Pharmaceutical System Transparency and Accountability Assessment Tool

Good Governance for Medicines

Progressing access in the SDG era

World Health Organization

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List of abbreviations

CoC	Code of Conduct
CoI	Conflict of Interest
CMS	Central Medical Store
CRO	Contract Research Organization
CT	Clinical Trials
EML	Essential Medicines List
GCP	Good Clinical Practice
GDP	Good Distribution Practices
GGM	Good Governance for Medicines
GLD	Good Laboratory Practices
GMP	Good Manufacturing Practices
IEC	Independent Ethics Committee
INN	International Nonproprietary Name
IRB	Institutional Review Board
MA	Marketing Authorization
MoH	Ministry of Health
NGO	Nongovernmental Organization
NRA	National Regulatory Authority
NEML	National Essential Medicines List
SDG	Sustainable Development Goals
SF	Substandard and falsified
SOP	Standard Operating Procedure
ToR	Terms of Reference
WHO	World Health Organization

Contents

Introduction

The Sustainable Development Goals (SDGs) underscore the important role of governance across all sectors including health and across all developmental challenges including the achievement of universal health coverage. It is now widely accepted that robust public accountability and participation mechanisms are indispensable for effectively pursuing universal health coverage. [2] Universal health coverage aims to ensure that all people obtain the health services they need without suffering financial hardship when paying for them.

Weak governance and inefficient practices leave health systems vulnerable to corruption and mismanagement and can have a detrimental effect on health budgets, patients' health and well-being as well as on the image of and trust in the public institutions. The pharmaceutical system[1] is particularly vulnerable to the absence of good sector governance which can:

- reduce the resources effectively available for medicines;
- reduce the government's capacity to provide good quality essential medicines;
- contribute to the entry of substandard or falsified medical products on the market;
- contribute to shortages of medicines supplies; and
- contribute to the purchase of medicine at higher prices than necessary or the purchase of ineffectual or unnecessary medicines.

A number of factors contribute to weak governance including information asymmetries, complexity of the system and weak institutional capacity for the enforcement of standards. In addition, the absolute amounts of money and value of the medicines circulating in the pharmaceutical system is considerable. Worldwide, they tempt the many different public as well as private actors involved to divert funds or medicines, to use unethical practices or exert influence to for personal or professional gain.

Transparency and accountability are consistently identified as key to attaining stronger pharmaceutical system governance (see box 1 for definitions). [3,4]. Increasing the level of transparency and accountability in the pharmaceutical system decreases vulnerabilities for corruption and unethical practices and improves efficiency, credibility and public trust in government institutions. Opportunities for corrupt practices such as bribery, embezzlement, misappropriation of funds and diversion of medicines that occur throughout the pharmaceutical system can be minimized when standards and clear responsibilities are assigned; decisions and results are documented and made public to show whether standards and commitments have been met; and corrective actions, including sanctions, are enforced if necessary.

When interested stakeholders have access to the right information they are empowered to hold those responsible to account with respect to the decisions concerning them and the handling of

[1] Pharmaceutical system refers to the relationship/interactions between the various actors of the pharmaceutical sector, the rules that govern these interactions, and the way decisions are made, in particular in the government

public resources. Essential to accountability is the establishment of a fair process for making decisions and the handling of public resources. Daniels states that "a fair process requires publicity about the reasons and rationales that play a part in decisions […] for people should not be expected to accept decisions that affect their well-being unless they are aware of the grounds for those decisions". [5]

Box 1: Definitions used in this tool[6]

Transparency	Transparency is understood as governments making information publicly available so that their actions and decisions are visible and understandable to the public and so they can, therefore, be held to account.
Accountability	Individuals and institutions: (i) are responsible for acting according to certain standards and commitments; (ii) are answerable for their actions; and (iii) will face consequences when standards or commitments are not met.

WHO Pharmaceutical system governance work

Good governance has been high on WHO's medicines policy agenda for many years. The efforts commenced with a strategy to improve good governance in the public pharmaceutical system as outlined in the WHO Global Medicines Strategy 2004-2007. In response to the WHA resolution on access to essential medicines [7] WHO continues to support Member States to "[…] *strengthen good governance of pharmaceutical systems –including regulatory, procurement and distributions systems […] in order to improve their availability, affordability, quality and rational use."*

Since its inception in 2004, 37 countries from around the globe have participated in the Good Governance for Medicines programme. Countries carried out the *WHO Assessment for measuring transparency in the public pharmaceutical sector* as a first step in understanding vulnerabilities to corruption in the pharmaceutical system. In a second phase, the findings of the assessment and potential interventions to address the identified gaps were discussed through a nationwide consultation process with key stakeholders in order to develop a National Framework for Good Governance. The third phase was the implementation of the plans in the National Framework.

The use of the assessment tool has supported the strengthening of governance by identifying areas for improvement in the pharmaceutical system. Implementation of activities in the National Frameworks for Good Governance has helped countries to achieve value based and rules based improvements. The importance and value of the assessment and GGM process is evidenced by the evaluation report of the GGM programme. The assessment proved effective in engaging major national stakeholders in the GGM process and acted as a means to increase awareness, stimulate dialogue and identify shortfalls. Positive outcomes identified included:

- awareness about the impact of weak governance, including unethical behaviour, on the capacity of countries to achieve universal access to affordable and quality medicines;
- increased transparency in specific regulatory functions including registration and licensing; major advances in management of conflict of interest; and increased public availability of information on medicines policy and governance;
- improvements in medicines procurement practices; and
- revision of pharmaceutical laws and regulations.

Development of the assessment tool

The *Pharmaceutical system transparency and assessment tool* is based on the *WHO Assessment Instrument for measuring transparency in the public pharmaceutical sector* published in 2009. The impetus for the revision came from feedback from countries having implemented the Good Governance for Medicines programme and from results of the evaluation carried out on the programme. [8] Feedback on the use of the 2009 version of the tool in countries showed that the assessment had been a useful means to identify gaps in transparency and vulnerabilities to corruption. Users indicated that a simplified and updated methodology was needed.

In February 2014, a questionnaire was sent out to users to survey the use of the 2009 version. The feedback was discussed at a meeting of the GGM Technical Working Group in Tunis in April 2014 and plans for revision were made.[9] A second meeting of the GGM Technical Working Group was held in Geneva in May 2015 to review the proposed revisions. Following this meeting numerous consultations were held with experts and country representatives. A first draft of the revised version was alpha tested at WHO headquarters and then field tested in 5 sites. Feedback from the field tests was discussed at a meeting in Geneva in December 2017 and used to finalize the tool. [10]

The major modifications to the assessment tool include a change from qualitative interviews to desk research as the basis for assessing transparency, a refinement of the scope of the assessment to include components of accountability and a simplification of the methodology to analyze the results. In addition, efforts were made to reduce duplication with any other pharmaceutical system assessment tools. The resulting *Pharmaceutical system transparency and assessment tool* is now easier to administer, uses less resources and can be used for both assessment and monitoring of progress.

Objectives and overview

WHO has developed the *Pharmaceutical System Transparency and Accountability Assessment Tool* (hereafter referred to as 'the assessment tool') to assist countries with the assessment of the public availability of key documentation that facilitates accountability of the pharmaceutical system. This document is intended for policy makers and concerned stakeholders with an interest in improving governance in the pharmaceutical system as well as for those who will carry out an assessment.

The assessment results are intended to be used to:

- ➢ Identify strengths and weaknesses with regards to transparency of pharmaceutical information
- ➢ Inform priority setting
- ➢ Develop targeted policy interventions
- ➢ Periodically to monitor progress

The main focus of the assessment is on transparency and accountability in the public sector. Other sectors are included in the assessment when relevant for accountability.

Transparency of processes and decisions is assessed rather than the performance of those processes and decisions. As such, this this tool complements other tools that assess operational capacity of the pharmaceutical system such as the WHO Regulatory System Strengthening Benchmarking Tool.

The following cross-cutting areas and eight core functional areas of the pharmaceutical system are included in the assessment:

Cross-cutting areas

Access to information
Public participation
Medicines policy
Code of conduct and anti-corruption measures
Managing conflict of interest

Functional areas

I. Registration and marketing authorization of pharmaceutical products
II. Licensing premises of manufacturers, wholesalers and retailers
III. Regulatory inspections of manufacturers, wholesalers, retailers and CROs
IV. Pharmaceutical promotion and independent information
V. Clinical trial oversight
VI. Medicine selection and reimbursement lists
VII. Public procurement
VIII. Distribution

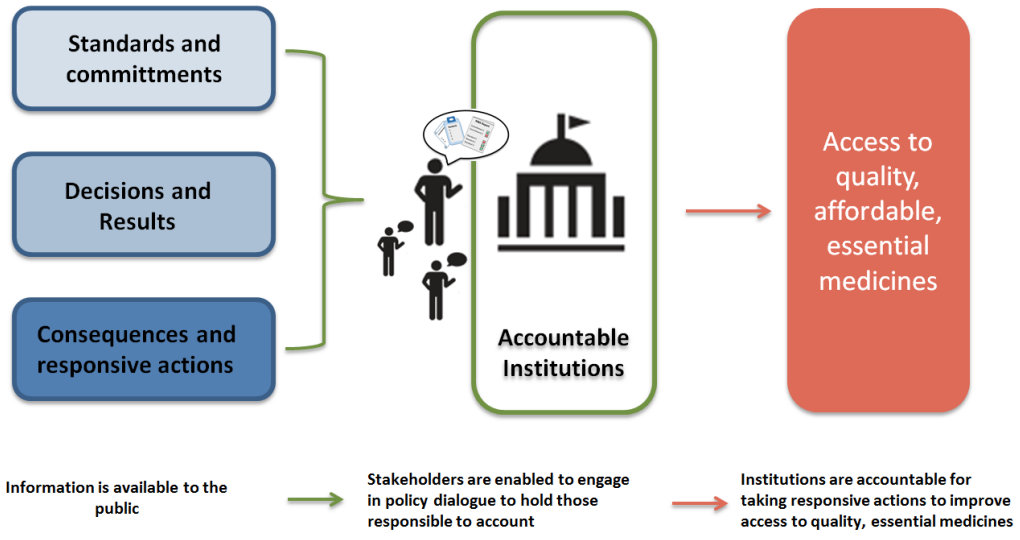
The assessment reviews the public availability of information regarded as a prerequisite for accountability. This information has been classified into three categories: (i) standards and commitments; (ii) decisions and results, and (iii) consequences and responsive actions (Box 2). More background on these categories and the supporting conceptual framework is provided by Paschke et al. [6]

Box 2: Information that should be in the public domain to enable accountability

Category of information that should be publicly available	**Examples of information**
STANDARDS AND COMMITMENTS	*Legislation, regulations, guidelines, SOPs, policy commitments*
DECISIONS AND RESULTS	*Decisions of committees, declarations of interest, progress reports on policy commitments, audit reports*
CONSEQUENCES AND RESPONSIVE ACTIONS	*Follow up of investigated complaints, rulings on appeals filed, list of corrective actions, list of suspended suppliers*

When information is in the public domain, stakeholders are better able to participate in policy dialogue and to hold those responsible to account for improving access to safe, effective, quality medicines (Figure 1).

Figure 1. Transparency and accountability to improve access to medicines



Assessment methodology

1. Initiate the assessment

The assessment may be initiated by the Ministry of Health (MoH), by WHO, partners, civil society or other interested stakeholders. If the results are to be used to inform policy making it is important to involve officials in the MoH and other relevant government institutions (e.g. the National Regulatory Authority). Having the relevant stakeholders involved from the start makes it easier to discuss the results later and to move forward with an action plan.

The initiator of the assessment or other appointed person should document minutes of meetings with relevant persons. The initiator should work with the relevant partners and stakeholders to set goals and objectives, schedule meetings and identify the resources required to implement the plan (see Annex 1 for example plan).

2. Appoint an independent assessor

An assessor should ideally:

- ➢ Be impartial with no conflict of interest (COI), i.e. not directly involved in carrying out any of the functions under review.
- ➢ Be a senior professional(s) coming from an academic institution (pharmacy, medicine, etc.), a research institute, a nongovernmental organization (NGO) or a consulting firm.
- ➢ Have knowledge of and experience in the pharmaceutical system of the country.
- ➢ Have knowledge of legal text or a legal background.

Two assessors may be appointed to improve impartiality, speed up the review and provide the necessary expertise. While anyone may conduct this assessment, knowledge of laws and the pharmaceutical system in the country will considerably speed up the review and improve the accuracy of answers. See Annex 2 for an example of terms of reference for engaging an assessor.

Once the assessor(s) is appointed, he/she should familiarize himself/herself with the assessment tool and all relevant accompanying materials. A discussion with relevant staff at WHO can help to address any questions pertaining to the methodology. The modular format of the assessment tool allows users to select the functional areas most relevant to the national context. Some sections may not apply to every context and can be omitted.

3. Hold a multi-stakeholder meeting to discuss governance in the national pharmaceutical system

Early engagement of stakeholders has been found to increase the likelihood of commitment to developing and implementing an action plan following the assessment. It is recommended for the initiator, government or other organization with convening power to organize a meeting prior to the assessment to discuss governance issues and to inform stakeholders of the assessment. A suggested agenda for a first meeting is outlined in Annex 3 and the suggested stakeholders to include are outlined in Annex 4.

4. Prepare for the assessment

Various sources might be consulted to obtain relevant evidence, including but not limited to:

- Government website(s) such as the Ministry of Health and or National Regulatory Authority and other relevant sites
- Media reports (newspaper articles, television news broadcasts, radio broadcasts)
- Public agencies

Other assessments carried out in the country on governance[11], anti-corruption and / or the pharmaceutical sector may reduce the time involved in compiling the information and completing the data collection tables. These may include reports by NGOs, partners and donors. Other relevant assessments may include the following:

- WHO Regulatory System Strengthening Benchmarking Assessment
- Pharmaceutical system assessments that include governance issues
- World Bank Governance Report
- Transparency International Global Corruption Barometer
- United Nations Development Programme (UNDP) Governance Report
- State anti-corruption commission reports

5. Conduct the assessment

The assessment involves desk research to assess what information is publicly available on government or other websites. If information cannot be found on a website, the assessor may contact government offices by phone, by writing or in person to request the information.

The information to be assessed is outlined in the following sections of this document. ***Main questions*** are used to determine whether a particular piece of information is publicly available. In some cases, **sub-questions** are included to further identify essential elements of the information that should be publically available for a particular piece of information. Answers to these sub-questions provide a level of comprehensiveness of the information available.

6. Complete the data collection tables

Data collection tables are provided in the form of excel spreadsheets at http://www.who.int/medicines/areas/governance/en/.

Responses to whether or not the information is publicly available should be recorded as explained in Table 1.

Table 1: Response options for whether or not information is publicly available

	Response options		
	Yes	**In process**	**No**
Main questions	If information is readily available on a website or readily available to the public upon request (no later than the time period specified in national legislation or 6 weeks after request).[2]	If information is being developed or revised and publication is pending.	If information is not readily available on a website or to the public upon request or is provided later than the time period specified in legislation (or later than 6 weeks after request).
Sub-questions	If the information can be found in the document referenced in the main question **or in related documentation**.[3]	If the information is being developed or revised and publication is pending.	If there is no mention of the information in the document referenced in the main question **or in related documentation.**

In order to inform report writing and policy discussions, it is essential to record **additional information** in the data collection tables. This includes:

A. The title of the document(s)
B. Where the information can be obtained (website URL, public office address)
C. Payment required & waiting time after requesting information (if any)
D. Contextual information
E. Explanation of any question marked“ in process“

[2] If a freedom of information act exists in the country the time limit for making information available as stated in the law should not be exceeded. When no such official response time is stated in the law assessors might wait a maximum of 4-6 weeks. In most countries with freedom of information acts the time limits for responding to requests are 20 working days or less .

[3] If the answer to any of the sub-questions is found in a different document or on another webpage than in the document of the corresponding main question, please provide the alternative reference in the Data Collection Tool and answer the sub-question with ‘yes’.

Providing title and source is essential as it validates the recorded answers through evidence. Furthermore once the completed data collection tables are shared publicly, any interested stakeholder knows which sources to consult for a particular piece of information. It will also facilitate repeating the assessment in the future to check for progress. If partial scores are reported, explanation is essential to explain why the information is not fully available.

7. Analyze the results

As responses are recorded in the excel spreadsheet, 'yes' answers are highlighted in green,' in process' answers in red and 'no' answers in red. Once all responses have been recorded on the excel spreadsheet, overall transparency and accountability results are generated automatically for each cross-cutting and functional section (See example in Figure 1).

Figure 1: Example of overall transparency results

Overall results for publically available information				
Main questions	**Yes**	**Partial**	**No**	**Total**
Absolute number	7	3	6	16
Percentage	44%	19%	38%	100%
Level of transparency and accountability	**moderate**			

The calculation for the overall level of transparency and accountability is made as follows:

$$\text{Score} = \frac{\text{(Main question answered 'Yes')} + 0{,}5*\text{(Main questions answered 'In process')}}{\text{Number of main question in that section}} * 100$$

The overall level of transparency and accountability is assigned as high, moderate or low as follows:

% main-questions answered yes	**Overall level of transparency and accountability**
>/=67%	High
<67 and >/=33%	Moderate
<33%	Low

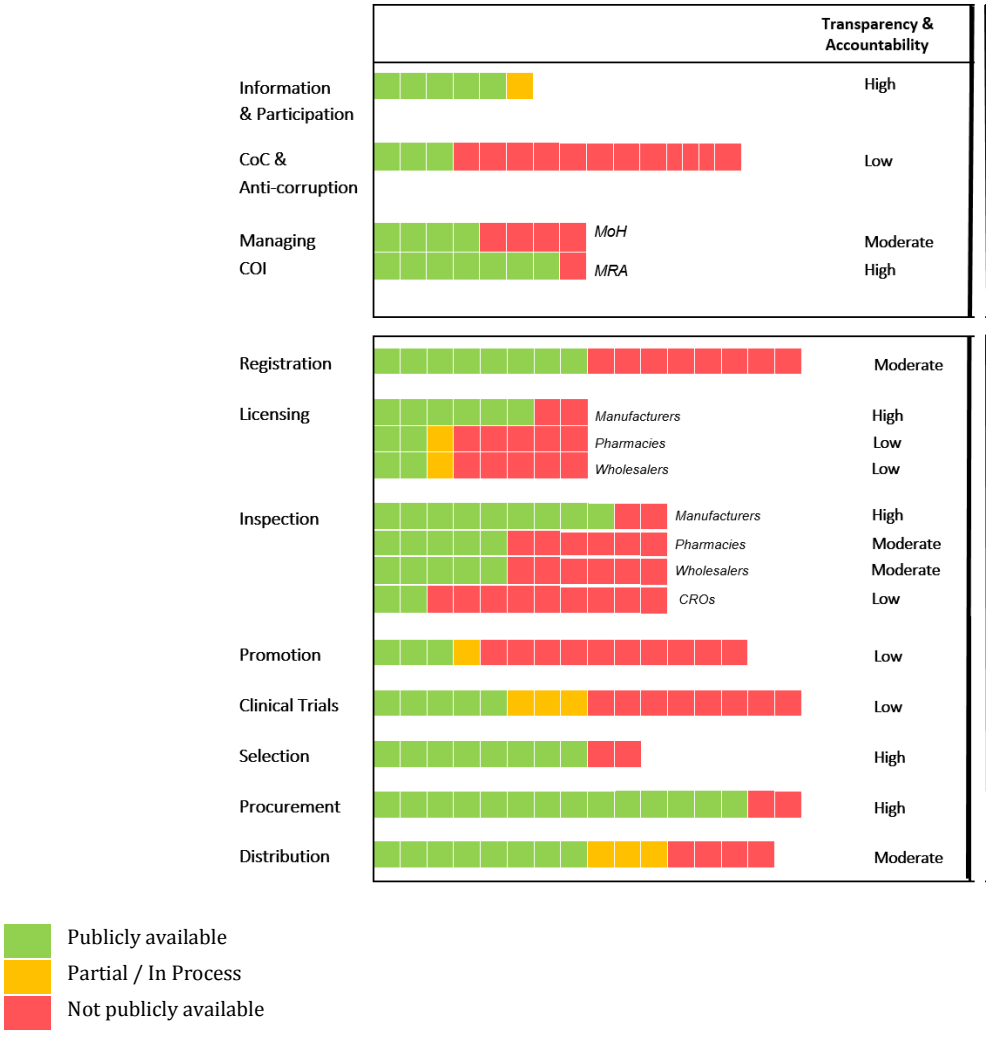
Overall scores of transparency and accountability do not take into account the results of the sub-questions. Answers to sub-questions should be used for qualitative analysis of particular main questions. Analysis may also include a review of results by accountability component (standard setting, processes and decisions and consequences and responsive actions) within each functional area / cross-cutting section.

7. Write the report

A **short report** on the findings, conclusions and recommendations should be prepared. The outline of the report could include:

- Cover page with title, author and date
- Introduction and background
- Overview including graphic representation of traffic light results and overall level of accountability for each cross cutting and functional area (see example in Figure 1 and in Annex 5).
- Summary of findings per cross cutting area and per functional area including:
    - The overall transparency results
    - Explanation of any questions that were not applicable to the country context
    - Explanation of contextual information and 'in process' results
    - Sub-question analysis
    - Areas that may need further exploration
- Conclusions and recommendations including areas that may require additional research
- Completed data collection table

Figure 1: Example of overview of traffic light results and overall level of transparency and accountability by cross-cutting and functional areas



8. Validate the results

It is recommended to send the report to someone who was not involved in the national assessment or the areas assessed such as WHO, an academic institution or a civil society institution for third party review. This can add to the robustness of the findings.

9. Use the results for policy dialogue

Results may be presented at one or more multi-stakeholder meetings to provide an opportunity for a wider audience to participate in the discussion on identifying priority areas for future action. Future action may include additional research such as qualitative key informant interviews or an action plan to address the priority areas.

The key output of the multi-stakeholder meeting can be a report with recommendations or a policy brief that outlines the key messages to be conveyed to senior policymakers and other relevant stakeholders. The policy brief might include: the policy issue, the magnitude of the problem as evidenced from the assessment, and the policy options to address the problem.

Assessment of transparency and accountability: pharmaceutical system cross-cutting areas

The following cross-cutting areas address key elements and mechanisms that are instrumental in achieving transparency and accountability in the pharmaceutical system. While these mechanisms are relevant to some or all of the specific pharmaceutical functions addressed later in this tool, they are summarized here as cross-cutting issues to highlight their importance.

X. Access to information
XX. Participation

A. Medicines policy
B. Code of conduct and anti-corruption
C. Managing conflicts of interest

X. Access to information

X.	Legislation or supporting regulations on freedom of information / defining which information needs to be made available to the public?	☐
X.x	If it is publicly available does it mention:	
	That information must be disclosed where this is in the overall public interest, even when a private interest may be harmed	☐
	A time limit for responding to requests?	☐
	A mechanism to complain when requests are not responded to within the time limit specified?	☐

XX. Participation

XX.	Law or supporting regulation recognizing the right of citizens to participate in decision-making processes that can be applied to the pharmaceutical system?	☐

A. Medicines policy

Is the following information publicly available:

STANDARDS AND COMMITMENTS		
A.1	National medicines policy?	☐
A.1+	If it is publicly available does it include:	
	An objective or a component on transparency?	☐
	An objective or a component on participation?	☐
	An objective for monitoring and evaluation of the implementation of the policy?	☐
A.2	National medicines plan or strategy?	☐
A.2+	If it is publicly available does it include:	
	Activities, responsibilities, budget and timelines?	☐
A.3	Mandate of a body responsible for auditing federal ministries including the Ministry of Health?	☐
DECISIONS AND RESULTS		
A.4	Progress report on implementation of national medicines policy?	☐
A.5	Information or report on availability or stock-outs of medicines in the public sector?	☐
A.6	Information or report on public pharmaceutical expenditures?	☐
A.7	Information or report on medicine utilization?	☐
A.8	Audit report of Ministry of Health?	☐
A.8+	If it is publicly available does it include:	
	Information on whether policy objectives were achieved?	☐
	Information on whether budget objectives were achieved?	☐
CONSEQUENCES AND RESPONSIVE ACTIONS		
A.9	Information on consequences if policy and / or budget targets were not met?	☐

B. Code of Conduct and anti-corruption

Is the following information publicly available:

STANDARDS & COMMITMENTS		
B.1	Legislation or supporting regulations for the implementation and management of code of conduct (CoC) for public employees?	☐
B.2	A code of conduct that applies to all public employees including MoH employees?	☐
B.3	A code of conduct that applies to all NRA employees (could be the same as the public employee CoC)?	☐
B.4	Mandate of an administrative body or individual within the MoH that is responsible for implementation of the CoC for public employees?	☐
B.4+	If information on such a mandate for the is available does it specify that it is responsible for the following tasks:	
	Monitor the implementation of the CoC?	☐
	Training on CoC?	☐
	Process complaints about CoC?	☐
	Enforce consequences in case of violations?	☐
	Publish reports about implementation and / or monitoring of the CoC?	☐
	Publish responses to investigated complaints?	☐
B.5	Mandate of an administrative body or individual that is responsible for implementation of the CoC for NRA employees?	☐
B.5+	If information on such a mandate for the same or different bodies is available does it specify that it is responsible for the following tasks:	
	Monitor the implementation of the CoC?	☐
	Training on CoC?	☐
	Process complaints about CoC?	☐
	Enforce consequences in case of violations?	☐
	Publish reports about implementation and / or monitoring of the CoC?	☐
	Publish responses to investigated complaints?	☐
B.6	Anti-corruption legislation?	☐
B.7	Anti-corruption strategy or plan (national or sectoral)?	☐
B.8	Mandate of an anti-corruption agency?	☐
B.9	Laws or policies that require the establishment of a mechanism for the public to complain or reporting wrongdoings?	☐
B.10	Mechanism(s) open to the public to report complaints or wrongdoings that occur in the pharmaceutical system?	☐
B.10+	Are complaints or wrongdoings regarding the following reported through this mechanism or another specific mechanism:	
	Unethical promotional practices?	☐
	Complaints arising from inspectorate activities?	☐

	Reports on potential substandard or falsified medicines?
	Research misconduct in clinical trials?
	Problems experienced by the public in accessing documents held by public institutions or agencies

B.11	A law or policy to protect whistleblowers?	

DECISIONS AND RESULTS		
B.12	Summary report about implementation / monitoring of a CoC for NRA employees?	
B.13	Summary report about implementation / monitoring of a CoC for public MoH employees?	
B.14	Progress report on anti-corruption plan?	
B.15	Report on monitoring and / or evaluation of complaints and wrongdoings?	
B.15+	If publicly available does this report or another report cover the following:	
	Unethical promotional practices?	
	Complaints arising from inspectorate activities?	
	Reports on potential substandard or falsified medicines?	
	Research misconduct in clinical trials?	
	Problems experienced by the public in accessing documents held by public institutions or agencies.	

C. Managing conflicts of interest

Is the following information publicly available:

STANDARDS AND COMMITMENTS		MOH	NRA
C.1	A policy to manage conflicts of interests of employees?		
C.1+	If it is publicly available does it mention:		
	What a conflict of interest is?		
	Who needs to make a declaration of interest?		
	When an interest needs to be declared?		
	What needs to be declared (types of interest)?		
	Rules to prevent CoI?		
	The process for the review and management of CoI?		
	Sanctions in case of non-compliance with CoI policy?		
C.2	A standard declaration of interest form for employees?		
C.3	A policy to manage conflicts of interests of experts serving as consultants or expert advisors?		
C.3+	If it is publicly available does it mention:		
	What a conflict of interest is?		
	Who needs to make a declaration of interest?		
	When an interest needs to be declared?		
	What needs to be declared (types of interest)?		
	Rules to prevent CoI?		
	The process for the review and management of CoI?		
	Sanctions in case of non-compliance with CoI policy?		
C.4	A specific policy to manage conflicts of interests of committee members?		
C.4+	If yes it is obligatory for the recruitment or appointment of		
	Market registration committee members?		
	Selection/reimbursement committee members?		
	Procurement / tender committee members?		
	Drugs and therapeutics committees?		
	Standard treatment guideline development committee members?		
C.5	An official mandate of a specific body or individual to monitor and evaluate declarations of interest forms?		
C.6	Policy / rules to manage “revolving doors”, i.e. movement of personnel from roles as decision makers or regulators into positions in the pharmaceutical sector and/or private entities (such as limitations on taking consultancies within a specified period of time)?		

DECISIONS AND RESULTS			
C.7	A register / registers for declarations of interests or summary reports of declaration of interest evaluation and management for committee members?		
C.7+	If such a register is publicly available is there evidence that declarations of interest have been made public for the following:		
	Registration committee members?		
	Selection/reimbursement committee members?		
	Procurement / tender committee members?		
	Drugs and therapeutics committee members?		
	Standard treatment guideline development committee members?		

CONSEQUENCES AND RESPONSIVE ACTIONS			
C.8	Information on how conflicts of interests were mitigated / resolved?		

Assessment of transparency and accountability: pharmaceutical system functional areas

I. Registration and marketing authorization of pharmaceutical products
II. Licensing premises of manufacturers, wholesalers and retailers
III. Regulatory inspections of manufacturers, wholesalers, retailers and CROs
IV. Pharmaceutical promotion and independent information
V. Clinical trials oversight
VI. Medicine selection and reimbursement lists
VII. Public procurement
VIII. Distribution

I. Registration and marketing authorization of pharmaceutical products

Is the following information publicly available:

STANDARDS AND COMMITMENTS		
I.1	Legislation or supporting regulations requiring registration of medicinal products?	
I.1+	If they are publicly available do they:	
	Define the types of medicinal products requiring registration and those exempted?	
	Identify the body responsible for final marketing authorization decisions?	
	Require information on efficacy, safety and quality of the products in application?	
	State period of validity?	
	Requirement for renewal?	
	Require clinical use information to be provided as part of the packaging/ package insert?	
	Provide for an appeals system independent of the registration body?	
	Specify sanctions in case an unauthorized change is made to a registered product without informing the NRA?	
I.2	Guideline on expedited review / fast-track / adaptive licensing procedures / prioritization to handle backlog?	
I.3	Guidelines and procedures for marketing authorization?	
I.3+	If they are publicly available do they specify:	
	The process to follow in submitting an application?	
	Format /template for submitting application (e.g. similar to common technical documentation)?	
	Criteria and standards against which the application will be assessed?	
	A timeframe for processing?	
	Setting of fees if applicable?	
	Content of the marketing authorization assessment report?	
I.4	Guidelines for meetings between registration officers and applicants?	
I.4+	If they are publicly available do they specify that:	
	Meetings should take place on NRA premises?	
	More than one NRA staff member should be present?	
	Prior request for a meeting in writing is required?	
	Criteria for documenting minutes?	
I.5	TORs for an expert advisory committee (or otherwise named, e.g.: scientific committee, technical committee) that advises the NRA on assessing applications for marketing authorization?	
I.5+	If they are publicly available do they specify the:	
	Selection criteria for committee members and external experts?	
	Procedure for making a decision on applications?	
	Requirement to declare interests?	
I.6	Procedure / criteria for recognizing medicines that are already undergone a stringent evaluation process (approved by another stringent national regulatory agency)?	
I.7	Guidelines on how to handle unauthorized changes to registered products?	

I.8	Guideline for applicants to file appeals?	

DECISIONS AND RESULTS

I.9	Meeting minutes of the expert advisory /scientific committee for registration?	
I.10	Names and roles of appointed members of the expert advisory /scientific committee?	
I.11	A list / database of all pharmaceutical products registered in the country updated at least annually?	
I.11+	If they are publicly available do they specify the:	
	Generic name (INN) and active ingredients?	
	Trade name?	
	Dosage form?	
	Strength?	
	Product price?	
	Pack size	
	Date of authorization	
	Date of (potential) expiration date of authorization	
	Marketing authorization holder	
	Product marketing authorization number	
	Dispensing category (OTC / prescription-only)	
I.12	Technical evaluation reports/summaries of reports for approved products?	
I.13	A list/database of all pharmaceutical products that were refused Marketing Authorization including reasons for refusal?	

CONSEQUENCES AND RESPONSIVE ACTIONS

I.14	Rulings on appeals for rejected applications for marketing authorizations?	
I.15	Regulatory actions taken after marketing authorization approval?	
I.16	List / database of products that had their MA suspended or revoked?	

II. Licensing premises
of manufacturers, wholesalers and retailers

Is the following information publicly available for each pharmaceutical establishment listed:		Manufacturers	Pharmacies	Wholesalers
STANDARDS AND COMMITMENTS				
II.1	Legislation or supporting regulation requiring a license to operate a pharmaceutical establishment?			
II.1+	If they are publicly available do they:			
	Specify the requirements for a license to operate a pharmaceutical establishment?			
	Specify the conditions for renewal, suspension and revocation of licenses?			
	Provide for an appeals system independent of the licensing body?			
	Define and require compliance with GxP (Good Manufacturing/Distribution/Pharmacy Practice)			
II.2	Explicit mentioning of responsible body with the legal mandate to issue, renew and revoke licenses in the law or supporting regulations?			
II.3	Good Manufacturing / Pharmacy / Distribution Practice?			
II.4	Guidelines and procedures for licensing of pharmaceutical establishments?			
II.4+	If they are publicly available do they specify:			
	The process for applicants to follow in submitting an application?			
	The assessment criteria (e.g. compliance with GxP)?			
	A timeframe for processing an application?			
	Setting of fees if applicable?			
	A standard application form?			
	Rules overseeing meetings between assessors and applicants?			
II.5	An official procedure to revoke the license of any establishment that brought substandard or falsified medicines into the regulated supply chain?			
DECISIONS AND RESULTS				
II.6	A list / database of pharmaceutical establishments with a licence/ operating permit?			
II.6+	If it exists does it include:			
	Name and address of premises?			
	Validity date of license?			
	Name of responsible person/contact person?			
	Date of last inspection?			
	Type of establishment?			
CONSEQUENCES AND RESPONSIVE ACTIONS				
II.7	Rulings from an independent formal appeals system on appeals filed by applicants that had their applications rejected?			
II.8	A list of pharmaceutical establishments that had their licenses revoked and / or closed down?			

III. Regulatory Inspections

Of manufacturers, wholesalers, retailers and CROs

Is the following information publicly available for each pharmaceutical establishment listed:		Manufacturers	Pharmacies	Wholesalers	CROs
STANDARDS & COMMITMENTS					
III.1	Legislation or supporting regulations on inspections of pharmaceutical establishments?				
III.1+	If they are publicly available do they:				
	Provide legal powers to inspectors to inspect premises, utilities and activities?				
	Provide legal powers to inspectors to seize and quarantine?				
	Provide legal power to inspectors to enact consequences if necessary?				
	Provide legal power to inspectors to take visual records during the inspection?				
	Provide legal power to inspectors to collect samples for testing?				
	Require inspectors to show an identification document during inspection?				
	Include pre-licensing inspections?				
	Include post-licensing inspections?				
	Authorize the NRA to collect fees and use them to finance inspections?				
III.2	Standard operating procedures for inspectors on how to conduct inspections?				
III.2+	If they are publicly available do they specify:				
	Inspection report standards?				
	Actions in case of non-compliance with Good Manufacturing Practices (GMP) ?				
	Actions in case of non-compliance with Good Pharmacy Practice (GPP)				
	Actions in case of non-compliance with Good Distribution Practice (GDP)				
	Actions in case of non-compliance with Good Clinical Practice (GCP				
III.3	Criteria for composition of inspection teams?				
III.3+	If they are publicly available do they require:				
	Inspection in teams?				
	One new inspector on each follow up inspection?				
	A peer review report on inspection by an observing inspector?				
III.4	An official rule that restricts gift giving between inspectors and the operator of and personnel at the inspected facility?				
III.5	An official rule prohibiting operator of the inspected facility to directly pay for and/ or organize travel, accommodation and catering of inspectors (only through fee paid to NRA)?				
III.6	Procedure / criteria for recognizing inspection results from other stringent NRA?				
III.7	A rule/procedure to perform regular internal audit/periodic review of the inspectorate to check for consistency of inspections?				
III.7+	If publicly available does it include information about the following procedures:				

The identification of a body/person responsible to enforce corrective actions?				
Review whether action has been taken to effectively correct non-compliances revealed in previous reviews and audits?				
Records of all audits are kept for a specified period of time?				

DECISIONS AND RESULTS					
III.8	Summary findings of inspection reports?				
III.9	Summary findings of audit reports of inspectorate(s)?				
CONSEQUENCES AND RESPONSIVE ACTIONS					
III.10	Establishments that have been notified of critical/significant inspection findings that need to be addressed?				
III.11	Corrective actions taken based on inspection results?				

IV. Pharmaceutical promotion and independent information

Is the following information publicly available:

STANDARDS AND COMMITMENTS		
IV.1	Legislation or supporting regulations governing and/or restricting pharmaceutical promotion?	☐
IV.1+	If they are publicly available do they state that:	
	Promotional activities must be consistent with national regulatory approved product information?	☐
	Promotional activities must not be deceptive or present inaccurate information?	☐
	Promotional material must be pre-approved by a body independent of the pharmaceutical industry?	☐
	Promotional material must be monitored?	☐
	Non-compliant promotional material must be retracted?	☐
	Non-compliant promotional material must be publicly corrected?	☐
IV.2	Legislation or supporting regulations specifying which forms of pharmaceutical promotion are prohibited and/or restricted?	☐
IV.2+	If they are publicly available do they mention prohibition or restriction of the following:	
	Direct to consumer advertising for prescription medicines?	☐
	Condition-oriented campaigns (disease awareness campaigns)?	☐
	Promotional activities of medical representatives?	☐
	Sponsored continuing medical education?	☐
	Hospitality and gifts?	☐
	Free samples?	☐
	Post-marketing scientific studies?	☐
	Promotion through social media?	☐
IV.3	Legislation or supporting regulations requiring disclosure of payments by the pharmaceutical industry to health professionals and / or healthcare organizations?	☐
IV.3+	If they are publicly available do they require the following to disclose:	
	Pharmaceutical companies (payments made)?	☐
	Health professionals (payments received)?	☐
IV.4	Legislation or supporting regulations on pharmaceutical promotion requiring sanctions in case of violations?	☐
IV.4+	If they are publicly available do they include:	
	Sanctions or fines for pharmaceutical companies?	☐
	Sanctions for health professionals?	☐
	Provisions that non-compliant promotional material has to be retracted and / or publicly corrected?	☐
IV.5	Mandate of a body (or bodies) responsible for the active monitoring of promotional material?	☐
IV.5+	If they are publicly available do they include:	
	Mandate to review medical education events?	☐
	Mandate to impose sanctions if non-compliance is identified?	☐
IV.6	Medicine information center (e.g. website) or bulletin for health professionals provided by government or not-for-profit entities (independent from the pharmaceutical industry)?	☐
DECISIONS AND RESULTS		
IV.7	A central register for payments made from pharmaceutical companies to health professionals	☐

	and / or healthcare organisations listing both the payer and the recipient?	☐
IV.8	Evaluation report of sponsored medical educational events for health professionals?	☐
IV.8+	If they are publicly available do they include:	
	Number of sponsors for each event?	☐
	Percentage of sponsored CME events in relation to all CME events per year?	☐
	Payment received by speakers?	☐
	Conflicts of interests of speakers identified?	☐
CONSEQUENCES AND RESPONSIVE ACTIONS		
IV.9	Warning letters demanding retractions or corrections sent to pharmaceutical companies?	☐
IV.10	Promotional material identified for retractions / public corrections?	☐

V. Clinical Trials Oversight

Is the following information publicly available:

STANDARDS AND COMMITMENTS		
V.1	Legislation or supporting regulations requiring the regulation of interventional clinical trials (CT)?	
V.1+	If they are publicly available do they mention:	
	the establishment of independent ethics committee(s) mandated to review CT protocols?	
	compliance of clinical trials with Good Clinical Practice (GCP) / Good Laboratory Practice (GLP)?	
	Protection of confidential information of subjects?	
	Prompt reporting of serious events?	
	Protection mechanisms and medical insurance of volunteers in clinical trials?	
	Sanctions in case of research misconduct?	
	Designating a body responsible for enforcement of sanctions?	
V.2	Legislation or supporting regulations requiring the registration of clinical trials (CT)?	
V.2+	If they exist do they require:	
	all CTs to be registered in the International Clinical Trials Platform (ICTRP) (or an ICTRP compliant or other publicly available registry) prior to commencing the trial?	
	Public disclosure of results of any newly conducted CT?	
	Public disclosure of unreported results for CTs conducted in the past?	
	Sanctions if CT is not registered and / or results are not reported?	
V.3	Body with the legal mandate to respond to allegations of ethical misconduct in clinical trials?	
V.4	Legislation or supporting regulations that give the legal mandate to the medicine regulatory authority or other authorized institution to authorize and regulate clinical trials?	
V.4+	If they are publicly available do they mention that the NRA has the authority to:	
	Review CT applications?	
	Make the final decision on approving or rejecting a clinical trial application?	
	Terminate a CT if official standards are not met?	
	Run on-site inspections to verify quality and reliability of data obtained?	
	Conduct audit of trials?	
	Review the results of clinical trial reports?	
V.5	Guidelines on reporting serious adverse events?	
V.6	TORs of one or more independent ethics committee responsible for reviewing clinical trial protocols?	
V.6+	If they exist do they specify the:	
	Recruitment criteria of ethics committee members?	
	Professional qualification requirements?	
	Representation of different stakeholders?	
	Time limitation for membership?	
	Funding of the ethics board?	
V.7	Guidelines for submission of applications to conduct clinical trials?	
V.7+	If they exist do they specify:	
	The process to follow in submitting an application?	
	The data that needs to be submitted?	

	Criteria for the inclusion and exclusion of trial subjects?	
	Required process for obtaining informed consent in local language?	
	The assessment criteria for approving CTs?	
	A timeframe for processing?	
	Setting fees if applicable?	

DECISIONS AND RESULTS		
V.8	Decisions on applications of clinical trials?	
V.8+	If it is publicly available does it include:	
	CT applications approved?	
	CT applications amended?	
	CT applications rejected?	
	reasons for rejections?	
V.9	Evaluation report / statistics on registration of clinical trials conducted in the country?	
V.10	Evaluation report / statistics on disclosure of results for clinical trials ongoing in the country?	
V.11	Evaluation report about ethical review practices?	
CONSEQUENCES AND RESPONSIVE ACTIONS		
V.12	Information about research misconduct and corresponding corrective actions?	
V.13	Information on corrective actions taken in case of non-compliance with registration and / or disclosure requirements for CTs?	

VI. Medicine selection and reimbursement lists

Is the following information publicly available?

STANDARDS AND COMMITMENTS		
VI.1	Legislation, supporting regulations or policy for a national essential medicines list (EML) / public reimbursement list?	☐
VI.2	TORs of committee for the selection of medicines for EMLs/reimbursement lists?	☐
VI.2+	If they are publicly available do they specify:	
	Limitation of period of time for membership?	☐
	requirements for composition of the committee?	☐
	requirement for members to declare interests?	☐
	requirement to generate meeting minutes or decisions?	☐
VI.3	Guidelines / SOPs for an evidence based selection process of essential medicines to guide the work of the selection committee?	☐
VI.3+	If they are publicly available do they define criteria for:	
	approval of medicine applications?	☐
	rejection of medicine applications?	☐
	deleting medicines from EML or reimbursement list?	☐
VI.3++	If they are publicly available do they require inclusion of medicines to be based on specified Criteria.	
	Public health relevance and burden of disease?	☐
	Proven efficacy on clinically important outcomes?	☐
	Favourable risk-benefit profile?	☐
	Cost/budget implications?	☐
VI.4	Criteria for recruitment of selection committee members?	☐
VI.4+	If they are publicly available do they define criteria for:	
	Professional qualifications required?	☐
	requirement to involve experts from different fields?	☐
DECISIONS AND RESULTS		
VI.5	A national selection or other reimbursement list that has officially been adopted by government and has been revised in the past 2 years?	☐
VI.6	Names and roles of appointed committee members publicly available?	☐
VI.7	Applications for consideration by the selection/reimbursement committee for inclusion of medicines on the national EML/ reimbursement list?	☐
VI.8	Statements made by the public , NGOs or other interested parties on applications to or decisions by the selection/reimbursement committee?	☐
VI.9	Explanations for selection/reimbursement committee decisions?	☐
CONSEQUENCES AND RESPONSIVE ACTIONS		
VI.10	Responses of the selection committee to requests for clarification of decisions and / or reinstatements of previously deleted or rejected medicines?	☐

VII. Public procurement

Does your country have a procurement system that is:

- ❑ **Centralized**
- ❑ **Decentralized** (in this case, the questions below apply to each procurement facility)

Is the following information publicly available:

STANDARDS AND COMMITMENTS		
VII.1	Legislation, supporting regulations or policy on public sector procurement of medicines?	
VII.1+	If they are publicly available do they mention:	
	Separation of responsibilities for key procurement functions?	
	Annual financial audit of the procurement system?	
	Mandatory use of generic names?	
	Purchasing limited to the EML and /or procurement list?	
	Supplier pre-qualification?	
	Mandatory publishing of tenders?	
	Mandatory publishing of prices for winning contract?	
	That tendering should be competitive, whenever possible?	
VII.2	Policy / requirement that key procurement functions and responsibilities are divided between different offices, committees or individuals?	
VII.2+	If yes, are the following functions mentioned to be independent from others:	
	Selection of medicines that should be publicly procured?	
	Quantification of medicines that should be publicly procured?	
	Product specification?	
	Technical evaluation of offers?	
	Adjudication of tenders (decision on which supplier is awarded the contract)?	
VII.3	SOPs for the quantification committee?	
VII.4	TORs for a tenders board or procurement committee(s) that is responsible for final contract decisions (adjudication)?	
VII.4+	If they are publicly available do they mention:	
	Professional qualifications required for membership?	
	Requirement for members to declare interests?	
	Periodical rotation of membership?	
	That written minutes of committee meetings are required?	
VII.5	Criteria on which pre-selection of suppliers for open-bidding is based?	
VII.6	SOPs on procurement procedures?	
VII.6+	If they are publicly available do they mention:	
	Steps for processing bids?	
	Obligatory use of generic names?	
	Requirement for public advertisement of tenders?	
	Requirement for publishing of contract specifications?	
	Requirement to issue order in a specified time period?	
	Minimum number of days for the tender to be open?	

	Requirement for procurement to be based on national EML (e.g. hospital medicine list, EML for adults; EML for children; immunization list etc.)?	
	Exemptions from regular procedures?	
	Criteria for choosing contract types?	
VII.7	Guidelines for direct purchasing?	
VII.7+	If they are publicly available do they mention purchasing of medicines:	
	An adjudication report explaining necessity of direct purchasing?	
VII.8	Guidelines for financial audits of the procurement unit?	
VII.8+	If they are publicly available do they mention:	
	Is it performed by a unit independent of the office audited?	
	Is it performed at least annually?	
	Is a body/person responsible to enforce corrective measures if irregularities are identified?	
DECISIONS AND RESULTS		
VII.9	Evidence that the procurement authority monitors supplier compliance with contracts?	
VII.10	List of prequalified medicines suppliers for public sector medicines tenders?	
VII.11	A document with names and roles of appointed tender committee members publicly available?	
VII.12	Summary results of financial audits of the procurement unit?	
VII.13	A list / database of public sector medicines call for tenders?	
VII.14	A list / database of prices of winning contracts?	
VII.15	A list of contracts for publicly procured medicines exempted from tendering?	
CONSEQUENCES AND RESPONSIVE ACTIONS		
VII.16	A list that details corrective measures enforced as identified through a financial audit?	
VII.17	Rulings from an independent formal appeals system on appeals filed by applicants who have their bids rejected?	
VII.18	A list of suspended suppliers that have not respected their contracts?	

VIII. Distribution **of publicly procured medicines**

Is the following information publicly available:

STANDARDS AND COMMITMENTS		
VIII.1	Legislation, supporting regulations or policy on distribution of publicly procured medicines?	
VIII.1+	If they are publicly available do include the following:	
	Designated persons and entities entitled to requisition of pharmaceutical products?	
	Specification for practices liable to sanction or misconduct in distribution?	
	Identification of the body/bodies responsible for enforcing sanctions for wrongdoings in distribution?	
VIII.2	Procedures to organize and expedite customs clearance of consignments at designated ports of entry for import/export of medical products?	
VIII.2+	If they are publicly available do they include:	
	That document requirements for port clearing need to be specified in procurement contract?	
	A paper-based or computerized monitoring of clearance activities?	
	Assigning responsibility for monitoring and expediting to appropriately trained personnel / clearing agent?	
	A requirement for regulatory presence at ports?	
	Official fee structure for clearing process?	
VIII.3	A procedure that a delivery voucher must be issued for every delivery?	
VIII.3+	If information about such a procedure is publicly available does it include:	
	Requirement to be signed by the recipient and the provider after physical count?	
	Requirement to be archived/ stored at the level of recipient and provider?	
	That a voucher must be issued for delivery to warehouses?	
	That a voucher must be issued for delivery to health facilities?	
VIII.4	Procedure for inspection of medicines upon receipt at public warehouses / facilities?	
VIII.4+	If they exist, do they specify:	
	Who is responsible for inspection?	
	That new medicines must be kept separate from other stock until inspection is completed (quarantine during inspection)?	
	If differences between the content of the delivery and the requisition form need to be investigated?	
VIII.5	System for performance monitoring and evaluation of the distribution system?	
VIII.6	A requirement for audits of warehouses to be performed at regular intervals?	
VIII.6+	If such a procedure is publicly available does it state that it must be:	
	Performed by an external party?	
	Followed by an audit report?	
	Followed by an operational plan to implement recommendations?	
	Procedure that requires the routine reporting of stock discrepancies and circumstances for carrying out and reporting investigations at medicine warehouses?	
VIII.7	SOPs / guidelines on how to handle the disposal of expired and spoiled pharmaceutical commodities?	
VIII.7+	If they exist do they specify:	

	Procedure for secured storage of the expired or spoiled medicine?	
	Procedure for disposal?	

DECISIONS AND RESULTS		
VIII.8	Information on confirmed seizures / alerts of substandard or falsified medical products?	
VIII.9	Information about medicines requiring disposal / medicines wastage?	
VIII.10	Monitoring and evaluation data of the distribution system?	
VIII.10+	If yes is data available for:	
	Central level?	
	Peripheral level?	
	Losses detected?	
VIII.11	Summary findings of warehouse audit reports?	
CONSEQUENCES AND RESPONSIVE ACTIONS		
VIII.12	Information on follow-up of seized substandard or falsified medical products?	
VIII.13	Information on how identified weaknesses of the distribution system were addressed?	

Annex 1: Example of a plan for implementing the pharmaceutical system transparency and accountability assessment

Activity	**Objective**	**Timing**	**Responsibility**	**Budget**
Government agreement	To inform senior government officials of the plans for assessment and multi-stakeholder discussion	Week 1	WHO/MoH pharma department	
Appoint an assessor (s)	To identify and appoint a person to carry out the assessment	Week 2- 3	WHO	
Multi-stakeholder meeting	To inform the different stakeholders of the plans for the assessment and to review available evidence on governance in the national pharmaceutical system	Week 3	MoH	
Assessment	To complete the assessment and write a report	Week 4-5	Assessor	Approx. 18 days x daily rate
Validation of report	To add to the robustness of the findings	Week 6	NGO	
Endorsement of report	To obtain agreement on the report findings	Week 7	MOH	
Multi-stakeholder meeting	To inform the different stakeholders of the results of the assessment, to discuss priorities and to make policy and/or practice recommendations	Week 8	MoH	
Develop policy brief and present to senior government	To present recommendations for policy and/or practice recommendations	Week 9	Stakeholders	
Develop implementation plan	To follow up on policy and practice recommendations	Week 10	MoH	

Annex 2: Example terms of reference for an independent assessor

Objective: to carry out the assessment of transparency and accountability using the *WHO Pharmaceutical system transparency and accountability assessment tool*

Specific Objectives:

- Define scope of the assessment
- Collect reports from related assessments
- Refine questions for the national context
- Carry out desk research
- Write report
- Present results to stakeholders

Deliverables:

- Completed data collection table
- A written report with conclusions and recommendations
- A presentation to stakeholders

Qualifications:

- Advanced knowledge of the national pharmaceutical system
- Experience with desk research, report writing and presentations

The work will take place from: date to date

Number of days: 18

Annex 3: Example agenda for multi-stakeholder meeting on governance in the pharmaceutical system

TIME	ACTIVITY	RESPONSIBLE
09:00	Arrival and registration	
9:30	Opening remarks	
	Brief Statement	Minister of Health
	Welcome Remarks	WHO Representative
	Solidarity messages	● Other government institutions ● Partners ● CSO
	Thematic presentation on governance in the pharmaceutical sector	Academic
	Keynote address on national pharmaceutical situation	Representative from Ministry of Health
	Partner and stakeholder presentations	● Other government institutions ● Partners ● CSO
	Discussion	
	Media interactions	
12:30	Close	

Annex 4: Potential participants to a multi-stakeholder meeting

- MoH officials
- Officials from other ministries such as Ministry of Trade or Finance
- Regulatory officials
- Procurement officials from public and private system
- Customs officers
- Members of committees, such as tender committees, therapeutics committees, selection of essential medicines committees, ethics committees;
- Local anti-corruption organizations/commission;
- Audit departments (internal, external, and state auditors);
- Pharmaceutical industry (multinational and national) and associations;
- Nongovernmental organizations and civil society organizations, such as those engaged in health service activities, patient advocacy groups, “watch-dog” organizations; Transparency International, Oxfam
- International organizations, such as the World Health Organization, the United Nations Children’s Fund, the United Nations Development Programme, the World Bank and the Global Fund;
- Academic institutions (national colleges, state universities and research institutes);
- Professional associations (medical, pharmacy, biochemist associations, etc.);
- Media
- Health insurance funds
- Development partners

Annex 5: Example of presentation of summary results of transparency and accountability

References

[1] Baghdadi-Sabeti, G., Kohler JC, Wondemagegnehu, E. Measuring Transparency in the Public Pharmaceutical Sector: Assessment Instrument. Geneva: World Health Organization; 2009 http://www.who.int/medicines/areas/policy/goodgovernance/measuring_transparency/en/, accessed 30 March 2018).

[2] World Health Organization. Making fair choices on the path to universal health coverage. Geneva: World Health Organization; 2014 (http://www.who.int/choice/documents/making_fair_choices, accessed 2 June 2018).

[3] Barbazza, E., & Tello, J. E. A review of health governance: definitions, dimensions and tools to govern. Health Policy, 2014; *116*(1), 1-11

[4] OECD. Accountability, transparency, participation: Key elements of good governance. Paris: OECD; 2013 (http://www.oecd.org/governance/regulatory-policy/irrc.htm, last accessed 31 October 2018).

[5] Daniels, N. Accountability for reasonableness: Establishing a fair process for priority setting is easier than agreeing on principles. BMJ: British Medical Journal. 2000; 321(7272), 1300., p.1301

[6] Paschke A, Dimancesco D, Vian T, Kohler JC and Forte G (2018) Increasing transparency and accountability in national pharmaceutical systems. Bulletin of the World Health Organization. Advance online publication. Bulletin of the World Health Organization. 2018;96:782-791.

[7] Resolution WHA67.22. Access to Essential Medicines. In: Sixty-seventh World Health Assembly, 24 May 2014. Geneva: World Health Organization; 2014 (http://apps.who.int/medicinedocs/en/d/Js21453en/, accessed 5 July 2016).

[8] Martin John and Ollier L. Evaluation of the Good Governance for Medicines Programme (2004–2012): Brief summary of findings. Geneva: World Health Organization; 2012(http://www.who.int/entity/medicines/areas/policy/goodgovernance/ggm_evaluation_report/en/index.html, accessed 5 July 2018).

[9] Good governance in the pharmaceutical sector: report of a World Health Organization technical working group meeting. Tunis, 17-21 March 2014. WHO/EMP/PAU/2014.2. Geneva: World Health Organization; 2014. [http://www.who.int/medicines/areas/governance/ggm_tunis_meeting_report.pdf , accessed 10 Oct 2018].

[10] WHO technical working group on good governance in pharmaceutical systems. December 2017. Meeting report. Geneva: World Health Organization; 2018. (http://www.who.int/medicines/areas/governance/en/ , accessed 27 Aug 2018).

[11] Governance Data Alliance. Modernizing the Marketplace for Governance Data. Undated (http://www.governancedata.org/, accessed 5 July 2018).