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ETHIOPIAN FOOD & DRUG AUTHORITY

# EFDA VOICES

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## IN THIS ISSUE

**Article ·1·**
EFDA announces to work with the PROFORMA project in East Africa to reduce unexpected side effects of medicines
(PAGE 1)

**Article ·2·**
EFDA launches a Food Safety Alert application
(PAGE 2)

**Article ·3·**
EFDA held a discussion with stakeholders on food and health products control
(PAGE 3)

**Article ·4·**
EFDA conducts a joint steering committee meeting with regional health regulatory bodies.
(PAGE 3)

**Article ·5·**
The WHO global benchmarking tool: an Instrument to strengthen medical products regulatory system
(PAGE 4)

# EFDA announces to work with the PROFORMA project in East Africa to reduce unexpected side effects of medicines

The sixth annual meeting of the PROFORMA project, which focuses on developing capacities in drug adverse effects monitoring and post-marketing surveillance, took place in Addis Ababa on January 30, 2023. During the meeting's opening remarks, the Ethiopian Food and Drug Authority (EFDA's) Director General, Ms. Heran Gerba, noted that the Authority is taking part in a PROFORMA project and it has been operating a drug side effects monitoring section for 21 years.


The Director General stated that it is necessary to build a strong system and train experts to identify, investigate and follow up reports of unexpected side effects of drugs. For this purpose, collaboration with higher education, public health organizations, and regulatory organizations is needed to resolve the problem, she said.

PERFORMA is a project funded by European and Developing Countries Clinical Trials Partnership (EDCTP2), which started operation five years ago. It is implemented in five universities of the National Drug Incident Infrastructure, four drug regulatory authorities, and two regional regulatory excellence centers in Africa, including Ethiopia, Kenya, Tanzania, and Rwanda. Regulatory bodies conduct post-market surveillance and consolidation of clinical trial activities.

## IMPORTANT MESSAGE

**Ethiopian Food and Drug Authority (EFDA's) Director General, Ms. Heran Gerba, noted that the Authority is taking part in a PROFORMA project and it has been operating a drug side effects monitoring section for 21 years.**

## EFDA VISION

To be a center of excellence in food and health products regulation in Africa

## EFDA MISSION

To protect and promote public health by ensuring the safety, effectiveness, quality and proper use of regulated products through licensing, inspection, registration, laboratory testing, post-marketing surveillance, community participation, and provision of up-to-date regulatory information.

## EFDA OBJECTIVE

**To protect and promote public health through realization of the following objectives:**

1. Protect the public from unsafe food
2. Safeguard the public from falsified, substandard and ineffective health products
3. Protect the public from tobacco and alcohol related health risks
4. Attain public confidence on food and health product regulation

## Strategic Directions

1. Strengthen food safety regulation.
2. Strengthen detection, prevention and response to food adulteration and illegal trade
3. Improve regulation of safety, efficacy, quality and proper use of medicines
4. Strengthen safety, quality and performance regulation of medical devices
5. Improve regulation of safety of cosmetic products
6. Strengthen tobacco and alcohol control system
7. Enhance public ownership
8. Improve efficiency and effectiveness
9. Enhance partnership and collaboration
10. Enhance good governance
11. Improve human resource development and Management
12. Improve evidence-based decision making
13. Strengthen Food and health products regulatory infrastructures
14. Improve quality management system
15. Improve formulation and implementation of legal frameworks

# EFDA launches a Food Safety Alert application

On February 23, 2023, EFDA, in collaboration with Digital Health Activity (DHA), launched a food safety alert and notification system https://ras.efda.gov.et for the rapid exchange of information about food safety incidents among stakeholders and the public.

This unique food alert and notification system is a web-based application that enables the public and organizations to report food safety incidents to ensure timely detection and response to incidents that result from unsafe food consumption.

Once the incidents are reported, EFDA reviews and disseminates the notification of the incidents to stakeholders as well as the public using the system.

In the opening remarks at the launching event, the Director General of EFDA, Mrs. Heran Gerba, stated that the application would help to inform food safety issues to relevant stakeholders through the system, which enables quick communication, and prompt action to safeguard the public from food-borne illnesses.




The Director General added that this food safety alert web application promotes a digitized operational system in cooperation with different partner organizations and key stakeholders, which further strengthens the food safety monitoring system.

To increase the number of reports reaching the authority office, to support the effort of controlling potential harm to consumers related to food, and to create similar understandings, the Director General urged the stakeholders to spread this cutting-edge online reporting method widely with others.

> **"It is necessary to build a strong system and train experts to identify, investigate and follow up reports of unexpected side effects of drugs."**
>
> **Ms. Heran Gerba, EFDA Director General,**

# EFDA held a discussion with stakeholders on food and health products control

On February 24, 2015, EFDA held a stakeholder review meeting on the six-month implementation performance of food, medicine, medical equipment, tobacco, and other controls.

At the opening of the discussion, the Director General of EFDA, Mrs. Heran Gerba said, important ideas raised by the stakeholders in the discussion will be included in future plans of the Authority and it is expected a lot from the stakeholders in identifying the challenges and proposing solutions.


The Director General pointed out that the Authority is in the process of reforms in terms of organizational structure, operations and human resources. She added that after the completion of the reform the Authority will be on the right track to achieve its vision of becoming a center of excellence in Africa by gaining international recognition in the field of food and health.

Representatives drawn from the Drug Manufacturers Association, Food Manufacturers Association, Drug and Medical Equipment Importers Association, hospitals, federal government institutions, and other stakeholders participated in the discussion.

# EFDA conducts a joint steering committee meeting with regional health regulatory bodies.

EFDA announced that it is necessary to consolidate the best practices obtained by each health regulatory body and to expand it to all regional health regulatory bodies, in a joint steering committee meeting which has conducted from March 14 to 15 in Harar City. The meeting evaluated the execution plan for the first half fiscal year of the 2015 E.C. During the meeting, the Director General of EFDA, Ms. Heran Gerba stated that each regulatory body has registered its own best practices such as law adaptation, public mobilization and others that they should expand to all regional regulatory bodies including supportive supervision.

As she said, regarding law enforcement, the Dire Dawa City Administration Food and Drug Authority and the Afar National Regional Government's Health Bureau have both approved their control regulations for health and medical-related resources and services. In addition, different guidelines and laws have been prepared, approved, and expect to be enforced.




According to the Director General, in terms of infrastructure, laboratory test kits and other equipment have been prepared and put into operation. She added that the renovation of the vaccination laboratory in Hawassa has completed and the contract for the Kaliti Center of Excellence has also signed and started implementation. She said that the Bahir Dar branch office is under renovation which will increase the laboratory testing capacity.

Regarding resources, new vehicle has to purchased and distributed to all regulatory bodies, which helps create greater capacity to control and monitor vaccine safety.

The food laboratory has successfully passed the audit process of the Ethiopian Accreditation Service and is preparing to receive the accreditation certificate 17020, the Director General stated.

The Director General also added that they expect the regional health regulatory bodies to send an up-to-date plan and report to the authority to strengthen the incoming reports and send it to the Ministry of Health to have up-to-date and reliable national health information.

To create a uniform system and structure within the federal authority office, the regional regulatory bodies have requested the Food and Drug Administration Proclamation 1112/11 to be approved according to the existing conditions of their region. They also requested the heads of the health bureaus to push for the implementation of the structure approved by the federal office at the regional level.

After the evaluation of the first half fiscal year plan execution, the meeting set directions that will make the control mechanism more effective in the future.

# The WHO global benchmarking tool: an Instrument to strengthen medical products regulatory system

**By Kidanemariam G/Michael**
Pharmaceutical Regulation Adviser

National regulatory authorities (NRAs) are the gatekeepers of the supply chain of medical products, and ensure the quality, safety, and efficacy of medical products. Medical products are considered one of the six building blocks of health systems. However, end users and healthcare workers are not in a position to judge the quality of medical products. Hence, the interests and safety of the public must be entrusted to a regulatory body responsible for ensuring the quality, safety, and efficacy of medical products throughout the product life cycle.

Effective, efficient and transparent regulatory systems are an essential component of health systems. Instituting and ensuring a robust regulatory system has to be objectively assessed and calibrated using a global standard tool. The Global Benchmarking Tool (GBT) represents the primary means introduced by the World Health Organization (WHO) to objectively evaluate regulatory systems. This was mandated by World Health Assembly (WHA) Resolution 67.20 on Regulatory System Strengthening for medical products as per member states' request.

In response to the World Health Assembly's Resolution 67.20 on regulatory system strengthening for medical products, WHO began developing the Global Benchmarking Tool (GBT) in 2014. The Resolution called for supporting member states in strengthening regulatory systems by using WHO tools. The GBT Revision VI was finalized and released in 2018 and serves as the global standard for objectively assessing regulatory capacity for medicines and vaccines. The GBT Plus was also released in 2019 and 2022 by including blood & blood products, and medical devices respectively. The tool and benchmarking methodology enable WHO and regulatory authorities to:

- identify strengths and areas for improvement;
- facilitate the formulation of an institutional development plan (IDP);
- prioritize IDP interventions; and
- monitor progress and achievements.

The WHO began assessing regulatory systems in 1997 using a set of indicators designed to evaluate the regulatory program for vaccines. Since that time, several tools and revisions have been introduced. In 2014 work began on the development of a unified tool for the evaluation of medicines and vaccine regulatory program. This is followed by a mapping of existing tools in use within and outside WHO.

WHO's five-step model for strengthening regulatory systems

The WHO has established, implemented and refined a five-step model for strengthening regulatory systems (Figure 1).

1. Development and maintenance of a global benchmarking tool 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 program outcomes and impact.

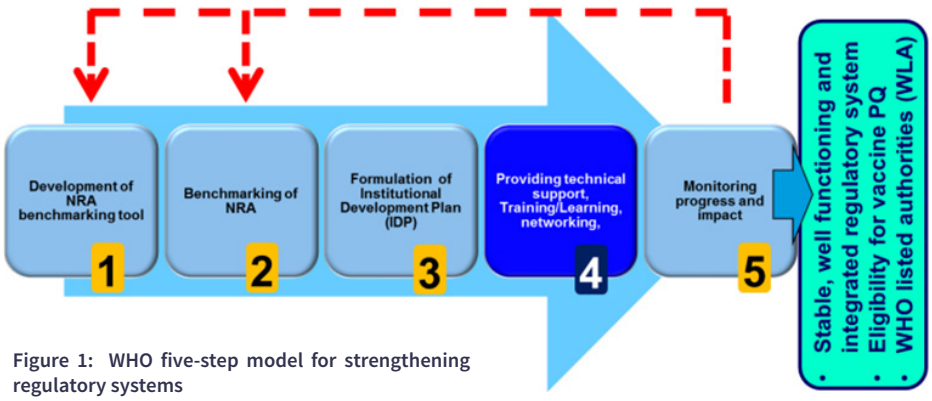


**Figure 1: WHO five-step model for strengthening regulatory systems**

## Maturity levels of regulatory systems

The WHO GBT consists of a well-structured hierarchy of indicators, sub-indicators and accompanying fact sheets. It incorporates the concept of maturity levels (MLs), adapted from the international standard (i.e the ISO 9004). 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 allows for the identification of more advanced systems that in turn should facilitate reliance and greater regulatory cooperation.

There are four performance maturity levels that were adopted from the International Standard ISO 9004 and are an expression of the extent to which a regulatory system has been formalized as stable, well-functioning and integrated. The four maturity levels (Figure 2) of regulatory systems are characterized as follows:

1. Maturity Level 1: no formal approach - regulatory systems in which some elements of regulatory systems exist.
2. Maturity Level 2: reactive approach - evolving national regulatory systems that partially perform essential regulatory functions.
3. Maturity Level 3: stable formal system approach - stable, well-functioning and integrated regulatory systems.
4. Maturity Level 4: continual improvement emphasized - regulatory systems operating at an advanced level of performance and continuous improvement.

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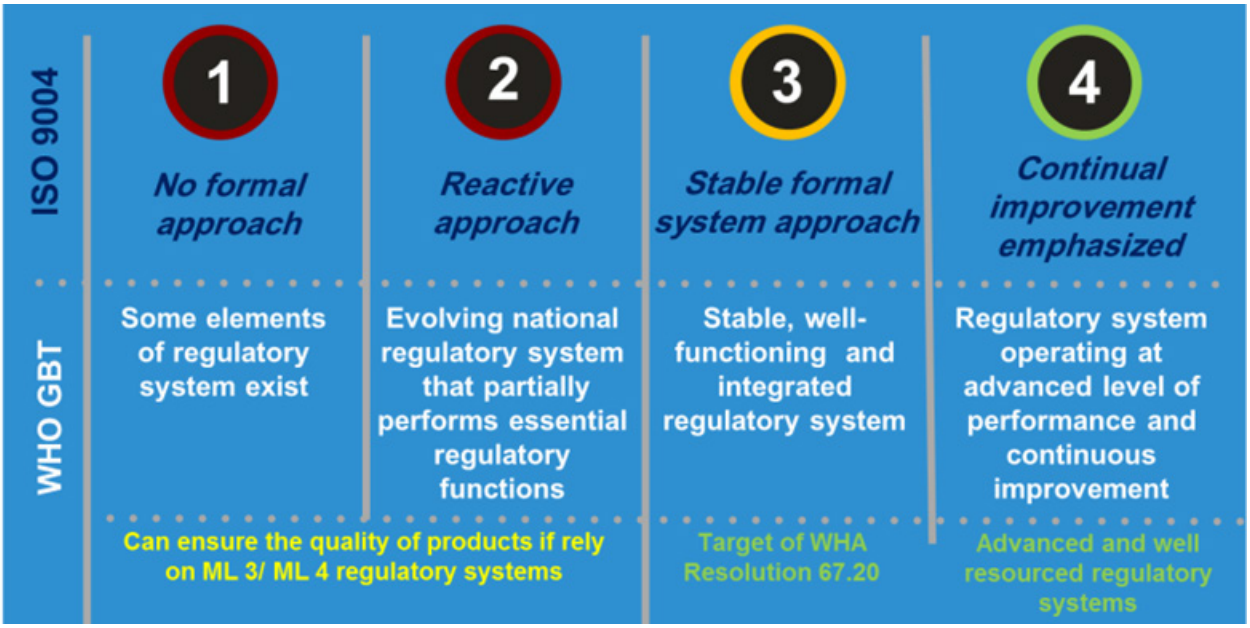


Figure 2: Maturity levels as defined by WHO

## Country requests and prioritization model for regulatory system strengthening

The resolution WHA 67.20 stresses the importance of providing support in regulatory system strengthening particularly for developing countries upon request. This in turn demands the need to ensure the quality, safety and efficacy of medical products. The positioning of the regulatory authorities concerning the GBT is the country's interest and the formal benchmarking process follows accordingly. Formal benchmarking may be requested by the country for the reasons:

1. to provide a picture of maturity, strengths and areas for improvement of the system, thereby serving as a roadmap for regulatory system strengthening, 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).

In responding to the requests, the WHO acknowledges the requests to consider the capacity building of the regulatory system strengthening and the impact on access to safe, effective and quality-assured medical products, when prioritizing its efforts and investments.

The WHO considers the following points in prioritizing country requests for capacity building to strengthen the regulatory systems:

- 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 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.

## Global Benchmarking Tool (GBT)

WHO supports its Member States in strengthening their regulatory systems for medical products by setting norms and standards, promoting smart regulation, identifying strengths and gaps, providing specialized technical assistance, capacity-building opportunities, and advising them on issues related to the quality assurance of medicines.

The GBT Revision VI is the first globally accepted tool for objectively assessing and strengthening NRAs. It is designed to benchmark the regulatory programs of a variety of product types, including medicines, vaccines, blood products and medical devices. The WHO defines a national regulatory system in terms of the enabling legal system and infrastructure, common regulatory functions, and non-common regulatory functions. There are eight core regulatory functions addressed by the GBT which cover the whole medical product life cycle.

- National Regulatory System (RS)
- 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)

## Benefits of the WHO GBT

The requirements of the GBT has impact on international, national, organizational and individual activities. The goal of GBT ensures 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. The GBT promotes good regulatory practices and facilitates reliance, collaboration and harmonization, builds trust in the regulatory system and medical products and boosts pharmaceutical trade and access, which provide both public health and economic benefits. Some of the common benefits are:

- Strengthen medical products regulation and promote universal health coverage.
- Helps to improve timely access to quality assured medicines.
- Enabler to reduce the problem of substandard and falsified medical products.
- Facilitates coordination and improves effectiveness of regulatory strengthening efforts.

continued to page 6

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- Facilitates regulatory reliance and harmonization
- Help for regulatory body to be listed in WHO data base as WHO listed agency and eligible for vaccine manufacturing.
- Facilitates communication and coordination between countries and donors supporting the strengthening of NRAs. It creates trust and confident for donors, public and other stakeholders
- Encourage continuous improvement of regulatory systems
- Act as quality reference for international and domestic supply, including for products not eligible for prequalification, and expands pool of regulatory authorities contributing to efficiency of Prequalification programme
- Help to for NRAs to be prepared for better response to emergencies

## Scope of the WHO GBT

Concerning the products covered, the scope of the current GBT (revision VI) is for benchmarking of regulatory systems for (1) medicines; (2) vaccines; and (3) blood products including whole blood, blood components, plasma for fractionation, plasma-derived medical products, and blood associated substances and (4) medical devices including in-vitro diagnostics.

For the institutions covered, the GBT is intended for use in benchmarking national and sub-national (e.g., federal, provincial, or state levels) regulatory systems. It 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. The GBT is not currently designed or intended for use in the benchmarking of supranational (e.g., regional) regulatory systems.

Structure of the Global Benchmarking Tool

The GBT is divided into four levels as depicted in Figure 3.

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.

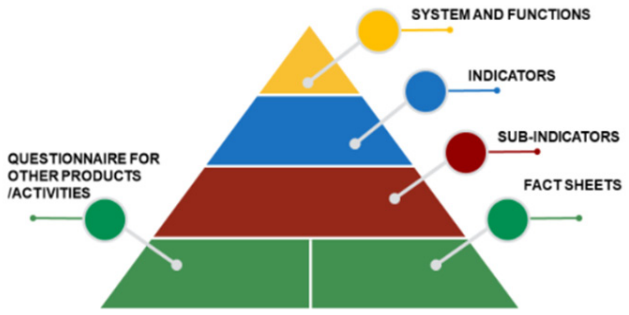


**Figure 3: Overview of GBT structure as defined by WHO**

Within each regulatory function, the GBT uses a set of indicators, each with its sub-indicators. The sub-indicators and accompanying fact sheets represent the basic blocks of the GBT tool. Sub-indicators are grouped under a parent indicator that aids data compilation and analysis. The fact sheets for each sub-indicator provide further details and clarify the scope of each sub-indicator. This brings consistency and quality to the process and outcome of benchmarking. There are 268 sub-indicators disaggregated into nine indicator categories and eight-core regulatory functions in the GBT (Table 1).

The GBT indicators are categorized 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 the impact

**Table 1: Indicator categories by regulatory function**

| Indicator categories | Regulatory functions | | | | | | | | | Total |
|---|---|---|---|---|---|---|---|---|---|---|
| | RS | MA | VI | MC | LI | RI | LT | CT | LR | |
| Leadership and crisis management | 5 | | | | | | | | | 5 |
| Legal provisions, regulations, and guidelines | 9 | 13 | 7 | 7 | 5 | 5 | 2 | 11 | 2 | 61 |
| Monitoring progress and assessing impact | 2 | 2 | 2 | 3 | 2 | 5 | 4 | 4 | 4 | 28 |
| Organization and governance | 4 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 20 |
| Policy and strategic planning | 5 | | | | | | 7 | | | 12 |
| Quality and risk management system | 14 | | | | | | | | | 14 |
| Regulatory process | | 10 | 8 | 8 | 4 | 6 | 6 | 7 | 3 | 52 |
| Resources | 12 | 4 | 4 | 4 | 4 | 4 | 6 | 4 | 4 | 46 |
| Transparency, accountability and communication | 9 | 4 | 3 | 3 | 2 | 4 | 1 | 2 | 2 | 30 |
| Total | 60 | 35 | 26 | 27 | 19 | 26 | 28 | 30 | 17 | 268 |

## Scoring and algorithm used for determining ML

The finding of the assessment based on the GBT tool needs scoring. Scoring the findings of the assessment and using the algorithm for determining maturity 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 maturity level of each regulatory function and the overall maturity of the regulatory system.

A four-tier scoring system measures the level of implementation and monitors the progress of each sub-indicator. The rating scale of every single sub-indicator ranges from not implemented, ongoing implementation, partially implemented, and fully implemented. The options for scoring the sub-indicators are listed below with a short description.

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%).
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 fully implemented. It may also entail the implementation of some but not all components of the concerned sub-indicator. Subsequently, one or more IDP activities of the relevant sub-indicator should be reflected in the GBT to contribute to the full implementation of the sub-indicator. Ongoing implementation is scored as 0.25 out of one (i.e., 25%).

continued to page 7

continued from page 6

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 activities of the relevant sub-indicator should be reflected in the GBT to ensure consistent implementation and to address any area of improvement. Partially implemented is scored as 0.75 out of one (i.e., 75%).
4. Fully implemented (I): 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. 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%).
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 that should exist only prior to the self-benchmarking exercise. Once a 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%).
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 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).

Each sub-indicator under each regulatory function is linked to a particular maturity level (i.e., ML1, ML2, ML3 or ML4) as indicated in the corresponding fact sheet of the GBT. It is worth mentioning that the overall maturity level of a system is calculated based on the lowest maturity level of individual regulatory functions. For example, if a regulatory system is scored for all functions as ML 3 and only one function is scored as ML 2 then the overall maturity level of the regulatory system will be calculated as ML2.

## The benchmarking processes

Countries requesting assistance from WHO to benchmark their regulatory system using the GBT follow a clear process, from planning and pre-screening, including pre-visit to re-benchmarking when necessary. Self-benchmarking is then validated ahead of the formal benchmarking process (Figure 4).

The benchmarking process includes planning and scheduling, pre-assessment, self-benchmarking, formal benchmarking, follow up and monitoring. The formal benchmarking process consists of independent experts using the GBT factsheets and a computerized version of the tool.

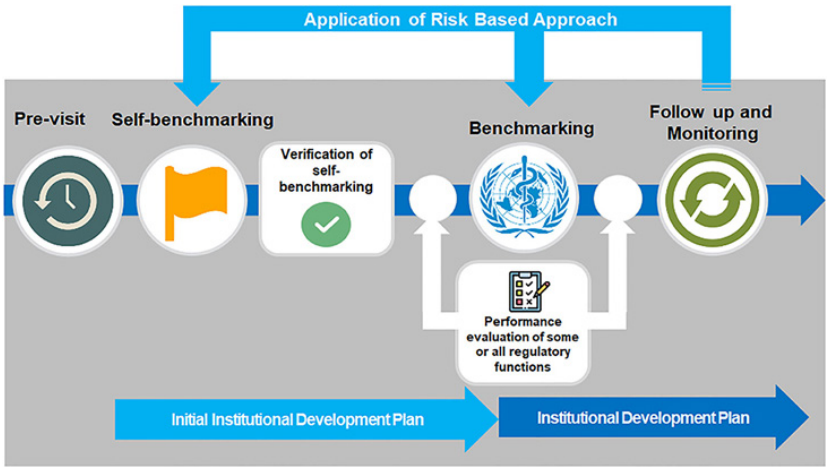


Figure 4: Benchmarking process.

## African Countries that reach maturity levels three and four

Various countries use the GBT to conduct self-benchmarking exercises before the formal WHO benchmarking and got ranked their maturity levels. As of November 2022, five countries from Africa (Tanzania, Ghana, Nigeria, South Africa, and Egypt) achieved maturity level three.

## EFDA's Commencement for maturity level three initiative

The WHO Benchmarking program is a method deployed by the WHO to assess the maturity level of NRAs. The assessment is done using a computerized Global Benchmarking Tool. The computerized GBT is used to generate automated reports after being populated with responses and evidence. The EFDA used the WHO GBT and assessed its core regulatory functions. The assessed regulatory functions are:

- National Regulatory System (RS)
- Registration and Marketing Authorization (MA)
- Licensing Establishments (LI)
- Market Surveillance and Control (MC)
- Vigilance (VL)
- Regulatory Inspection (RI)
- Clinical Trials Oversight (CT)
- Laboratory Testing (LT)

continued to page 8

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There have been visits from the WHO since 2011 to strengthen the regulatory systems of the Ethiopia. The WHO/IGAD rapid benchmarking visits were also conducted in 2017. Considering previous visits and follow-up IDP visits, an organized WHO self-benchmarking program commenced in EFDA in January 2019. The report of the January 2019 self-assessment revealed various gaps to be addressed and placed the authority at maturity level 2.

To address the gaps identified in the 2019 self-benchmarking, the top management of the authority has revitalized the team and worked tirelessly, and a great deal of improvement has been made in all regulatory functions. The second most robust self-benchmarking exercise was conducted in 2021, which showed a maturity level 3 for most regulatory functions. Furthermore, the WHO self-assisted virtual audit took place in April 2023 in a preparation for the formal benchmarking audit to be conducted on June 12–16, 2023. In all the steps, the top management of the authority has been reviewed, followed the progress, and provided directions and decisions when deemed necessary.

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