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WHO Data Collection Tool for the Review of Drug Regulatory Systems

(to be used jointly with the Practical Guidance for Conducting a Review)

Technical Cooperation for
Essential Drugs and Traditional Medicine

Geneva
2007

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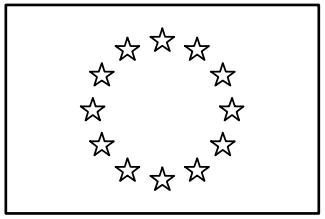

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Content

MODULE 1 GENERAL INFORMATION:
1.1 Information on the country
Country:
Name and address(es) of Institution(s) assessed:
Assessment focal point:
Address of focal point:
Tel of focal point:
Fax of focal point:
Email of focal point:
1.2 Information on the assessment
Date of the assessment:
Purpose of the assessment:
Scope of the assessment:
Assessment performed by:
Address of assessors:
Tel of assessors:
Fax of assessors:
Email of assessors:

MODULE 2 NATIONAL REGULATORY SYSTEM		**COMMENTS:**
	2.1 Organization	
2.1.1	The Ministry of Health has delegated or assigned to one or more authorities (institutions/agencies/autonomous bodies) its responsibilities regarding the regulation of pharmaceutical products.	
2.1.2	The responsibilities/functions/organization of each of these authorities are clearly defined, in particular as regards the scope of the regulation (regulatory functions) they have under their control.	
2.1.3	All the regulatory areas (regulatory functions) are under the supervision of at least one of these authorities in charge of it.	
2.1.4	The activities of the various authorities involved are coordinated by an administrative mechanism.	
	2.2 Legal basis for the establishment of the regulatory system	
2.2.1	The legal basis of the regulatory system applied to the pharmaceutical sector is clear and comprehensive.	
2.2.2	The main steps to be followed for the implementation of the legislation are defined and followed.	
2.2.3	The legislation enables the appropriate institutions to issue regulations.	
2.2.4	The development of regulations involves the Regulatory Authorities in charge of their implementation and enforcement.	
2.2.5	The development of regulations involves the various sectors of the civil society (such as NGOs, consumers and patients, representatives of health professionals and industry,).	
2.2.6	Adequate regulations have been enacted and published.	
2.2.7	The legislation is made known to the people who are to be governed by it and the ways of communication used are adequate.	

Key findings and gaps

MODULE 3 NATIONAL REGULATORY AUTHORITY (NRA)		**COMMENTS:**
	3.1 Legal basis	
3.1.1	The legislation provides for the establishment of a NRA and clearly defines, its mission, Terms of Reference, powers, functions and responsibilities.	
3.1.2	If more than one institution is involved, legislation provides for coordination/linkage among these institution and the respective empowerment is defined.	
3.1.3	The legal provisions specify that the NRA has the power to/or the delegation to decide whether a specific product falls within the definition of a medicinal product, a medical device, or any another category of products.	
3.1.4	The legal provisions specify that the NRA has the power to/or the delegation for appointing special officers/inspectors and provides them with adequate powers to carry out inspection of pharmaceutical products and practices.	
3.1.5	The legal provisions specify that the NRA has the delegation, the enforcement powers and responsibilities to deal with non-compliant products.	
3.1.6	The legal provisions specify that the NRA has the power to/or the delegation to issue a written notice of violations to companies and recommend their prosecution.	
3.1.7	The legal provisions enable the NRA to issue and publish appropriate guidance or notes for applicants.	
3.1.8	The legal provisions enable the NRA to set up technical/scientific advisory committees for regulatory purposes.	
3.1.9	The legal provisions define the terms of reference for each advisory committee in particular their role in the decision making process, and circumstances under which the advice of the experts/advisory committees must be obtained by the NRA.	
3.1.10	The legal provisions enable the NRA to collect fees for regulatory service provided	
	3.2 Corporate Governance	
3.2.1	There is a governing /administrative body for strategic development.	

3.2.2	The functions of the Governing Board/Council are defined, documented and implemented particularly in advising on strategy and orientation of the NRA.	
3.2.3	There are bodies within the DRA to manage and organize routine functions.	
3.2.4	The roles and responsibilities of such bodies are defined and documented particularly for implementation of routine decisions, strategic objectives and reporting thereof	
3.2.5	Communication channels among such bodies are established.	
3.2.6	There is a scientific body to advise the NRA on scientific matters and future orientations.	
	3.3 Institutional Development	
3.3.1	The NRA has established an Institutional Development Plan which is implemented and updated.	
3.3.2	The Vision and the Mission Statement for the NRA is established.	
3.3.3	The objectives of the NRA have been set in particular target time frames for the various functions.	
3.3.4	Action plans are established and implemented to achieve the objectives set.	
3.3.5	Indicators are established to monitor/assess progress towards the objectives.	
	3.4 Organization and structure	
3.4.1	Regulatory activities are organized and performed at a central level of the country	
3.4.2	Decentralized activities to other agencies/authorities follow the standards, guidelines and procedures as agreed/decided with the central authority.	
3.4.3	In case of decentralization, a mechanism of exchange of information is established and implemented in order for the decentralized organization to receive requests and/or directives from the central authority and to report to it.	
3.4.4	The mechanisms in place allow exchange and harmonization of best practices, appropriate cooperation and collaboration among the decentralized organizations.	
	3.5 Quality Management System	
3.5.1	The NRA has implemented a Quality Management System for all the regulatory processes.	

3.5.2	The NRA's top management is committed to the development and implementation of the Quality Management System in particular by providing financial and organizational support.	
3.5.3	The Quality Management System is based on recognized standards as reference (e.g. WHO, PIC/S, ISO, other).	
3.5.4	A quality policy and related quality objectives are defined and documented.	
3.5.5	A qualified person is designated as responsible for the development and implementation of the Quality Management System.	
3.5.6	The NRA has identified its processes for each regulatory function, determined their interactions and methods needed to control these processes.	
3.5.7	The documentation needed to establish, implement and maintain the QMS is defined (Quality manual, records, SOPs, etc).	
3.5.8	The documentation required by the QMS is controlled following a documented procedure.	
3.5.9	A documented procedure is established by the NRA to plan, and to assess if the QMS is effectively implemented and conforms to planned arrangements.	
3.5.10	Internal audits of the complete QMS are done at least once every 12 months. Records of the results are maintained.	
3.5.11	The corrective and preventive actions taken as a result of audits or from other non conformities are implemented and documented. Their efficacy is checked and documented.	
3.5.12	The top management of the NRA reviews on a regular basis, at least once every 12 months, the QMS to evaluate its efficiency as well as its effectiveness. Records of the review are maintained.	
	3.6 Funding	
3.6.1	The sources of funding of the NRA to perform its regulatory functions are defined.	
3.6.2	The scale of fees for regulatory services provided are established and published, including any preferences applied to local products or industry.	
3.6.3	Provisions concerning fee reductions or exemptions to ensure the availability of vital or life-saving drugs for a limited market are provided.	

3.6.4	Funding is partly provided by development partners or donors such as WHO, The World Bank, etc.	
3.6.5	The NRA has the authority and the procedures in place to collect fees and internally utilize the generated funds.	
3.6.6	The NRA is obliged to periodically publicize its budget.	
	3.7 Management of human resource	
3.7.1	An organization Chart / organigram for the NRA staff is established and updated.	
3.7.2	The NRA's key technical and scientific personnel have been identified based on their authorities and responsibilities.	
3.7.3	The duties, functions and responsibilities of the key personnel are established in the respective job descriptions.	
3.7.4	The NRA has established the necessary competencies (education, training, skill and experience) for the key personnel to perform the assigned work.	
3.7.5	The NRA is able to select and recruit its own staff following documented procedures based on its own written criteria (experience, minimum educational background, advanced training, etc.).	
3.7.6	An initial and periodic staff appraisal system is established to review performance and competencies, identify academic and training needs; and agree on performance targets.	
3.7.7	There is an induction program for newly recruited staff.	
3.7.8	A training plan is established for all staff in order to satisfy/fulfil the needs identified. Training activities are performed and recorded by the NRA.	
3.7.9	A documented mechanism is in place to evaluate the impact and to demonstrate the effectiveness of the training activities.	
3.7.10	Budgetary provisions are made for staff training.	
	3.8 Committees and external expertise	
3.8.1	The NRA takes advantage of external experts and involves them in its regulatory processes.	

3.8.2	A model contract between the NRA and each external expert defining roles and responsibilities is established and signed by both parties.	
3.8.3	The NRA has set up advisory committees of experts involved in the regulatory processes of the NRA.	
3.8.4	There is a written policy / procedure for the recruitment and the designation of external experts and members of experts committees calling for candidates, defining the review by a selective jury/panel, appointments and publishing of the final decision but also to cross off.	
3.8.5	Documented procedures are implemented for the management of the advisory committees (designation of chair and composition, secretariat responsibilities, quorum, declaration of interests, agenda, minutes and operational procedures).	
3.8.6	There is a general policy on potential conflicts of interest for external experts and members of advisory committees.	
3.8.7	There is a general policy on confidentiality and a code of conduct for external experts and members of advisory committees.	
3.8.8	The NRA is involved in a global network with relevant scientific associations and professional societies.	
3.8.9	There is a documented mechanism to manage potential conflicts of interest of internal and external experts and members of committee by collecting declarations of interests, including ensuring updates of these declarations, for all regulatory functions.	
3.8.10	The agenda of the technical/advisory committee is elaborated prior to the meeting and the minutes of the discussions are recorded.	
	3.9 Transparency and confidentiality	
3.9.1	The legislation stipulates the requirements on confidentiality and transparency.	
3.9.2	There is a documented policy on public disclosure of information with exemptions/exceptions.	
3.9.3	Information on legislation, regulations, procedures and guidelines are publicly available and are kept up to date on websites or other mechanisms used to ensure the proper availability of information.	

3.9.4	An annual report with the allocated budget mentioning the origin of funds, is published on a periodic basis and is publicly available.	
3.9.5	The decision-making processes as well as decision criteria are publicly available.	
3.9.6	The information on decisions are publicly available, including the negative decisions in specific cases (i.e. when legislation permits) in a timely manner.	
3.9.7	The Information on outputs of regulatory functions performed are publicly available and kept up to date (web sites or other mechanisms).	
3.9.8	The information on sanctions, recalls and public health warnings are published and are publicly available.	
3.9.9	A guideline on complaints and appeals against regulatory decisions is available.	
3.9.10	An appeal mechanism against the NRA's decisions is available and implemented.	
3.9.11	The NRA consults or involves specific sectors of the civil society (such as NGOs representing health professionals, the industry, consumers and patients) during the development of guidelines.	
3.9.12	A documented procedure is implemented to consult, collect and to deal with the comments received during the development of guidances.	
3.9.13	The declarations on interests of internal and external experts as well as members of technical/advisory committee are publicly available.	
3.9.14	The industry, consumers and patients' representatives are involved as observers in technical/advisory committee meetings.	
3.9.15	The agendas of the technical/advisory committees are published in advance and the minutes of the meetings are publicly available.	
3.9.16	A competent contact person or a public relations unit is established and known by the interested parties.	
3.9.17	The NRA regularly organizes meetings with the key stakeholders and open days for the public.	
3.9.18	The NRA is represented at meetings organized by the stakeholders (industry associations, professional associations of practitioner, patients associations,…).	

	3.10 Independence and impartiality	
3.10.1	There is a documented Code of conduct for staff members involved in drug regulatory functions.	
3.10.2	There is an internal policy on potential conflicts of interest for staff members/personnel.	
3.10.3	There is a model format for a declaration of conflicts of interest.	
3.10.4	There is a documented policy/procedure to avoid the accumulation of responsibilities for registration, procurement or reimbursement agreements with the same authority/individuals.	
	3.11 Infrastructure	
3.11.1	The work space and work environment are adequate.	
3.11.2	The equipment provided for performing the regulatory functions are adequate.	
3.11.3	Support services provided (for example in terms of transport and communication) are adequate.	
	3.12 Monitoring and accountability	
3.12.1	The legislation provides requirements for monitoring and accountability of the NRA by stakeholders.	
3.12.2	The regulatory processes are regularly and systematically reviewed in order to identify problems, gaps and inconsistency within the regulatory authority.	
3.12.3	Periodic reports on regulatory processes performed are submitted to the institution/organization in charge of the overseeing and reviewing of the NRA functions.	
	3.13 Information management systems	
3.13.1	The NRA uses computerized systems for automation of repetitive functions and for reporting activities.	
3.13.2	The NRA uses computerized systems for data management and for enhancing data import/export capacity.	
3.13.3	The NRA uses computerized systems for accessing technical/scientific information.	

3.13.4	The NRA has established an integrated network of all computers related to regulatory functions.	
3.13.5	The NRA has its own website or has made an arrangement to use others.	
3.13.6	The NRA employs its own IT staff or has assured access to IT services.	
3.13.7	Documented procedures are in place to gather data and use the software applications as well as query tools.	
	3.14 Communication activities	
3.14.1	The NRA has established a communications strategy to maintain confidence in the regulations and to provide timely, necessary and helpful information.	
3.14.2	This strategy considers the different target audience (patient, public, industry, healthcare professionals) and the available means of communication (media, website, stakeholders meeting, conference)	
3.14.3	The NRA has prepared a crisis plan for coping with major incidents and information that could potentially alarm the public.	
3.14.4	Success of this communications strategy is measured by adequate means.	
Key findings and gaps		

MODULE 4 MARKETING AUTHORIZATION (MA)		**COMMENTS:**
	4.1 Legal basis	
4.1.1	The legal provision requires one to hold a Marketing Authorization (MA) before putting a pharmaceutical product on the market.	
4.1.2	The legislation enables the NRA to issue a marketing authorization for a pharmaceutical product, to suspend it for a period of time and to withdraw it.	
4.1.3	There are legal provisions requiring the applicants to demonstrate the quality, safety and efficacy of the pharmaceutical product that is subject of the application.	
4.1.4	There are legal provisions regarding the information to be provided with the products (packaging, labelling, leaflet, Summary of characteristics, etc…).	
4.1.5	There is a legal requirement regarding the limited duration of the validity of the MA and for handling periodic reviews to MAs.	
4.1.6	The legal provisions require the notification to the NRA of any variations to the initial MA which may affect the quality, safety and efficacy of the products. Specific kinds of variations can be subject to authorization by the NRA.	
4.1.7	The legal provisions envisage the case of demonstrated bioequivalence of multisource/generic products with innovator.	
4.1.8	The legal provisions envisage the case of provisional or conditional MA exempting applicants from meeting specific requirements based on the established criteria (orphan drug, public health interest, presumed positive benefit/risk balance).	
4.1.9	There is an exemption for pharmaceutical product donations following the established criteria.	
4.1.10	The legal provisions specify the MA holder/manufacturer’s liability for defective products.	
	4.2 Guidelines	
4.2.1	There are guidelines on the applicable requirements on quality, safety and efficacy.	
4.2.2	There are guidelines on the content of Product Information Leaflets, Summary of Product Characteristics (SPC), packaging and labelling.	

4.2.3	There are guidelines on the applicable requirements on various process validation (manufacturing, IT, etc…).	
4.2.4	There are guidelines on the applicable requirements on analytical method validation.	
4.2.5	There are guidelines on the applicable requirements on stability testing of pharmaceutical products (API, finished products).	
4.2.6	There are guidelines on the applicable requirements to the demonstrate bioequivalence/bioavailability.	
4.2.7	There are guidelines for applicants or their representatives on the content of the application, the format and the procedures to follow in order to submit an application for a MA.	
4.2.8	There are guidelines for marketing authorization holders defining the types and scopes of variations, the format and the documentation required as well as specifications of the variations that are subjected to prior approval.	
4.2.9	There is a guideline on drug donation.	
4.2.10	There is guidance on risk management programs, pre-marketing risk assessment and development of pharmacovigilance plans	
	4.3 Organization and structure	
4.3.1	Marketing authorization activities are organized and performed at a central level of the country.	
	4.4 Assessment procedures	
4.4.1	A documented procedure is implemented on a voluntary basis to allow applicants to meet with the DRA before the submission of an application.	
4.4.2	Documented procedures/tools are implemented for the assessment of the different parts of the application and for the assessment of specific requirements of specific classes of products (e.g. multisource/generics, products containing new active substances, new strengths, high-tech or particularly innovative products etc.).	
4.4.3	A documented procedure is implemented to exchange information between the applicant and the DRA if needed.	

4.4.4	Documented procedures are implemented to periodically review the MAs granted.	
4.4.5	Documented procedures are implemented for assessing the applications for variation of MAs.	
4.4.6	There is a model format for the assessment/evaluation report.	
4.4.7	The same criteria are used for the evaluation of MA applications regardless of the source (e.g. domestic, foreign, public/private sector) of the products concerned.	
4.4.8	The product information, Summary of Product Characteristics (SPC), packaging and labelling is approved by the NRA as part of the MA.	
4.4.9	The risk management program and pharmacovigilance plan are approved by the NRA as part of the MA	
4.4.10	A documented procedure is implemented to follow the commitments of the MAH and in particular the Risk Management Program (see also Module 11 on pharmacovigilance)	
4.4.11	External information (information sources and reference materials) for decision making on the applications submitted are readily available.	
4.4.12	Documented procedures are implemented to control the quality of the assessment process in place such as peer-review.	
4.4.13	External experts are involved in the assessment of the applications for MAs.	
4.4.14	An advisory committee of experts is involved in the review of MAs applications.	
4.4.15	A documented procedure is implemented for decision-making.	
4.4.16	The decision making procedure takes into account a cost / benefit analysis.	
4.4.17	A documented procedure is implemented to issue the marketing authorization in a standardized format.	
4.4.18	The NRA recognizes and/or uses regulatory decisions, reports or information from other NRAs or international bodies for decision making.	
4.4.19	The procedure takes into account the integration of the different parts of the dossier into an overall benefit/risk analysis assessment.	

4.4.20	Documented procedures are implemented to ensure the involvement and communication between the assessors and the QC laboratory for product compliance and the regulatory inspectorate for compliance to applicable good practices.	
4.4.21	There are time limit(s) for the assessment of the applications.	
4.4.22	An internal tracking system is established to follow the targeted time frames (statutory or not).	
4.4.23	There is a documented fast-track mechanism for specific products of particular public health interest.	
4.4.24	The steps/requirements for waived MA assessment are documented.	
4.4.25	There is a model format for the decision on a marketing authorization application (approval, rejection, withdrawal).	
4.4.26	A written marketing authorization, signed by a person with the adequate delegation, is sent to the applicant, accompanied by the approved product information, including conditions or restrictions of this approval.	
4.4.27	Each pharmaceutical product receives a unique identification number that appears on the labelling/packaging and product information.	
	4.5 Human and other resources	
4.5.1	The job descriptions for the following staff are defined: head of registration (supervisor), head of registration unit by products and assessors with their areas of assessment (bioequivalence, chemist, medical officer, microbiologist, statistics, Toxicology, PD/PK, etc…).	
4.5.2	There is enough personnel (internal and external) with the adequate expertise (education, experience and training) for the assessment of the different parts of the application for all types of authorized pharmaceutical products.	
4.5.3	There is internal planning of human resource utilisation for performing any upcoming and periodical reviews of the applications.	
4.5.4	The manufacturer's or licence holder's representatives are never involved in assessment work at any level/stage, including expert committees.	

4.5.5	There are lines of authority reflecting the independence of decision-making in the MAs system from manufacturers, supply systems or government.	
4.5.6	There is an adequate office, working environment and storage space for MAs files.	
4.5.7	There is an adequate equipment for MAs functions.	
	4.6 Records and outputs	
4.6.1	There is an up-to-date list/data base of all the product applications received, approved, suspended or withdrawn and of the applications refused.	
4.6.2	The NRA retains a master file of each product licensed or application refused as well as of all the variations and renewals with the supporting documentation including the application, approved drug information, assessment report, risk/benefit assessment, etc. All exemptions are documented in this file.	
	4.7 Availability of information	
4.7.1	A list of all the approved products is established, updated, published and made publicly available.	
4.7.2	A summary of the assessment report as a basis for decision-making is published and is publicly available (positive or negative decision).	
4.7.3	The list/database of all the licenses withdrawn, suspended or refused is published and is publicly available.	
Key findings and gaps		

MODULE 5 LICENSING OF MANUFACTURERS		**COMMENTS:**
	5.1 Legal basis	
5.1.1	The legislation requires a company which manufactures or intends to manufacture a pharmaceutical product or an active pharmaceutical ingredient to hold a licence.	
5.1.2	The legislation enables the NRA to issue a licence for a manufacturer of pharmaceutical products or active pharmaceutical ingredient, to suspend it for a period of time and to withdraw it.	
5.1.3	The legal provisions require the manufacturers to comply with the applicable good manufacturing practices. Compliance with applicable GMP is a condition for keeping its license.	
5.1.4	The legal provisions require notification of the NRA of significant changes/variations to the initial licensing conditions.	
5.1.5	There are specific legal provisions concerning repacking/relabelling of pharmaceutical products and quality control activities performed by manufacturers.	
5.1.6	There are legal provisions requiring at least one qualified responsible person for each manufacturing premises.	
5.1.7	There are legal exemptions to licensing requirements with defined criteria.	
	5.2 Guidelines	
5.2.1	A guidance provides detailed information on compliance with GMP requirements. This guidance is mainly based on the WHO model and its supplementary guidance.	
5.2.2	There are guidelines for manufacturers on the content of the application, the format and the procedure to follow in order to submit an application for a manufacturing license.	
5.2.3	There are guidelines for waiving license requirements/procedures/steps.	
5.2.4	There are guidelines for applicants on the definition of types and scopes of variations and the documentation required.	
5.2.5	There are guidelines on the content of the Site Master File.	
5.2.6	There are guidelines on the appointment and qualification of the Qualified Responsible Person.	

	5.3 Organization and structure	
5.3.1	Licensing activities are organized and performed at a central level of the country.	
5.3.2	Decentralized activities to other agencies/authorities follow the standards, guideline and procedures as agreed/decided with the central authority.	
5.3.3	In case of decentralization, a mechanism of exchange of information is established and implemented in order for the decentralized organization to receive requests and/or directives from the central authority and to report to it.	
5.3.4	The mechanisms in place allow exchange and harmonization of best practices, appropriate cooperation and collaboration among the decentralized organizations.	
	5.4 Licensing assessment procedures	
5.4.1	Documented procedures are implemented for meetings with applicants before an application is officially lodged.	
5.4.2	Documented procedures/ checklists are implemented to assess the applications for licensing.	
5.4.3	A documented procedure is implemented for waiving certain requirements or steps.	
5.4.4	A documented procedure is implemented for assessing the applications for variation of licenses.	
5.4.5	Documented quality control measures are in place such as peer-review.	
5.4.6	A documented procedure is implemented for decision-making.	
5.4.7	Documented procedure is implemented to issue the licence in a standardized format.	
5.4.8	The NRA recognizes and/or uses regulatory decisions, reports or information from other NRAs or international bodies for decision-making.	
5.4.9	Documented procedures are implemented to ensure the involvement and communication between the administrative staff in charge of the assessment of the application for licensing and the regulatory inspectorate for compliance to applicable good practices.	
5.4.10	The same criteria are used for licensing regardless of the affiliation (e.g. domestic, foreign, public, private sector, NGO) of the manufacturer concerned.	

5.4.11	There are defined timelines for the assessment of applications.	
5.4.12	An internal tracking system is established to follow the targeted time frames (statutory or not).	
5.4.13	A written license, signed by a person with the adequate delegation, is sent to the applicant, including conditions or restrictions attached to the licence (validity and renewal).	
	5.5 Human and other resources	
5.5.1	There is enough personnel (internal and external) with adequate expertise (education, experience and training) for the assessment of the applications and for issuing of licences.	
5.5.2	There is adequate office and storage space (documents,).	
5.5.3	There is adequate equipment for licensing activities.	
	5.6 Records and outputs	
5.6.1	There is a list/data base of all licensed manufacturers.	
5.6.2	The NRA retains a site master file of each premise licensed, including the approved changes with the supporting documentation. The file contains at least the following information: company name, key personnel, premises address/map of the facilities and contact details, equipment, list of drugs and dosage forms approved for manufacture. All exemptions are documented in this file.	
	5.7 Availability of information	
5.7.1	The list/data base of all the licensed manufacturers is published.	
5.7.2	The list/data base of all the licenses withdrawn, suspended or refused for manufacturers is published and is publicly available.	
Key findings and gaps		

MODULE 6 LICENSING OF IMPORTERS, EXPORTERS, WHOLESALERS AND DISTRIBUTORS		**COMMENTS:**
	6.1 Legal basis	
6.1.1	The legislation requires that a company which imports or intends to import any pharmaceutical product or active pharmaceutical ingredient to hold a licence.	
6.1.2	The legislation requires that a company which exports or intends to export any pharmaceutical product or active pharmaceutical ingredient to hold a licence.	
6.1.3	The legislation requires that a company which acts as a wholesaler or distributor of pharmaceutical products or active pharmaceutical ingredient or intends to do so to hold a licence.	
6.1.4	The legislation enables the NRA to issue a licence for an importer, an exporter and a wholesaler/distributor, to suspend it for a period of time and to withdraw it.	
6.1.5	The legal provisions require importers, exporters, wholesalers and distributors to comply with the applicable good storage and good distribution practices for licensing.	
6.1.6	The legal provisions require the notification to the NRA of significant changes/variations to the initial license.	
6.1.7	There is a legal provision for at least one qualified responsible person for each importer, exporter wholesaler or distributor.	
6.1.8	There are legal exemptions to licensing requirements with defined criteria.	
	6.2 Guidelines	
6.2.1	There is a guidance that provides detailed information on compliance with Good Distribution Practice requirements. This guidance is in line with the relevant WHO Guidance.	
6.2.2	There are guidelines for importers, exporters, wholesalers and distributors on the content of the application, the format and the procedure to follow in order to submit an application for licensing.	
6.2.3	There are guidelines on waiving license requirements/procedures/steps.	
6.2.4	There are guidelines for applicants that define the types and scopes of variations and the documentation required.	

6.2.5	There are guidelines for the content of the Site Master File.	
6.2.6	There are guidelines for the appointment and qualification of the Qualified Responsible Person.	
	6.3 Organization and structure	
6.3.1	Licensing activities are organized and performed at a central level of the country.	
6.3.2	Decentralized activities to other agencies/authorities follow the standards, guidelines and procedures as agreed/decided with the central authority..	
6.3.3	In case of decentralization, a mechanism of exchange of information is established and implemented in order for the decentralized organization to receive requests and/or directives from the central authority and to report to it.	
6.3.4	The mechanisms in place allow exchange and harmonization of best practices, appropriate cooperation and collaboration among the decentralized organizations.	
	6.4 Licensing assessment procedures	
6.4.1	Documented procedures for meetings with applicants and other interested parties.	
6.4.2	A documented procedure/standard checklist to assess the applications for licensing of importers, exporters, wholesalers and distributors.	
6.4.3	A documented procedure is implemented to issue the licence in a standardized format.	
6.4.4	A documented procedure is implemented for waiving certain requirements or steps.	
6.4.5	A documented procedure is implemented for assessing the applications for variation of licenses.	
6.4.6	Documented quality control measures are in place such as peer-review.	
6.4.7	Documented procedures are implemented for decision-making and for the issuance of the licence.	
6.4.8	Documented procedures are implemented to ensure the involvement and communication between the administrative staff and the regulatory inspectorate for compliance with applicable good practices.	
6.4.9	The same criteria are used for licensing regardless of the affiliation (e.g. domestic, NGO, foreign, public, private sector) of the applicant concerned.	

6.4.10	There are timelines for the assessment of the applications.	
6.4.11	An internal tracking system is established to follow the targeted timeframes (statutory or not).	
6.4.12	A written license, signed by a person with the adequate delegation, is sent to the applicant, including conditions or restrictions attached to the licence (validity and renewal).	
	6.5 Human and other resources	
6.5.1	There is enough personnel (internal and external) with adequate expertise (education, experience and training) for the assessment of the applications for and issuing of licences.	
6.5.2	There is adequate office and storage space and the equipment for licensing.	
6.5.3	There is adequate equipment for licensing activities..	
	6.6 Records and outputs	
6.6.1	There is a list/data base of all licensed importers, exporters, wholesalers and distributors.	
6.6.2	The NRA retains a site master file of each premise licensed, including the approved changes with the supporting documentation. This file contains at least the following types of information: company, name and contact details, key personnel, premises address, equipment, list of drugs supplied (if adequate). All exemptions are documented in this file.	
	6.7 Availability of information	
6.7.1	The list/data base of all the licensed importers, exporters, wholesalers and distributors is published and is publicly available.	
6.7.2	The list/data base of all the licenses withdrawn, suspended or refused for importers, exporters, wholesalers and distributors is published and is publicly available.	
Key findings and gaps		

MODULE 7 LICENSING PHARMACIES AND RETAIL OUTLETS		**COMMENTS:**
	7.1 Legal basis	
7.1.1	The legislation requires that pharmacies and retail outlets or prospective pharmacies and retail outlets of pharmaceutical products to hold a licence.	
7.1.2	There is a legal provision for licensing internet pharmacy or retailers.	
7.1.3	The legislation enables the NRA to issue a licence for a pharmacy, a retail outlet or an internet pharmacy, to suspend it for a period of time and to withdraw it.	
7.1.4	The legal provisions require the retailers, sellers or dispensers to comply with the applicable Good Dispensing Practices or Good Pharmacy Practices.	
7.1.5	The legal provisions require the notification of the NRA of significant changes/variations to the initial license.	
7.1.6	There is a legal provision for at least one qualified responsible person for each pharmacy and retail outlet .	
7.1.7	There are legal exemptions to licensing requirements with defined criteria.	
	7.2 Guidelines	
7.2.1	There are guidelines for pharmacies and retail outlets on the content of the application, the format and the procedure to follow when applying for a licence.	
7.2.2	There are guidelines on waiving license requirements/procedures/steps.	
7.2.3	There are guidelines for applicants on the definition of the types and scopes of variations and the documentation required.	
7.2.4	There are guidelines for pharmacies and retail outlets on the Good Dispensing Practices or Good Pharmacy Practices.	
7.2.5	There are guidelines on the appointment and qualification of the responsible person.	

	7.3 Organization and structure	
7.3.1	Licensing activities are organized and performed at a central level of the country.	
7.3.2	Decentralized activities to other agencies/authorities follow the standards, guideline and procedures as agreed/decided with the central authority..	
7.3.3	In case of decentralization, a mechanism of exchange of information is established and implemented in order for the decentralized organization to receive requests and/or directives from the central authority and to report to it.	
7.3.4	The mechanisms in place allow exchange and harmonization of best practices, appropriate cooperation and collaboration among the decentralized organizations.	
	7.4 Licensing assessment procedures	
7.4.1	A documented procedure is implemented for meetings with applicants and other interested parties.	
7.4.2	Documented procedures/ standard checklists are implemented to assess applications for licensing.	
7.4.3	Documented procedures are implemented for waiving certain requirements or steps.	
7.4.4	Documented procedures are implemented for assessing the applications for the variation of licences.	
7.4.5	Documented quality control measures are in place such as peer-review.	
7.4.6	Documented procedures are implemented for decision-making and for the issuance of the licences.	
7.4.7	A documented procedure is implemented to issue the licence in a standardized format	
7.4.8	The same criteria are used for licensing regardless of the affiliation (e.g. public, private sector, NGO) of the applicant concerned.	
7.4.9	There are defined timelines for the assessment of applications.	
7.4.10	An internal tracking system is established to follow the targeted time frames (statutory or not).	

7.4.11	A written license, signed by a person with the adequate delegation, is sent to the applicant, including conditions or restrictions attached to the licences (validity and renewal).	
	7.5 Human and other resources	
7.5.1	There is enough personnel (internal and external) with adequate expertise (education, experience and training) for the assessment of the applications and for issuing of licences.	
7.5.2	There is adequate office and the storage space.	
7.5.3	There is adequate equipment for licensing activities.	
	7.6 Records and outputs	
7.6.1	There is a list/data base of all licensed pharmacies and retail outlets.	
7.6.2	The NRA retains a site master file of each premise licensed, including the approved changes with the supporting documentation. This file contains at least the following types of information: name, key personnel, premises address, list of drugs approved for dispensing/sale (if adequate). All the exemptions are documented in this file.	
	7.7 Availability of information	
7.7.1	The list/data base of all the licensed pharmacies and retail outlets is published and is publicly available.	
7.7.2	The list/data base of all the licenses for pharmacies and retail outlets withdrawn, suspended or refused is published and is publicly available.	
Key findings and gaps		

MODULE 8 REGISTRATION OF PHARMACY PERSONNEL	**COMMENTS:**
8.1 Legal basis	
8.1.1 There is a legal requirement for a person not to practise as a pharmacist unless his/her name has been registered by a Regulatory Authority.	
8.1.2 There is a legal requirement for a person not to practise as a pharmaceutical technician unless his/her name has been registered by a Regulatory Authority.	
8.1.3 There are legal requirements for the pharmacists and the pharmaceutical technicians to perform their duties in accordance with a code of ethics of the pharmaceutical profession.	
8.1.4 There are legal requirements defining the necessary criteria that must be met regarding the pharmaceutical qualification and the experience for a pharmacist.	
8.1.5 There are legal requirements defining the necessary criteria that must be met regarding the pharmaceutical qualification and experience for a pharmaceutical technician.	
8.2 Pharmaceutical Practice Committee	
8.2.1 There is a legal provision for the establishment of a Pharmaceutical Practice Committee (PPC).	
8.2.2 The composition of the PPC is clearly defined.	
8.2.3 The mission, responsibilities and powers of the PPC are clearly defined and include in particular: • the issuance of standards of practice and conduct, • the setting of standards of education and training for pharmacists and pharmaceutical technicians.	
8.3 Disciplinary Committee	
8.3.1 There is a legal provision for the establishment of a Disciplinary Committee (DC).	
8.3.2 The composition of the DC is clearly defined.	
8.3.3 The mission, responsibilities and the powers of DC are clearly defined and include in particular: • the issuance of a reprimand or a warning, • the recommendation to suspend or to remove a registered pharmacist or a registered technician from the respective register.	

	8.4 Guidelines	
8.4.1	There is a guideline on the content, the format of the applications and the procedure to follow for the registration: • as a pharmacist • as a pharmaceutical technician.	
	8.5 Organization and structure	
8.5.1	Registration activities are organized and performed at a central level of the country.	
8.5.2	Decentralized activities to other agencies/authorities follow the standards, guideline and procedures as agreed/decided with the central authority.	
8.5.3	In case of decentralization, a mechanism of exchange of information is established and implemented in order for the decentralized organization to receive requests and/or directives from the central authority and to report to it.	
8.5.4	The mechanisms in place allow exchange and harmonization of best practices, appropriate cooperation and collaboration among the decentralized organizations.	
	8.6 Registration procedures	
8.6.1	Documented procedures are implemented for assessing the applications for registration and for issuing the licenses and renewal: • as a pharmacist • as a pharmaceutical technician.	
8.6.2	This procedure considers in particular a continual professional education	
	8.7 Human and other resources	
8.7.1	There is enough personnel (internal and external) with adequate expertise (education, experience and training) for the assessment of the applications for registration of pharmacy personnel.	
8.7.2	There is adequate office and the storage space.	
8.7.3	The equipment is adequate and well maintained for regulatory activities.	

	8.8 Records and outputs	
8.8.1	A list/data base of all registered pharmacists and technicians is established and kept up-to-date.	
8.8.2	The NRA retains a file of each registered pharmacist and pharmaceutical technician containing at least the following types of information: name, place of exercise, diploma or qualification and contact details.	
	8.9 Availability of information	
8.9.1	The list/data base of all the registered pharmacists and technicians is published and is publicly available.	
Key findings and gaps		

MODULE 9 POST MARKETING SURVEILLANCE AND CONTROLS		**COMMENTS:**
	9.1 Import and export controls	
9.1.1	The legal provisions require the importer to hold a marketing authorisation or to have its pharmaceutical products registered before organising the importation activities.	
9.1.2	The legal provisions require the importers/exporters to hold an authorization for each importing and exporting act of a pharmaceutical product.	
9.1.3	The legal provisions require the importers and exporters to register information on the origin and the destination of the products imported and exported.	
9.1.4	There are guidelines for importers and exporters on the format and content of the application and the procedure to follow for these authorizations.	
9.1.5	The activities are organized and performed at a central level of the country by the NRA.	
9.1.6	Decentralized activities to other agencies/authorities follow the standards, guideline and procedures as agreed/decided with the central authority..	
9.1.7	In case of decentralization, a mechanism of exchange of information is established and implemented in order for the decentralized organization to receive requests and/or directives from the central authority and to report to it.	
9.1.8	The mechanisms in place allow exchange and harmonization of best practices, appropriate cooperation and collaboration among the decentralized organizations.	
9.1.9	Documented procedures are implemented in the NRA to assess the application for import and export certificates/authorizations.	
9.1.10	Documented procedures are implemented to issue import and export certificates/authorizations, in standardized formats.	
9.1.11	There are records or a data base kept by the RA on imported and exported products.	
9.1.12	There is a collaboration/agreement with the Customs or other enforcement agencies on the control of import and export.	

	9.2 Market Controls	
9.2.1	There are legal provisions to deal with non-compliant products.	
9.2.2	There is a legal provision for sampling and testing samples of pharmaceutical products on the market.	
9.2.3	Documented procedures are implemented to sample the products sold or supplied on the market and to send them for testing to the drug control quality laboratory.	
9.2.4	The criteria for sample collection are based on risk assessment.	
9.2.5	There are provisions and criteria for compensation for the samples collected.	
9.2.6	The activities are organized and performed at a central level of the country.	
9.2.7	Decentralized activities to other agencies/authorities follow the standards, guidelines and procedures as agreed/decided with the central authority.	
9.2.8	In case of decentralization, a mechanism of exchange of information is established and implemented in order for the decentralized organization to receive requests and/or directives from the central authority and to report to it.	
9.2.9	The mechanisms in place allow exchange and harmonization of best practices, appropriate cooperation and collaboration among the decentralized organizations.	
9.2.10	Documented procedures/programs are implemented for collecting information, detecting and combating non-compliant products.	
9.2.11	A market surveillance strategy based on inspection activities, control activities and other information is established and implemented under the format of surveillance program for example.	
9.2.12	A surveillance program (quality control plans and sampling strategy) is established to cover various dosage forms of different drug/medicinal products and is based on the potential health risks identified or expected for the patients.	
9.2.13	The strategy and the surveillance program are periodically reviewed and its effectiveness is assessed.	
9.2.14	The RA keeps the records or information/data base on the samples collected of non-compliant products.	

9.2.15	A collaborative agreement with the Customs and other enforcement agencies is established for market control activities, in particular for sharing information and exchanging best practices.	
9.2.16	A documented procedure is implemented for communication/collaboration and cooperation with the relevant authorities/jurisdiction in the investigations and the prosecution of breaches of regulation.	
	9.3 Non-compliant products and recall procedures	
9.3.1	The legislation enables the RA to instruct for the recall of pharmaceutical products (e.g. due to defects, inappropriate labelling or packaging or contamination).	
9.3.2	The legislation enables the RA to suspend or stop the manufacture, import, export, distribution, sale or use of pharmaceutical products.	
9.3.3	There is a legal requirement for records to be maintained within the distribution chain to ensure batch traceability and facilitate an effective recall system.	
9.3.4	There is a legal provision concerning the disposal of defective/non-compliant products.	
9.3.5	There is a legal requirement for manufacturers/importers to notify the NRA before initiating a recall and upon request to inform on the progress.	
9.3.6	There is a legal requirement for manufacturers/importers to notify the NRA about product complaints regarding quality.	
9.3.7	There are guidelines for manufacturers, importers, exporters and distributors on how to organise a recall and to organise the disposal of defective/non-compliant products.	
9.3.8	Documented procedures are implemented in the NRA to assess the notification of recalls and product complaints.	
9.3.9	Documented procedures are implemented in the NRA to ensure the removal of defective products, organize an effective recall and disposal of defective/non-compliant products.	
9.3.10	There are defined criteria to determine the appropriate means and the level of communication of a recall with a feedback mechanism.	
9.3.11	The effectiveness of the recall system is regularly validated.	

9.3.12	There is guidance on the mechanism to ensure that appropriate actions (including destruction when necessary) have been taken.	
9.3.13	The NRA approves the closure of a recall and certifies the disposal of defective/non-compliant products.	
9.3.14	The NRA keeps the records or an information/data base on recalled and disposed defective/non-compliant products.	
Key findings and gaps		

MODULE 10 CONTROL OF DRUG PROMOTION AND ADVERTISING		**COMMENTS:**
	10.1 Legal basis	
10.1.1	There are legal provisions for the control of promotion of pharmaceutical products to avoid communication of false or misleading information.	
10.1.2	The legal provisions allow, under certain conditions and criteria, the promotion of the pharmaceutical products to the general public.	
10.1.3	The legal provisions allow under certain conditions and criteria the promotion of pharmaceutical products to those persons qualified to prescribe, supply or dispense these products.	
10.1.4	The legislation enables the NRA to grant the authorization of marketing products, to suspend and to withdraw it or to stop any promotional campaign and to cease the distribution of promotional documents.	
10.1.5	The legal provisions prohibit the distribution of free samples of pharmaceutical products to the general public for promotional purposes.	
10.1.6	The legal provisions allow under certain conditions the distribution of free samples of pharmaceutical products to those persons qualified to prescribe, supply or dispense these products.	
10.1.7	The legal provisions require the medical or sales representatives to have adequate scientific knowledge and training.	
10.1.8	The legal provisions require to use the approved product information (e.g. SPC) as reference materials to monitor promotion and advertising activities and materials.	
10.1.9	The same legal provisions are applicable to the promotion of pharmaceutical products on internet.	
10.1.10	The legal provisions prohibit the supply, offer or promise to persons qualified to prescribe, to supply and to dispense the pharmaceutical products any gift, pecuniary advantage or benefit of any kind unless strict conditions are met.	
	10.2 Guidelines	
10.2.1	There are guidelines on the content, the format of the application and the procedure to follow for receiving the approval of promotional and advertising material.	

10.2.2	There are guidelines on the control of advertisements and promotion during symposiums and other scientific meetings.	
10.2.3	There are guidelines on the control of the operations of Medical and Sales Representatives.	
	10.3 Organization and structure	
10.3.1	Promotion and advertisement authorization activities are organized and performed at a central level of the country.	
	10.4 Internal procedures	
10.4.1	Documented procedures are implemented in the NRA to assess and to approve promotional and advertising materials.	
10.4.2	Documented procedures are implemented in the NRA to review any complaints received regarding medicine promotion and advertising activities.	
10.4.3	External experts are involved in the assessment of the applications for promotion and advertising authorization.	
10.4.4	An advisory committee of experts is involved in the review of the applications for promotion and any matters related to the control of drug promotion.	
10.4.5	The NRA has developed a proactive monitoring program to check advertisement and promotions in scientific journals or literature for healthcare practitioners.	
10.4.6	Civil Society groups, professional associations and NGOs are involved in detecting unethical promotion and advertising activities.	
10.4.7	The Inspectorate staff is involved in the detection of unethical or unauthorized promotional and advertising materials.	
10.4.8	The NRA staff responsible for issuing MAs of pharmaceutical products is involved in the assessment of the applications for the promotion of pharmaceutical products and any investigations on promotional activities.	

	10.5 Human and other resources	
10.5.1	There is enough personnel (internal or external) with the adequate expertise for the assessment of the applications, for issuing the approvals and for implementing the surveillance program.	
10.5.2	There is adequate office and storage space.	
10.5.3	The equipment is adequate and well maintained for regulatory activities.	
	10.6 Records and outputs	
10.6.1	The RA keeps the records or information / data base on approved and refused promotional material and advertisements with the supporting documentation.	
	10.7 Availability of information	
10.7.1	The list of authorized promotional materials and advertising campaigns is published and is publicly available.	
10.7.2	The list of unauthorized and unethical promotional materials and advertising campaigns is published and is publicly available.	
Key findings and gaps		

MODULE 11 PHARMACOVIGILANCE	**COMMENTS:**
11.1 Legal basis	
11.1.1 There are legal provisions on post marketing safety monitoring of pharmaceutical products.	
11.1.2 The legal provisions require the NRA to implement a vigilance system in order to collect the information useful in the surveillance of medicines, to evaluate such information and to take the appropriate decisions.	
11.1.3 There are legal provision for all stakeholders to report adverse reactions/event or any safety issues to the NRA under defined conditions.	
11.1.4 There are legal provisions for MA holders that require the registration, data collection and maintenance, assessment and monitoring of adverse reactions/event and to report to the NRA on these activities.	
11.1.5 The legal provisions require the manufacturers, distributors, importers, exporters to report the adverse reactions/events to the MAH and NRA under specific conditions.	
11.1.6 The legal provisions requires the healthcare professionals to report any adverse events/reactions to MA holders or to the RA or another delegated authority.	
11.1.7 There are specific requirements for reporting safety issues related to specific categories of products (e.g. vaccines, biologicals, biological products, etc).	
11.1.8 There are specific requirements for Marketing authorization holders, manufacturers, importers, exporters, distributors, wholesalers to designate a qualified person in charge of post Marketing Authorization safety monitoring.	
11.1.9 There are legal provisions to define the terminology used such as adverse event, adverse reaction, serious adverse event, etc.	
11.1.10 The legal provisions specify the delay and/or the periodicity for reporting of adverse events.	
11.1.11 There are specific requirements for health care institutions (clinics, hospitals, etc..) to designate a focal person for post marketing safety monitoring.	

	11.2 Guidelines	
11.2.1	There are guidelines on post MA safety monitoring regarding the registration, the reporting and the format to be used (initial report, periodic reporting).	
11.2.2	There are guidelines on classification of safety events.	
11.2.3	The guidance on safety reporting provides for a scientific evaluation of the risk/benefit balance of medicines.	
11.2.4	There are guidelines defining the adequate scientific knowledge and training of qualified persons and focal persons in charge of vigilance.	
11.2.5	There are guidelines on the criteria to determine the reporting timelines and means of reporting of safety events (serious, expected, etc…).	
	11.3 Organization and structure	
11.3.1	Vigilance activities are organized and performed at a central level of the country.	
11.3.2	Decentralized activities to other agencies/authorities follow the standards, guideline and procedures as agreed/decided with the central authority.	
11.3.3	In case of decentralization, a mechanism of exchange of information is established and implemented in order for the decentralized organization to receive requests and/or directives from the central authority and to report to it.	
11.3.4	The mechanisms in place allow exchange and harmonization of best practices, appropriate cooperation and collaboration among the decentralized organizations.	
	11.4 Internal procedures	
11.4.1	External information (information sources and reference materials) for decision making on ADR and safety monitoring are readily available.	
11.4.2	Documented procedures are implemented in the NRA to register and to assess day to day ADR reports.	

11.4.3	A documented procedure is implemented to follow implementation of pharmacovigilance plan (see also module 4 on MA)	
11.4.4	Documented procedures are implemented in the NRA to analyse the safety trends for signal detection.	
11.4.5	A well-established system is in place for prioritization of drug safety signals according to the public health impact and to demonstrate that high risk issues are investigated immediately or in the first instance.	
11.4.6	External experts are involved in the assessment of the information on safety transmitted through the vigilance network.	
11.4.7	An advisory committee of experts is involved in the review of the information on safety transmitted through the vigilance network and any other matters related to the safety of pharmaceutical products.	
11.4.8	There are defined timelines for the assessment and decision making on ADR.	
11.4.9	An internal tracking system is established to follow the targeted time frames (statutory or not).	
11.4.10	Documented procedures are implemented for decision-making and for defining the recommended actions to be taken by the NRA, by the MAH, by the manufacturer or any other stakeholders.	
11.4.11	There are documented quality control measures in place such as peer-review.	
11.4.12	The NRA organizes on a regular basis campaigns to promote adhesion to vigilance.	
11.4.13	Consumers and patients are involved in the safety monitoring program.	
11.4.14	The NRA has developed a proactive monitoring program to check compliance of the MAH to applicable regulatory requirements and best practices.	
11.4.15	MAH, manufacturers, importers, exporters, distributors are periodically inspected by inspectorate on pharmacovigilance practices.	
	11.5 Human and other resources	
11.5.1	There is enough personnel (internal or external) with adequate expertise (education, experience and training) for safety monitoring activities.	

11.5.2	There is adequate office and storage space.	
11.5.3	The equipment is adequate and well maintained for regulatory activities.	
	11.6 Records and outputs	
11.6.1	The information collected on safety is used for making or amending regulatory decisions on initial MA (adding information on SPC, restricting the use of drug, review of PIL, recall or withdrawal of products, etc.).	
11.6.2	The NRA keeps the information/data base on safety events reported and on the actions taken. The terminology used is the one promoted by the WHO (WHO-ART).	
11.6.3	Query tools on the data collected enables the NRA to assess and interpret safety signals (calculation of incidence rate, assessing of causality).	
	11.7 Availability of information	
11.7.1	Information on ADR and safety monitoring measures taken are communicated to the public, including the safety notice.	
Key findings and gaps		

MODULE 12 CLINICAL TRIALS	**COMMENTS:**
12.1 Legal basis	
12.1.1 There is a legal provision for the authorization, suspension and withdrawal of clinical trials by the NRA or by another delegated authority for pharmaceutical products.	
12.1.2 There is a legal provision requesting the establishment of IRB/IEC.	
12.1.3 There is a legal provision requesting an ethics opinion of an IRB/IEC.	
12.1.4 The legal provisions require the notification and approval of the NRA of significant changes/variations to the initial clinical trial protocols.	
12.1.5 The legal provisions require the investigational/research centres to comply with Good Clinical Practices and Good Laboratory Practices.	
12.1.6 There are legal provisions on licensing of manufacturers and importers of investigational products.	
12.1.7 These is a legal provision requiring the products for investigation to comply with the applicable GMP.	
12.1.8 There are legal provisions on specific labelling and packaging requirements for the investigational products.	
12.1.9 There are legal provisions requiring authority for the importation and exportation of investigational products.	
12.1.10 There are legal provisions requiring during the conduct of a clinical trial, the notification, data collection, assessment and monitoring of adverse drug reactions/events and to report to the NRA under specific conditions.	
12.1.11 There are legal provisions defining the terminology used, for clinical trial purpose, such as adverse event, adverse reaction, serious adverse event, unexpected, etc.	
12.1.12 Legal provisions specify the delay and/or the periodicity for reporting of adverse events during the clinical trial.	
12.1.13 There are exemptions to clinical trial requirements following defined criteria.	

	12.2 Guidelines	
12.2.1	There are guidelines for sponsors or sponsors representatives on the content of the application, the format and the procedure to follow in order to submit an application for conducting clinical trials.	
12.2.2	There are guidelines for applicants on the types and scopes of variations/amendments and on the documentation required.	
12.2.3	There are guidelines on conditions (e.g. validity, amendment of the protocol, etc) attached to the clinical trial approvals issued.	
12.2.4	There is a guideline on monitoring of adverse reactions (give details) and on periodical reporting of their results to the NRA.	
12.2.5	There is a guideline on the criteria for selecting the Principal Investigator and his roles and responsibilities.	
12.2.6	There are guidelines for licensing manufacturers and importers of investigational products.	
12.2.7	There are guidelines on compliance with the GMP requirements for the manufacturers of investigational products.	
12.2.8	A guidance for investigation centres/clinical trial sites provides detailed information on compliance with GCP and GLP requirements. This guidance is in line with the WHO format.	
12.2.9	There are guidelines on the control of importation and exportation of investigational products.	
	12.3 Ethical oversight	
12.3.1	The ethical oversight established is based on the Declaration of Helsinki.	
12.3.2	There is a requirement on the composition, functions and mode of operation of the IRB/IEC.:	
12.3.3	Documented procedures are implemented to review the trial in particular the clinical trial protocols and amendments, documented informed consent and recruitment procedure.	
12.3.4	There is a requirement on the establishment of an IRB/IEC supervising authority.	
12.3.5	The funding for IRB/IEC is based on the fees for the services provided.	

12.3.6	There is an approval and supervisory system for IRB/IEC.	
12.3.7	A procedure details the review and the methodology used for the supervision of the IRB/IEC.	
12.3.8	A general policy on potential conflicts of interest for members of IRB/IEC is established and implemented.	
12.3.9	A general policy on confidentiality and a code of conduct for members of IRB/IEC is established and implemented.	
12.3.10	There is a documented mechanism to manage potential conflicts of interest of members of IRB/IEC by collecting declarations of interests, including ensuring updates of these declarations.	
	12.4 Organization and structure	
12.4.1	The activities are organized and performed at a central level of the country.	
12.4.2	Decentralized activities to other agencies/authorities follow the standards, guideline and procedures as agreed/decided with the central authority.	
12.4.3	In case of decentralization, a mechanism of exchange of information is established and implemented in order for the decentralized organization to receive requests and/or directives from the central authority and to report to it.	
12.4.4	The mechanisms in place allow exchange and harmonization of best practices, appropriate cooperation and collaboration among the decentralized organizations.	
	12.5 Assessment procedures	
12.5.1	Documented procedures are implemented for the assessment of CT applications.	
12.5.2	Documented procedures are implemented for assessing the application for amendments of CT protocols.	
12.5.3	The Investigator's Brochure, Informed Consent procedure, investigation plan, data collection tools are assessed and approved as part of the approval for the clinical trial.	
12.5.4	External experts are involved in the assessment of CT applications.	
12.5.5	An advisory committee of experts is involved in the review of CT applications and any other matters related to the research/investigations on human being.	

12.5.6	Documented procedures are implemented for decision-making on CT.	
12.5.7	The assessment report on the CT is fulfilled following a standardized format.	
12.5.8	Documented procedures are implemented to ensure the involvement and communication between the assessors and the regulatory inspectorate for compliance to applicable good practices (GMP, GCP and GLP).	
12.5.9	The NRA has developed a proactive monitoring program to check compliance with applicable regulatory requirements, applicable good practices and as per the authorization delivered.	
12.5.10	IRB/IEC, investigators and sponsors are periodically inspected by the inspectorate of the DRA.	
12.5.11	The same criteria are used for the evaluation of CT applications regardless of the origin of the request (e.g. domestic, foreign, public/private sector).	
12.5.12	There are timelines for the assessment of CT applications.	
12.5.13	An internal tracking system is established to follow the targeted time frames (statutory or not).	
12.5.14	There is a fast-track mechanism for the assessment of CT applications for specific products of particular public health value.	
12.5.15	A documented procedure is implemented to issue CT related authorization in a standardized format.	
12.5.16	A written authorization, signed by a person with the adequate delegation, is sent to the sponsor, including conditions or restrictions attached to this authorization.	
	12.6 Human and other resources	
12.6.1	There is enough personnel with adequate internal and external expertise (education, experience and training) for the assessment of CT applications.	
12.6.2	Manufacturer's or sponsor's representatives are never involved in the assessment of CT (at any level/stage including expert committees).	
12.6.3	There are lines of authority reflecting the independence of decision-making in the CT approval system from sponsors, investigators or government.	
12.6.4	There is adequate office and storage space.	

12.6.5	The equipment is adequate and well maintained for regulatory activities.	
12.6.6	Adequate support services are provided in terms of communication, equipment and infrastructure.	
	12.7 Records and outputs	
12.7.1	There is a list/data base of all the approved and rejected CT applications.	
12.7.2	The NRA retains a file of each CT approved and rejected, including the amendments approved or rejected and the supporting documentation which includes the summary assessment reports. All the exemptions to clinical trials requirements are documented.	
	12.8 Availability of information	
12.8.1	A list of CT approved and CT applications rejected, including the summary assessment reports is published and is publicly available.	
	Key findings and gaps	

MODULE 13 REGULATORY INSPECTIONS AND ENFORCEMENT ACTIVITIES		**COMMENTS:**
	13.1 Legal basis	
13.1.1	There is a legal provision to inspect premises where regulated activities are performed in order to check compliance with the applicable regulation, good practices and standards.	
13.1.2	There is a legal provision specifying the periodicity for regulatory inspections.	
13.1.3	There is a legal provision allowing the inspection of foreign sites of manufacturers.	
13.1.4	There is a legal provision designating the inspectors and their powers.	
13.1.5	The inspectors have adequate powers and authority to carry on their missions.	
13.1.6	There are exemptions to the inspection requirements with defined criteria.	
13.1.7	The legislation provides for adequate and proportional sanctions, penalties and prosecution upon conviction based on violation of the applicable legislation.	
	13.2 Guidelines	
13.2.1	There is a guidance on the compliance and enforcement strategy taken by the NRA defining the pyramid of sanctions applicable.	
13.2.2	This enforcement strategy is based on voluntary decisions (voluntarily stop sale, recall) and regulatory measures (warning letter, cancellation of licence or MA).	
13.2.3	There is a deadline for GMP, GCP, GLP and GDP compliance for all domestic facilities (in case of recently adopted legal provisions).	
13.2.4	There are guidelines for conducting pre- and post- licensing inspections.	
13.2.5	There are guidelines for the environmentally-conscious disposal of expired/unusable substances, reagents and finished products.	
	13.3 Organization and structure	
13.3.1	Inspection activities are organized and performed at a central level of the country.	

13.3.2	Decentralized activities to other agencies/authorities follow the standards, guideline and procedures as agreed/decided with the central authority.	
13.3.3	In case of decentralization, a mechanism of exchange of information is established and implemented in order for the decentralized organization to receive requests and/or directives from the central authority and to report to it.	
13.3.4	The mechanisms in place allow exchange and harmonization of best practices, appropriate cooperation and collaboration among the decentralized organizations.	
	13.4 Quality management system	
13.4.1	A quality management system is implemented for the inspectorate.	
13.4.2	The management of the inspectorate is committed to the development and implementation of the Quality Management System, in particular providing financial and organizational support.	
13.4.3	The quality management system is based on recognized standards as reference (WHO, PIC/S, ISO, other).	
13.4.4	The quality policy and related quality objectives of the Inspectorate are defined and documented.	
13.4.5	A qualified person is designated as responsible within the inspectorate for the development and implementation of the quality management system.	
13.4.6	The documentation needed to establish, implement and maintain the QMS is defined (Quality manual, records, SOPs).	
13.4.7	The documentation required by the QMS is controlled following a documented procedure.	
13.4.8	A documented procedure is established by the Inspection to plan, and to assess if the QMS is effectively implemented and conforms to planned arrangements.	
13.4.9	The Inspectorate performs internal audit of its QMS at least once every 12 months. Records of the results are maintained.	
13.4.10	The corrective and preventive actions taken as a result of audits or from any other non conformity are implemented and documented. Their effectiveness is checked and documented.	

13.4.11	The top management of the inspection reviews on a regular basis, at least once every 12 months, the QMS to evaluate its efficiency as well as its effectiveness. Records of the review are maintained.	
	13.5 Internal planning and procedures	
13.5.1	The inspectorate establishes compliance monitoring programs based on activities that are supervised (GMP, GDP, GCP, Pharmacy, Retail outlets, etc…).	
13.5.2	Documented procedures/tools are implemented for the planning of inspection activities showing in particular the duration and frequency of the inspections.	
13.5.3	The internal planning for inspection activities is established and updated to cover all regulated activities.	
13.5.4	Documented procedures/tools are implemented for the preparation and the development of adequate materials for an inspection (check-list, reference materials, plans, etc…).	
13.5.5	Documented procedures/tools are implemented to perform the inspections and in particular on assessing the critical steps of the processes and validation.	
13.5.6	Documented procedures/tools are implemented to check compliance with the GMP, GDP, GCP, GLP, Good vigilance practices and good dispensing practices.	
13.5.7	Documented procedures are implemented for inspections based on specific requirements for specific classes of products and facilities (generics, sterilisation, innovator products).	
13.5.8	There is a standard format for reporting inspection gaps or deficiencies such as an inspection report.	
13.5.9	The observations of non compliance are classified/categorized according to the risk (critical, major and minor).	
13.5.10	Documented quality control measures are in place such as peer-review.	
13.5.11	External experts are involved in the inspection processes.	
13.5.12	A committee of internal experts within the DRA is involved in the inspection, evaluation of the inspection reports and in decision-making.	
13.5.13	Documented procedures are implemented for decision-making.	

13.5.14	Documented procedures are implemented for follow-ups on deficiencies/violations to enforce compliance (including timeframes) and to issue notices on the violations.	
13.5.15	Documented procedures are implemented on investigation activities, any seizure or prosecution.	
13.5.16	Documented procedures are implemented to ensure the adequate involvement and communication between the inspectors, QC laboratory staff and licensing or registration staff.	
13.5.17	The same criteria are used for the inspection of domestic, foreign, public and private facilities.	
13.5.18	There are time limits for the publication of Inspection reports.	
13.5.19	An internal tracking system is established to follow the targeted time frames (statutory or not).	
13.5.20	A documented procedure is implemented to issue Good Practices related certificates in a standardized format.	
	13.6 Human and other resources	
13.6.1	Job descriptions are established for the following staff: head of the inspectorate (supervisor), head of the inspection unit by products, inspection team leader and inspector.	
13.6.2	There is enough personnel (internal and external) with adequate expertise (education, experience and training) for the inspection of all pharmaceutical products and regulated activities such as: • manufacturers of active pharmaceutical ingredients, • manufacturers of finished pharmaceutical products, • pharmaceutical quality control laboratories • importers and exporters, • wholesalers and distributors, • Institutions for conducting clinical and non-clinical trials, • Pharmacies and retail outlets • MA Holders.	
13.6.3	The minimum qualification, experience and training for performing all kinds of inspections is defined.	
13.6.4	The inspectors have the knowledge of the local judiciary procedures if they are supposed to initiate actions in the courts of justice.	

13.6.5	There is a documented process on qualification and review to confirm the competencies required for being inspectors.	
13.6.6	A documented procedure is implemented for the designation of inspectors.	
13.6.7	The inspectors are trained on the specific areas (GMP, GDP, GCP, GLP).following a training program. The training activities are recorded and such records are kept up-to-date.	
13.6.8	Manufacturer's or licence holder's representatives are never used to conduct inspections.	
13.6.9	The list of inspectors that are qualified with their specific areas of competencies is available and is kept up-to-date.	
13.6.10	There is adequate office and storage space for the inspectorate’s activities.	
13.6.11	The equipment is adequate and well maintained for regulatory activities.	
13.6.12	Adequate support services are provided in terms of transport and communication.	
	13.7 Records and outputs	
13.7.1	There is a list/data base of all inspected facilities.	
13.7.2	The NRA retains a file of each inspection including the information on the mission, the inspection report, the comments of the company inspected and the final decision taken with supporting documentation. Each exemption is documented in this file.	
13.7.3	The information collected on the company is used for making or amending regulatory decisions on initial licenses or MA (Recall or withdrawal of products, etc).	
	13.8 Availability of information	
13.8.1	The list and identity of the designated inspectors is available to the companies subjected to inspection.	
13.8.2	The list/data base of all the inspected facilities is published and is publicly available.	
13.8.3	A summary of the inspection reports are published and are publicly available, following applicable local confidentiality requirements.	

13.8.4	The information regarding the enforcement activities such as notices of compliance, penalties, prosecutions engaged are published and are publicly available.	

Key findings and gaps

MODULE 14 QUALITY CONTROL LABORATORY	**COMMENTS:**
14.1 Legal basis	
14.1.1 There is a legal provision for the establishment of a Regulatory Quality Control Laboratory (RQCL).	
14.1.2 The RQCL is part of the NRA.	
14.1.3 There is a legal provision on the designation of analysts and their powers.	
14.1.4 The legislation empowers a RQCL to perform quality control testing of the pharmaceutical products and to issue official results.	
14.2 Guidelines	
14.2.1 There is a defined policy for testing in the pre-marketing and post-marketing period.	
14.2.2 There are guidelines on collection, packaging and submission of samples.	
14.2.3 There are guidelines on the references or standards applied by the RQCL.	
14.2.4 There are guidelines on how to complain and appeal against the decisions of the RQCL.	
14.3 Organization and structure	
14.3.1 Testing activities are organized and performed at a central level of the country.	
14.3.2 Decentralized activities to other agencies/authorities follow the standards, guidelines and procedures as agreed/decided with the central authority..	
14.3.3 In case of decentralization, a mechanism of exchange of information is established and implemented in order for the decentralized organization to receive requests and/or directives from the central authority and to report to it.	
14.3.4 The mechanisms in place allow exchange and harmonization of best practices, appropriate cooperation and collaboration among the decentralized organizations.	

	14.4 Quality management system	
14.4.1	A quality management system is implemented for the RQCL.	
14.4.2	The management of the RCQL is committed to the development and implementation of the Quality Management System, in particular providing financial and organizational support.	
14.4.3	The quality management system is based on recognized standards as reference (WHO, PIC/S, ISO, other).	
14.4.4	The quality policy and related quality objectives of the RQCL are defined and documented.	
14.4.5	A qualified person is designated as responsible within the RCQL for the development and implementation of the quality management system.	
14.4.6	The documentation needed to establish, implement and maintain the QMS is defined (Quality Manual, records, SOPs).	
14.4.7	The documentation required by the QMS is controlled following a documented procedure.	
14.4.8	A documented procedure is established by the RQCL to plan, and to assess if the QMS is effectively implemented and conforms to planned arrangements.	
14.4.9	The RQCL performs internal audit of its QMS at least once every 12 months. Records of the results are maintained.	
14.4.10	The corrective and preventive actions taken as a result of audits or from any other non conformity are implemented and documented. Their efficacy is checked and documented.	
14.4.11	The RQCL is regularly audited by an external organization (e.g. certification, accreditation) and the results are available.	
14.4.12	The RQCL participates in a proficiency testing scheme and in external quality assurance programs.	
14.4.13	Top management of the RQCL reviews on a regular basis, at least once every 12 months, the QMS to evaluate its efficiency as well as its effectiveness. Records of the review are maintained.	
	14.5 Quality control procedures	
14.5.1	Documented procedures are implemented for meetings with clients and other interested parties.	

14.5.2	Documented procedures are implemented for preparation and storage of standards, samples, etc.	
14.5.3	Documented procedures are implemented for performing the testing.	
14.5.4	There is appropriate planning of testing and maintenance activities.	
14.5.5	Documented procedures are implemented for handling and storage of in-coming and retention samples.	
14.5.6	Documented procedures are implemented for testing specific ranges of products.	
14.5.7	There are specific documented procedures to deal with non-compliant products.	
14.5.8	There are strategies, programs and procedures for the introduction and validation of new/improved tests.	
14.5.9	Documented procedures are implemented for the evaluation of test results and decision-making.	
14.5.10	Documented procedures are implemented for handling out-of-specification results, including a retesting policy.	
14.5.11	There is a standard format for recording and reporting results of analysis (work sheet and CoA).	
14.5.12	Documented procedures are implemented for follow-ups of non-compliant products to enforce compliance (including timeframes).	
14.5.13	The same criteria are used for testing all products from domestic, foreign, public and private facilities.	
14.5.14	A documented procedure is implemented to issue certificates in a standardized format.	
14.6	**Human resources**	
14.6.1	Job descriptions are established for the following staff: head of RQCL (supervisor), Analysts, storekeeper and reference material coordinator.	

14.6.2	There is enough personnel (internal and external) with adequate expertise (education, experience and training) for the testing of: • Active pharmaceutical ingredients, • Pharmaceutical products, • Biological, • Traditional/Herbal medicines	
14.6.3	There are mechanisms to manage any conflicts of interest, including ensuring updates of declarations of conflicts of interest.	
14.6.4	There are mechanisms to ensure that confidentiality requirements are met, for example by the observance of a code of conduct by the analysts.	
	14.7 Infrastructure and equipment	
14.7.1	There is adequate working space, work environment and storage space for laboratory activities.	
14.7.2	Equipment and instruments for testing activities are adequate and well maintained.	
14.7.3	Documented procedures are implemented for the correct use of the equipment according to the manufacturer's instructions.	
14.7.4	There are operation manuals and logs books for the equipment (registers of operations/use/maintenance/calibration)	
14.7.5	Plans for cleaning, calibration and maintenance activities are established and implemented.	
14.7.6	There are qualification protocols and reports for the equipment.	
14.7.7	There are adequate support services provided in terms of transport and communication.	
	14.8 Reference standards/materials and reagents	
14.8.1	There is a system to establish and qualify the national reference standards/materials.	
14.8.2	There is a regular supply system for reference standards/materials.	
14.8.3	Documented procedures are implemented for the appropriate handling and use of reference standards/materials	

14.8.4	Documented procedures are implemented for sourcing, preparation, storage and use of reagents of assured quality.	
	14.9 Safety programme	
14.9.1	A list of hazardous substances is available and updated.	
14.9.2	The responsible staff is designated for the management of a safety programme.	
14.9.3	A documented procedure are implemented for the storage, handling and disposal of hazardous substances.	
	14.10 Sub-contracting	
14.10.1	A list of all the categories of testing activities the NDCL sub-contacts to another laboratory or organization is established.	
14.10.2	A formal agreement/contract defines the roles and responsibilities of each stakeholder in particular as regards conflict of interest and confidentiality.	
14.10.3	A documented procedure is implemented to ensure that the requirements that apply to the NDCL are also applied in the same way to the sub-contracting organization.	
	14.11 Records and outputs	
14.11.1	There is a list/data base of all the products tested.	
14.11.2	Testing records/reports are maintained and are readily available at the RQCL.	
14.11.3	The RQCL issues certificates of analysis under its own name or in the name of the NRA.	
Key findings and gaps		

MODULE 15 CONTROL OF NARCOTICS, PSYCHOTROPIC SUBSTANCES AND PRECURSORS		**COMMENTS:**
15.1.1	The country is a signatory to the International Conventions on the control of Narcotics, Psychotropic Substance and their Precursors.	
15.1.2	There are legal requirements for manufacturing, importing, exporting, storage, distribution, consumption of Narcotics, Psychotropic Substances and their Precursors.	
15.1.3	There are legal requirements for reporting, reconciliation and disposal of Narcotics, Psychotropic Substances and their Precursors.	
15.1.4	There are guidelines on the formats for permits, for advice of receipt and for submission of returns of the controlled substances.	
15.1.5	These activities are organized and performed at a central level of the country.	
15.1.6	Decentralized activities to other agencies/authorities follow the standards, guidelines and procedures as agreed/decided with the central authority.	
15.1.7	In case of decentralization, a mechanism of exchange of information is established and implemented in order for the decentralized organization to receive requests and/or directives from the central authority and to report to it.	
15.1.8	The mechanisms in place allow exchange and harmonization of best practices, appropriate cooperation and collaboration among the decentralized organizations.	
15.1.9	There is a specific requirement for institutions to designate a focal person for the control of Narcotics, Psychotropic Substances and their Precursors in each facility using or utilizing these substances.	
15.1.10	Documented procedures are implemented to evaluate the returns for quantification and detection of abuse or diversion.	
15.1.11	There is enough personnel (internal and external) with adequate expertise (education, experience and training) for control of narcotics, psychotropic substances and their Precursors.	
15.1.12	The civil society and healthcare professional are involved in the activities for the control of Narcotics, Psychotropic Substances and their Precursors.	
15.1.13	There are defined reporting timelines and means of submitting returns on these substances.	

15.1.14	There is information/data base on consignments received and returns submitted for these substances.	
15.1.15	Any abuse or diversions and actions taken are registered and documented by DRA.	
15.1.16	Information sources and reference materials on the control of Narcotics, Psychotropic Substance and their Precursors are readily available.	
Key findings and gaps		

MODULE 16 INTERNATIONAL COOPERATION AND HARMONISATION		**COMMENTS:**
16.1.1	There is an internal policy to facilitate international cooperation and harmonization.	
16.1.2	There are agreements signed between the DRA and RA of other countries or agencies for cooperation and harmonization.	
16.1.3	The NRA participates or follows the development of International and/or Regional standards	
16.1.4	The NRA participates or follows any harmonization initiative or forum.	
16.1.5	The NRA participates in working groups within the harmonization initiative or forum for regulators.	
16.1.6	The NRA recognizes and/or uses regulatory decisions, reports (inspection, evaluation, vigilance), guidance or information from other NRAs or international bodies.	
16.1.7	The NRA recognizes and uses the WHO recommended certification schemes and formats.	
16.1.8	The NRA issues CPP certificates following a documented procedure.	
16.1.9	The Inspectorate participates in peer-reviewed or joint activities (e.g. PIC/S).	
16.1.10	The RQCL participates in proficiency testing schemes, regional collaborative studies or the WHO External Quality Assurance Assessment Scheme (EQAAS).	
16.1.11	The NRA participates in the WHO Drug Safety Monitoring Programme.	
16.1.12	The NRA participates in INCB's international monitoring operations on control of Narcotics, Psychotropic Substances and their Precursors.	
16.1.13	The NRA participates in coordinating activities/measures in case of identification of non-compliant products at a regional/international level.	
16.1.14	Documented procedures are implemented to ensure satisfactory cooperation, collaboration and exchange of information with other RA for the various regulatory functions (MA, Inspection, Vigilance).	
Key findings and gaps