Processor: 64-bit (x64) processor
- RAM: 2 GB minimum (4 GB recommended)
- Operating Systems: 64- bit (x64) macOS (an update to the latest macOS version is recommended)

**cGBT Online training:**
The links to the computer-based training of the cGBT are provided below. From this training, users can learn about the cGBT and receive instruction on its use.
11.2 Distribution and archiving of reports

**Master files:** The electronic copy of the final report is stored at the WHO NRA information sharing platform in a password-protected folder. This master file includes all documents collected prior to, during or following the formal benchmarking activity; all correspondence, pre-screening information, analyses, presentations, and pictures taken by team members during visits to the NRA; and any other reports related to the benchmarking process.

![Figure 8: WHO NRA information sharing platform – Main menu](image)

All documents and reports in the master file are archived as confidential documents with restricted access. All archives are kept as electronic documents and distributed only on a need-to-know basis. Requests for official copies of master file documents should be submitted to WHO headquarters. Distribution of copies, either inside or outside WHO, is possible only if WHO has obtained clearance from the NRA.

Working documents used by the team members should be destroyed. Access of external team members to the information sharing platform should be discontinued when the report is finalized and submitted to the NRA.

**Access to the WHO information sharing platform server:** Access to the WHO information sharing platform is controlled and password restricted.

The RSS SharePoint is access-restricted. Access should be granted only after the confidentiality agreement and the DOI are signed. The SharePoint administrator can then grant access to users:

1. **For WHO staff:** WHO staff can use their WHO identity management system (WIMS) account credentials to access the WHO secure information sharing platform after receiving the SharePoint invitation.
2. **For non-WHO staff** (e.g., external team members): non-WHO staff can gain access using their personal or organisational account after receiving an invitation from the SharePoint administrator.

   - Users can receive an invitation as shown below. This invitation indicates that their account is recognised by the organisation and the user can proceed and log in using their existing credentials.

   Here's the site that “Name of SharePoint Administrator” shared with you.

   Go to Regulatory Systems Strengthening (RSS)
   Follow this site to get updates in your newsfeed.

   ![Get the SharePoint mobile app!](image)

   - Alternatively, users can receive an invitation as shown below. This invitation means that user is required to link their email address to a Microsoft identity for authentication purposes.

   ![Office 365](image)

   Hello,

   Go To Regulatory Systems Strengthening (RSS)

   ![Office 365](image)

   Instructions:
   - User should follow the screen prompts and instructions to initiate setup (as shown below).
   - Please be sure to check for the verification code that will be sent to the user by email during the verification process.
   - The user should save and remember the password because the password and email address will be needed to log into WHO resources and any other Microsoft Cloud resources that are needed in the future.
When logging in for the first time (or if asked to link to a Microsoft identity), user will then receive the prompt below. The user should “Accept” WHO review permissions and authenticate the login. This step concludes the authentication process.

Distribution of the final benchmarking report: The final benchmarking report is posted on the NRA information sharing platform. Distribution of the report is restricted to NRA and WHO staff,
including WHO regional and country staff who either have been involved in the benchmarking or have responsibility for its oversight. Prior to its issuance, the RO and CO should specify those to whom the report shall be distributed and should ensure confidentiality of all reports distributed. A list of all WHO staff receiving the report should be communicated to WHO headquarters.

12. Transparency and information-sharing

As noted in the WHO Constitution, “Informed opinion and active co-operation on the part of the public are of the utmost importance in the improvement of the health of the people.” WHO is committed to transparency in all its activities. RSS and regulatory system benchmarking are not exceptions in this context. Towards this end, WHO has made the GBT publicly available. This manual, essential to a proper understanding of how the GBT is applied in benchmarking of regulatory systems, is also available on the WHO website.

WHO considers transparency of benchmarking operations and outcomes critical to promoting RSS and to enhancing reliance among regulatory authorities. While benchmarking information and outcomes are owned by the relevant MS, there are many incentives for countries to share their information. The key among these are to facilitate capacity-building support, increase public trust, enhance regulatory cooperation, and promote trade and export of quality medical products.

As noted, the consent-based sharing of benchmarking activities and results, notably the IDP, is necessary to enabling a coordinated approach to capacity-building. Sharing of this information also serves to mobilize donor support for meaningful capacity-building efforts.

If necessary, in order to ensure smooth and secure sharing of benchmarking related information which may be deemed confidential, the benchmarked NRA and WHO may engage in a Confidential Disclosure Agreement. Annex 4 of this manual can be used for this purpose.

WHO intends to introduce greater transparency of benchmarking outcomes with the introduction of the WLA framework. While still under development, one could foresee two levels of transparency involving: 1) the public, and 2) other NRAs that have also gone through the WLA process (i.e., via a secure platform).

As interim measures, WHO encourages the disclosure of the benchmarking outcomes as follows:

1. For regulatory systems benchmarked as ML3 and ML4, the outcomes of the benchmarking results would be published on the WHO website as part of the pre-agreement reached related to the benchmarking exercise.
2. Upon request, a detailed benchmarking data of a particular regulatory system can be shared with donors, implementation partners, and other countries, provided that the consent of the NRA to share its data with the requesting entity is obtained. Such approach is also central to a proactive CIP effort to provide regulatory support.
3. Selected anonymous data can be disclosed for the purpose of highlighting key regulatory challenges and trends.

More broadly speaking, transparency is a key enabler for adopting new, more efficient ways of conducting regulatory operations, both locally and internationally. It is incumbent upon NRAs to practice transparency in regulatory operations and decisions not only as a fundamental principle of GRPs and “open government”, but also as a way to build trust and maximize opportunities for cooperation and reliance as part of a shared regulatory community responsibility. In other words, regulatory authorities are an increasingly important audience for and beneficiary of measures that promote transparency in regulation through the publishing and sharing of regulatory information.

A high level of public trust and confidence in the regulation of medical products is in the best interest of all stakeholders, including, patients, consumers, governments, healthcare professionals,
manufacturers, distributors and procurement agencies. Trust depends, in part, on regulations that are seen to be proportionate to policy objectives, that are developed openly and transparently, that are effective in achieving their goals, and that are enforced appropriately, fairly and in a timely manner. Transparency, then, is the hallmark of a well-functioning regulatory system. Transparency indicators embedded within the GBT consequently provide an important measure of the maturity of a regulatory system.
13. References

This manual was developed based on several other documents and guidance including those belonging to GBT predecessor tools (e.g., WHO vaccine assessment tool and PAHO tools). The below non exhaustive list is provided to recognize the valuable inputs which were taken into account to develop and produce this manual.

5. Abbreviated procedure for designating regulatory authorities of regional reference for medicines (NRAr), WHO/AMRO (PAHO)
9. Report of the international consultation of experts on regulatory systems strengthening: policy, strategic directions, benchmarking process and indicators
10. Regulation of vaccines: building on existing drug regulatory authorities. WHO/V&B/99.10
11. Training manual: licensing, lot release, laboratory access. WHO/V&B/01.16
14. Acknowledgment

The Regulation and Safety (REG) Unit under the Regulation and Prequalification Department of the World Health Organization would like to thank all Member States, partners, stakeholders, entities, individuals, and WHO staff who over the years have so willingly given their time and expertise, not only for their suggestions and contributions to this manual but for their valuable contribution to the development and implementation of the WHO global benchmarking tool. We acknowledge their continued support in ensuring the maintenance as well as success and sustainability of the WHO regulatory systems strengthening programme.

The RSS programme has been supported with the technical and financial assistance of various organizations and partners. Without their support this work would not have been possible.

The REG unit would like to acknowledge the following individuals and entities who contributed to this work, reflecting the global dimension of this effort.

<table>
<thead>
<tr>
<th>Participants of the WHO International consultation of experts to review the WHO programme, policy, process and indicators for strengthening NRAs regulating health products and technologies, January 2015</th>
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<tr>
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Participants of the WHO International consultation of experts to respond to the comments received on the draft GBT, June – July 2018

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Members of the Blood Regulators Network (BRN) who contributed to integration of the blood assessment criteria into the GBT and the creation of the GBT plus blood

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WHO Secretariat

Country offices


Regional offices

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Headquarters

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Bernadette; Yuyun Maryuningsih; Yvonne Melounou; Zafar Mirza.

**Partners who contributed technically, including through comments, or financially to the development, maintenance and implementation of the GBT**

- Bill & Melinda Gates Foundation (BMGF)
- Gavi, the Vaccine Alliance
- Pandemic Influenza Preparedness (PIP) Framework
- U.S. Food and Drug Administration (FDA)
- United Nations Children's Fund (UNICEF)
- International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
- International Generics and Biosimilars Medicines Association (IGBA)
- International Society of Pharmacovigilance (ISoP)
- United States Pharmacopeia (USP), Promoting the Quality of Medicines (PQM) Program
- Management Sciences for Health (MSH)

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**Editor of the GBT and the benchmarking manual**

Bruce Meade, Meade Biologics LLC, United Stated of America
15. Annexes

Annex 1: List of documents including manuals and procedures complementing the WHO benchmarking manual

This manual is complemented by several other document as below listed. Some of the these documents are publicly available while others are for the internal use by the WHO and consequently not published.

5. Standard Operating Procedure for Preparation for Formal Benchmarking Missions (including composition of the team, information sharing, DOI and CA).
Annex 2: Generic terms of reference (TORs): formal benchmarking

The following generic terms of reference serve as a template in drafting TORs for formal benchmarking.

STRENGTHENING NATIONAL REGULATORY SYSTEMS
WHO formal benchmarking mission
COUNTRY: add country name in CAPITAL letters
PROPOSED DATE: indicate dates

TERMS OF REFERENCE

BACKGROUND
The World Health Assembly (WHA) resolution 67.20 on regulatory systems strengthening for medical products recognizes that effective regulatory systems are an essential component of health system strengthening, contribute to better public health outcomes and are necessary to the implementation of universal health coverage*. The resolution also recognizes that inefficient regulatory systems can be a barrier to access to safe, effective and quality medical products.

The World Health Organization (WHO) supports countries in strengthening regulatory systems as a means of promoting equitable access to quality assured medical products. An important area of support involves the benchmarking of regulatory systems as mandated by the WHA 67.20, which calls upon WHO to apply assessment tools to generate and analyze evidence of regulatory system performance; facilitate the formulation and implementation of institutional development plans (IDPs); and provide technical support to national regulatory authorities (NRAs) and governments.

The benchmarking referred to in WHA 67.20 implies a structured and documented process by which Member States can identify and address gaps with the goal of reaching a level of regulatory oversight commensurate with a stable, well-functioning and integrated regulatory system. The global benchmarking tool (GBT) represents the primary means by which WHO assesses regulatory systems. The GBT represents the product of over three decades experience assessing NRAs under the five-step capacity-building model for regulatory systems strengthening (RSS).

These TORs are designed for the formal benchmarking of the NRA and other relevant regulatory institutions of name of country, in particular the name of NRA and any affiliated institutions that form part of the benchmarking mission.

Include a summary of prior engagement with the NRA, including self-benchmarking and formal benchmarking missions.

These TORs outline the objectives, expected outcomes, deliverables, methodology and scope of the formal benchmarking exercise.

OBJECTIVES
The objective of the workshop is to conduct a formal benchmarking of the regulatory programme for scope: medicines, vaccines and/or blood and blood products in country name.

Specific objectives of the mission:
1. Inform name of NRA and other relevant regulatory institutions of name of country on the WHO RSS programme and the WHO GBT;

2. Benchmark the national regulatory system and functions against the WHO GBT and measure the maturity of the system; and

3. Update the institutional development plan (IDP) for name of NRA and other relevant regulatory institutions of name of country and agree on a roadmap for its implementation.

EXPECTED OUTCOMES
At the end of the mission, the following outcomes are expected:

1. Documented status of the national regulatory systems, their functions and maturity level (ML);
2. Identified strengths and gaps for the regulatory system; and
3. Agreement on IDP to build upon identified strengths and address areas for improvement.

DELIVERABLES
1. A presentation of findings to the NRA, other relevant regulatory institutions and the WHO Country Office, including measures required to update or amend the final score of indicators or sub-indicators;
2. A draft benchmarking report of the national regulatory system and functions with documented status (ML) of the NRA and other relevant regulatory institutions of name of country; and
3. A detailed IDP including a training and/or technical support plan and a roadmap for its implementation.

METHODOLOGY
The WHO GBT revision and version number will be used to assess the regulatory system and functions. The benchmarking exercise is prepared, organized and conducted according to quality management system principles and the benchmarking methodology is described in relevant manuals and documents available at the WHO NRA information sharing platform:

https://workspace.who.int/sites/att/default.aspx

Guidance documents include the Manual for benchmarking of the national regulatory system of medical products and formulation of institutional development plans, revision dated add date.

The benchmarking exercise will identify strengths, gaps and deficiencies and measure ML of the regulatory system and its component regulatory functions. WHO will perform a desk review of existing information and populate the benchmarking tool prior to the mission.

All previous reports and information are archived and stored at the WHO NRA share point site at the following address: http://workspace.who.int/sites/ATT/default.aspx, under the country name site.

The mission is coordinated between WHO HQ and WHO Regional Office (RO) as well as the WHO Country Office (CO) in country name.

It is imperative that a focal person is appointed by the name of NRA to coordinate the on-site visit with the various departments and institutions involved.

WHO will fund the travel of the WHO team and will organize flight bookings, hotel booking and visa requests.

DATE OF THE MISSION
The WHO mission will take place dates of the mission.

SCOPE
The scope of the benchmarking exercise will cover indicate scope of benchmarking mission, i.e., medicines, vaccines, and/or blood/blood products. Assessors will review relevant documents (i.e., national medical products policy, legislation, guidelines, plans, procedures and other relevant documents) and identify relevant
departments, institutions and other organizations directly or indirectly involved in medicines, vaccine and/or blood/blood product regulation.

The benchmarking exercise will focus on the regulatory system for medicines, vaccines and/or blood/blood products, including the following:

1. Regulatory policy, legal framework and organizational setup.
2. Regulatory and administrative guidelines, documents, procedures and plans.
3. Financial resources and sustainability.
4. Human resource capacity to undertake the regulatory mandate in terms of qualifications, competencies, skills, and experience.
5. Legal provisions and documents, including how they managed, implemented and lead to expected results.
6. Monitoring and assessment framework and system.
8. System of rapid response in the event of public health threats.
9. Extent to which existing reviews and/or ongoing plans might address identified gaps.

RELEVANT INSTITUTIONS AND PERSONS

The team will visit list all entities of the NRA, affiliated institutions and other key stakeholders such as expanded programme on immunization (EPI) responsible for the following functions:

1. National Regulatory System (RS)
2. Registration and Marketing Authorization (MA)
3. Vigilance (VL)
4. Market Surveillance and Control (MC)
5. Licensing Establishments (LI)
6. Regulatory Inspection (RI)
7. Laboratory Access and Testing (LA)
8. Clinical Trials Oversight (CT)
9. NRA Lot Release (LR)

WHO TEAM

The WHO benchmarking team will be composed of regulatory experts from NRAs, National Professional Officers (NPOs) in the WHO Country Office (WCO), if available, and the WHO RO under the leadership of experts from WHO HQ.

The proposed composition of the WHO benchmarking team and respective functions to be assessed are provided below. 

Indicate the names, titles, positions, duty stations and assigned functions for each benchmarking assessor.

<table>
<thead>
<tr>
<th>Duty Station/Country</th>
<th>Name</th>
<th>Title</th>
<th>Regulatory Function(s)</th>
<th>Institutional Affiliation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>WHO staff title, temporary adviser, WHO consultant, other</td>
<td>Team Leader, assigned regulatory function(s) or IT support</td>
<td>WHO office, home organization, other</td>
</tr>
</tbody>
</table>

PROGRAMME

The WHO visit will be conducted according to the programme below.

A generic outline is provided below as a basis for developing the benchmarking mission programme.
<table>
<thead>
<tr>
<th>Start</th>
<th>End</th>
<th>Session and location</th>
<th>Institutions and individuals involved</th>
</tr>
</thead>
<tbody>
<tr>
<td>14:00</td>
<td>18:00</td>
<td>Benchmarking team meeting at hotel</td>
<td></td>
</tr>
</tbody>
</table>

*Date: arrival and preparations of WHO team*

<table>
<thead>
<tr>
<th>Start</th>
<th>End</th>
<th>Session and location</th>
<th>Institutions and individuals involved</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:00</td>
<td>11:30</td>
<td>Opening remarks</td>
<td>Name of NRA representatives</td>
</tr>
<tr>
<td></td>
<td></td>
<td>a. Name of NRA representative</td>
<td>WHO Country Representative (or delegate)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>b. WHO Country Representative</td>
<td>Name of RO regional advisors/representatives</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WHO HQ: Presentation of WHO RSS programme, mission objectives, expected outcomes, work programme, and team of assessors</td>
<td>WHO benchmarking team</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NRA overview of the national regulatory system</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>1. General overview of the national regulatory system</td>
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<tr>
<td></td>
<td></td>
<td>(10 min)</td>
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<tr>
<td></td>
<td></td>
<td>2. Registration and marketing authorization</td>
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<tr>
<td></td>
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<td>(10 min)</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>3. Vigilance (10 min)</td>
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<tr>
<td></td>
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<td>4. Market surveillance and control</td>
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<td></td>
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<td>(10 min)</td>
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<tr>
<td></td>
<td></td>
<td>5. Licensing premises (10 min)</td>
<td></td>
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<td></td>
<td></td>
<td>6. Regulatory inspections (10 min)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>7. Laboratory access and testing</td>
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<td></td>
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<td>(10 min)</td>
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<td>8. Clinical trials oversight</td>
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<td>(10 min)</td>
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<td></td>
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<td>9. Lot release (10 min)</td>
<td></td>
</tr>
<tr>
<td>11:30</td>
<td>12:30</td>
<td>Benchmarking of regulatory functions by the assigned benchmarking streams begins</td>
<td>Plenary/interview</td>
</tr>
<tr>
<td>12:30</td>
<td>13:30</td>
<td>Lunch break (light lunch or lunch boxes recommended)</td>
<td></td>
</tr>
<tr>
<td>13:30</td>
<td>17:30</td>
<td>Benchmarking of regulatory functions by the assigned benchmarking streams (continued)</td>
<td>Plenary/interview</td>
</tr>
<tr>
<td>17:30</td>
<td>18:00</td>
<td>Wrap up of the day and review of next day’s programme</td>
<td>WHO benchmarking team (closed meeting)</td>
</tr>
</tbody>
</table>

*Date: first day of WHO benchmarking mission*

<table>
<thead>
<tr>
<th>Start</th>
<th>End</th>
<th>Session and location</th>
<th>Institutions and individuals involved</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:00</td>
<td>17:30</td>
<td>Benchmarking of different regulatory functions by the assigned benchmarking streams (continued)</td>
<td>Plenary/interview</td>
</tr>
<tr>
<td>17:30</td>
<td>18:00</td>
<td>Wrap up of the day and review next day’s programme</td>
<td>WHO benchmarking team (closed meeting)</td>
</tr>
</tbody>
</table>

*Date: second day of benchmarking mission*

<table>
<thead>
<tr>
<th>Start</th>
<th>End</th>
<th>Session and location</th>
<th>Institutions and individuals involved</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:00</td>
<td>17:30</td>
<td>Benchmarking of different regulatory functions by the assigned benchmarking streams (continued)</td>
<td>Plenary/interview</td>
</tr>
<tr>
<td>17:30</td>
<td>18:00</td>
<td>Wrap up of the day and review next day’s programme</td>
<td>WHO benchmarking team (closed meeting)</td>
</tr>
</tbody>
</table>

*Date: third day of benchmarking mission*

<table>
<thead>
<tr>
<th>Start</th>
<th>End</th>
<th>Session and location</th>
<th>Institutions and individuals involved</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:00</td>
<td>17:30</td>
<td>Benchmarking of regulatory functions by the assigned benchmarking streams (continued)</td>
<td>Plenary/interview</td>
</tr>
<tr>
<td>Start</td>
<td>End</td>
<td>Session and location</td>
<td>Institutions and individuals involved</td>
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<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>17:30</td>
<td>18:00</td>
<td>Wrap up of the day and review of next day’s programme</td>
<td>WHO benchmarking team (closed meeting)</td>
</tr>
</tbody>
</table>

**Date:** fourth day of benchmarking mission

<table>
<thead>
<tr>
<th>Start</th>
<th>End</th>
<th>Session and location</th>
<th>Institutions and individuals involved</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:00</td>
<td>11:00</td>
<td>➢ Wrap up session of WHO team: review of findings of individual work streams ➢ Discussion and agreement on findings and recommendations to be included in the IDP</td>
<td>WHO benchmarking team (closed meeting)</td>
</tr>
<tr>
<td>11:00</td>
<td>15:00</td>
<td>Drafting of the benchmarking report by the different work streams (includes light working lunch)*</td>
<td>WHO benchmarking team (closed meeting)</td>
</tr>
</tbody>
</table>
| 15:00  | 17:30 | Presentation of preliminary findings to *name of NRA* senior management for comment and discussion of issues, if any, and how to address | • *name of NRA* senior management  
  • WHO benchmarking team |

**Date:** fifth and final day of benchmarking mission

<table>
<thead>
<tr>
<th>Start</th>
<th>End</th>
<th>Session and location</th>
<th>Institutions and individuals involved</th>
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</thead>
<tbody>
<tr>
<td>09:00</td>
<td>13:00</td>
<td>Finalization of findings and recommendations</td>
<td>WHO benchmarking team (closed meeting)</td>
</tr>
<tr>
<td>13:00</td>
<td>14:00</td>
<td>Break (light lunch or lunch boxes recommended)</td>
<td></td>
</tr>
</tbody>
</table>
| 14:00  | 15:30 | ➢ WHO presentation of assessment findings and recommendations, including IDP ➢ Discussion | • *name of NRA* representatives  
  • WHO Representative (or delegate)  
  • *name of RO* regional advisors/representatives  
  • WHO benchmarking team |
| 15:30  | 16:00 | Final remarks and adjournment                            | Plenary                                                                  |
| to be scheduled |  | Debrief of WHO Representative (WR)                                      | CO and WHO benchmarking team                                           |

* Includes scoring of indicators and sub-indicators, summary of each function, major findings and progress, IDP, presentation for debriefing session, lists of institutions visited and persons met, and list of evidence uploaded to NRA information sharing platform and referenced in computerized GBT.

**LIST OF DOCUMENTS AND INFORMATION REQUIRED FOR THE BENCHMARKING EXERCISE**

Information requested below should be provided for all institutions responsible for the regulatory system to be benchmarked.

1. List of staff of the institutions designated to meet with WHO benchmarking team (name, function, title, physical and email addresses, telephone and fax numbers)
2. Structural or governance relationships between all institutions or organizations involved in medicines, vaccines and/or blood/blood product regulation
3. Organogram of the institutions to be visited (including list of staff, titles and qualifications)
4. Presentations on the regulatory system and functions to be benchmarked
5. Legal mandates and acts for the establishment of NRA
6. Mission, vision and objectives of the NRA
7. Acts, laws, decrees, regulations and other legal provisions regarding the national regulatory system, including its implementation, enforcement and financing
8. Strategic and operational plans
9. Emergency preparedness framework and plans
10. Relevant regulatory and administrative guidance documents and guidelines published or in development
11. Quality management system quality manual
12. List of standard operating procedures and other relevant internal procedures
13. Lists of and mandates for technical and expert advisory committees, together with a list of external experts and their qualifications
14. Training and career development programs, including list of training activities, numbers trained, and any impact assessment reports
15. Monitoring and assessment framework
16. Performance targets for regulatory activities and workload metrics
17. Self-assessment tools and manuals, external audits, annual reports and current IDP
18. Current list of approved medicines, vaccines and/or blood/blood products
19. Stakeholder engagement framework, transparency policies and description of information publicly available
20. Website address(es), including those in English, if available
21. Other documents relevant to the benchmarking exercise

Additional documents may be requested depending on the regulatory program to be benchmarked, for example:

- Description of and key individuals involved in the EPI
- National pandemic influenza preparedness plan
- National deployment and vaccination plan for pandemic influenza vaccines
Annex 3: Confidentiality undertaking and declaration of interest for WHO benchmarking assessors

CONFIDENTIALITY UNDERTAKING

Should be sent with the invitation or appointment letter

1. The World Health Organization (WHO), acting through its Department of , has access to certain information relating to , which information WHO considers to be proprietary to itself or to parties collaborating with it (hereinafter referred to as "the Information").

2. The Undersigned, as a member of the advisory meeting, group or committee (collectively referred to as the "the Advisory Process"), may have access to the Information in the course of his/her participation in the Advisory Process (whether at or in relation to Advisory Process meetings, internet-based collaborative workspaces, telephone conferences or otherwise).

3. WHO is willing to provide the Undersigned the Information, or arrange for the provision of the Information to the Undersigned, for the purpose of performing his/her responsibilities in connection with the activities of the Advisory Process ("the Purpose"), provided that the Undersigned undertakes to treat the Information as confidential and proprietary, and to disclose it only to persons who have a need to know for the Purpose and are bound by like obligations of confidentiality and non-use as are contained in this Undertaking.

4. The Undersigned undertakes to regard the Information as confidential and proprietary to WHO or parties collaborating with WHO and agrees to take all reasonable measures to ensure that the Information is not used, disclosed or copied, in whole or in part, other than as provided in this Undertaking, except that the Undersigned shall not be bound by any such obligations if and to the extent he/she is clearly able to demonstrate that the Information:

   a) was known to him/her prior to any disclosure by or for WHO to the Undersigned; or
   b) was in the public domain at the time of disclosure by or for WHO to the Undersigned; or
   c) becomes part of the public domain through no fault of the Undersigned; or
   d) becomes available to the Undersigned from a third party not in breach of any legal obligations of confidentiality.

5. The Undersigned also undertakes not to communicate the deliberations and decisions of the Advisory Process to third parties except as agreed by WHO.

6. If requested to do so, the Undersigned agrees to return to WHO any and all copies of the Information.

.../..
7. The obligations of the Undersigned shall survive the termination of his/her membership in the Advisory Process.

8. Any dispute relating to the interpretation or application of this Undertaking shall, unless amicably settled, be subject to a conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or, in the absence of agreement, with the UNCITRAL rules of arbitration. The parties shall accept the arbitral award as final.

Name: 
Signature: 
Date:
DECLARATION OF INTERESTS FOR WHO EXPERTS

WHO's work on global health issues requires the assistance of external experts who may have interests related to their expertise. To ensure the highest integrity and public confidence in its activities, WHO requires that experts serving in an advisory role disclose any circumstances that could give rise to a potential conflict of interest related to the subject of the activity in which they will be involved.

All experts serving in an advisory role must disclose any circumstances that could represent a potential conflict of interest (i.e., any interest that may affect, or may reasonably be perceived to affect, the expert's objectivity and independence). You must disclose on this Declaration of Interest (DOI) form any financial, professional or other interest relevant to the subject of the work or meeting in which you have been asked to participate in or contribute towards and any interest that could be affected by the outcome of the meeting or work. You must also declare relevant interests of your immediate family members (see definition below) and, if you are aware of it, relevant interests of other parties with whom you have substantial common interests and which may be perceived as unduly influencing your judgement (e.g. employer, close professional associates, administrative unit or department). Please note that not fully completing and disclosing all relevant information on this form may, depending on the circumstances, lead WHO to decide not to appoint you to WHO advisory bodies/functions in the future.

Please complete this form and submit it to WHO Secretariat if possible at least 4 weeks but no later than 2 weeks before the meeting or work. You must also promptly inform the Secretariat if there is any change in this information prior to, or during the course of, the meeting or work. All experts must complete this form before participation in a WHO activity can be confirmed. Please note that not fully completing and disclosing all relevant information on this form may, depending on the circumstances, lead WHO to decide not to appoint you to WHO advisory bodies/functions in the future.

Answering "Yes" to a question on this form does not automatically disqualify you or limit your participation in a WHO activity. Your answers will be reviewed by the Secretariat to determine whether you have a conflict of interest relevant to the subject at hand. One of the outcomes listed in the next paragraph can occur depending on the circumstances (e.g, nature and magnitude of the interest, timeframe and duration of the interest).

The Secretariat may conclude that no potential conflict exists or that the interest is irrelevant or insignificant. If, however, a declared interest is determined to be potentially or clearly significant, one or more of the following three measures for managing the conflict of interest may be applied. The Secretariat (i) allows full participation, with public disclosure of your interest; (ii) mandates partial exclusion (i.e., you will be excluded from that portion of the meeting or work related to the declared interest and from the corresponding decision making process); or (iii) mandates total exclusion (i.e., you will not be able to participate in any part of the meeting or work).

All potentially significant interests will be disclosed to the other participants at the start of the activity and you will be asked if there have been any changes. A summary of all declarations and actions taken to manage any declared interests will be published in resulting reports and work products. Furthermore, if the objectivity of the work or meeting in which you are involved is subsequently questioned, the contents of your DOI form may be made available by the Secretariat to persons outside WHO if the Director-General considers such disclosure to be in the best interest of the Organization, after consulting with you. Completing this DOI form means that you agree to these conditions.

If you are unable or unwilling to disclose the details of an interest that may pose a real or perceived conflict, you must disclose that a conflict of interest may exist and the Secretariat may decide that you be totally recused from the meeting or work concerned, after consulting with you.

<table>
<thead>
<tr>
<th>Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institution:</td>
</tr>
<tr>
<td>Email:</td>
</tr>
</tbody>
</table>
Date and title of meeting or work, including description of subject matter to be considered (if a number of substances or processes are to be evaluated, a list should be attached by the organizer of the activity):

Please answer each of the questions below. If the answer to any of the questions is “yes”, briefly describe the circumstances on the last page of the form.

The term "you" refers to yourself and your immediate family members (i.e., spouse (or partner with whom you have a similar close personal relationship) and your children). "Commercial entity" includes any commercial business, an industry association, research institution or other enterprise whose funding is significantly derived from commercial sources with an interest related to the subject of the meeting or work. "Organization" includes a governmental, international or non-profit organization. "Meeting" includes a series or cycle of meetings.

EMPLOYMENT AND CONSULTING

Within the past 4 years, have you received remuneration from a commercial entity or other organization with an interest related to the subject of the meeting or work?

1a Employment

Yes □ No □

1b Consulting, including service as a technical or other advisor

Yes □ No □

RESEARCH SUPPORT

Within the past 4 years, have you or has your research unit received support from a commercial entity or other organization with an interest related to the subject of the meeting or work?

2a Research support, including grants, collaborations, sponsorships, and other funding

Yes □ No □

2b Non-monetary support valued at more than US $1000 overall (include equipment, facilities, research assistants, paid travel to meetings, etc.)

Yes □ No □

Support (including honoraria) for being on a speakers bureau, giving speeches or training for a commercial entity or other organization with an interest related to the subject of the meeting or work?

INVESTMENT INTERESTS

Do you have current investments (valued at more than US $5 000 overall) in a commercial entity with an interest related to the subject of the meeting or work? Please also include indirect investments such as a trust or holding company. You may exclude mutual funds, pension funds or similar investments that are broadly diversified and on which you exercise no control.

3a Stocks, bonds, stock options, other securities (e.g., short sales)

Yes □ No □

3b Commercial business interests (e.g., proprietorships, partnerships, joint ventures, board memberships, controlling interest in a company)

Yes □ No □

INTELLECTUAL PROPERTY

Do you have any intellectual property rights that might be enhanced or diminished by the outcome of the meeting or work?

4a Patents, trademarks, or copyrights (including pending applications)

Yes □ No □

4b Proprietary know-how in a substance, technology or process

Yes □ No □
PUBLIC STATEMENTS AND POSITIONS (during the past 3 years)

5a As part of a regulatory, legislative or judicial process, have you provided an expert opinion or testimony, related to the subject of the meeting or work, for a commercial entity or other organization?  
Yes □ No □

5b Have you held an office or other position, paid or unpaid, where you represented interests or defended a position related to the subject of the meeting or work? Yes □ No □

ADDITIONAL INFORMATION

6a If not already disclosed above, have you worked for the competitor of a product that is the subject of the meeting or work, or will your participation in the meeting or work enable you to obtain access to a competitor's confidential proprietary information, or create for you a personal, professional, financial or business competitive advantage? Yes □ No □

6b To your knowledge, would the outcome of the meeting or work benefit or adversely affect interests of others with whom you have substantial common personal, professional, financial or business interests (such as your adult children or siblings, close professional colleagues, administrative unit or department)? Yes □ No □

6c Excluding WHO, has any person or entity paid or contributed towards your travel costs in connection with this WHO meeting or work? Yes □ No □

6d Have you received any payments (other than for travel costs) or honoraria for speaking publicly on the subject of this WHO meeting or work? Yes □ No □

6e Is there any other aspect of your background or present circumstances not addressed above that might be perceived as affecting your objectivity or independence? Yes □ No □

7. TOBACCO OR TOBACCO PRODUCTS (answer without regard to relevance to the subject of the meeting or work)

Within the past 4 years, have you had employment or received research support or other funding from, or had any other professional relationship with, an entity directly involved in the production, manufacture, distribution or sale of tobacco or tobacco products or representing the interests of any such entity? Yes □ No □

EXPLANATION OF "YES" RESPONSES: If the answer to any of the above questions is "yes", check above and briefly describe the circumstances on this page. If you do not describe the nature of an interest or if you do not provide the amount or value involved where relevant, the conflict will be assumed to be significant.

<table>
<thead>
<tr>
<th>Nos. 1 - 4:</th>
<th>Type of interest, question number and category (e.g., Intellectual Property 4.a copyrights) and basic descriptive details.</th>
<th>Name of company, organization, or institution</th>
<th>Belongs to you, a family member, employer, research unit or other?</th>
<th>Amount of income or value of interest (if not disclosed, is assumed to be significant)</th>
<th>Current interest (or year ceased)</th>
</tr>
</thead>
</table>

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Nos. 5-6: Describe the subject, specific circumstances, parties involved, time frame and other relevant details

CONSENT TO DISCLOSURE. By completing and signing this form, you consent to the disclosure of any relevant conflicts to other meeting participants and in the resulting report or work product.

DECLARATION. I hereby declare on my honour that the disclosed information is true and complete to the best of my knowledge.

Should there be any change to the above information, I will promptly notify the responsible staff of WHO and complete a new declaration of interest form that describes the changes. This includes any change that occurs before or during the meeting or work itself and through the period up to the publication of the final results or completion of the activity concerned.

Date: ___________________ Signature________________________________

Date: ___________________ Signature________________________________
Annex A

Guidance to Experts in Connection with the Completion of WHO DOI Forms

_Should be sent with the DOI form_

The following table provides guidance to experts as to the type and extent of information that experts should disclose as they complete WHO Declaration of Interest Form.

<table>
<thead>
<tr>
<th>Type of Interest in Relation to subject of meeting or work</th>
<th>Examples of Information Required</th>
</tr>
</thead>
</table>
| Expert's employment or that of an immediate family member | Indicate:  
  a. name of employer  
  b. title and function  
  c. period of employment |
| Consulting work                                           | Indicate:  
  a. name of contracting party  
  b. period of consultancy  
  c. nature / subject of consultancy  
  d. amount of income earned per consultancy |
| Research support                                          | Indicate:  
  a. source of the support  
  b. amount of support  
  c. whether support provided to expert personally, immediate family member or institution to which the expert is affiliated  
  d. subject matter of research supported  
  e. expert's role in the conduct of the research supported (e.g. head of research team, director of programme, scientist part of a larger team) |
| Investments                                               | Indicate whether investment in any single company is valued at:  
  a. the nature of the investment (e.g. stock, bonds, partial or total ownership interest etc)  
  b. more than $5,000  
  c. provide the name of the company |
| Intellectual Property                                     | Describe:  
  a. nature and object of the IP  
  b. whether IP is still protected  
  c. relevant licensing arrangements relating to the IP  
  d. whether royalties are being paid |
| Public Statements and Positions                           | Describe:  
  a. fora in which public position taken (e.g. court, parliamentary committee etc.)  
  b. year concerned  
  c. in brief, the position held  
  d. the capacity in which the statement was made or position taken (e.g. Mr. Smith in his capacity as president of ABC society)  
  e. indicate for how long approximately the position taken has been held or defended, if applicable  
  e. whether there is a public record of the position held |
| Unfair or Competitive Advantage                           | a. state whether information obtained as a result of participation in the advisory body or activity could provide you with an unfair competitive advantage and/or a clear actual and direct financial or pecuniary benefit.  
  b. Explain how you would propose to mitigate this concern |
Annex B

**Code of Conduct for WHO Experts**

*Should be sent with the DOI form*

WHO values and relies upon the normative and technical advice that is provided by leading subject matter experts in the context of its advisory/technical committees, meetings and other similar processes. Such advice contributes to the formulation of public health policies and norms that are promulgated by WHO for the benefit of its Member States.

In order to ensure the integrity of such processes, thereby contributing to their credibility in the eyes of WHO’s stakeholders, it is critical that experts appointed by WHO to render technical or normative advice:

a. fully and honestly disclose all relevant interests and biases on the DOI Form that may give rise to real or perceived conflicts of interest. Such disclosure must also be made orally to all fellow expert committee, meeting or group members at the outset i.e. unless this is done by the Chairperson or Secretariat.

b. spontaneously report any material changes to their disclosed interest on an on-going basis during the period in which the expert serves the Organization;

c. respect the confidential nature of committee or meeting deliberations or of the advisory function assigned by WHO and not make any public statements regarding the work of the committee or meeting or regarding the expert’s advice without prior consent from WHO;

d. undertake not to engage in activities that may bring reputational harm to the WHO process that they are involved in;

e. undertake to represent their views in a personal and individual capacity with the best interest of WHO in mind as opposed to representing the views of their employers, other institutions or governments.

f. actively and fully participate in discussions and deliberations within the relevant advisory group, committee or meeting.
Annex 4: Confidential Disclosure Agreement between the NRA and WHO

Note: Whenever a confidential disclosure agreement is in need to be signed between the NRA and WHO, the following template should be used as a reference to the relevant discussions however the final agreed version of the agreement should be subject to review and clearance by WHO’s Legal Department.

CONFIDENTIAL DISCLOSURE AGREEMENT

This Confidential Disclosure Agreement (this “Agreement”), effective as from the last date of signature, is entered into by and between:

the Full name of the regulatory authority (hereinafter “Acronym of the regulatory authority”) having its headquarters at please add address of the regulatory authority, of the one part, and

the WORLD HEALTH ORGANIZATION (“WHO”), having its headquarters at 20 avenue Appia, 1211 Geneva 27, Switzerland, of the other part.

WHEREAS, representatives of Acronym of the regulatory authority and WHO (hereinafter referred to jointly as the “Parties” and individually as a “Party”) intend to hold discussions or other exchanges aimed at coordinating and/or facilitating Acronym of the regulatory authority’s regulatory activities and WHO’s regulatory systems strengthening;

WHEREAS, during the course of the above mentioned discussions or other exchanges, each Party (“Disclosing Party”) may disclose to the other Party (“Receiving Party”) certain materials, data and other information relating Acronym of the regulatory authority’s regulatory activities and/or WHO’s regulatory systems strengthening, in each case, which the Disclosing Party considers to be confidential and/or proprietary to the Disclosing Party and/or third parties collaborating with it;

WHEREAS the aforementioned confidential and/or proprietary materials, data or other information of Acronym of the regulatory authority or WHO, as the case may be, is hereinafter collectively referred to as the “Information”.

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WHEREAS Acronym of the regulatory authority and WHO are willing to disclose the Information to each other for the purposes of coordinating and facilitating (i) Acronym of the regulatory authority’s regulatory activities, as well as (ii) WHO’s regulatory systems strengthening activities, without limitation, activities in the context of WHO’s benchmarking of Acronym of the regulatory authority (hereinafter collectively the “Purpose”); without prejudice to the confidentiality obligations of each Party hereunder.

NOW IT IS HEREBY AGREED as follows:

1. The Parties agree that the abovementioned discussions and exchanges, as well as any disclosure of the Information by one Party to the other Party, will take place subject to following terms and conditions set forth in this Agreement.

2. Any Information disclosed under this Agreement that is provided or otherwise made available: (i) in written or other tangible form, shall be marked as being confidential; or (ii) in oral form, shall be stated to be confidential and shall be confirmed by the Disclosing Party (as defined above) in written summary form within thirty (30) days from the date of oral disclosure.

3. In accepting the Information, each Party shall (subject to the provisions of paragraph 2 above) abide by the following:

(a). The Information disclosed or otherwise made available by the Disclosing Party shall be regarded by the Receiving Party (as defined above) as confidential and proprietary to the Disclosing Party. The Receiving Party shall use such Information only for the Purpose and shall make no other use thereof unless and until a further written agreement is signed by the Disclosing Party permitting such other use of the Information.

(b). Nothing in this Agreement shall prevent the Disclosing Party from disclosing its Information to any third party.
(c). Nothing in this Agreement shall be construed as granting to the Receiving Party of any rights to the Information other than those expressly set forth in this Agreement.

(d). The Receiving Party shall maintain the Information received from the Disclosing Party in confidence. For a period of five years from the date of disclosure, the Receiving Party shall take all reasonable measures to ensure that the Information: (i) shall not be used for any purpose other than the Purpose, and (ii) shall not be disclosed to any third party, except for a third party who needs to know the Information for the Purpose and who is legally bound by similar obligations of confidentiality and restrictions on use as those contained in this Agreement, in which case the Information shall only be disclosed to such third party to the extent strictly necessary to achieve the Purpose. The said period of five years referred to herein shall be extended at the written request of the Disclosing Party for one further period not to exceed 5 years, in order to protect the confidentiality of the Information disclosed by the Disclosing Party.

(e). The obligations of confidentiality and restrictions on use contained in this Agreement shall not apply to any part of the Information which the Receiving Party is clearly able to demonstrate:

   i. was lawfully in its possession and known to it prior to disclosure by the Disclosing Party (as evidenced by written records or other competent proof); or

   ii. was in the public domain or the subject of public knowledge at the time of disclosure by the Disclosing Party; or

   iii. becomes part of the public domain or the subject of public knowledge through no fault of the Receiving Party; or

   iv. becomes available to the Receiving Party from a third party not in breach of a legal obligation of confidentiality or restriction on use; or

   v. was subsequently and independently developed by or on behalf of the Receiving Party without access to the Information of the Disclosing Party.
(f). In addition, the Receiving Party shall be permitted to disclose Information received hereunder as may be strictly required to be disclosed by applicable law, provided that the Receiving Party shall immediately notify the Disclosing Party in writing of such requirement and shall provide adequate opportunity to the Disclosing Party to object to or restrict such disclosure, or request confidential treatment thereof.

4. This Agreement shall not be construed as (i) conveying rights under any patents or other intellectual property which either Party may have or may hereafter obtain; or as (ii) placing either Party under any obligation to enter into any subsequent agreements.

5. Upon completion of the Purpose, the Receiving Party shall (unless otherwise agreed in writing by the Disclosing Party) immediately cease all use and make no further use of the Information disclosed or otherwise made available to the Receiving Party hereunder. Upon written request from the Disclosing Party, the Receiving Party shall promptly return to the Disclosing Party or destroy all of the Information disclosed or otherwise made available to the Receiving Party, except that the Receiving Party may retain one copy of the Information in its files to determine any continuing obligations hereunder.

6. Any notice required or permitted to be given pursuant to this Agreement shall be in writing and in the English language and shall be sent via registered mail or international courier (postage prepaid) to the Party to be notified at its address shown at the beginning of this Agreement. Information in writing and communication relating to Information, unless hand delivered, shall be sent via an agreed internet media (by way of example, and without limitation: the WHO-RSS secure SharePoint will be used for the purpose of benchmarking, with the link and access to be granted by WHO’s RSS team) or by delivery of password protected and encrypted files to addresses as are notified between the Parties.

7. This Agreement constitutes the entire understanding of the Parties with respect to the subject matter hereof and supersedes any prior agreements, arrangements and/or other communications with respect to such subject matter. This Agreement shall not be modified, except by mutual written agreement signed by duly authorized representatives of both Parties.
8. Any dispute relating to the interpretation or application of this Agreement shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the Parties or, in absence of agreement, under the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the said Rules. The Parties shall accept the arbitral award as final.

9. Nothing contained in or relating to this Agreement shall be construed as a waiver of any of the privileges and immunities enjoyed by either Party or any of its officials under national or international law and/or as submitting WHO to national court jurisdiction,

Made in two (2) original copies,

For and on behalf of the For and on behalf of the

Name of the regulatory authority in full World Health Organization

Name: Name:
Title: Title:
Date: Date:
Place: Place:
## Annex 5: Global Benchmarking Tool Quantitative Indicators (GBTQI)

<table>
<thead>
<tr>
<th>#</th>
<th>Indicator</th>
<th>Related function</th>
</tr>
</thead>
<tbody>
<tr>
<td>QN01</td>
<td>Total annual budget</td>
<td>RS</td>
</tr>
<tr>
<td>QN02</td>
<td>Total number of full time staff of the National Regulatory Authority (NRA) at central (federal) level</td>
<td>RS</td>
</tr>
<tr>
<td>QN03</td>
<td>Total number of full time staff of the National Regulatory Authority (NRA) at all other peripheral levels</td>
<td>RS</td>
</tr>
<tr>
<td>QN04</td>
<td>Number of full time staff with post-graduate education (Master's / Doctorate / other (specify))</td>
<td>RS</td>
</tr>
<tr>
<td>QN05</td>
<td>Percentage of medical product market share by value produced by domestic manufacturers in the last year</td>
<td>RS</td>
</tr>
<tr>
<td>QN06</td>
<td>Percentage of medical product market share by volume produced by domestic manufacturers in the last year</td>
<td>RS</td>
</tr>
<tr>
<td>QN07</td>
<td>Total number of medical products with valid registration/marketing authorization</td>
<td>MA</td>
</tr>
<tr>
<td>QN08</td>
<td>Total number of medicines with valid registration/marketing authorization</td>
<td>MA</td>
</tr>
<tr>
<td>QN09</td>
<td>Total number of vaccines with valid registration/marketing authorization</td>
<td>MA</td>
</tr>
<tr>
<td>QN10</td>
<td>Total number of medical devices with valid registration/marketing authorization/approvals</td>
<td>MA</td>
</tr>
<tr>
<td>QN11</td>
<td>Total number of blood, blood components and plasma derived products with valid registration/marketing authorization</td>
<td>MA</td>
</tr>
<tr>
<td>QN12</td>
<td>Number of medical products applications received for registration/marketing authorization over the last year</td>
<td>MA</td>
</tr>
<tr>
<td>QN13</td>
<td>Number of applications received for new medicines in the last year</td>
<td>MA</td>
</tr>
<tr>
<td>QN14</td>
<td>Number of applications received for generic medicines in the last year</td>
<td>MA</td>
</tr>
<tr>
<td>QN15</td>
<td>Number of applications received for vaccines in the last year</td>
<td>MA</td>
</tr>
<tr>
<td>QN16</td>
<td>Number of applications received for medical devices with valid registration/marketing authorization</td>
<td>MA</td>
</tr>
<tr>
<td>QN17</td>
<td>Number of applications received for blood, blood components and plasma derived products with valid registration/marketing authorization</td>
<td>MA</td>
</tr>
<tr>
<td>QN18</td>
<td>Maximum number of days for decision-making on new medicine applications (as per the related guidelines or regulations)</td>
<td>MA</td>
</tr>
<tr>
<td>QN19</td>
<td>Maximum number of days for decision-making on new generic medicine applications (as per the related guidelines or regulations)</td>
<td>MA</td>
</tr>
<tr>
<td>QN20</td>
<td>Maximum number of days for decision-making on new vaccine applications (as per the related guidelines or regulations)</td>
<td>MA</td>
</tr>
<tr>
<td>QN21</td>
<td>Total number of assessors of medical products</td>
<td>MA</td>
</tr>
<tr>
<td>QN22</td>
<td>Number of notifications of adverse events received in the last year (according to scope of benchmarking)</td>
<td>VL</td>
</tr>
<tr>
<td>QN23</td>
<td>Number of notifications of serious adverse events received in the last year</td>
<td>VL</td>
</tr>
<tr>
<td>QN24</td>
<td>Number of safety alerts published and distributed in the last year</td>
<td>VL</td>
</tr>
<tr>
<td>QN25</td>
<td>Number of specific pharmacovigilance inspections carried out in the last year</td>
<td>VL</td>
</tr>
<tr>
<td>QN26</td>
<td>Number of regulatory actions and administrative regulatory measures carried out for reasons of drug safety in the last year (e.g., changes in over-the-counter vs. prescription status, conditions of use, warnings or other safety-related changes in labelling, withdrawals of products or lots, cancellations of registration, fines, suspensions, or closures of establishments)</td>
<td>VL</td>
</tr>
<tr>
<td>#</td>
<td>Indicator</td>
<td>Related function</td>
</tr>
<tr>
<td>-----</td>
<td>---------------------------------------------------------------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>QN27</td>
<td>Number of <strong>applications</strong> received for the <strong>import</strong> of medical products in the last year</td>
<td>MC</td>
</tr>
<tr>
<td>QN28</td>
<td>Number of batches <strong>monitored</strong> by the market <strong>surveillance and control programme</strong> in the last year</td>
<td>MC</td>
</tr>
<tr>
<td>QN29</td>
<td>Number of batches of <strong>substandard or falsified</strong> medical products detected by the market <strong>surveillance and control programme</strong> in the last year</td>
<td>MC</td>
</tr>
<tr>
<td>QN30</td>
<td>Number of batches <strong>recalled by manufacturer</strong> in the last year</td>
<td>MC</td>
</tr>
<tr>
<td>QN31</td>
<td>Number of <strong>medical products</strong> for which advertisement and promotion <strong>applications</strong> were received in the last year</td>
<td>MC</td>
</tr>
<tr>
<td>QN32</td>
<td><strong>Maximum</strong> number of days to grant advertisement and promotion <strong>authorization</strong> (as per the related guidelines and regulations)</td>
<td>MC</td>
</tr>
<tr>
<td>QN33</td>
<td>Total number of <strong>medicines</strong> manufacturing <strong>facilities</strong> with valid license</td>
<td>LI</td>
</tr>
<tr>
<td>QN34</td>
<td>Total number of <strong>active pharmaceutical ingredients</strong> manufacturing <strong>facilities</strong> with valid license</td>
<td>LI</td>
</tr>
<tr>
<td>QN35</td>
<td>Total number of <strong>vaccines</strong> manufacturing <strong>facilities</strong> with valid license</td>
<td>LI</td>
</tr>
<tr>
<td>QN36</td>
<td>Total number of medical products <strong>distributors</strong> with valid license</td>
<td>LI</td>
</tr>
<tr>
<td>QN37</td>
<td>Total number of medical products <strong>wholesalers</strong> and stores with valid license</td>
<td>LI</td>
</tr>
<tr>
<td>QN38</td>
<td>Total number of <strong>pharmacies</strong> and medical products <strong>outlets</strong> with valid license</td>
<td>LI</td>
</tr>
<tr>
<td>QN39</td>
<td>Number of <strong>domestic GMP inspections</strong> carried out in the last year</td>
<td>RI</td>
</tr>
<tr>
<td>QN40</td>
<td>Number of <strong>overseas GMP inspections</strong> carried out in the last year</td>
<td>RI</td>
</tr>
<tr>
<td>QN41</td>
<td>Number of <strong>GDP inspections</strong> carried out in the last year</td>
<td>RI</td>
</tr>
<tr>
<td>QN42</td>
<td>Number of <strong>Good Clinical Practice (GCP) inspections</strong> carried out in the last year</td>
<td>RI</td>
</tr>
<tr>
<td>QN43</td>
<td>Number of <strong>regulatory actions and administrative regulatory measures</strong> carried out for reasons of medical products quality in the last year (e.g., restrictions of use, withdrawals of products or lots, cancellations of registration, or fines, suspensions, or closures of establishments)</td>
<td>RI</td>
</tr>
<tr>
<td>QN44</td>
<td>Total number of <strong>full time GMP inspectors</strong></td>
<td>RI</td>
</tr>
<tr>
<td>QN45</td>
<td>Total number of <strong>full time GDP inspectors</strong></td>
<td>RI</td>
</tr>
<tr>
<td>QN46</td>
<td>Total number of <strong>full time GCP inspectors</strong></td>
<td>RI</td>
</tr>
<tr>
<td>QN47</td>
<td>Total number of <strong>batches tested</strong> by NCL in the last year</td>
<td>LT</td>
</tr>
<tr>
<td>QN48</td>
<td>Total number of <strong>batches for which notices of non-conformity</strong> (or similar document) issued in the year</td>
<td>LT</td>
</tr>
<tr>
<td>QN49</td>
<td>Total number of NCL <strong>staff</strong></td>
<td>LT</td>
</tr>
<tr>
<td>QN50</td>
<td>Total number of NCL <strong>analysts</strong></td>
<td>LT</td>
</tr>
<tr>
<td>QN51</td>
<td>Number of <strong>medicine</strong> clinical trial <strong>applications</strong> received in the last year</td>
<td>CT</td>
</tr>
<tr>
<td>QN52</td>
<td>Number of <strong>vaccine</strong> clinical trial <strong>applications</strong> received in the last year</td>
<td>CT</td>
</tr>
<tr>
<td>QN53</td>
<td>Number of <strong>medicine</strong> clinical trial <strong>authorizations</strong> issued in the last year</td>
<td>CT</td>
</tr>
<tr>
<td>QN54</td>
<td>Number of <strong>ethics committees</strong> authorized or accredited by the NRA or the corresponding National Health Authority</td>
<td>CT</td>
</tr>
<tr>
<td>QN55</td>
<td>Maximum number of <strong>days for decision-making</strong> on clinical trial applications (as per the related guidelines and regulations)</td>
<td>CT</td>
</tr>
<tr>
<td>QN56</td>
<td>Number of vaccines lots <strong>released</strong> in the last year</td>
<td>LR</td>
</tr>
</tbody>
</table>