Questionnaire for Regulatory System assessment using World Health Organization (WHO) Global Benchmarking Tools (GBTs)

Overall Instruction

This questionnaire contains three sections including section 1: background questions, section 2: specific questions and section 3: opinion questions. Please carefully read the instructions for each section and answer the questions based on the factual information.

Section I: Background questions for WHO-GBT assessment

Instruction I: please select the answer and bold the circle ("●") based on the background history of your National Regulatory Authority.

Questions	Answers	Remark
1. Has the regulatory authority been analyzed by WHO with WHO-GBT for the evaluation of National Regulatory System (NRS)?	O Yes O No	If yes, please indicate the year and the overall maturity level rate (1-4). Level 1 - existence of some elements of the regulatory system Level 2 - NRS that partially performs essential regulatory functions Level 3 - National Regulatory Authority with a stable, well-functioning and integrated regulatory system Level 4 - Operating at an advanced level of performance and continuous improvement
2. Has the regulatory authority performed self-assessment with WHO-GBT for the evaluation of NRS?	O Yes O No	If yes, please indicate the year and the overall maturity level rate (1-4). Level 1 - existence of some elements of the regulatory system Level 2 - NRS that partially performs essential regulatory functions Level 3 - National Regulatory Authority with a stable, well-functioning and integrated regulatory system Level 4 - Operating at an advanced level of performance and continuous improvement

Section II: Specific questions based on WHO-GBT indicators

Instruction and explanation for Section II: please select the answer and bold the circle ("●") based on the regulatory system of your National Regulatory Authority.
Yes = implemented with track record
Partial = recently developed or less than 2 years implementation
Ongoing = only demonstrable steps but not yet implemented
No = not implemented

Questions	Answers	Remark
National Regulatory System (RS) (8)		
1. Is there any legal provision, regulations, and guidelines for the regulatory functions of NRS?	O Yes O Partial O Ongoing O No	In the legislations, regulations, and guidelines, all the definitions, terms, objectives, and responsibilities should be well-described.
2. Do all regulatory entities (central and decentralized ones) follow non-contradictory regulations, standards, guidelines, procedures?	O Yes O Partial O Ongoing O No	All regulatory authorities from central and peripheral such as state and province should be followed non-contradictory regulations and guidelines to be consistency in regulatory functions.
3. Is there any legal provisions and relevant regulations to take actions on recall, suspension, withdrawal and/or destruction of substandard and falsified (SF) medical products?	O Yes O Partial O Ongoing O No	
4. Does the National Regulatory Authority (NRA) consult or involve specific sectors of the civil society (such as non-governmental organizations (NGOs) representing health professionals, industry, consumers, and patients) during the development or adoption of regulations and guidelines?	O Yes O Partial O Ongoing O No	The participants may vary according to the draft regulation or guideline under consideration, if regulations are approved without input from the key stakeholders involved, it is doubtful that they will be fully understood or successfully implemented.

Section II: Specific questions based on WHO-GBT indicators

Instruction and explanation for Section II: please select the answer and bold the circle ("●") based on the regulatory system of your National Regulatory Authority.
Yes = implemented with track record
Partial = recently developed or less than 2 years implementation
Ongoing = only demonstrable steps but not yet implemented
No = not implemented

Questions	Answers	Remark
National Regulatory System (RS) (8)		
5. Is there any guideline on complaints and appeals against regulatory decisions that is available to public?	O Yes O Partial O Ongoing O No	An efficient and effective enforcement system must provide readily accessible and transparent means for receiving complaints and appeals against regulatory decisions, NRA should have implemented guidelines on review, evaluation, communication of complaints and appeals against regulatory decisions.
6. Is there any mechanism to evaluate the satisfaction of internal and external customers and other interested parties in place for regulatory system improvement?	O Yes O Partial O Ongoing O No	
7. Human resources with a trained, experienced, and skilled workforce to perform the regulatory functions.	O Yes O Need recruitment	Yes = human resource is suitable and enough to perform regulatory functions. Need recruitment = human resource is below the capacity to perform regulatory functions, and need more human resources
8. Is there enough infrastructure and equipment to perform regulatory activities?	O Yes O Partial O Ongoing O No	Infrastructure includes buildings, workspaces and associated utilities, lighting, and ventilation in the workspace.
Registration and Marketing Authorization (MA) (7)		
9. Are there legal provisions, regulations, and guidelines for regulatory framework of registration and/or marketing authorization of medical products?	O Yes O Partial O Ongoing O No	Marketing authorization (MA) means product licensing or registration. MA refers to a procedure for approval of medical product for marketing after evaluation to the safety, efficacy, and quality of the product.
10. Are there legal provisions or regulations for specifying the validity of registration (i.e., renewals) and for the requirement of renewal registration?	O Yes O Partial O Ongoing O No	If yes, please describe the validity of the product registration.
11. Are there specific guidelines on the quality, non-clinical and clinical requirements (as well as guidelines for bioavailability and bioequivalence (BA/BE) studies in the case of multisource generic medicines) for registration of medical products?	O Yes O Partial O Ongoing O No	
12. Are the same criteria applying for assessing applications regardless of the origin or destination for the medical products (e.g., domestic, foreign, public sector, or private sector).	O Yes O Partial O Ongoing O No	
13. Are there defined timelines for the assessment of the applications and internal tracking system to monitor adherence to the targeted time frames?	O Yes O Partial O Ongoing O No	
14. Are GMP inspection report and certification required for medical authorization process?	O Yes O Partial O Ongoing O No	
15. Is the list of all registered medical products publicly available?	O Yes O Partial O Ongoing O No	If yes, please describe the channel.

Section II: Specific questions based on WHO-GBT indicators

Instruction and explanation for Section II: please select the answer and bold the circle ("●") based on the regulatory system of your National Regulatory Authority.
Yes = implemented with track record
Partial = recently developed or less than 2 years implementation
Ongoing = only demonstrable steps but not yet implemented
No = not implemented

Questions	Answers	Remark
Market Surveillance and Control (MC) (5)		
16. Are there legal provisions, regulations and guidelines required for regulatory framework of market surveillance and control activities?	O Yes O Partial O Ongoing O No	Market surveillance and control activities are primarily concerned with four themes: (1) control of import activities, (2) prevention, detection, and response to substandard and falsified medical products, (3) market surveillance program for monitoring the quality of medical products throughout the supply chain, and (4) control of promotional, marketing and advertising activities.
17. Are there any legal provisions and regulations exist for placement of a product's unique identification number on its outer packaging?	O Yes O Partial O Ongoing O No	
18. Documented procedures or mechanisms are implemented to ensure the involvement and communication between NRA and all stakeholders for market surveillance and control activities.	O Yes O Partial O Ongoing O No	Stakeholders may include not only different organizations (e.g., organizations, institutions, or departments) but also other entities (e.g., laboratories, police departments, customs, and judicial authorities), regional, international, and non-governmental organizations, professional associations, customer representative associations and industry representatives). Documented procedures such as agreements, memoranda of understanding (MOUs).
19. Are there sufficient competent staffs (i.e., education, training, skills, and experience) to perform market surveillance and control activities?	O Yes O Partial O Ongoing O No	Yes=has a sustained number of competent staff No = does not have enough competent staff Partial = has initiated the implementation of the human resources development plan Ongoing = recently developed a plan to recruit adequate staff but the plan has not been implemented.
20. Findings and regulatory decisions of market surveillance and control activities are appropriately communicated to all national stakeholders including the general public.	O Yes O Partial O Ongoing O No	
Licensing Establishments (LI) (7)		
21. Are there legal provisions, regulations, and guidelines for licensing activities?	O Yes O Partial O Ongoing O No	NRA is responsible for coordinating licensing activities and should be supported by published and readily available legal provisions, regulations and guidelines which ensure that licensing of facilities throughout the supply chain is based on compliance with Good Practices (GXP) and that the NRA is empowered to issue, suspend, or revoke licenses for premises and establishments. Most relevant GXPs for this function are good manufacturing practice (GMP), good distribution practice (GDP) including good cold chain management practices.
22. Are there sufficient competent staff (i.e., education, training, skills, and experience) to perform licensing activities?	O Yes O Partial O Ongoing O No	Yes=has a sustained number of competent staff No = does not have enough competent staff Partial = has initiated the implementation of the human resources development plan Ongoing = recently developed a plan to recruit adequate staff but the plan has not been implemented.
23. Is there any validity of the licensing establishment?	O Yes O Partial O Ongoing O No O Not applicable	If yes, please describe the validity period of specific license. No = no procedures for making decisions on license issuance, renewal, modification, or revocation Not applicable = In some countries, license renewal might not be applicable. Rather the license is maintained based on regular inspections for compliance with GXPs.

Section II: Specific questions based on WHO-GBT indicators

Instruction and explanation for Section II: please select the answer and bold the circle ("●") based on the regulatory system of your National Regulatory Authority.
Yes = implemented with track record
Partial = recently developed or less than 2 years implementation
Ongoing = only demonstrable steps but not yet implemented
No = not implemented

Questions	Answers	Remark
Licensing Establishments (LI) (7)		
24. Is the inspection required for granting or re-granting a license or approval of substantial modification?	O Yes O Partial O Ongoing O No	In some cases, a license or approval of a substantial modification may be granted without inspection. However, these should be an exceptional situation and need to be justified, well described and compatible with guidelines.
25. Are there clearly defined timelines for the assessment of licensing applications?	O Yes O Partial O Ongoing O No	If yes, please specify the timelines for the assessment (in days).
26. Are the same criteria used for the licensing of domestic, public, and private establish-ments regardless of ownership?	O Yes O Partial O Ongoing O No	
27. Inspection reports or summaries (or excerpts) relevant to licensing activities are published and publicly available.	O Yes O Partial O Ongoing O No	In some countries, full inspection reports, redacted or non-redacted might be published. In other countries, only inspection summaries or excerpts might be publicly available. This indicator intends to build confidence and accountability in the licensing, to enhance transparency through publication of the licensing-related inspection data.
Regulatory Inspection (RI) (4)		
28. Are there legal provisions and regulations allowing the recognition of and/or reliance on foreign NRA inspections and enforcement actions based on well-defined criteria?	O Yes O Partial O Ongoing O No	
29. Are there any arrangement for effective orga-nization and good governance of regulatory inspection activities?	O Yes O Partial O Ongoing O No	Organization structure with clear responsibilities, duties and roles should be clearly defined and documented to ensure effective organization and good governance of regulatory inspection activities.
30. Are there sufficient competent staff (i.e., education, training, skills, and experience) to perform regulatory inspection activities?	O Yes O Partial O Ongoing O No	Yes = has a sustained number of competent staff No = do not have enough competent staff Partial = has initiated the implementation of the human resources development plan Ongoing = recently developed a plan to recruit adequate staff but the plan has not been implemented.
31. Are there any procedures established and implemented to perform inspection and enforcement activities?	O Yes O Partial O Ongoing O No	SOPs and procedures for planning, conducting, and monitoring of GXP inspections, GXP inspection reports and documentation of processes for inspection review and follow-up must be well-documented and followed the written procedures.
Laboratory Testing (LT) (5)		
32. Is there any legal provisions, regulations, and guidelines to define the regulatory framework of laboratory testing activities?	O Yes O Partial O Ongoing O No	
33. Do the laboratory activities implement as per well-established plans and policies according to quality management system (QMS)?	O Yes O Partial O Ongoing O No	
34. Are there sufficient competent staff (i.e., education, training, skills, and experience) to perform laboratory testing activities?	O Yes O Partial O Ongoing O No	Yes = has a sustained number of competent staff No = does not have enough competent staff Partial = has initiated the implementation of the human resources development plan Ongoing = recently developed a plan to recruit adequate staff but the plan has not been implemented.

Section II: Specific questions based on WHO-GBT indicators

Instruction and explanation for Section II: please select the answer and bold the circle ("●") based on the regulatory system of your National Regulatory Authority.
Yes = implemented with track record
Partial = recently developed or less than 2 years implementation
Ongoing = only demonstrable steps but not yet implemented
No = not implemented

Questions	Answers	Remark
Laboratory Testing (LT) (5)		
35. Are there adequate laboratory facilities to perform quality testing activities?	O Yes O Partial O Ongoing O No	Yes= are adequate to perform targeted testing activities Partial = upgrade to adequate laboratory facilities less than a year ago Ongoing = plan to upgrade laboratory facilities but no evidence.
36. Are there any documents or channels for laboratory activities communicated to the public community to promote transparency, consistency, public trust, and confidence in the regulatory system?	O Yes O Partial O Ongoing O No	Yes = activity reports are regularly and consistently published and publicly available. Partial = there are documents or other relevant information and capacity but has only limited number of documented events or experience Ongoing = has a procedure only but not yet implemented

Section III: Opinion questions on WHO-GBT

1. For your organization, please rank GBT items by its priority from the highest (1) to the lowest (6). (One or more GBT items could be ranked at the same priority)

_____National Regulatory System (RS)
_____Registration and Marketing Authorization (MA)
_____Market Surveillance and Control (MC)
_____Licensing Establishments (LI)
_____Regulatory Inspection (RI)
_____Laboratory Testing (LT)

2. Which GBT item is the most difficult to achieve?

O National Regulatory System (RS)
O Registration and Marketing Authorization (MA)
O Market Surveillance and Control (MC)
O Licensing Establishments (LI)
O Regulatory Inspection (RI)
O Laboratory Testing (LT)

3. What are the major challenges to achieve WHO-GBT in regulatory functions?

O Limited human resources
O Limited budget supply
O Limited technical support
O Limited number of facilities and laboratory equipment
O Limited support from High Administrative level
O Limited coordination and cooperation of other stakeholders
O Other ----------