# Regulatory Systems Assessment Tool


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**About SIAPS**

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to ensure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

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# Instructions for Assessing Medicines Regulatory Systems and Capacity of National Regulatory Authorities using the Regulatory Systems Assessment Tool (RSAT)

## Background

As the availability of pharmaceutical products in low- and middle-income countries (LMICs) has improved in recent years, the need for functional national regulatory systems is becoming paramount in ensuring the safety, quality, and efficacy of those products. However, national regulatory authorities in LMICs struggle to fulfill their respective mandates to meet this increasing demand for their services in line with international standards. Outdated legal frameworks, inadequate staffing, inefficient processes, weak information systems, and insufficient financing are among the challenges they face. Increasingly, donors and development agencies are acknowledging the importance of regulatory systems strengthening and are looking for ways to work with national regulatory authorities to define and prioritize their system needs, identify feasible evidence-based and cost-effective system strengthening interventions, and support regulatory authorities to monitor progress toward their goals.

RSAT examines the system components and regulatory functions of a national medicines regulatory system. It can be implemented by either National Medicines Regulatory Agency (NMRA) staff for the purpose of self-assessment and monitoring or independent assessors and technical assistance providers that provide support to NMRAs to pinpoint and prioritize the specific areas of the regulatory system that most need improvement to achieve greater efficiency and effectiveness. The tool is designed to populate a combination of quantitative and qualitative data from multiple pre-existing sources. The data are intended to be analyzed and interpreted together, thereby creating a complete, context-specific understanding of the regulatory system and the interconnected factors that influence its performance. Sample indicators provide the means by which the performance and system improvements, within specific regulatory functions, can be measured over time. Notably, RSAT does not evaluate the regulatory system and its functions against validated benchmarks or established international standards that aim to designate a specific level of system performance/maturity. Such measurements can be done more effectively with other tools that have been designed by the World Health Organization (WHO) specifically for that purpose.

## Development of RSAT

RSAT was developed by Jude Nwokike of the Strengthening Pharmaceutical Systems (SPS) Program in 2010 to serve as a holistic and comprehensive tool to support regulatory system strengthening initiatives. The tool captures a breadth of information not fully covered by any other single tool. RSAT's methodology and many of its assessment questions and indicators are drawn and adapted from existing tools, including WHO's Guide for data collection to assess drug regulatory performance;[1] Data collection tool for review of national regulatory system;[2]

[1] World Health Organization. "Practical Guidance for Conducting a Review." Geneva 2007. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/GuideAssessRegSys.pdf

[2] World Health Organization. "WHO Data Collection Tool for the Review of Drug Regulatory Systems." Geneva 2007. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/ENdatacollectiontool.pdf

Building capacity through the review of national regulatory systems;[3] USP/DQI's Rapid Assessment of Quality Assurance and Quality Control of Medicines;[4] and MSH/SPS's indicator-based pharmacovigilance assessment tool (IPAT).[5] In addition, the SPS team incorporated additional assessment questions not previously included in other tools to cover additional areas of medical product regulation that are relevant to regulatory system strengthening in LMICs, such as governance. The first draft of the tool was piloted in Namibia in 2011. The tool was later used in 2012 by the SIAPS Program to conduct an assessment of the regulatory system and capacity of the Directorate General for Drug Administration in Bangladesh.

## Organization of RSAT

The tool consists of four sections to help users conduct an assessment of the national regulatory system.

- Section A serves as an introduction to the tool and has information and instructions on how to use it.
- Section B lists all supporting documents that need to be reviewed for data compilation and verification.
- Section C consists of the assessment questions and the data fields organized by regulatory system function.
- Section D includes a list of suggested quantitative indicators, also grouped by regulatory system function.

Both the assessment questions and the indicators are classified according to the following regulatory system components and functions:

1. Component 1: Regulatory policy, legislation, structure, and systems
2. Component 2: Regulatory functions and processes
   - 2.1 Product evaluation and registration function
   - 2.2 Licensing function
   - 2.3 Inspection of manufacturing sites and distribution facilities function
   - 2.4 Medicines information and control of advertising and promotion function
   - 2.5 Quality control function
   - 2.6 Pharmacovigilance function
   - 2.7 Clinical trials function
3. Component 3: Monitoring and evaluation

## Objectives of an RSAT Assessment

The objectives of a regulatory system assessment using RSAT can vary from one country to another and will depend on the specific needs and circumstances that have prompted the assessment. Countries should define the objectives of their assessment at the onset to ensure that the tool is appropriate for their intended purpose and, if necessary, adapt it accordingly.

Objectives that can be fulfilled by the application of RSAT include:

1. Review the status of the medical products regulatory system or the status of any select functions of the system in a particular country

[3] World Health Organization. "Strengthening National Regulatory Authorities: Building Capacity Through the Review of National Regulatory Systems." http://www.who.int/medicines/areas/quality_safety/regulation_legislation/reg_review_regul_capac.pdf

[4] United States Pharmacopeia. "Rapid Assessment of Medicines Quality Assurance and Medicines Quality Control." March 2007.

[5] Strengthening Pharmaceutical Systems (SPS) Program. 2009. Indicator-Based Pharmacovigilance Assessment Tool: Manual for Conducting Assessments in Developing Countries. Submitted to the U.S. Agency for International Development by the SPS Program. Arlington, VA: Management Sciences for Health.

2. Provide the required data to conduct options analysis, inform stakeholder identification of priorities, and design improvement interventions to strengthen the national medicines regulatory authority and system
3. Establish a baseline against which regulatory system improvements can be measured over time

As noted earlier, RSAT is not designed to score or grade the level of performance/maturity of the national regulatory system to undergo a particular task/function or to meet particular international regulatory standards—for example, RSAT cannot determine the stringency of a national medicines regulatory authority. If that is the intended objective of an assessment, countries are encouraged to use the tools available from WHO.

The following sections provide high-level guidance on how to conduct an assessment using RSAT. This guidance may be contextualized and expanded on by in-country teams based on country needs and settings.

# A: Data Collection Methods

RSAT employs two data collection methods, both of which should be used concurrently to generate the greatest amount of data and/or to validate elements of the collected data. The methods are:

1. Pre-assessment document review
2. Structured interviews and document collection, using the RSAT questionnaire as a guide. Responses related to availability of documents, including policies, procedures, manuals, tools, and other written materials, need to be verified by the data collector. Data should not be merely collected from key informants' verbal responses; they need to be validated with the supporting documentation.

## Preparing for Data Collection

1. Plan the team. Recommendations for required human resources include the engagement of three data collectors and one expert in regulatory affairs. The latter needs to be independent of the national regulatory authority being surveyed and of the regulated industry. The expert normally serves as the assessment lead.
2. The assessment lead should develop an assessment plan in coordination with the NMRA. The plan will have an outline of the different steps, a data collection strategy, the division of responsibilities among the data collectors, a schedule of events, and a timeline for the assessment.
3. Prior to the start of data collection, the tool should be reviewed with the assessment team and, if possible, department heads within the NMRA should customize it based on the setting and the specific objectives of the assessment.
4. Once the tool has been reviewed and finalized, the assessment lead should provide training to the data collectors on the application of the tool and the two data collection methods.
5. Buy in from NMRA leadership and other key stakeholders is essential for an effective assessment. The assessment team is encouraged to meet with stakeholders to discuss assessment objectives, share the tool, and review the assessment plan to secure their cooperation and, when appropriate, their participation.

## Data Collection Points and Recommended Sampling

| Data collection point | Recommended sample |
|---|---|
| National Medicines Regulatory Authority (NMRA) | 1 respondent per regulatory function |
| Provincial and regional offices of the regulatory authority | 1 respondent per regulatory function |
| The data collection points listed below are *recommended* for additional information on the performance of the regulatory system and the role of other stakeholders. These can be used for the validation of the data collected from entities directly responsible for the regulation of medical products (i.e., the NMRA). | |
| Regulated industry: | |
| Pharmaceutical manufacturers/companies | 1 respondent per company |
| Wholesalers, distributors, and manufacturers | 1 respondent per company |
| Public hospitals and health facilities using regulated products | 1 facility per health system delivery level (national hospital, regional/district hospital, health center) and<br><br>3 respondents per facility (pharmacists, physician, nurse) |
| Private hospitals and health facilities using regulated products | 1 facility per region and<br><br>3 respondents per facility (pharmacist, physician, nurse) |
| Complementary products manufacturers and dealers | 1 respondent per company (at the national level) |
| Government ministries: | |
| Public health programs | 1 respondent per public health program |
| Ministry of Justice | 1 respondent at the national level |
| Ministry of Trade | 1 respondent at the national level |
| Ministry of Industry | 1 respondent at the national level |
| Civil societies: | |
| Consumer organizations | 1 respondent at the national level |
| Health professional societies | 1 respondent per professional society at the national level |
| Health professional regulatory organizations (e.g., Pharmacy Council) | 1 respondent per professional organization at the national level |
| Traditional healers, complementary and alternative medicine dealers | 1 respondent per group at the national level |

## Data Validation

1. RSAT requires verification of the responses of many of its assessment questions. This typically involves not only confirming availability of documents but also collecting copies of such relevant documents and locating the information within the documents that verifies specific responses.
2. If available, the most recent regulatory system assessment report using any tool from the country being assessed can be used to validate or check at least some of the responses to the RSAT questions.
3. The source and date of the data should be indicated for all relevant questions.
4. Data and preliminary results should be validated with relevant officials/stakeholders and source documents.

## Data Analysis, Interpretation of Findings, and Dissemination of Results

After due data collection and validation, the process of data analysis should include:

1. Entering the values and calculating the percentages for indicators where specified in the data collection tool
2. Identifying and synthesizing common themes from the descriptive information gathered during key informant interviews

Quantitative and qualitative results from the assessment should be synthesized, interpreted, and documented in a technical report. The assessment team is encouraged to share a draft with key NMRA officials and stakeholders for review and feedback prior to finalization.

In most cases, assessment findings will have the greatest impact if they are shared at a stakeholder workshop for discussion, prioritization of areas for improvement, and identification of regulatory system strengthening interventions. The stakeholder workshop should include a group of individuals with diverse expertise and interests (see recommended list below).

Outputs from the workshop will inform strategic and/or work plans that are developed to address the results of the assessment and aim at strengthening the regulatory system. Results of the regulatory system assessment may be used to inform an options analysis to critically and systematically assess and compare intervention options,[6] either before or after the dissemination of results to stakeholders.

Stakeholders to include in dissemination, options analysis, and planning activities should include:

- NMRA officials
- Regulators and other health officials involved in regulatory activities at the subnational levels, including inspectors
- Representatives from public health programs (e.g., HIV/AIDS; tuberculosis; malaria; maternal, newborn, and child health; family planning /reproductive health; and neglected tropical diseases)
- Representatives from pharmaceutical manufacturers/companies
- Representatives from wholesalers, importers, and distributors
- Representatives from government (public) health facilities
- Representatives from private health facilities
- Representatives from professional associations
- Members of civil society (e.g., patient and consumer groups)
- Government officials representing ministries of health, justice, and trade/commerce

[6] Soucy Brown M, Chin DL. 2016. Analyzing Options for Strengthening Pharmaceutical Systems. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health.

## Development of Strategic and Work/Action Plans

Assessment findings should be used to define strategies and design activities for addressing priority gaps and weaknesses in the regulatory system in collaboration with key stakeholders. These strategies should be documented in concrete strategic and work plans along with estimated budgets and timelines for their implementation and evaluation. Such plans can help countries effectively advocate for additional funds and technical support to implement these plans. Findings can also be used to select appropriate strategic indicators and establish baseline and targets against which regulatory system improvements can be measured as interventions are implemented.

# B: Supporting Documents

The supporting documents listed below should be requested and, if possible, reviewed prior to data collection. If they cannot be obtained prior to data collection, they should be requested when the associated RSAT question is asked.

| Associated RSAT Question | List of Supporting Documents | Available from NRA? | Reviewed? | Archived (electronic or hard copy)? | Comments |
|---|---|---|---|---|---|
| 1.8 | Assessment of the regulatory system conducted within the last two years | | | | |
| 2.2 | National Medicines Policy | | | | |
| 2.7 | Formal organizational structure (organization chart) for the NRA | | | | |
| 2.10 | Formal organizational structure (flow chart) for medicines regulation | | | | |
| 2.13 | Sample of NRA transparency/conflict of interest declarations currently being practiced | | | | |
| 2.20 | List of accountable persons in NRA (as per formal accountability system) | | | | |
| 2.22 | Copy or list of enforcement framework | | | | |
| 2.28 | Mapping of staff (and full-time equivalent "consultant") needs | | | | |
| 2.30 | Job descriptions for all positions within the NRA | | | | |
| 2.36 | Financial audit and/or government accountability audit in the last year | | | | |
| 3.2 | Standard application form and/or guideline for submission of dossiers for registration | | | | |
| 3.6 | Regulations listing the required information and evidence to be submitted with dossiers | | | | |
| 3.9 | SOPs and/or flow charts showing the process of evaluation and registration | | | | |
| 3.1.11 | Registration certificate (including conditions for registration, including indication) | | | | |
| 3.1.14 | Sample of documents issued following approval for registration | | | | |
| 3.1.16 | Documentation of system for re-evaluation, if there is no registration expiry | | | | |
| 3.2.7 | Survey to determine unlicensed dealers in pharmaceutical products | | | | |
| 3.2.8 | List of licensed premises/establishments and persons | | | | |
| 3.3.4 | GMP inspection plan (annual) | | | | |
| 3.3.15 | Risk-based inspection strategy/model | | | | |
| 3.4.4 | Document containing formal organizational relationship among the medicines information center and the NRA, MoH, health facilities, patients, consumer/public, media, etc. | | | | |
| 3.4.5 | Document containing role of the medicine information center/unit within NRA | | | | |
| 3.4.7 | Inventory of reference resources at the medicines information unit | | | | |
| 3.4.9 | Strategy or code use for monitoring advertising and promotion | | | | |
| 3.4.3 | MOUs with external quality control labs used by the NRA (labs that are not within the NRA) | | | | |
| 3.4.7 | Sample collection strategy of NRA quality control labs | | | | |
| 3.4.18 | ADR or medicine safety bulletin (or any other health-related newsletter that routinely features ADR or medicine safety issues) published in the last six months | | | | |
| 3.4.22 | Form for reporting suspected ADRs | | | | |
| 4.2 | NRA work plan (including activities) | | | | |
| 4.3 | NRA systems for self-assessment of its regulatory activities | | | | |
| 4.5 | Audit or evaluation carried out in the past five years to assess implementation/performance of the regulatory system | | | | |

# C: Regulatory Systems Assessment Tool (RSAT)

## 1. BACKGROUND INFORMATION

1. Name of the National Regulatory Authority (NRA) _____
2. Address of the NRA _____
3. Tel _____
4. Fax _____
5. Email _____
6. Date of assessment _____
7. Name of data collector _____

8. Assessment of the regulatory system conducted within the past two years?

   ☐ Yes (please complete information below)

   ☐ No

| Copy Obtained | | Document title | Date |
|---|---|---|---|
| ☐ Yes | ☐ No | | |

9. Provide the following expenditure data

| Demographic and expenditure data | Amount | Year | Source |
|---|---|---|---|
| Total government pharmaceutical expenditure (USD million) | | | |
| Total pharmaceutical expenditure (government, household, international aid, etc.) (USD million) | | | |

10. Provide data on situation of the pharmaceutical industry

| Pharmaceutical production status | Amount | Year |
|---|---|---|
| **Pharmaceutical manufacturing plants** | | |
| Total number of pharmaceutical manufacturing plants in the country | | |
| Number of pharmaceutical manufacturing plants producing pharmaceutical active ingredients only | | |
| Number of pharmaceutical manufacturing plants producing finished pharmaceutical dosage forms | | |
| Number of pharmaceutical manufacturing plants packaging only finished pharmaceutical dosage forms | | |
| Total number of research-based pharmaceutical manufacturers | | |
| Total number of manufacturers producing generic pharmaceutical products (including branded generics) | | |
| Total number of nationally owned pharmaceutical manufacturers (government and private) | | |

11. Provide data on situation of pharmaceutical supply and distribution system

| Distribution | Amount | Year |
|---|---|---|
| Importers | | |
| Wholesalers | | |
| Government hospital pharmacies | | |
| Private hospital pharmacies | | |
| Private for-profit retail pharmacies | | |
| Private not-for-profit retail pharmacies | | |
| Other medicines dispensing outlets (e.g., dispensing doctors, clinics) | | |
| Unlicensed dispensing outlets | | |

12. Provide data on pharmaceutical products in the country

| Pharmaceutical products | Amount | Year |
|---|---|---|
| Total number of pharmaceutical products registered in the market | | |
| Number of generic products, including branded generics, registered | | |
| Generics as % of the total number of pharmaceutical products registered | | |

## 2. REGULATORY POLICY, LEGISLATION, STRUCTURE, AND SYSTEMS

1. Existence of national law, regulations, or policy on pharmaceutical regulation

☐ Yes (please complete information below)

☐ No

| Copy Obtained | | Document title | Date |
|---|---|---|---|
| ☐ Yes | ☐ No | | |

2. Legal provisions define the role of government to set up structures and systems for ensuring quality, safety, and efficacy of health products

☐ Yes (please complete information below)

☐ No

| Copy Obtained | | Relevant section(s) of the law, regulation, or policy |
|---|---|---|
| ☐ Yes | ☐ No | |

3. Title and date of enactment of the most recent medicines law/act of the country

| Document title | Date of enactment |
|---|---|
| | |

4. Legislative history of medicines regulation (indicate below the title(s) and date(s) of enactment of the different medicines legislation/regulations previously and currently used to regulate medicines in the country, including international/regional conventions, schemes, etc., to which the country is signatory)

| Title and description of legislative document | Date of enactment |
|---|---|
| | |
| | |
| | |
| | |

5. Existence of national regulatory authority

☐ Yes (please complete information below)

☐ No

| Describe functions |
|---|
| |

6. What is the legal organizational status of the NRA?
   - ☐ MoH unit
   - ☐ Government agency
   - ☐ Corporate/autonomous parastatal
   - ☐ Private and independent

7. Does the NRA have a mission statement consistent with its legal mandate?
   - ☐ Yes (please complete information below)
   - ☐ No

| Copy Obtained | | Document title | Date |
|---|---|---|---|
| ☐ Yes | ☐ No | | |

8. What body is responsible for the following regulatory functions?

| Function | Name of authority/organization |
|---|---|
| Licensing of pharmaceutical manufacturers | |
| Licensing of pharmaceutical importers | |
| Licensing of pharmaceutical wholesalers | |
| Licensing of retail/dispensing outlets | |
| Product assessment and registration/marketing authorization | |
| Good manufacturing practice (GMP) inspection | |
| Inspection of distribution channels | |
| Control of promotion and advertising | |
| Performing quality tests/quality control laboratory | |
| Price regulation/control | |
| Regulating generic substitution | |
| Control of prescribing | |
| Adverse drug event (ADE) monitoring | |
| Clinical trial regulation | |
| Provision of medicine information to professionals and the consumer | |
| Other (specify) | |

9. Existence of organizational structure for national regulatory authority
   - ☐ Yes (please complete information below)
   - ☐ No

| Copy Obtained | | Document title | Year |
|---|---|---|---|
| ☐ Yes | ☐ No | | |

10. What regulatory function(s) is/are carried out at the different government administrative levels (state, province, etc.)?

| Administrative level | Functions |
|---|---|
| Central/federal level | |
| Province/state level | |
| District level | |
| Other (specify) | |

11. Are there any written materials describing the roles, responsibilities, functions, or powers of regulatory bodies at the province and district levels?

☐ Yes (please complete information below)

☐ No

| Document title(s) |
|---|
| |
| |
| |
| |

12. List all committees that participate in regulatory functions and indicate their role (e.g., advisory, decision making)

| Name of committee | Function/role |
|---|---|
| | |
| | |
| | |
| | |
| | |
| | |

13. Governance practices and structures mandated by legislation/regulations for the NRA and its committees

| Governance structures | Yes | No | Relevant sections of the legislation/regulation |
|---|---|---|---|
| Conflict of interest | ☐ | ☐ | |
| Declaration of assets | ☐ | ☐ | |
| Confidential financial disclosure | ☐ | ☐ | |
| Policies, procedures, and guidelines for meetings and contacts between the NRA and regulated industries | ☐ | ☐ | |
| Dissemination of NRA deliberations/freedom of information/website | ☐ | ☐ | |
| Ombudsman | ☐ | ☐ | |
| Existence of transparency measures and indicators | ☐ | ☐ | |
| Involvement of civil societies in regulatory deliberations | ☐ | ☐ | |
| Inputs solicited before regulations are formalized | ☐ | ☐ | |

14. Are conflict of interest declarations currently in practice?

☐ Yes (please complete information below)

☐ No

| Copy and paste sample | Reasons not practiced |
|---|---|
| | |

15. To whom do conflict of interest declarations apply?

☐ NRA council

☐ Committees

☐ NRA staff

☐ Consultants

16. Are any government-owned and run entities involved in the following?

| Function | Yes/no | If yes, give the name of the organization(s) or attach a list | NRA involvement |
|---|---|---|---|
| Pharmaceutical manufacturing | | | |
| Pharmaceutical import and distribution | | | |
| Retail pharmacy sales | | | |

17. Is there a comprehensive list of guidelines, SOPs, and protocols used by the NRA?

☐ Yes (please complete information below)

☐ No

| Copy Obtained | | Document title |
|---|---|---|
| ☐ Yes | ☐ No | |

18. Infrastructure available for NRA's regulatory duties

| Infrastructure | Number in use | Adequate for current operations | |
|---|---|---|---|
| | | Yes | No |
| Computers | | ☐ | ☐ |
| Software programs for regulatory functions | | ☐ | ☐ |
| Local databases | | ☐ | ☐ |
| Regulatory intelligence database | | ☐ | ☐ |
| Internet (reliable and functioning) | | ☐ | ☐ |
| Reference texts and documents (including pharmacopeia) | | ☐ | ☐ |
| In-house laboratory | | ☐ | ☐ |
| Office space | | ☐ | ☐ |
| Archives (designated room or electronic) | | ☐ | ☐ |

19. Does the NRA have an enforcement framework?

☐ Yes (please complete information below)

☐ No

| Copy Obtained | | Document title |
|---|---|---|
| ☐ Yes | ☐ No | |

20. What are the different types of offenses and ranges of sanctions provided?

| Type of offense | Range of sanctions |
|---|---|
| | |
| | |
| | |

21. Violations registered and administrative measures and judiciary sanctions applied in the last five years *(specify years)*

| | Year | Year | Year | Year | Year |
|---|---|---|---|---|---|
| Total number of violations registered | | | | | |
| Number of administrative measures implemented by the regulatory authority | | | | | |
| Number of legal sanctions implemented by a judicial body/court | | | | | |

22. Number of enforcement measures taken in the last five years (*specify years*)

| Enforcement measures | *Year* | *Year* | *Year* | *Year* | *Year* |
|---|---|---|---|---|---|
| Written warning | | | | | |
| Fine | | | | | |
| Imprisonment | | | | | |
| License suspended | | | | | |
| License revoked | | | | | |
| Production suspended | | | | | |

23. Has a mapping or assessment of staff needs for regulatory functions been conducted?

☐ Yes (please complete information below)

☐ No

| Copy Obtained | | Document title |
|---|---|---|
| ☐ Yes | ☐ No | |

24. List the number of the staff working in the NRA

| | Number of staff members | | | |
|---|---|---|---|---|
| | Administrative | | Technical | |
| Regulatory functions | Full time | Part time | Full time | Part time |
| Licensing | | | | |
| Product evaluation and registration | | | | |
| Inspections of manufacturing sites and distribution facilities | | | | |
| Medicines information and control of advertising and promotion | | | | |
| National quality laboratory | | | | |
| Pharmacovigilance | | | | |
| Clinical trials | | | | |
| Total | | | | |

25. Job descriptions developed for all positions in the NRA

☐ Yes (please complete information below)

☐ No

| Copy Obtained | | Document title |
|---|---|---|
| ☐ Yes | ☐ No | |

26. Provide information below on the type and number of regular full-time staff working at the NRA

| Position | Number of staff |
|---|---|
| Administration staff | |
| Pharmacists | |
| Physicians (all types) | |
| Chemists | |
| Epidemiologists | |
| Microbiologists | |
| Pharmacologists/clinical pharmacologists | |
| Veterinarians | |
| IS/IT specialists and technicians | |
| Toxicologists | |
| Other (specify) | |

27. Budget and source of funding for medicines regulation in each of the last five years (*specify years*)

| **Budget** | ***Year*** | ***Year*** | ***Year*** | ***Year*** | ***Year*** |
|---|---|---|---|---|---|
| Budget | | | | | |
| Actual expenditure | | | | | |
| Gap | | | | | |
| Source(s) of funding | | | | | |

28. Budget allocated for the following regulatory functions in the past five years (*specify years*)

| **Budget** | ***Year*** | ***Year*** | ***Year*** | ***Year*** | ***Year*** |
|---|---|---|---|---|---|
| Licensing | | | | | |
| Product evaluation and registration | | | | | |
| Inspections of manufacturing sites and distribution facilities | | | | | |
| Medicine information and control of advertising and promotion | | | | | |
| Quality control | | | | | |
| Pharmacovigilance | | | | | |
| Clinical trials | | | | | |

29. List of NRA regulatory services provided for a fee

| **Type of service provided** | **Fee charged (USD)** | **Total fee collected last year (USD)** | **Percent of collected fees retained by NRA** |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

30. What were the total fees collected during each of the last five years? (*specify years*)

| | ***Year*** | ***Year*** | ***Year*** | ***Year*** | ***Year*** |
|---|---|---|---|---|---|
| Fees collected (USD) | | | | | |

31. Has an external financial audit been conducted within the last year?

☐ Yes (please complete information below)

☐ No

| **Copy Obtained** | | **Document title** |
|---|---|---|
| ☐ Yes | ☐ No | |

32. Indicate the main weaknesses/challenges related to regulatory policy, legislation, structure, and systems, and current efforts (if any) to address them

| **Weaknesses/challenges** | **Current efforts to address them** |
|---|---|
| | |
| | |
| | |
| | |
| | |

# 3. REGULATORY FUNCTIONS AND PROCESSES

## 3.1 PRODUCT EVALUATION AND REGISTRATION

1. Is product evaluation and registration required by legislation?

   ☐ Yes (please complete information below)

   ☐ No

| Copy Obtained | | List relevant part of the law |
|---|---|---|
| ☐ Yes | ☐ No | |

2. Is there a written guideline for the submission of dossiers for registration applications?

   ☐ Yes (please complete information below)

   ☐ No

| Copy Obtained | | Document title |
|---|---|---|
| ☐ Yes | ☐ No | |

3. Is there a fast-track registration system?

   ☐ Yes (please complete information below)

   ☐ No

| Copy Obtained | | Conditions for fast-track |
|---|---|---|
| ☐ Yes | ☐ No | |

4. Check all that product types that require product registration

| Product category | Requires registration? |
|---|---|
| Pharmaceuticals (medicines, vaccines, biologics) | |
| Medical devices | |
| Combination products (e.g., drug+device) | |
| Complementary and alternative medicines (including herbal medicines) | |
| Donations/aid | |
| Other (specify) | |

5. Are there regulations and/or guidelines that specify the information and data required for applications for registration?

   ☐ Yes (please complete information below)

   ☐ No

| Copy Obtained | | List relevant part of source document |
|---|---|---|
| ☐ Yes | ☐ No | |

6. Does the registration unit follow Good Review Practices? Does it adapt good review processes and has it adopted any guidelines?

   ☐ Yes (please complete information below)

   ☐ No

| Copy Obtained | | Document title |
|---|---|---|
| ☐ Yes | ☐ No | |

7. Are there SOPs and flow charts showing the process of evaluation and registration?

   ☐ Yes (please complete information below)

   ☐ No

| Copy Obtained | | Document title |
|---|---|---|
| ☐ Yes | ☐ No | |

8. Is a WHO-type Certificate of Pharmaceutical Product a requirement for the registration of imported drugs?

   ☐ Yes (please complete information below)

   ☐ No

| Copy Obtained | | List relevant part of source document |
|---|---|---|
| ☐ Yes | ☐ No | |

9. Are guidelines for evaluation and criteria for approval or rejection evaluation defined and documented?

   ☐ Yes (please complete information below)

   ☐ No

| Copy Obtained | | Document title |
|---|---|---|
| ☐ Yes | ☐ No | |

10. What types of documents are issued following approval for registration?

| Copy Obtained | | Document type |
|---|---|---|
| ☐ Yes | ☐ No | |
| | | |
| | | |

11. Are terms of registration, including indication for use, listed in the registration certificate or comparable document?

    ☐ Yes (please complete information below)

    ☐ No

| Copy Obtained | | Document title |
|---|---|---|
| ☐ Yes | ☐ No | |

12. Are any of the activities in the evaluation and registration process contracted out?

☐ Yes

☐ No

13. Indicate the evaluation functions that are contracted out and the reasons

| Function contracted out | Reason |
|---|---|
| | |
| | |
| | |

14. How long is the registration of a product valid?

15. If there is no registration expiry, is there a system for product re-evaluation?

☐ Yes (please complete information below)

☐ No

| Copy Obtained | | Document title |
|---|---|---|
| ☐ Yes | ☐ No | |

16. Indicate the average time taken to evaluate and register products by class

| Class of product | Average time taken (in days) |
|---|---|
| Generic products | |
| Products containing a new active pharmaceutical ingredient | |
| Fast-track products | |

17. Is there a maximum time limit for the NRA to process applications for registration?

☐ Yes (please complete information below)

☐ No

| Copy Obtained | | List relevant part of source document |
|---|---|---|
| ☐ Yes | ☐ No | |

18. Where is the list of registered pharmaceuticals and health products made available? *(check all that apply)*

☐ Government gazette

☐ Database

☐ Online

☐ Kept only by the NRA

19. Indicate the maximum time limit to evaluate and register products by class:

| Class of product | Maximum time limit allowed (in days) |
|---|---|
| Generic products | |
| Products containing a new active pharmaceutical ingredient | |
| Fast-track products | |

20. Is there a review or appeals process in place to dispute a registration decision?

☐ Yes (please complete information below)

☐ No

| Copy Obtained | | List relevant part of source document |
|---|---|---|
| ☐ Yes | ☐ No | |

21. Is an electronic system or software used for managing the evaluation and registration process and information?

☐ Yes (please complete information below)

☐ No

| Copy Obtained | | Name of tool/software | Year implemented |
|---|---|---|---|
| ☐ Yes | ☐ No | | |

22. To whom is the list of registered health products disseminated? *(check all that apply)*

☐ Pharmaceutical companies

☐ Government staff

☐ Civil society

☐ NRA staff only

23. How are new registration decisions and/or changes in registration status communicated? *(check all that apply)*

☐ Government memo

☐ NRA website

☐ Letters sent to affected persons/companies

24. Provide information on the types of registration services on which fees are levied and the amount charged

| Types of registration services on which fees are levied | Fees charged (USD) |
|---|---|
| | |
| | |
| | |
| | |

25. How many applications have been received and processed in the last five years? (*specify years*)

| No. of applications received | *Year* | | *Year* | | *Year* | | *Year* | | *Year* | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Received | Processed | Received | Processed | Received | Processed | Received | Processed | Received | Processed |
| New applications for registration of products containing new active pharmaceutical ingredients | | | | | | | | | | |
| New applications for registration of generic/well-established multisource products | | | | | | | | | | |
| New applications for registration by fast-track procedure | | | | | | | | | | |
| Applications for variations | | | | | | | | | | |
| Applications for renewal | | | | | | | | | | |
| Applications for export certificate | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |
| Total | | | | | | | | | | |

26. Are there provisions in the law/regulation to ensure that donated health products are registered or receive waivers?

☐ Yes (please complete information below)

☐ No

| Copy Obtained | | List relevant part of the regulations |
|---|---|---|
| ☐ Yes | ☐ No | |

## 3.2 LICENSING

1. Are there provisions in the law/regulation that require licensing of pharmaceutical businesses?

☐ Yes (please complete information below)

☐ No

| Copy Obtained | | List relevant part of the law/regulation |
|---|---|---|
| ☐ Yes | ☐ No | |

2. List below all types of licenses issued by the NRA and other agencies/institutions that are related to pharmaceutical premises and personnel

| Type of license issued | Issuing authority |
|---|---|
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |

3. Is the submission of an inspection report one of the requirements for issuing a license to engage in pharmaceutical business?

☐ Yes (please complete information below)

☐ No

| Copy Obtained | | List relevant part of the regulations/guidelines |
|---|---|---|
| ☐ Yes | ☐ No | |

4. Is the submission of an inspection report a requirement for the renewal of a license?

☐ Yes (please complete information below)

☐ No

| Copy Obtained | | List relevant part of the regulations/guidelines |
|---|---|---|
| ☐ Yes | ☐ No | |

5. How many licenses have been issued, renewed, suspended, or revoked in the last five years? (*specify years)*

| Action (specify year) | *Year* | *Year* | *Year* | *Year* | *Year* |
|---|---|---|---|---|---|
| Issued (new) | | | | | |
| Renewed | | | | | |
| Suspended | | | | | |
| Revoked | | | | | |
| Other (specify) | | | | | |

6. Indicate in the table below the total number of licensed pharmaceutical establishments in the country

| Type of pharmaceutical establishment | Govern-ment/public | Private for-profit | Private not-for-profit | Other | N/A |
|---|---|---|---|---|---|
| Manufacturers of pharmaceutical products | | | | | |
| Manufacturers of traditional medicines | | | | | |
| Pharmaceutical importers | | | | | |
| Pharmaceutical wholesalers | | | | | |
| Retail pharmacies | | | | | |
| Hospital pharmacies (all) | | | | | |
| Other health care facility drug outlets (e.g., clinics) (all) | | | | | |
| Pharmaceutical companies exporting products | | | | | |
| Dispensing physicians | | | | | |
| Other (specify) | | | | | |
| Total | | | | | |

7. Has a survey to determine unlicensed pharmaceutical establishments/vendors been conducted?

☐ Yes (please complete information below)

☐ No

| Copy Obtained | | Document title |
|---|---|---|
| ☐ Yes | ☐ No | |

8. Is a list of licensed pharmaceutical premises/establishments published and made publicly available?

☐ Yes (please complete information below)

☐ No

| Copy Obtained | | Document title |
|---|---|---|
| ☐ Yes | ☐ No | |

9. Is a list of licensed pharmaceutical personnel published and made publicly available?

☐ Yes (please complete information below)

☐ No

| Copy Obtained | | Document title |
|---|---|---|
| ☐ Yes | ☐ No | |

10. List the import/export licenses and permits that are required in the country

| Type of permit/license | Relevant section of the law/regulation |
|---|---|
| | |
| | |
| | |
| | |
| | |

## 3.3 INSPECTION

1. Are there provisions in the law/regulations that require GMP inspections

☐ Yes (please complete information below)

☐ No

| Copy Obtained | | List relevant part of the law/regulations |
|---|---|---|
| ☐ Yes | ☐ No | |

2. Does the inspectorate have GMP guidelines?

☐ Yes (please complete information below)

☐ No

| Copy Obtained | | Document title |
|---|---|---|
| ☐ Yes | ☐ No | |

3. Is a GMP certificate issued to manufacturers of pharmaceutical products?

☐ Yes (please complete information below)

☐ No

| Copy Obtained | | List relevant part of the regulations/guidelines |
|---|---|---|
| ☐ Yes | ☐ No | |

4. Is there an annual GMP inspection plan?

   ☐ Yes (please complete information below)

   ☐ No

| Copy Obtained | | Document title |
|---|---|---|
| ☐ Yes | ☐ No | |

5. Provide information on GMP inspections carried out in the last five years (*specify year*)

| Number of plants and type of inspection | *Year* | *Year* | *Year* | *Year* | *Year* |
|---|---|---|---|---|---|
| Total number of manufacturing plants inspected (domestic and international) | | | | | |
| Domestic/local plants inspected | | | | | |
| Plants inspected for issue of new license | | | | | |
| Plants inspected for renewal of license | | | | | |
| Plants inspected because of complaints | | | | | |
| Plants inspected as follow-up | | | | | |
| Other (specify) | | | | | |
| Total number of inspections carried out | | | | | |
| Total number of inspections planned | | | | | |

6. Indicate the number of products collected during manufacturer/GMP inspections and tested during each of the last two years (*specify years*)

| Samples collected and tested in connection with | *Year* | | | *Year* | | |
|---|---|---|---|---|---|---|
| | # of samples collected | Passed | Failed | # of samples collected | Passed | Failed |
| Planned inspections | | | | | | |
| Follow-up inspections | | | | | | |
| Complaints | | | | | | |
| Other (specify) | | | | | | |
| Total | | | | | | |

7. Are there sanctions for products that fail laboratory tests as part of GMP inspection?

   ☐ Yes (please complete information below)

   ☐ No

| Copy Obtained | | List relevant part of the regulation |
|---|---|---|
| ☐ Yes | ☐ No | |

8. Indicate the number of recalls made as a result of product testing during the GMP inspection process per year in the last five years (*specify year*)

| | *Year* | *Year* | *Year* | *Year* | *Year* |
|---|---|---|---|---|---|
| Number of recalls made | | | | | |
| Number of products affected by the recall | | | | | |

9. Which external GMP reports may be used in place of the NRA's inspection for regulatory decision making? *(check all that apply)*

   ☐ PIC/S
   ☐ WHO PQM
   ☐ Stringent NRA
   ☐ Other NRAs (specify)
   ☐ Only rely on our own inspection

10. Are there provisions in the law/regulation to ensure that donated health products are inspected or granted waivers?

    ☐ Yes (please complete information below)
    ☐ No

| Copy Obtained | | List relevant part of the regulation |
|---|---|---|
| ☐ Yes | ☐ No | |

11. Are there provisions in the law/regulations that define the responsibility and authority of the inspectors?

    ☐ Yes (please complete information below)
    ☐ No

| Copy Obtained | | List relevant part of the law/regulations |
|---|---|---|
| ☐ Yes | ☐ No | |

12. Are there formalized structural and functional relationships between regional/proxy inspectors and inspectors at the central NRA office?

    ☐ Yes (please complete information below)
    ☐ No

| Copy Obtained | | List relevant part of the regulations/guidelines |
|---|---|---|
| ☐ Yes | ☐ No | |

13. How many planned in-country inspections of distribution channels were conducted in each of the last five years? (*specify year*)

| Planned inspections | *Year* | *Year* | *Year* | *Year* | *Year* |
|---|---|---|---|---|---|
| Number of Inspections planned | | | | | |
| Number of planned inspections carried out | | | | | |

14. Is there a risk-based inspection strategy/model in place?

    ☐ Yes (please complete information below)
    ☐ No

| Copy Obtained | | Document title |
|---|---|---|
| ☐ Yes | ☐ No | |

## 3.4 MEDICINES INFORMATION AND CONTROL OF ADVERTISING AND PROMOTION

1. Are there provisions in the law/regulations that require the control of advertising and promotion?

   ☐ Yes (please complete information below)

   ☐ No

| Copy Obtained | | List relevant part of the law/regulations |
|---|---|---|
| ☐ Yes | ☐ No | |

2. Are there provisions in the law/regulations that require the provision of unbiased medicine information services to health workers and consumers?

   ☐ Yes (please complete information below)

   ☐ No

| Copy Obtained | | List relevant part of the law/regulations |
|---|---|---|
| ☐ Yes | ☐ No | |

3. Is there a medicines information center?

   ☐ Yes (please complete information below)

   ☐ No

| Location |
|---|
| |

4. What are the roles of the medicines information center/unit? *(check all that apply)*

   ☐ Review SMC

   ☐ Review patient information leaflet

   ☐ Review advertising/promotions

   ☐ Provide literature for product evaluation

   ☐ Generate safety alerts

   ☐ Publish safety bulletins

   ☐ Manage consumer communication

   ☐ Handle all NRA communication to public

   ☐ Other

5. Is there a publicly available website or electronic database for the provision of medicine information?

   ☐ Yes (please complete information below)

   ☐ No

| Copy Obtained | | List available repositories |
|---|---|---|
| ☐ Yes | ☐ No | |

6. Is there an inventory of reference resources at the medicines information unit?

☐ Yes (please complete information below)

☐ No

| Copy Obtained | | Document title |
|---|---|---|
| ☐ Yes | ☐ No | |

7. List regular reports and publications of the unit and how often they are produced

| Reports/publications | Frequency |
|---|---|
| | |
| | |
| | |
| | |
| | |
| | |
| | |

8. What strategy or code is used for monitoring advertising and promotion?

☐ Industry self-regulation

☐ IFPMA code

☐ WHO 1988 criteria for promotion

☐ Country-specific code

☐ Other

☐ None

9. Indicate where prescription medicines are legally advertised *(check all that apply)*

☐ Lay press (e.g., newspapers)

☐ Health professional journals

☐ Radio and television

☐ Billboards

10. Is preapproval required for promotional and advertising materials?

☐ Yes (please complete information below)

☐ No

| Copy Obtained | | List relevant part of the regulations/guidelines |
|---|---|---|
| ☐ Yes | ☐ No | |

11. Is a product information sheet approved at the time of registration?

☐ Yes (please complete information below)

☐ No

| Copy Obtained | | List relevant part of the regulations/guidelines |
|---|---|---|
| ☐ Yes | ☐ No | |

12. Are labels, patient information leaflets, and medication guides subject to approval?

☐ Yes (please complete information below)

☐ No

| Copy Obtained | | List relevant part of the regulations/guidelines |
|---|---|---|
| ☐ Yes | ☐ No | |

## 3.5 QUALITY CONTROL

1. Are there provisions in the law/regulations that require analysis of medicine quality by government or independent labs?

☐ Yes (please complete information below)

☐ No

| Copy Obtained | | List relevant part of the regulations |
|---|---|---|
| ☐ Yes | ☐ No | |

2. Does the NRA have its own quality control laboratory?

☐ Yes (please complete information below)

☐ No

| List other labs that are used |
|---|
| |
| |
| |

3. Does the NRA have MOUs with other labs?

☐ Yes (please complete information below)

☐ No

| Copy Obtained | | Lab with MOU |
|---|---|---|
| ☐ Yes | ☐ No | |

4. What are the functions of the quality control laboratory? *(check all that apply)*

☐ Testing of pharmaceuticals (nonbiological products)

☐ Testing of biological products such as vaccines

☐ Participation in registration activities

☐ Inspection of industry quality control laboratories

☐ Research

☐ Training of analysts

☐ Other (specify)

5. Provide the following information on samples collected for the last two years (*specify years*)

| | *Year* | | | *Year* | | |
|---|---|---|---|---|---|---|
| | **# of samples collected** | **Passed** | **Failed** | **# of samples collected** | **Passed** | **Failed** |
| Planned quality surveillance | | | | | | |
| Follow-up of complaints | | | | | | |
| Target testing/risk assessment | | | | | | |
| Other (specify) | | | | | | |
| Total | | | | | | |

6. Indicate below the number of drug samples submitted to the laboratory for testing in the last five years for each of the various sources of test requests listed (*specify years*)

| **Requested by** | ***Year*** | ***Year*** | ***Year*** | ***Year*** | ***Year*** |
|---|---|---|---|---|---|
| Government inspectors | | | | | |
| NRA | | | | | |
| Manufacturers | | | | | |
| Public-sector procurement agencies | | | | | |
| Hospitals, clinics | | | | | |
| Individuals | | | | | |
| Other (specify) | | | | | |
| Total | | | | | |

7. Does NRA have a sampling strategy or protocol?

☐ Yes (please complete information below)

☐ No

| **Copy Obtained** | | **Document title** |
|---|---|---|
| ☐ Yes | ☐ No | |

8. Indicate below the testing rates of the NRA laboratory in the last five years (*specify years*)

| **Activities** | ***Year*** | ***Year*** | ***Year*** | ***Year*** | ***Year*** |
|---|---|---|---|---|---|
| Number of products submitted for quality control (QC) testing | | | | | |
| Number of products tested | | | | | |
| Number of products that failed QC testing | | | | | |
| Number of products that passed QC testing | | | | | |
| Number of samples on which QC testing could not be performed (because of lack of reagents, reference standards, procedures, expertise, equipment, etc.) | | | | | |

9. Indicate below the tests/assay methods performed by the NRA laboratory

| **Test/assay method** | **Yes/No** | **Remarks (if any)** |
|---|---|---|
| All types of chemical tests and assays | | |
| Identification by infrared spectrophotometer | | |
| Identification by thin layer chromatography | | |
| UV-visible spectrophotometer | | |
| Polarimetry | | |
| High-performance liquid chromatography | | |
| Atomic absorption spectrophotometer | | |
| Disintegration test | | |
| Dissolution test | | |
| Microbial limit test | | |
| Pyrogen test, LAL, or rabbit method | | |
| Sterility test | | |
| Toxicity | | |
| Other (specify) | | |

## 3.6 PHARMACOVIGILANCE

1. Are there specific legal provisions for pharmacovigilance in the national medicines legislation or similar legislation?

   ☐ Yes (please complete information below)

   ☐ No

| Copy Obtained | | List relevant part of the policy/regulations |
|---|---|---|
| ☐ Yes | ☐ No | |

2. Is there a policy document that contains essential statements on pharmacovigilance or medicine safety (standalone or part of another policy document)?

   ☐ Yes (please complete information below)

   ☐ No

| Copy Obtained | | List relevant part of the law |
|---|---|---|
| ☐ Yes | ☐ No | |

3. Do any legal provisions require the marketing authorization holder to conduct postmarketing surveillance activities, including pharmacovigilance, for products as required by stringent regulatory authorities?

   ☐ Yes (please complete information below)

   ☐ No

| Copy Obtained | | List relevant part of the law/regulations |
|---|---|---|
| ☐ Yes | ☐ No | |

4. Do any legal provisions require the marketing authorization holder to mandatorily report all serious ADRs to the national drug regulatory authority?

   ☐ Yes (please complete information below)

   ☐ No

| Copy Obtained | | List relevant part of the law/regulations |
|---|---|---|
| ☐ Yes | ☐ No | |

5. Are risk management plans required for registration?

   ☐ Yes (please complete information below)

   ☐ No

| Reasons |
|---|
| |

6. Is there a pharmacovigilance center or unit in the NRA?

   ☐ Yes

   ☐ No (provide name of other agency)

| Agency |
|---|
| |

7. Does the pharmacovigilance center or unit have a clear mandate, structure, roles, and responsibilities?

   ☐ Yes (please complete information below)

   ☐ No

| Copy Obtained | | Document title |
|---|---|---|
| ☐ Yes | ☐ No | |

8. Is there a national medicine safety advisory committee or a subcommittee with similar functions that has met at least once in the last year?

   ☐ Yes (please complete information below)

   ☐ No

| Copy Obtained | | Document title |
|---|---|---|
| ☐ Yes | ☐ No | |

9. Are there national pharmacovigilance guidelines that have been updated within the last five years?

   ☐ Yes (please complete information below)

   ☐ No

| Copy Obtained | | Document title |
|---|---|---|
| ☐ Yes | ☐ No | |

10. Has an ADR or medicine safety bulletin (or any other health-related newsletter that routinely features ADR or medicine safety issues) been published in the last six months?

    ☐ Yes (please complete information below)

    ☐ No

| Copy Obtained | | Document title |
|---|---|---|
| ☐ Yes | ☐ No | |

11. Is the national pharmacovigilance center a full or associate member of the WHO Collaborating Centre for International Drug Monitoring?

    ☐ Full member

    ☐ Associate member

12. Is there a system for coordinating and collating pharmacovigilance data from all sources in the country (e.g., health programs, immunization program, active surveillance studies)?

    ☐ Yes (please complete information below)

    ☐ No

| Describe system |
|---|
| |

13. Is there a database for tracking pharmacovigilance information?

☐ Yes (please complete information below)

☐ No

| Describe system |
|---|
| |

14. Is there a form for reporting adverse drug events?

☐ Yes (please complete information below)

☐ No

| Copy Obtained | | Document title |
|---|---|---|
| ☐ Yes | ☐ No | |

15. Is there a form for reporting? *(check all that apply)*

☐ Suspected ADRs

☐ Product quality

☐ Treatment failure

☐ Medication errors

☐ Single form for all of the above

## 3.7 CLINICAL TRIALS

1. Do provisions in the law/regulations require oversight of clinical trials?

☐ Yes (please complete information below)

☐ No

| Copy Obtained | | List relevant part of the regulations |
|---|---|---|
| ☐ Yes | ☐ No | |

2. Is the NRA responsible for regulating clinical trials of pharmaceutical products conducted in the country?

☐ Yes (please complete information below)

☐ No

| List relevant part of the regulations | List other bodies that regulate clinical trials |
|---|---|
| | |

3. Are any of the following documents available in relation to clinical trials?

☐ Policy

☐ Clinical trial guidelines

☐ Ethics committee TOR

☐ Institutional review board TOR

4. Is the national clinical trial policy/guideline consistent with

   ☐ The Helsinki Declaration
   ☐ WHO GCP guidelines
   ☐ ICH guidelines

5. Clinical trial applications in the last five years (*specify years*)

| **No. of clinical trial applications** | ***Year*** | ***Year*** | ***Year*** | ***Year*** | ***Year*** |
|---|---|---|---|---|---|
| Applications received | | | | | |
| Applications approved | | | | | |

## 4. MONITORING AND EVALUATION

1. Is the NRA required to submit performance reports?

   ☐ Yes (please complete information below)
   ☐ No

| **Copy Obtained** | | **List relevant part of the law/regulations/policy** |
|---|---|---|
| ☐ Yes | ☐ No | |

2. Are the activities of the NRA defined in an annual work plan?

   ☐ Yes (please complete information below)
   ☐ No

| **Copy Obtained** | | **Document title** |
|---|---|---|
| ☐ Yes | ☐ No | |

3. Does the NRA have a system for routine self-assessment of its regulatory activities?

   ☐ Yes (please complete information below)
   ☐ No

| **Copy Obtained** | | **Document title** |
|---|---|---|
| ☐ Yes | ☐ No | |

4. List the key performance metrics and indicators that are routinely used to measure NRA regulatory activities and performance

| Performance metrics | Frequency of reporting | Report provided to |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
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| | | |
| | | |
| | | |

5. Has an audit or formal evaluation been carried out in the past five years to evaluate the implementation/performance of the regulatory system?

   ☐ Yes (please complete information below)

   ☐ No

| Copy Obtained | | Document title |
|---|---|---|
| ☐ Yes | ☐ No | |

6. What are the key weaknesses/problems and strengths identified in the most recent monitoring/evaluation report?

| Weaknesses/problems | Strengths |
|---|---|
| | |
| | |
| | |
| | |

# D: Quantitative Indicators

| No. | Indicator | Category |
|---|---|---|
| 1 | Number of violations against which administrative measures have been taken in the last year, out of the total number of violations registered | Enforcement |
| 2 | Number of violations against which penal sanctions have been applied by the judiciary in the last year, out of the total number of violations submitted to court | |
| 3 | Number of registered pharmaceutical products:<br>▪ New applications for registration of products containing new active pharmaceutical ingredients<br>▪ New applications for registration of generic/multisource products<br>▪ New applications for registration by fast-track procedure<br>▪ Applications for variations of approved products (if variations are required)<br>▪ Applications for renewal<br>▪ Applications for export certificate<br>▪ Other (specify) | Registration |
| 4 | Number of licensed pharmaceutical business operators (e.g., manufacturers, wholesalers, importers/exporters, pharmacies) out of the total number of pharmaceutical businesses in the last year | Inspection |
| 5 | Number of planned pharmaceutical plant inspections conducted out of the total number of planned inspections carried out in the previous year | |
| 6 | Number of samples collected out of the total number of samples planned to be collected | Quality control (surveillance) |
| 7 | Number of products tested out of the total number of products submitted/collected | |
| 8 | Number of products that failed quality testing out of the total number of products tested | |
| 9 | Average time taken to evaluate and register:<br>▪ Generic products<br>▪ Products containing a new active pharmaceutical ingredient<br>▪ Fast-track products | |
| 10 | Percent of all medicines in the essential medicines list registered | |
| 11 | Percent of all medicines in the standard treatment guidelines registered | |
| 12 | Percent of all products sampled from the central medical store that are registered | |
| 13 | Number of risk mitigation recommendations that were informed by pharmacovigilance data and activities | Pharmacovigilance |
| 14 | Number of medicine safety actions (other than ADR reporting) taken to inform clinical management, guideline revisions, regulatory decisions, or health worker/patient education | |
| 15 | Number of medicines information services provided to support training of health care providers, treatment guidelines revision, or regulatory decisions | Medicine information |
| 16 | Number of advertisements/promotional materials found to be in violation of the law out of the total number of promotions/advertisements monitored (indicate year) | |
| 17 | Number of labels/inserts found to be inconsistent with what was approved during registration out of the total number of labels and inserts assessed (indicate year) | |