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MINISTRY OF PUBLIC HEALTH
GENERAL DIRECTORATE OF PHARMACEUTICAL AFFAIRS

**Situational Analysis of the Medicine Evaluation and Registration
System of Afghanistan**

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Situational Analysis of the Medicine Evaluation and Registration System of Afghanistan
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ACRONYMS AND ABBREVIATIONS

API	Avicenna Pharmaceutical Institute
EML	Essential Medicines List
GDPA	General Directorate of Pharmaceutical Affairs
GMP	Good Manufacturing Practices
LML	Licensed Medicines List
MoPH	Ministry of Public Health
NMFB	National Medicines and Food Board
NMRA	National Medicines Regulatory Authority
PRIS	Pharmaceutical Registration Information System
SOP	Standard Operating Procedure
SPS	Strengthening Pharmaceutical Systems
TOR	Terms of Reference
USAID	US Agency for International Development
WHO	World Health Organization

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FOREWORD

The Ministry of Public health (MoPH) is committed to ensure that all medicines available in the country, whether of domestic or foreign origin, are effective, safe and of good quality. To achieve this objective, an efficient and effective system is required to ensure that all medicines are screened for efficacy, safety and quality.

During the past three decades, like other sectors, Afghanistan's regulatory functions, especially *Medicines Registration* Systems, have been found to be weak compared to other countries. In addition, lack of a strong regulatory system in the country and the existence of long borders, which are uncontrollable, increase the risk of manufacturing and importation of ineffective, unsafe, and sub-standards or counterfeit medicines in Afghanistan. This is likely to result in wastage of resources, prolonged treatment periods, emergence of anti-microbial resistance and preventable deaths.

Information on the status of medicines registration system in the country, the opportunities and challenges in the sector, and the current legal framework such as Medicine Law, Regulations and Policies related to pharmaceuticals is important in guiding the process of strengthening the regulatory system to be in-line with World Health Organization's (WHO) requirements and standards. In order to make an evidence-based decision, the General Directorate of Pharmaceutical Affairs (GDPA) of Ministry of Public Health (MoPH) with the financial and technical support of Strengthening Pharmaceutical Systems (SPS) program conducted an assessment in May 2012 on the situation of medicines evaluation and registration system in Afghanistan. The Ministry of Public Health (MoPH) is committed to strengthening the Medicines Evaluation and Registration System in the country based on the recommendations made in this report.

The GDPA acknowledges the contribution of the stakeholders and GDPA staff involved. GDPA is also grateful to the technical support of SPS Program with the financial assistance of U.S Agency for International Development (USAID).

With Best Regards



Pharmacist Abdul Hafiz "Quraishi"

Director General of Pharmaceutical Affairs

EXECUTIVE SUMMARY

The pharmaceutical regulatory situation in Afghanistan is generally considered to be weak with most of the activities in the private sector and, to a large extent, in the public sector largely uncontrolled. Establishing a fully functional medicines evaluations and registration system has been identified as one of the priority areas in ensuring the control of medicines in Afghanistan with respect to safety, efficacy, and quality based on internal norms and standards. The aim of this assessment was to determine the current evaluation and registration or licensing process for medicines, identifying their strengths and weaknesses, and develop an action plan for improvement.

The assessment was based on the review of available documents and reports and key informant interviews. The current legal provisions are considered inadequate in making clear provisions for evaluation and registration of medicinal products as is understood in other countries and according to the World Health Organization (WHO) norms and standards. Afghanistan has an established and functional system for reviewing and approving medicines for the licensed medicines list (LML) and essential medicine list (EML) which address the safety and efficacy of pharmaceutical substances. Pharmaceutical products listed in the LML are the only products allowed to be in Afghanistan. However, this system only addresses pharmaceutical substances and formulations allowed and does not address specific products (finished pharmaceutical products) made by individual manufacturers. While there is a system for registering companies that includes some requirements for products intended to be marketed, a functional product evaluation and registration as is the norm in other countries to control the quality of pharmaceutical products does not exist. Consequently, there is no inventory (or register) containing data on products that have been approved or registered.

Afghanistan has a system for controlling the import of pharmaceutical products through pre-approval of import consignments, inspection, and release of consignments from the ports of entry. Nevertheless, this system can function more efficiently and effectively with a properly functional and established mandatory system for premarketing evaluation and registration of pharmaceutical products for both local and imported medicines. Consistent with previous findings, the current system has developed from an import and export control system for pharmaceutical products rather than a standard premarketing review and authorization of products.

Afghanistan also lacks an institutional framework such as appropriate and comprehensive guidelines, standard operating procedures, accurate and up to date records, financial resources, and qualified and trained human resources that allows a functional medicines evaluation and registration system to be implemented effectively and efficiently.

Registration of pharmaceutical products is considered a core regulatory function on which other regulatory functions depends on such as import and export controls and post-marketing surveillance. There is need to establish a proper system for mandatory pre-marketing scientific evaluation and registration system for pharmaceutical products. This system can be built on the already established and functional system for LML and EML, which address the safety and efficacy of pharmaceutical substances.

INTRODUCTION

The Ministry of Public Health (MoPH) is responsible for all public health care issues including ensuring that medicines distributed in the country are safe, effective, and of good quality. Both the public and private sector are involved in providing health care services. All medicines that can be imported and sold in Afghanistan are controlled by the Licensed Medicines List (LML) which was first published in 2005 and revised in 2007. There is very little local pharmaceutical production, so most medicines used in the country are imported from neighboring countries.

The General Directorate of Pharmaceutical Affairs (GDPA) within the MoPH is largely involved in the regulatory activities for pharmaceuticals among other responsibilities. The regulation of medicines is incorporated in the Medicine Law which was established in 2003. According to several reports, the pharmaceutical regulatory system is generally considered to be weak with most of the activities in the private sector and, to some extent, those in public sector largely uncontrolled (Dukes et al. 2011). A recent quality assurance survey reported 9 percent substandard medicines in both public and private sectors (Yusuf et al. 2010). Apart from the structures within MoPH involved in regulatory activities, a National Medicine and Food Board (NMFB) was established as an advisory board to the MoPH. The board has oversight of some regulatory functions for both food and medicine but there is no permanent structure that can effectively support all of the required regulatory functions for Afghanistan.

In October 2009, the Government of Afghanistan requested the Strengthening Pharmaceutical Systems (SPS) Program to provide technical assistance to establish a structure that addresses both medicines and food safety control. In April 2010, SPS conducted an initial assessment at the country level to evaluate Afghanistan's regulatory structure and capacity. In September 2010, the assessment report was drafted and shared with the MoPH on the key findings and proposed three options for a regulatory structure.

An options analysis was then conducted in March 2011 to identify an option that is feasible and sustainable to the country context and an action plan was drafted to begin building a regulatory structure and strengthening the elements necessary for a functional regulatory system.

The action plan included strengthening the NMFB capacity to provide oversight and advice, and coordinate the regulatory activities performed by the various government departments and strengthening the existing structures involved in implementing regulatory activities for medicines.

PURPOSE AND OBJECTIVES

Overall purpose

The overall objective of the assessment is to ensure that medicines available on the market in Afghanistan are properly evaluated and registered or licensed in terms of safety, efficacy, and quality.

Specific Objectives

1. Determine the current evaluation and registration or licensing process for medicines in Afghanistan
2. Identify the strengths and weaknesses of the current evaluation and registration/licensing system in ensuring quality, safety and efficacy of approved/licensed products
3. Develop an action plan for improvement of the evaluation and registration system for medicines in consultation with stakeholders

METHODOLOGY

Study design

This assessment used both qualitative and quantitative approaches in collecting information on the medicines evaluation and registration system.

Qualitative

Qualitative data were collected using (1) archival study – review of relevant documents, records, and previous assessments and (2) key informant interviews with personnel from GDPA, relevant external groups such as trade groups, and professional associations (annex A).

Quantitative

An assessment tool that was adapted from WHO (Prat 2007) was used to collect both qualitative and quantitative data (annex B).

Validity and reliability of information

In cases where subjective information was collected, e.g., through informant interviews, objective means were used to verify the information whenever possible. When reference was made to specific documents such as laws, regulations or other documents, the specific section and document title, version, and date were quoted.

Data analysis

The collected information was analysed on a comparative scale according to WHO and international norms and standards. Strengths and weaknesses were drawn out and evaluated.

Assessment of transparency was done using the methods and indicators described in the *WHO Measuring Transparency in Medicines Registration, Selection and Procurement: Four Country Assessment Studies*. However, quantitative measures could not be applied to the data collected in this assessment. Therefore, information was only analyzed using descriptive methods and compared with literature data and international norms and standards.

Limitations

Because of poor record keeping, quantitative data could not be collected. For example, there were no statistics on violations recorded and administrative measures and judiciary sanctions applied in the last five years. The strengths and weaknesses identified by the author reflect author's own technical judgment and the views expressed by the people interviewed.

The evaluation visit was relatively short and key tasks were not observed to actually verify how they were conducted. Nonetheless, it is thought that the most important issues for the medicine evaluation and registration system were identified.

DEVELOPMENT OF THE ASSESSMENT TOOL

The assessment tool used to gather information in the study is based on existing tools focusing on product registration, specifically the WHO Guidance for the Assessment of Drug Regulatory Systems (Prat 2007). Module 4 on registration is adapted to suit the context of the assessment based on the existing knowledge of the Afghanistan pharmaceutical regulatory system. The section on transparency is based on the WHO measuring transparency in medicines registration, selection, and procurement in four countries (WHO 2006).

Product assessment and registration or licensing of medicines require the following—

- Legal basis, giving institutions/departments responsible the power to grant, renew, amend, suspend, and withdraw registration
- Guidelines for applicants setting out the conditions, content, and format of applications; and the detailed technical requirements against which dossiers will be assessed, based on international guidelines
- Standard operating procedures (SOPs) to assess the submissions, and standard formats to communicate and publish the outcomes
- Expert assessors in adequate numbers and with specific, current expertise
- Logistics for management, secure storage, retrieval and exchange of data with other regulatory departments, as well access to current scientific and technical information
- Mechanisms to consider other stringent regulatory authorities decisions; the objective of the situational analysis is to assess the organization set in place to manage the registration process of pharmaceutical products

KEY FINDINGS AND DISCUSSION

The present medicine regulatory system in Afghanistan is different from corresponding systems that have proved successful in other countries. Medicines are not registered using a standard registration system that requires each product to go through a registration process and a registered list of medicinal products (also referred to as finished pharmaceutical products) that can be imported or used in the country is not maintained. However, the Afghan system only approves pharmaceutical substances listed in the LML for manufacture and importation in Afghanistan. An assessment report (Dukes et al. 2011) noted that Afghan regulatory system for medicines seem to have evolved in a random manner because of the three decades of war. In summary, the control of medicine importation and use in Afghanistan is largely based on LML and registration of manufacturers. This makes it nearly impossible to regulate the products available on the market.

Legal Provisions

Legal requirement for Mandatory Licensing and authorization of medicinal products

A good regulatory system requires a legal basis. Typically, the law should specify a mandatory system of licensing/ authorizing of all medicinal products, whether locally manufactured or imported, all local manufacturers, importing and exporting agents and distributors, and all premises and facilities used locally to manufacture, store or distribute medicinal products (WHO2011). Then institutions and departments responsible for registration for medicinal products would have the legal power to grant, renew, amend, suspend, and withdraw non-authorized medicines.

The current legislative framework includes the Medicine Law published in official gazette number 963 on 29/8/1387 (November 18, 2008) and the Regulation on Manufacturing and Importing Medicine and Medical Appliances and the Regulation on Pharmacy, both published in official gazette number 916 of 1385 (February 23, 2007). It was reported that a separate regulation on vaccine and immunological products was published in official gazette number 1030 on 23/4/1389 (2010). These legal provisions are publicly available on the Ministry of Justice website.

An assessment of the legal provisions with a focus on data on safety, efficacy, and quality shows that the Medicine Law 2008 is inadequate to make provisions for evaluating and granting registration of medicines products.

Some of the deficiencies in the current law follow—

- There is no current legal provision that requires one to register a specific product before putting a pharmaceutical product on the market.
- The legislation does not enable issuing, suspending, or withdrawing registration for a pharmaceutical product. There is also no legal requirement regarding the limited duration of the registration and for handling periodic reviews.

- The legislation does not require the notification of the regulatory agency for any variations or amendments to the initial registration which may affect the quality, safety, and efficacy of the products.
- There is no legal provision that requires the applicant to demonstrate the quality, safety, and efficacy of its pharmaceutical product. However, Item 12 under article 18 in regulations requires drug master file for each product.
- Afghanistan only allows well established products (generics) to be listed in its formulary. Brand name products are outlawed according to article 7 of the Medicine Law which states “*Brand name of medicines is not to be registered in the Afghan National Formulary.*” However, considering that only generics are registered in LML, the law does not require the demonstration of bioequivalence of multisource/generic products with originator/brand name product.
- There is also no legal provision for establishing and maintaining an inventory of the registered products (by product from specific manufacturers). The only list established and maintained is the LML.
- Legal provision for issuing a written market authorization (or rejection) on completion of the assessment process is only applicable for foreign company or foreign manufacturer registration.

The legal provisions are inadequate in making clear provisions for evaluation and registration of medicinal products and according to the WHO norms and standards.

Mandatory requirements for Manufacturing medicines

The licensing/authorizing system for medicines should be complemented by an efficient inspection system for manufacturing sites and distribution channels. Article 8 has requirements for license for manufacture, importation, and sale of medicines and medical supplies; article 9 outlaws the manufacture, importation, and supply of products not in LML except on proposal from GDPA approved by the National Drugs Board (now the NMFB) and MoPH. However, there is no specific requirement for mandatory current good manufacturing practice (GMP) inspection for either local or foreign manufacturing sites. Nevertheless, article 6 of the regulations on manufacture and importation of medicines requires the manufacturing site to comply with international standards.

Requirements for Licensing Medicines

Mandatory licensing of medicines requires access to quality control laboratories. Adequate provisions are made for manufactured and imported products to comply with quantitative and qualitative tests done by the Quality Control Laboratory before the product can be released for marketing.

Articles 18, 24, and 25 in the regulations for manufacture and importation of medicines provide some requirements on packaging, such as labeling, including a pamphlet, and summary of medicine characteristics.

There is a legal provision considering the case of provisional or conditional license exempting applicants from meeting specific requirements. Although no criteria is mentioned, the Medicine Law specifies in article 9 that unlicensed products can be manufactured or imported based on proposals by the GDPA and approved by the National Drugs Board, NMFB, and the MoPH.

Enforcement of the Law and Regulations

There is a legal provision specifying the MA holder/manufacture's liability for defective products, medicine-related deaths, disability, or other harm to consumers. Articles 51 and 52 stipulate license cancellations/ suspensions for companies in cases of non-compliance and banned importation.

The law provides different types of sanctions against offenses. For the manufacture and sale of medicines not in LML, the medicines are confiscated and a fine equivalent to the price of the medicines is paid. For the manufacture and importation of counterfeit medicines, the medicine is confiscated and there is legal prosecution. Repetition of this offense will result in permanent cancellation of the license.

Although Article 48 empowers medicines inspectors to monitor implementation provisions of the law, there is no specific legal provision to allow them access to premises where medicines are manufactured, stored, or sold to inspect the site and collect samples.

In addition, this situation was confirmed through the interviews with GDPA staff and the fact that no inventory exists with data on products that have been approved or licensed. However, with support from SPS, efforts are being made to create a pharmaceutical registration information system (PRIS). The current LML system has limited functionality for PMS as the list can only be used to monitor that the medicinal substances have been approved based on safety and efficacy. This system may not be ideal for monitoring quality of medicines, which is important especially for multisource (generic) products manufactured and sourced from different manufacturers.

Technical Standards and Criteria

Regulatory guidelines

For transparency purposes and to ensure efficiency, the regulatory authority should publish guidelines on the requirements for registration for different types of applications. Guidelines are required to provide more information and guidance for applicants to comply with legal requirements. Guidelines will also ensure consistency in regulatory approach by the regulatory staff.

The "*Registration rules for foreign companies in Afghanistan*" is the only document available for foreign companies wishing to register in Afghanistan. It specifies the information required for registration of foreign companies and their products and the requirements for import into

Afghanistan. These requirements include labeling requirements such as the registration number, batch number, serial number, manufacture date, expiry date, and the consumption period of the medicine which should not be less than two years. Item 14, which is more like GMP inspection, states that, “During registration of the company by this department and delegation from department of drug affairs for visiting and getting acquaintance which the company address lined of work quality of products, standardization of the company will travel to the company and the expenses will be covered by the company.” Table 1, shows the summary of information covered and not covered in the rules for company registration. The current document gives insufficient guidance on technical requirements and standards for medicine evaluation and registration.

Table 1: Comparison of Information for Registration of Medicines

Sections covered under the guidelines	Sections not covered under the guidelines
Content of product information leaflets, summary of product characteristics, packaging, and labeling	Stability testing of pharmaceutical products (active ingredients, finished products)
Various process validation	Demonstration of bioequivalence/bioavailability
Analytical method validation	Content of application, format, and procedures to be followed in the submission
Medicine donation	Variations/amendments to approved products
	Risk management programs, pre-marketing risk assessment, and development of pharmacovigilance plans

Standard Operating Procedures

There are no written SOPs for medicine assessment and registration. The criteria for medicine assessment and registration (reasons for approving or rejecting) are mentioned in the Registration Rule for Foreign Companies. However, there is no written policy or criteria for the registration of combination products. The registration is based on medicines in the LML. Such products are dealt with during the review of medicines included in the LML.

There are no documented procedures/tools to—

- Allow applicants to meet with the GDPA before submitting an application on a voluntary basis
- Assess the different parts of the application and for the assessment of specific requirements of specific classes of products
- Assess the applications for variation of licensed products
- Follow the commitments of the registration holder and in particular the Risk Management Program
- Control the quality of the assessment process such as peer review
- Issue the registration or license in a standardized format

- Ensure that the assessors and the Quality Control laboratory communicate about product compliance and the regulatory inspectorate for compliance to applicable good practices
- Fast track specific products of particular public health interest

Organization and structure

The marketing and authorization activities are all performed at central/national level. Given the issues of resources, capacity, and Afghan country context, this arrangement is considered appropriate. Company registration and product registration and the issue of import permits or approvals are done by the Registration and License Issuing Department within the GDPA. Avicenna Pharmacy Institute within the GDPA has the responsibility for the LML and the EML.

Processes and procedures

A clearly defined process for adding products to the LML is published and available, and includes the format for submission of new applications. However, for the registration of companies and products (figure 1), the process and procedures are not very clear and several deficiencies were observed. For instance, no proper records are maintained for submitted applications and decisions made thereof, no technical report is produced after the assessment process which implies that the process is more administrative rather than technical. In addition, decisions/recommendations are made either by the GDPA staff and submitted to the Minister of Public Health for approval. There is no stated period for registration expiry once a product is registered except if the product is blacklisted. In most countries and for transparency and good regulatory practice, use of Expert or Advisory Committees is considered the norm or recommended for regulatory decisions. The law makes provisions for the establishment of a Technical Board (Board of Drug Affairs Committee) for review and approval; nevertheless, this was not operational at the time of the assessment. Whilst in most countries, products are registered based on acceptable scientific review of documentation, GMP inspection of the manufacturer and in some countries pre-marketing testing; the current process only involves partial or administrative review of documentation and pre-marketing testing.

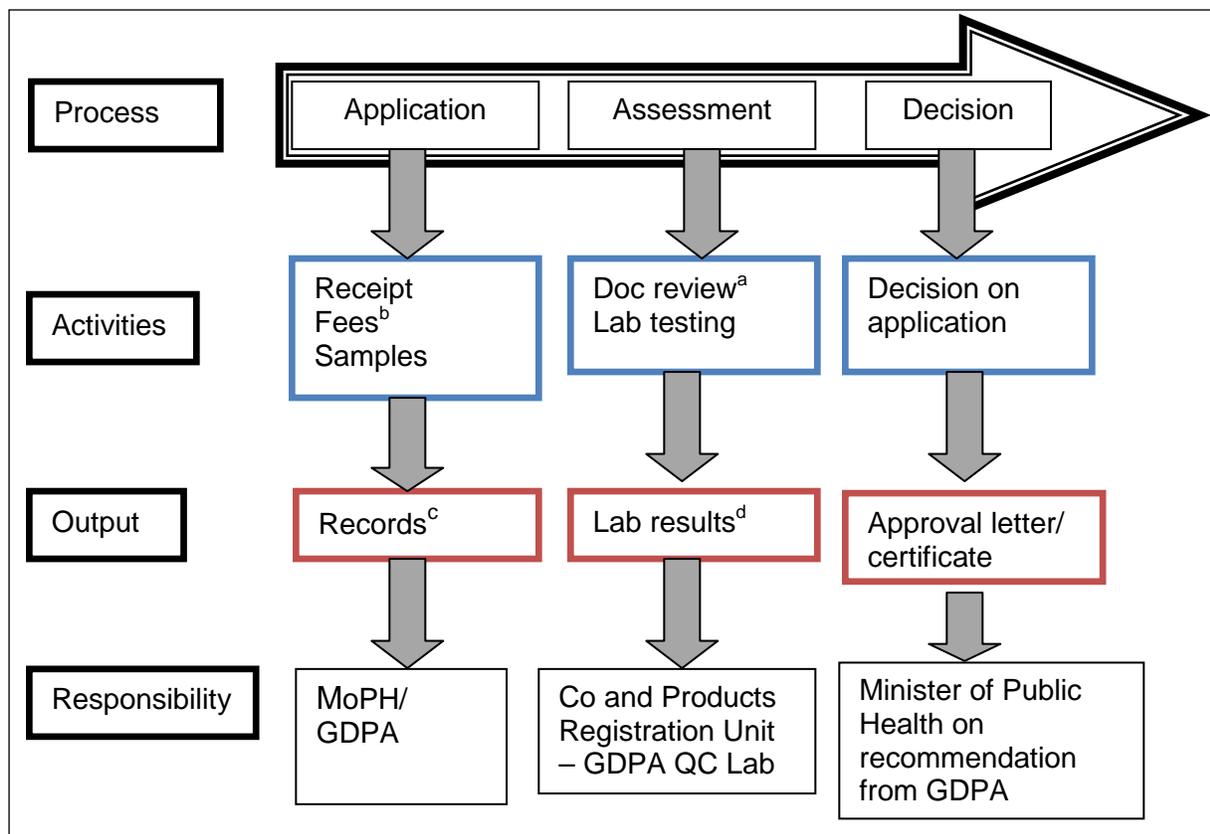


Figure 1: Schematic diagram of the company and product registration in Afghanistan

^a Only administrative review is conducted; there is no scientific technical assessment.

^b Fees refer to both application fees and fees for testing the products by the quality control (QC) lab before approval

^c Some sort of records are generated but it could not be ascertained if a proper standardized format for recording all applications received and process was established and maintained.

^d The laboratory was not covered during this assessment, and although communication is made between the quality control lab and the GDPA on outcome of testing, it is not clear whether a standardized format is used for the laboratory results.

The following data set is required before approving products for importation—

- Proof of registration in country of origin
- WHO-type certificate of pharmaceutical product
- Manufacturing authorization for the finished pharmaceutical product
- WHO type GMP certificate for finished pharmaceutical product manufacturer

Importers with a license, local manufacturing companies and foreign registered companies with a local representative can apply to register a pharmaceutical product. In order for them to be eligible to apply for the registration of a pharmaceutical product, these companies/individuals should be registered first according to the Rules for registration of foreign companies and local companies must be licensed first. The process of medicine assessment and registration applies to all pharmaceutical products for human use. There is no fast track registration system.

Table 2: Requirements for Registration of Products by Different Categories

Products that need to be assessed and registered before use	Products not requiring assessment and registration before use
<ul style="list-style-type: none">• Locally manufactured by private sector• Imported by private sector	<ul style="list-style-type: none">• Locally manufactured by government/public sector, e.g., pharmaceutical enterprise• Imported by government purchasing agency• Imported by non-governmental organizations• Donations

To ensure the quality, efficacy, and safety of these pharmaceutical products, samples for imported products are sent to the quality control laboratory for testing. However, some exemptions on this requirement are given by the MoPH on request for products imported by private not for profit (nongovernmental organizations) for the public sector.

The following classes of medicinal products are currently assessed and registered—

- Well established interchangeable multisource (generic) pharmaceutical products listed in LML
- Biological products, e.g., vaccines
- Herbal medicines—committee approvals
- Cosmetics, hygienic—committee approvals

Veterinary medicinal products are the responsibility of the Ministry of Agriculture, Irrigation and Livestock.

Some variations/amendments to registered or approved products have to be approved, such as changes in the name of the manufacturing company. However, there are no standards or rules for this requirement. Changes in the registration status such as category for distribution, for example, prescription only medicines or over the counter medicines are done by the LML/EML committee. Beginning in 2011, a WHO-type certificate of pharmaceutical product is required for registration of imported medicines. The external information such as information sources and reference materials such as pharmacopeias for decision making on applications, are not readily available.

Consistent with previous findings, the current system in place has developed more from an import and export control system for pharmaceutical products rather than a standard premarketing review and authorization of products. All medicinal products for import require authorization from the Minister of Public Health through the Technical Board of GDPA-Department of Pharmaceutical Affairs.

Table 3: Information Required for Approval for Importation or Registration of Foreign Companies

Finished pharmaceutical products	Required
Composition of the medicinal product (both active and non-medicinal ingredients)	Yes
Pharmaceutical development	No
Manufacturing process and process control, including control of critical steps and process validation	Yes
Controls related to excipients	No
Controls of medicinal product including validation of analytical procedures	Yes
Reference standards or materials	No
Container closure system	Yes
Stability studies	No

No data on active pharmaceutical ingredient or bioequivalence/efficacy data is required or assessed before approving products for importation.

While a WHO-type certificate of pharmaceutical product is now a requirement for approval of product and company registration, there are no mechanisms that would enable GDPA and MoPH to benefit from scientific assessment and inspections done by other well-resourced and established National Medicines Regulatory Authority (NMRA).

Transparency

Given the current state of the medicines evaluation and registration system, use of the transparency assessment tool was not practical. It was noted that for the LML and EML, a transparent system appears to be in place, with information on list of licensed products publicly available (latest publication 2007), standard application forms, flow chart of the process from submission to approval, and use of expert committee in the review and decision-making process. Nevertheless, the lack of clear and comprehensive standard guidelines and application forms, and no procedures and information decisions on submitted applications for company and product registration shows weaknesses in the current system. In cases of rejection, there is no place or authority to appeal the regulatory decision. The pharmaceutical industries/manufacturers and other interested parties have no access to decisions made by the regulatory authority or NMRA on medicine registration. While a list of registered foreign companies and approved products is available in MS Excel format, a copy could not be obtained and the information is not made available to the public. Generally, where an inventory of all approved products is available and maintained, such information is made available to the public through official government publications or notices or on regulatory authorities' websites.

Human and other resources

The analysis of the GDPA did not repeat the same assessment for human resources (Strengthening Pharmaceutical Systems 2012). There is an established organization structure for the GDPA. Job descriptions for the GDPA staff are available although some of the staff indicated lack of awareness of the existence of job descriptions for their positions. Currently, everything is processed manually as the GDPA is not computerized. Only 12 percent of the Registration and Licensing department staff members and 11 percent of the Avicenna Pharmaceutical Institute (API) staff members respectively have access to a computer. The LML and EML list is maintained and updated on a regular basis using MS Excel. There is no proper and appropriate

archival space to store confidential data securely. There are 25 staff members in the Registration and Licensing Department and 47 staff at API. Of the surveyed staff, only 12 percent believed they had all the necessary training to perform their jobs. Nearly two-thirds, 65 percent, felt they were only partially trained for their jobs but could still function in the position while only 1 percent felt that they were partially trained and could not do their job without further training. Another quarter, 23 percent, stated that they were totally untrained for their job requirements (Strengthening Pharmaceutical Systems 2012).

The GDPA is funded entirely from government budget. While fees are collected for services such as application for registration of companies and products and review and approval of pro-forma invoices for import permits, these fees do not reflect the actual costs of preparing the application. Any collected revenue goes to the government treasury.

Table 4: Human Resources in the General Directorate of Pharmaceutical Affairs¹

		Finance and Admin	API	Medicine Planning Affairs	Registration and License Issuing	Narcotics and Controlled Substances	Pharmaceutical Establishment	Inspection of Medicines and Importation Companies	Total
Qualifications/ training	Medical doctors	0	0	0	0	0	0	0	0
	Pharmacist	1	28	10	22	15	11	5	92
	Health professional	1	1	2	2	4	4	2	16
	Non-medical	14	3	2	0	2	2	0	23
	Support staff (admin)	10	8	4	1	2	3	1	29
	Vacant positions	0	7	2	0	0	1	0	9
Skill levels	Fully trained for job requirements	6	1	0	3	0	5	0	15
	Partially trained	8	16	14	21	4	12	7	82
	Untrained for job requirements	0	15	0	0	10	0	0	25

*The data on human resources was extracted from the Afghanistan SPS: Functional Analysis Study of the General Directorate for Pharmaceutical Affairs of the Ministry of Public Health of Afghanistan, March 2012. While the data were accurate at the time of the analysis, it was reported that all vacant positions had been recently filled at GDPA as of July 2012.

¹ Afghanistan SPS: Functional Analysis Study of the General Directorate for Pharmaceutical Affairs of the Ministry of Public Health of Afghanistan, March 2012. Submitted to the US Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program Arlington, VA: Management Sciences for Health

SUMMARY OF KEY FINDINGS

- There is an established and functional system for LML and EML which address the safety and efficacy of pharmaceutical substances.
- Afghanistan has an existing control system for import for pharmaceutical products. Nevertheless, this system can function more efficiently and effectively with a well-designed and established mandatory system for premarketing evaluation and registration of pharmaceutical products for both local and imported medicines.
- The legal provisions are considered inadequate in making clear provisions for evaluation and registration of medicinal products as is understood in other countries and according to the WHO norms and standards.
- While there is a system for registering companies which includes some requirements for products intended to be marketed, a functional product evaluation and registration to control the quality of pharmaceutical products is absent. Consequently, there is no inventory (or register) with data on products that have been approved or licensed.
- There is lack of clear and comprehensive regulatory tools such as comprehensive technical and administrative guidelines, SOPs, standard application forms and templates, reference materials, or access to information resources for medicine evaluation and registration.
- There is lack of requisite skills, training, competences of staff within the GDPA to fully implement a functional system for medicines evaluation and registration.

RECOMMENDATION AND NEXT STEPS

The mission for regulatory authorities on behalf of the government is protecting and promoting public health by ensuring that medicines are safe, efficacious, and of good quality. Mandatory registration of pharmaceutical products is important for regulatory authorities and it enables efficient and effective regulatory control of medicines on the market. To address the weakness or gaps in the current system in Afghanistan, the following recommendations are made.

Legal Provisions

The Medicine Law and the regulations should be reviewed and revised so that adequate provisions for regulatory control for pharmaceuticals can be made in the legislation. The law should take into account the existing situations and make provisions for possible transitional arrangements in the establishment of comprehensive mandatory system for review and licensing of pharmaceutical products.

Processes and Procedures

According to the WHO manual for medicine regulatory authorities (World Health Organization, 2011), countries without a comprehensive system in place for the regulation of medicinal products must—

- Formulate legislation or administrative provisions through “orders” or “decrees” for—
 - Authorizing/licensing of all products proposed for marketing after the "appointed date" for the licensing system
 - Transitional arrangements to ensure that products on the market before the appointed date can continue to be marketed, within the regulatory system
 - The subsequent review and full registration of products authorized under the transitional provisions
 - Provision should also be made for regulation of renewal of the product
 - Authorization/licence after lapse of period for which the licence is being issued
- Develop and maintain an inventory (or register) with data on approved products authorised or licensed for marketing in the country

Given that there is no established inventory of medicinal products on the market and no proper review and approval has been instituted, specific steps based on WHO are proposed for implementation of proper medicines product registration system.

Step 1: Inventory of products on the market (provisional registration)

1. An inventory is drawn up of all medicinal products on the market before the appointed date and the products have the status of being "provisionally authorized/licensed" until such time as full authorizations/licenses are granted. This should be limited to products that are in LML since this is an established requirement for product manufacture or importation in Afghanistan.
2. The inventory of products on the market can be established by—
 - a. Including requirements, that manufacturers, importers and distributors of medicinal products who intend to continue to manufacture, import, distribute and sell medicinal products after the appointed date must submit specified information on those products to the GDPA, before the appointed date
 - b. Compiling the inventory on a more "informal" basis, from available information such as pro-forma invoices, import records, quality control testing records, publications, etc. and data supplied voluntarily by companies

The information should be collected in a form suitable for entry into a computerized database such as the developed PRIS database. This will enable the inventory of products to be organized and sorted for subsequent review.

Step 2: Review of provisionally authorized/licensed products (full registration)

Based on the WHO recommendations, the legislation or administrative procedures should establish a framework for the review and assessment of provisionally authorized/licensed products for full registration under the product authorization procedures for new products. The

legal mandate to request for the submission of applications for registration of medicinal products marketed prior to the appointed date should be embodied in the legislation or administrative procedures. Regulatory guidelines should provide guidance for the applicants on submission formats and content of information.

Figure 2 and table 5 show the logic model and logical framework for premarketing and evaluation of medicinal products prior to marketing. Evaluation and registration of medicines for marketing in a country, based on a scientific evaluation of their safety, efficacy, and quality is considered as the core regulatory function.

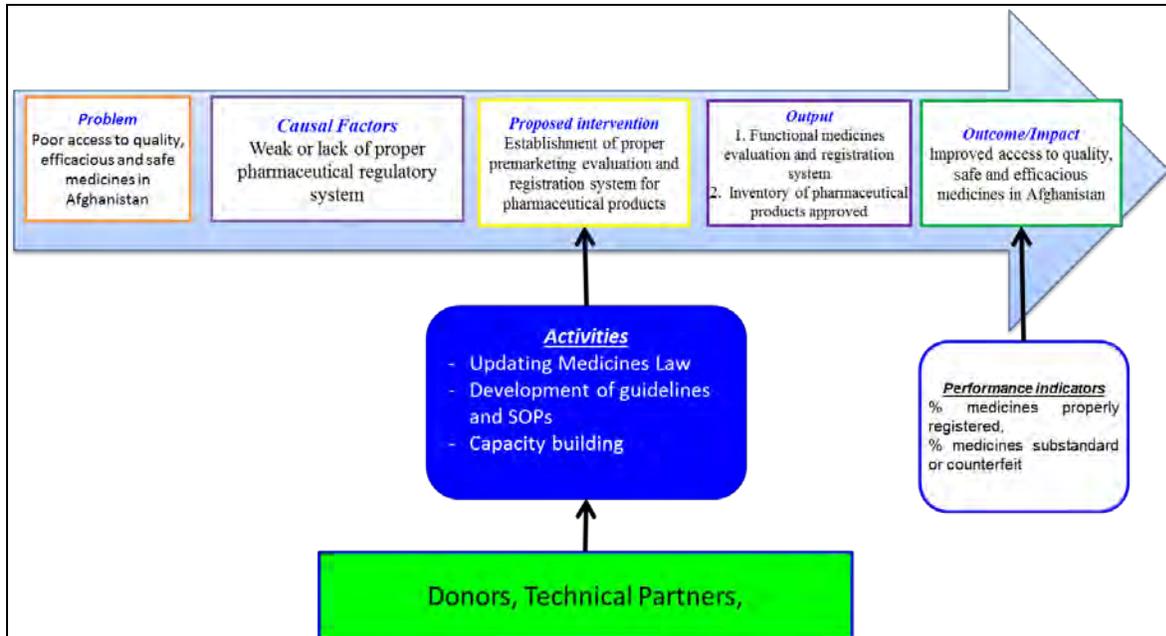


Figure 2: Logic model for premarketing evaluation and registration of medicinal products

Table 5: Proposed Premarketing Evaluation and Registration of Pharmaceutical Products Logical Framework

Objective: Leverage existing systems in the country to build and strengthen pharmaceutical regulatory system in Afghanistan				
Major Activities	Activities	Outputs	Outcomes	Indicators
Develop and revise the laws, bills, and regulations related to pharmaceuticals	1.1 Collect all current laws, regulations and bills related to pharmaceuticals	Compilation of all current laws, regulations and bills related to pharmaceuticals	1. Fully functional pre-marketing evaluation and registration system for pharmaceutical products in Afghan 2. Improved access to quality, safe and efficacious medicines	1. % of GDPA Registration and Licensing Unit staff trained 2. % of medicines properly registered 3. No. and % of manufacturing facilities that are GMP compliant 4. % prevalence of counterfeit and substandard medicines on the market 5. No. of safety decisions made at regional level (e.g., withdrawals, recalls)
	1.2 Review & update the list of current laws, regulations and bills related to pharmaceuticals for completeness	Compilation of current laws, regulations and bills reviewed by MC		
	1.3 Consultancy to review all the current laws and regulations related to pharmaceuticals to identify gaps and need for revisions and development of new laws	1. Comprehensive report on laws, bills and regulations related to pharmaceuticals 2. Proposed legal framework for the medicines regulation		
	1.4 Consultative workshop (x 1) to review report and proposed legal framework for medicines regulation	Consultative meeting held		
	1.5 prioritize revision or development of laws based on proposed legal framework	Priority list on revision of laws and regulations developed		
	1.6 Establish working groups for each law and regulations that require revision or to be developed	Working groups established based on priority list		
	1.7 Consultancy and workshop (x1) on revision of laws, regulation related to pharmaceuticals	Comprehensive pharmaceutical legislation		
Develop and implement a transitional arrangement for provisional medicine evaluation and registration	2.1 Inventory is drawn up of all medicinal products on the market	Inventory of medicinal products on market in electronic format		
	2.2 Administrative procedures to establish a frame-work for provisional registration of medicines on the market (limited to LML and other criteria)	Administrative procedures to establish framework for provisional registration of medicines on the market		
	2.3 Establishment of clear process and procedures for evaluation and registration of medicines	Clear and transparent process for medicines evaluation and registration established		
	2.4 Provisional approval of medicines on the market based on LML and predefined criteria	List of products granted provisional approval		
	2.5 Capacity building of GDPA registration staff	GDPA registration staff trained on medicines evaluation and registration		
	2.6 Acquiring necessary equipment & resources (e.g. computers, printers, reference materials such as pharmacopeias')	Adequate equipment and resources acquired		

Objective: Leverage existing systems in the country to build and strengthen pharmaceutical regulatory system in Afghanistan				
Major Activities	Activities	Outputs	Outcomes	Indicators
Develop and revise the guidelines and procedures related pharmaceuticals	2.7 Collect all current guidelines, rules and procedures related to regulatory activities	Compilation of current rules, guideline and procedures		
	2.8 Make current laws, regulations, guidelines, and procedures available and accessible to the stakeholders and public	Publication of current laws, regulations, guidelines and procedures related to pharmaceuticals (1 compilation)		
	2.9 Consultancy/ workshop to review and identify gaps on guidelines, rules and procedures for medicine regulatory activities (check for previous assessment reports and findings related to guidelines and procedures)	1. Report on status of guidelines and procedures 2. Recommendations on guidelines, procedures required in order of priority		
	2.10 Establish working groups to review and develop specific guidelines or procedures	Working groups for development of specific guidelines or procedures established		
	2.11 Consultancy/workshops on review of guidelines and/or procedures related to pharmaceutical regulation	Comprehensive tools for pharmaceutical regulation developed		
Full evaluation and registration system for pharmaceutical products	3.1 Pre-marketing registration of provisional and new products for marketing	Inventory of pharmaceutical products registered for marketing in Afghan		

Box 1. Basic requirements for assessing applications for product registration (WHO 2010)

1. **Legal basis**, giving the NMRA the power to grant, renew, vary, suspend and withdraw registration
2. **Guidelines for applicants**, setting out the conditions, content and format of applications, AND the detailed technical requirements against which dossiers will be assessed, based on international guidelines
3. **Standardized operating procedures** to assess the submissions, and standard formats to communicate and publish the outcomes
4. **Expert assessors** in adequate numbers and with specific, current expertise
5. **Logistics** for management, secure storage, retrieval and exchange of data with other regulatory departments, as well access to current scientific and technical information
6. Mechanisms to consider other, NMRAs' decisions

The proposed framework for functional premarketing evaluation and registration of pharmaceutical products (Figure 3) includes predefined processes, specific outputs, appropriate legal framework and existence of specific pieces of technical elements, administrative support system, management processes and human resources. This should be contextualized to the Afghanistan situation and taking into account current changes within the regulatory system in Afghanistan such as the establishment of technical committees under the NMFB, i.e., the Medicines Committee.

Technical Standards and Criteria

Development of clear and comprehensive regulatory tools such as guidance documents for applicants (e.g. registration guidelines), standard operating procedures (SOPs), and standard applications forms such as application for registration of companies, products and standard templates for technical reports, letters and certificates.

Human Resources:

Development of human resources plan to have adequate staff with requisite qualifications and equip the staff with necessary skills and competences required for assessment of product files for quality, efficacy and safety based on international or WHO standards.

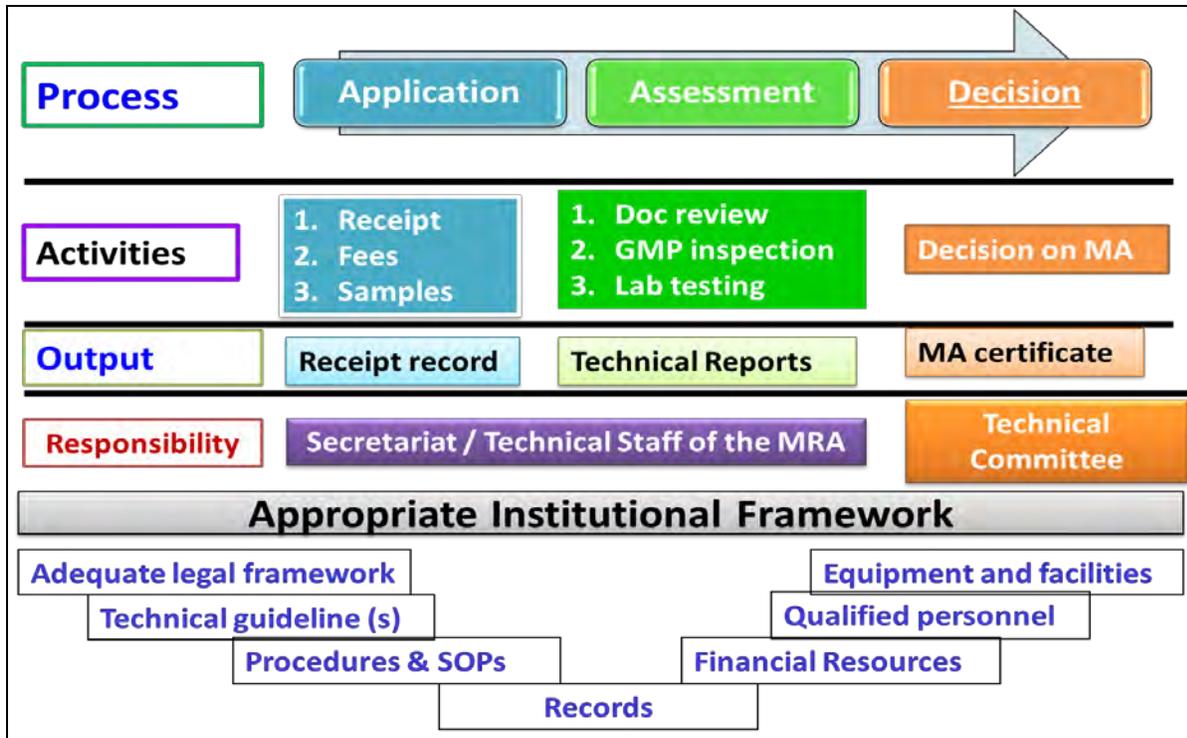


Figure 3: Proposed framework for pre-marketing evaluation and registration of medicinal products

Table 6: Implementation Plan for Strengthening the Pre-Marketing Evaluation and Registration System for Pharmaceutical Products in Afghanistan

Major activity	Specific activities	Responsibility/ resources required	Outputs	Period (months)																							
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Develop and revise laws, bills, and regulations related to pharmaceuticals	1.1 Collect all current laws, regulations and bills related to pharmaceuticals	TA/-	Compilation of all current laws, regulations and bills related to pharmaceuticals																								
	1.2 Review & update the list of current laws, regulations and bills related to pharmaceuticals for completeness	MC/MC meeting costs	Compilation of current laws, regulations and bills reviewed by MC																								
	1.3 Consultancy to review all current laws and regulations related to pharmaceuticals to identify gaps and need for revisions and development of new laws	MC/consultancy fees	a. Comprehensive report on pharmaceutical laws, bills and regulations b. Proposed legal framework for the medicines regulation																								
	1.4 Consultative workshop (x 1) to review report and proposed legal framework for medicines regulation	MC/workshop costs	Consultative meeting held																								
	1.5 Prioritise revision or development of laws based on proposed legal framework	MC/MC meetings costs	Priority list on revision of laws and regulations developed																								
	1.6 Establish working groups for each law and regulations that require revision or to be	MC/-	Working groups established based on priority list																								

Situational Analysis of the Medicine Evaluation and Registration System of Afghanistan

Major activity	Specific activities	Responsibility/ resources required	Outputs	Period (months)																							
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
	developed																										
	1.7 Consultancy and workshop (x1) on revision of laws, regulation related to pharmaceuticals	MC/workshop, meeting and consultancy costs	Comprehensive pharmaceutical legislation																								
Establishment of functional pre-marketing evaluation and registration system																											
Develop and implement a transitional arrangement for provisional medicine evaluation and registration	2.1 Inventory is drawn up of all medicinal products on the market	GDPA/consultancy fees/costs for meetings	Inventory of medicinal products on market in electronic format																								
	2.2 Administrative procedures to establish a framework for provisional registration of medicines on the market (limited to LML and other criteria)	GDPA/MC/NMFB/MoPH/workshop, meeting, and consultancy costs	Administrative procedures to establish framework for provisional registration of medicines on the market																								
	2.3 Establishment of clear process and procedures for evaluation and registration of medicines	GDPA/NMFB/consultancy fees/costs for meetings	Clear and transparent process for medicines evaluation and registration established																								
	2.4 Provisional approval of medicines on the market based on LML and predefined criteria	GDPA/GDPA/MC meetings costs	List of products granted provisional approval																								
	2.5 Capacity building of GDPA registration staff	GDPA/workshop consultancy, & meeting	GDPA registration staff trained on medicines evaluation and registration																								

Situational Analysis of the Medicine Evaluation and Registration System of Afghanistan

Major activity	Specific activities	Responsibility/ resources required	Outputs	Period (months)																							
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
		costs																									
	2.6 Acquiring necessary equipment & resources (e.g. computers, printers, reference materials such as pharmacopeias)	GDPA/NMF B/-	Adequate equipment and resources acquired																								
Develop and revise the guidelines and procedures related pharmaceuticals	2.7 Collect all current guidelines, rules and procedures related to regulatory activities	TA/-	Compilation of current rules, guideline and procedures																								
	2.8 Make current Laws, regulations, guidelines and procedures available and accessible to the stakeholders and public	MC/printing costs	Publication of current laws, regulations, guidelines and procedures related to pharmaceuticals (1 compilation)																								
	2.9 Consultancy/ workshop to review and identify gaps on guidelines, rules and procedures for medicine regulatory activities (check for previous assessment reports and findings related to guidelines and procedures)	MC/worksh op/ meeting for MC costs	<ul style="list-style-type: none"> Report on status of guidelines and procedures Recommendations on guidelines, procedures required in order of priority 																								
	2.10 Establish working groups to review and develop specific guidelines or procedures	MC/worksh op, meeting for MC costs	Working groups for development of specific guidelines or procedures established																								
	2.11 Consultancy /	MC/worksh	Comprehensive tools																								

Situational Analysis of the Medicine Evaluation and Registration System of Afghanistan

Major activity	Specific activities	Responsibility/ resources required	Outputs	Period (months)																							
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
	workshops on review of guidelines and / or procedures related to pharmaceutical regulation	op, meeting, and consultancy costs	for pharmaceutical regulation developed																								
Full evaluation and registration system for pharmaceutical products	3.1 Pre-marketing registration of provisional and new products for marketing	GDPA	Inventory of pharmaceutical products registered for marketing in Afghan																								

Notes to the work plan

- 1.1. In principle, this is available already; MSH/SPS compiled the list last year in preparation of the revised NMFB launch. Available in both English and Dari.
- 1.3. There are reports that reviewed the Law e.g. Graham Dukes review of the English version of the law. These should form the basis for the review and SPS should collect all the available reports on the Medicine law. Whatever is proposed for updating the law needs to be realistic and enforceable. No use in laws that cannot be implemented /enforced
- 1.4. Materials for the consultative workshop should be ready and distributed to MC members at least 2 weeks before the workshop. The workshop needs to be prepared and structured so that specific gaps and the proposed change are directly discussed and decisions made on endorsing proposed change. It cannot be a meeting that reviews the clauses one by one, but must be focused /targeted

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4. Dukes, G., Gwaza, L., Lee, D., et al. 2011. *Strengthening regulatory system and structure for Medicines and Food Products in Afghanistan: The way forward*. Submitted to the U.S. Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health.
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8. World Health Organization. 2006. *Measuring Transparency in Medicines Registration, Selection and Procurement: Four Country Assessment Studies*. Geneva: WHO .
9. WHO. (2011). *Marketing Authorization of Pharmaceutical Products with Special Reference to Multisource (Generic) Products, A manual for National Medicines Regulatory Authorities (NMRAs)*. 2nd ed. Geneva: WHO.
10. Yusuf, I., Mohammad, Z. O., Karwar, W., et al. 2010. *Afghanistan Medicines Sampling and Testing—A Quantitative Survey*. Submitted to the USAID by the Strengthening Pharmaceutical Systems (SPS) Program, Arlington, VA: Management Sciences For Health.

ANNEX A. MEETING SCHEDULE

Date (all dates are 2012)	Activity
March 27	Meeting with SPS staff
	Security briefing with MSH Head of Security and COMU Director
	Meeting with GDPA Director
March 28	NMFB Food Affairs Interviews
March 29	Meeting with Dr. Sandra Smulko to discuss SOPs for receiving and sending documents
March 31-April 1	Meetings with GDPA Registration Personnel
April 2-3	Workshop to review TOR for the Medicines Committee (MC) and Training of MC members
April 4	Meeting with Deputy Minister Administrative Affairs of the MoPH
April 5	Meeting with USAID mission in Kabul
April 7	Meeting with NMFB Medicines Technical Advisor
	Meeting with pharmaceutical private sector representative

ANNEX B. SITUATIONAL ANALYSIS OF THE MEDICINE EVALUATION AND REGISTRATION SYSTEM OF AFGHANISTAN

Name and address(es) of institution(s)	
Contact details	
Email	
Phone	
Date of assessment	
Purpose	
Scope	
Assessor(s)	
Contact details of assessor(s)	
Email	
Phone	

Section 1: Legal provisions

(In this section, check the existence and adequacy of the legal requirements for the evaluation and registration of medicines, the legal framework within which the applications for registration of pharmaceutical products are submitted to the responsible institution / agency, the procedures for the assessment of these applications and the granting or refusal of registration. The legislation should require the applicant to provide the information and data necessary for such an assessment. The system of medicine registration should include the review and approval of the information provided with the product such as data sheets and labels. The legislation should provide for adequate and proportional sanctions, penalties and prosecution upon conviction of violations of the applicable legislation).

1.1 What is the title of enactment of the medicine law / regulations?
1.2 What are the date(s) of enactment and /or revision of the medicine law/ regulations?
1.3 What is the article number of the provision requiring the assessment and registration of pharmaceutical products?

1.4 Is there legal provision that requires one to hold a Marketing Authorization (MA) before putting a pharmaceutical product on the market? Yes <input type="checkbox"/> No <input type="checkbox"/>
If yes, indicate the specific article in the law or regulations
1.5 Does the legislation enable the issue of a marketing authorization for a pharmaceutical product, to suspend it for a period of time and to withdraw it? Yes <input type="checkbox"/> No <input type="checkbox"/>
If yes, indicate the specific article in the law or regulations
1.6 Is there legal provision that requires the applicant to demonstrate the quality, safety and efficacy of the pharmaceutical product that is subject of the application? Yes <input type="checkbox"/> No <input type="checkbox"/>
If yes, indicate the specific article in the law or regulations
1.7 Is there legal provision regarding the information to be provided with the products (packaging, labelling, leaflet, Summary of characteristics, etc...)? Yes <input type="checkbox"/> No <input type="checkbox"/>
If yes, indicate the specific article in the law or regulations
1.8 Is there a legal requirement regarding the limited duration of the validity of the MA and for handling periodic reviews to MA? Yes <input type="checkbox"/> No <input type="checkbox"/>
If yes, indicate the specific article in the law or regulations and the period of validity of MA (in years)
1.9 Does the legislation require the notification to the regulatory agency of any variations to the initial MA which may affect the quality, safety and efficacy of the products? Yes <input type="checkbox"/> No <input type="checkbox"/>
If yes, give details and examples
1.10 Does the legislation require the demonstration of bioequivalence of multisource/generic products with originator? Yes <input type="checkbox"/> No <input type="checkbox"/>

1.11	Is there legal provision for considering the case of provisional or conditional MA exempting applicants from meeting specific requirements based on the established criteria (special situations, orphan medicine, public health interest, presumed positive benefit/risk balance, emergency situations)? Yes <input type="checkbox"/> No <input type="checkbox"/>																		
	If yes, state the criteria																		
1.12	Is there an exemption for pharmaceutical product donations following the established criteria? Yes <input type="checkbox"/> No <input type="checkbox"/>																		
	If yes, indicate the reference for the provision <i>e.g. section xx of Medicines Policy or section yy of the medicines regulations</i>																		
1.13	Is there a legal provision specifying the MA holder/manufacture's liability for defective products, medicine-related deaths, disability or other harm to consumers? Yes <input type="checkbox"/> No <input type="checkbox"/>																		
	If yes, give reference to the title, date of enactment and article number of the legislation																		
1.14	How many product liability cases have been recorded in the last 10 years?																		
1.15	Indicate the products reported.																		
1.16	Does the medicine law provide for sanctions against offences? Yes <input type="checkbox"/> No <input type="checkbox"/>																		
	If yes, what are the different types and ranges of sanctions provided?																		
	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 40%;">Type of offense</th> <th style="width: 60%;">Range of sanctions</th> </tr> </thead> <tbody> <tr><td> </td><td> </td></tr> </tbody> </table>	Type of offense	Range of sanctions																
Type of offense	Range of sanctions																		
1.17	How many violations were registered and administrative measures and judiciary sanctions applied in the last five years? Yes <input type="checkbox"/> No <input type="checkbox"/>																		
	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 40%;"></th> <th style="width: 10%;">2007</th> <th style="width: 10%;">2008</th> <th style="width: 10%;">2009</th> <th style="width: 10%;">2010</th> <th style="width: 10%;">2011</th> </tr> </thead> <tbody> <tr> <td>Total number of violations registered</td> <td> </td><td> </td><td> </td><td> </td><td> </td> </tr> <tr> <td>Number of administrative measures implemented by the regulatory</td> <td> </td><td> </td><td> </td><td> </td><td> </td> </tr> </tbody> </table>		2007	2008	2009	2010	2011	Total number of violations registered						Number of administrative measures implemented by the regulatory					
	2007	2008	2009	2010	2011														
Total number of violations registered																			
Number of administrative measures implemented by the regulatory																			

Situational Analysis of the Medicine Evaluation and Registration System of Afghanistan

authority						
Number of legal sanctions implemented by a judicial body/court						
1.18 Is there a legal provision for powers to access premises where medicines are manufactured, stored or sold in order to inspect the site and collect samples? Yes <input type="checkbox"/> No <input type="checkbox"/>						
Give details						
1.19 Is there legal provision ensuring that for new chemical entity (NCE) that a minimum set of non-clinical and clinical information is available? Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>						
1.20 Is there legal provision for establishing and maintaining an inventory of the products available on the local market - both public and private sector? Yes <input type="checkbox"/> No <input type="checkbox"/>						
1.21 Is there legal provision for issuing a written marketing authorization (or rejection) on completion of the assessment process? Yes <input type="checkbox"/> No <input type="checkbox"/>						
1.22 Are the law or legal provisions publicly available? Yes <input type="checkbox"/> No <input type="checkbox"/>						
If yes, give details on how public can access the law/regulations.						
Key findings and gaps						

Section 2: Technical standards and criteria

2.1 Are there guidelines on the applicable requirements on quality, safety and efficacy? Yes <input type="checkbox"/> No <input type="checkbox"/>			
If yes, give details			
Specific sections covered	Guidelines	YES	NO
2.2	Content of Product Information Leaflets, Summary of Product Characteristics (SPC), packaging and labelling	<input type="checkbox"/>	<input type="checkbox"/>
2.3	Various process validations (manufacturing, IT, etc...)?	<input type="checkbox"/>	<input type="checkbox"/>
2.4	Analytical method validation	<input type="checkbox"/>	<input type="checkbox"/>
2.5	Stability testing of pharmaceutical products (API, finished products	<input type="checkbox"/>	<input type="checkbox"/>
2.6	Demonstration of bioequivalence/bioavailability	<input type="checkbox"/>	<input type="checkbox"/>
2.7	Content of the application, format and procedures to be followed in the submission	<input type="checkbox"/>	<input type="checkbox"/>
2.8	Variations / amendments to approved products (defining the types and scopes of variations, format and documentation required as well as specifications of the variations that are subjected to prior approval before implementation	<input type="checkbox"/>	<input type="checkbox"/>
2.9	Medicine donation	<input type="checkbox"/>	<input type="checkbox"/>
2.10	Risk management programs, pre-marketing risk assessment and development of Pharmacovigilance plans	<input type="checkbox"/>	<input type="checkbox"/>
2.11 Are there written standard operating procedures (SOPs) for medicine assessment and registration? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, collect a copy of the SOP(s)			
2.12 If there is a flow chart showing the process of medicine assessment and registration collect a copy? If not, either make a chart or describe the process:			
2.13 Are criteria for medicine assessment and registration (reasons for approving or rejecting applications for registration) written down? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, get a copy of the criteria and indicate how applicants are made aware of them:			
2.14 Is there a written policy or criteria for the registration of combination products? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, what is the policy or criteria? Explain:			

<p>2.15 Is there a documented procedure that is implemented on a voluntary basis to allow applicants to meet with the MRA before the submission of an application? Yes <input type="checkbox"/> No <input type="checkbox"/> Give details</p>
<p>2.16 Are there documented procedures/tools that 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.)? Yes <input type="checkbox"/> No <input type="checkbox"/> Give details</p>
<p>2.17 Are documented procedures implemented for assessing the applications for variation of MA? Yes <input type="checkbox"/> No <input type="checkbox"/> Give details</p>
<p>2.18 Is there a documented procedure that is implemented to follow the commitments of the marketing authorization holder and in particular the Risk Management Program? Yes <input type="checkbox"/> No <input type="checkbox"/> Give details</p>
<p>2.19 Are there documented procedures that are implemented to control the quality of the assessment process in place such as peer-review? Yes <input type="checkbox"/> No <input type="checkbox"/> Give details</p>
<p>2.20 Is there a documented procedure that is implemented to issue the marketing authorization in a standardized format? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, collect copy of the MA (sample)</p>
<p>2.21 Does the procedure takes into account the integration of the different parts of the dossier into an overall benefit/risk analysis assessment? Yes <input type="checkbox"/> No <input type="checkbox"/></p>
<p>2.22 Are there documented procedures that 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? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, give details</p>

2.23 Is there a documented fast-track mechanism for specific products of particular public health interest? Yes <input type="checkbox"/> No <input type="checkbox"/>
2.24 Are the steps/requirements for waived MA assessment documented? Yes <input type="checkbox"/> No <input type="checkbox"/>
Key findings and gaps

Section 3: Organization and structure

3.1 Are marketing authorization activities organized and performed at different levels in the country? Yes <input type="checkbox"/> No <input type="checkbox"/>										
<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left; padding: 2px;">Administrative level</th> <th style="text-align: left; padding: 2px;">Function</th> </tr> </thead> <tbody> <tr> <td style="padding: 2px;">Central / national</td> <td style="padding: 2px;"></td> </tr> <tr> <td style="padding: 2px;">Provincial level</td> <td style="padding: 2px;"></td> </tr> <tr> <td style="padding: 2px;">District</td> <td style="padding: 2px;"></td> </tr> <tr> <td style="padding: 2px;">Others (specify)</td> <td style="padding: 2px;"></td> </tr> </tbody> </table>	Administrative level	Function	Central / national		Provincial level		District		Others (specify)	
Administrative level	Function									
Central / national										
Provincial level										
District										
Others (specify)										
3.2 Are there any written materials describing the roles, responsibilities, functions, and powers of the regulatory bodies at the different government levels? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, obtain copies										
3.3 Is there a system of reporting or information exchange amongst the regulatory authorities at the different levels? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, get a copy of the latest report.										
3.4 Is there written material showing the regulatory and enforcement strategies applied in medicine regulation? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, obtain a copy of the material										
Key findings and gaps										

Section 4: Processes and procedures

This section reviews the evaluation and registration processes and procedures. Wherever possible verify the information given through review of actual documents such as sample certificates, letters, and reports.

<p>4.1 Is there an operational product assessment and registration system Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, when did it commence</p>																																														
<p>4.2 Is there a written standard application form or guideline for submission of dossiers for the registration of medicinal products Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, collect a copy of the application form/ guidelines</p>																																														
<p>4.3 Who can apply for registration of a pharmaceutical product?</p>																																														
<p>4.4 What prerequisites should be met by a company / individual to apply for the registration of a pharmaceutical product? Explain</p>																																														
<p>4.5 Is there a fast track registration system? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, what are the conditions for a product to be eligible for fast track registration?</p>																																														
<p>4.6 Does the process of medicine assessment and registration apply to all pharmaceutical products for human use? Yes <input type="checkbox"/> No <input type="checkbox"/></p>																																														
<p>4.7 Is each of the following categories of products required to be assessed and registered before use?</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%;">Category</th> <th style="width: 10%;">Yes</th> <th style="width: 10%;">No</th> <th style="width: 10%;">NA</th> <th style="width: 20%;">Comments</th> </tr> </thead> <tbody> <tr> <td>Locally manufactured by private for profit sector</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> </tr> <tr> <td>Locally manufactured by government / public sector</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> </tr> <tr> <td>Locally manufactured by private not for profit sector</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> </tr> <tr> <td>Imported by private for profit sector</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> </tr> <tr> <td>Imported by government purchasing agency</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> </tr> <tr> <td>Imported by private not for profit organizations</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> </tr> <tr> <td>Donations / AID</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> </tr> <tr> <td>Other (specify)</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> </tr> </tbody> </table>	Category	Yes	No	NA	Comments	Locally manufactured by private for profit sector	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		Locally manufactured by government / public sector	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		Locally manufactured by private not for profit sector	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		Imported by private for profit sector	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		Imported by government purchasing agency	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		Imported by private not for profit organizations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		Donations / AID	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		Other (specify)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
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Other (specify)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																											

4.8 For products in the categories above where the answer is NO/ NA describe the system present for ensuring quality, efficacy and safety.

4.9 Which classes of medicinal products are currently assessed and registered?

Category	Yes	No	NA	Comments
Well – established interchangeable multi-source (generic) pharmaceutical products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Products containing new active pharmaceutical ingredients	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Biological products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Herbal medicines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Veterinary medicinal products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Other (specify)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

4.10 Which of the following registration procedures are used in granting marketing authorizations?

Category	Yes	No	NA	Comments
The procedure does not involve checking whether the medicinal product meets the basic safety, efficacy and quality criteria.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
The MRA registers a medicine following the decisions made available by the MRAs in other countries (a copy of an authorization, a certificate, etc...).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
The MRA registers a medicine following the assessment reports or inspection reports made by the MRA in other countries as a basis for decision-making on applications.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
The MRA registers a medicine following its own assessment of the quality, safety and efficacy of the product on the basis of the information submitted by the applicant.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

If a different procedure other than mentioned above is used, please provide a description

4.11 What information and evidence are required to be submitted with applications for registration of pharmaceutical products?

Type of product	Information and evidence required for registration
Generic products	
Products containing new active pharmaceutical ingredients	
Fast track medicines	
Other (specify)	

4.12 Do variations to registered or approved products have to be approved?

Yes No

If yes, give details and some examples

4.13 Can the registration authority initiate a change in the registration status of a product ?

Yes No

If, yes, give details and examples.

4.14 Is a WHO-type certificate of pharmaceutical product a requirement for the registration of imported medicines?

Yes No

If no what kind of certificate is requested? Explain

4.15 Does the assessment and registration authority have committees to support its activities?

Yes No

If yes, indicate the titles of the committees (not names of individuals), their respective functions, their powers, and members' terms of office:

Title of committee	Functions	Powers (e.g. refuse approval)	Members term of office

4.16 Are any of the activities of medicine assessment and registration contracted out or carried out by independent people who are not employees e.g. university professors?

Yes No

If yes, indicate which function(s) is/are contracted out and the conditions for contracting out:

Function / activities contracted out	Conditions

4.17 Who makes the final decision regarding the registration of a product?

4.18 What types of documents are issued following approval for registration? Explain:

4.19 For how long is the registration of a product valid?

4.20 If there is no registration expiry, are products re-evaluated periodically? Yes No

If yes, describe the system or get a copy of a written document on the system:

4.21	Indicate the established timelines to evaluate and register a product												
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 70%;">Class of product</th> <th style="width: 30%;">Maximum time limit (in days)</th> </tr> </thead> <tbody> <tr> <td>Generic products</td> <td></td> </tr> <tr> <td>Products containing a new active pharmaceutical ingredients</td> <td></td> </tr> <tr> <td>Fast – track products</td> <td></td> </tr> <tr> <td>Renewals</td> <td></td> </tr> <tr> <td>Variations / amendments</td> <td></td> </tr> </tbody> </table>		Class of product	Maximum time limit (in days)	Generic products		Products containing a new active pharmaceutical ingredients		Fast – track products		Renewals		Variations / amendments	
Class of product	Maximum time limit (in days)												
Generic products													
Products containing a new active pharmaceutical ingredients													
Fast – track products													
Renewals													
Variations / amendments													
4.22	What happens if the limit is not met by the MRA? Explain:												
4.23	<p>Is there a place or authority to appeal against regulatory decisions?</p> <p>If yes, indicate the name of the appellate body and its powers</p>												
4.24	Is the place or authority for appeals independent? Yes <input type="checkbox"/> No <input type="checkbox"/>												
4.25	<p>Is medicine registration process computerized? Yes <input type="checkbox"/> No <input type="checkbox"/> partly <input type="checkbox"/></p> <p>If yes, what system/software is used and when did computerized registration begin?</p>												
4.26	<p>Does the authority issue and update the list of registered medicines regularly?</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If yes, to whom is the list of registered products distributed and how?</p>												
4.27	<p>Do pharmaceutical industries/manufacturers have access to decisions made by the regulatory authority in medicine registration?</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If yes, what are the mechanisms? Explain:</p>												
4.28	<p>Do interested parties have access to decisions of the MRA on medicine registration?</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If yes, what are the mechanisms by which decisions of the MRA on medicine registration are made accessible to the interested parties? Explain:</p>												
4.29	<p>Are certificates issued for exported products? Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/></p> <p>If yes, collect samples of the certificates issued.</p>												
4.30	<p>Does the assessment and registration department have its own internal organogram?</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If yes, collect a copy. If no, indicate the different sections of the unit and their relationship below:</p>												

Situational Analysis of the Medicine Evaluation and Registration System of Afghanistan

Unit / department	Function	
4.31 Is there a model format for the assessment/evaluation report? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, obtain a copy		
4.32 Are the same criteria used for the evaluation of applications regardless of the source (e.g. domestic, foreign, public/private sector) of the products concerned? Yes <input type="checkbox"/> No <input type="checkbox"/> If no, explain		
4.33 Is the product information, Summary of Product Characteristics (SPC), packaging and labelling reviewed and approved as part of the marketing authorization? Yes <input type="checkbox"/> No <input type="checkbox"/> Comments		
4.34 Are the risk management program and pharmacovigilance plan approved as part of the MA? Yes <input type="checkbox"/> No <input type="checkbox"/> Comments		
4.35 Are external information (information sources and reference materials) for decision making on the applications submitted readily available? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes give details below		
Information sources and reference materials	Availability (<i>indicate the year and no of copies and whether electronic/hard copies</i>)	
	Electronic/year, no of hard copies/year	
<i>Pharmacopoeias</i>		
United States Pharmacopoeia		
International Pharmacopoeia		
British Pharmacopoeia		
European Pharmacopoeia		
Other, specify		
<i>Reference books</i>		
Martindale		
Hand book of Pharmaceutical Excipients		
WHO specifications of pharmaceutical substances		
Other, specify		
<i>Other information sources and reference materials</i>		

<p>4.36 Are external experts involved in the assessment of the applications for MA? Yes <input type="checkbox"/> No <input type="checkbox"/> Comments</p>																						
<p>4.37 Is there an internal tracking system that is established to follow the targeted time frames (statutory or not)? Yes <input type="checkbox"/> No <input type="checkbox"/> Comments</p>																						
<p>4.38 Is there a model format for the decision on a marketing authorization application (approval, rejection, withdrawal)? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, obtain copies</p>																						
<p>4.39 Is there a written marketing authorization, signed by a person with the adequate delegation, sent to the applicant, accompanied by the approved product information, including conditions or restrictions of this approval? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, Indicate the position of the person (s) authorised to sign</p>																						
<p>4.40 Does each pharmaceutical product receive a unique identification number that appears on the labelling/packaging and product information? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, give details</p>																						
<p>4.41 Is evaluation report generated in assessment of applications for registration?</p> <p>If yes, do they satisfy the following</p> <table border="1" style="width:100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="width: 50%;">Category</th> <th style="width: 10%;">Yes</th> <th style="width: 10%;">No</th> <th style="width: 30%;">Comments</th> </tr> </thead> <tbody> <tr> <td>Brief outline of the data provided in the application</td> <td align="center"><input type="checkbox"/></td> <td align="center"><input type="checkbox"/></td> <td></td> </tr> <tr> <td>Reasons for any disagreement with applicants' proposal e.g. shelf life or specification</td> <td align="center"><input type="checkbox"/></td> <td align="center"><input type="checkbox"/></td> <td></td> </tr> <tr> <td>Summary and evaluation of information on interchangeability with recommendations and reasons</td> <td align="center"><input type="checkbox"/></td> <td align="center"><input type="checkbox"/></td> <td></td> </tr> <tr> <td>Conclusion of the assessment i.e. reject, additional data required, approval</td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	Category	Yes	No	Comments	Brief outline of the data provided in the application	<input type="checkbox"/>	<input type="checkbox"/>		Reasons for any disagreement with applicants' proposal e.g. shelf life or specification	<input type="checkbox"/>	<input type="checkbox"/>		Summary and evaluation of information on interchangeability with recommendations and reasons	<input type="checkbox"/>	<input type="checkbox"/>		Conclusion of the assessment i.e. reject, additional data required, approval					
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<p>4.42 Indicate which of the following data set is required and assessed before issuing marketing authorizations.</p> <table border="1" style="width:100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th rowspan="2" style="width: 50%;">Data set</th> <th colspan="2">Required</th> <th colspan="2">Assessed</th> <th rowspan="2">Comments</th> </tr> <tr> <th>Yes</th> <th>No</th> <th>Yes</th> <th>No</th> </tr> </thead> <tbody> <tr> <td>Proof of registration in country of origin</td> <td align="center"><input type="checkbox"/></td> <td align="center"><input type="checkbox"/></td> <td align="center"><input type="checkbox"/></td> <td align="center"><input type="checkbox"/></td> <td></td> </tr> <tr> <td>WHO-type certificate of pharmaceutical product</td> <td align="center"><input type="checkbox"/></td> <td align="center"><input type="checkbox"/></td> <td align="center"><input type="checkbox"/></td> <td align="center"><input type="checkbox"/></td> <td></td> </tr> </tbody> </table>	Data set	Required		Assessed		Comments	Yes	No	Yes	No	Proof of registration in country of origin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		WHO-type certificate of pharmaceutical product	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Data set		Required		Assessed			Comments															
	Yes	No	Yes	No																		
Proof of registration in country of origin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																		
WHO-type certificate of pharmaceutical product	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																		

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Manufacturing authorization for the FPP	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
WHO type GMP certificate for FPP manufacturer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Active pharmaceutical ingredient	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Information on the source of the API and the manufacturer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Information on the characterization or structure of the medicinal product	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Manufacture of the active pharmaceutical ingredient including process validation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Information on impurities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Control of active pharmaceutical ingredient including validation of analytical procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Reference standards or materials	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Container closure system	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Stability studies (including stress, accelerated and long term testing) and storage conditions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Finished pharmaceutical product	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
composition of the medicinal product,(both active and non-medicinal ingredients)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
pharmaceutical development	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
manufacturing process and process control, including control of critical steps and process validation,	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
controls related to excipients	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
controls of medicinal product including validation of analytical procedures,	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
reference standards or materials	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
container closure system	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
stability studies	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Bioequivalence / efficacy data	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

4.43 What are the MRA perceived main constraints, weaknesses or problems and the strengths of the medicine assessment and registration system?

Constraints/weaknesses/ problems	Strengths

Key findings and gaps

Documented evidence to be studied

1. Acts, Laws, Decrees
2. Guidance published on the website
3. Internal procedures, templates and records
4. Assessment format and assessment reports
5. Minutes of advisory committees' or meetings of decision making chain
6. Decision format

7. *Product information and Summary of product characteristics format*
8. *Summary basis for decision format*
9. *List of staff with their qualification*
10. *List of external experts with their qualification*
11. *List of authorized products/application registered*
12. *List of applications refused or withdrawn*
13. *List of applications pending,*
14. *List and planning for periodic revision of the applications*
15. *Internal procedures for selecting and designating external experts,*
16. *Internal procedures for designating the members of the advisory committees,*
17. *List of the advisory committees that intervene in a regulatory process*
18. *List of the members of the advisory committees*
19. *Composition of the various advisory committees*
20. *Terms of reference of the various advisory committees*

Section5: Transparency

This section reviews the MRA's general practices and policies in dealing with transparency issues in all its procedures and outcomes. The information should be verified through interviews outside of the MRA; for example with the representatives of stakeholders to collect opinions or information on how the MRA is perceived or operates.

No	Indicator	Criteria	Rate
1	<i>Does the drug registration process have an information system?</i>	Name of company registering the drug	
		Contact of company registering the drug	
		Name of manufacturing company	
		Country of product manufacturing	
		Date of registration	
		Product description	
		Total	
		Score*	
2	<i>Are there written procedures on how to register a drug in the market for applicants and for assessors?</i>	Public access	
		Process description	
		Fees mentioned	
		Authorities involved in the registration process	
		Total	
		Score*	
3	<i>Is there a standard application form?</i>	Product name	
		Product manufacturer	
		Generic names of active substances	
		Pharmacological action	
		Therapeutic classification	
		Packaging insert	
		Total	

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		Score*	
4	<i>Is this document publicly available and easy to access?</i>	Readily available at govt office or website	
		Total	
		Score*	
5	<i>Is there a formal committee responsible for drug registration? If yes, what criteria are used for selecting committee members?</i>	Formally established	
		Composed of professionals w/ tech skills	
		Meet on a regular basis	
		Total	
		Score*	
6	<i>Is there an organogram that describes the composition of the committee available as a public document?</i>	Member names	
		Member responsibilities	
		Up to date	
		Public access	
		Total	
		Score *	
7	<i>Is the committee responsible for decision making or does it act in an advisory capacity</i>	Evidence that committee decisions are implemented	
		Total	
		Score *	
8	<i>Does the committee provide an official written report for all decisions (e.g. accepted and rejected files)</i>	Existence of rejection criteria for registration	
		Document explains reasons for rejection	
		Total	
		Score *	
9	<i>Do terms of reference exist which describe the purpose of the committee, its processes, duration, etc.? And, if so, are these available publicly?</i>	Existence of terms of reference	
		Terms of reference publicly available	
		Terms of reference comprehensive	
		Total	
		Score *	
10	<i>How does the committee reach its decision (for example, is a qualified majority required, consensus, etc.?) Are these procedures documented?</i>	Documented procedures for decision-making	
		Total	
		Score *	
11	<i>Are members of the committee or any other officials involved in the medicine registration process formally required to declare any conflict of interest</i>	Existence of standard form for declaring conflict of interest	
		Standard form publicly available	
		Total	
		Score *	
12	<i>Is there an appeals process for applicants who have their drug applications rejected?</i>	Formal appeal process in place which is transparent	
		Evidence protest mechanism is used	
		Total	

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		Score *	
13	<i>Have there been drug recalls in the past 3 years?</i>	Example of a drug recall with clear explanations	
		Evidence that information shared with professionals and consumers	
		Evidence of clear procedures for drug recalls	
		Total	
		Score *	
14	<i>Are there formalized procedures to deal with reporting of drug safety and efficacy?</i>	Information administration procedures	
		Availability of information on side effects of medicines	
		Total	
		Score *	
15	<i>Who does the committee report to and is this person responsible for making the final decision?</i>	Open and transparent procedures for decision-making	
		Democratic decision-making	
		Total	
		Score *	
16	<i>Is the registration fee set by law or regulation and publicly available?</i>	Regulation or law includes registration fee	
		Fee information publicly accessible	
		Total	
		Score *	
17	<i>Is the time from application to decision-making uniform from application to application?</i>	Consistency in registration time across sample of at least five	
		Total	
		Score *	
18	<i>Are there drugs in the market that are non-registered?</i>	No evidence of non-registered drugs on the market	
		Total	
		Score *	

Score* = total / number of criteria for respective indicator

Key findings and gaps

Section 6: Human and other resources

This section reviews the adequacy of the competencies of internal evaluators and external experts as regards their qualifications in pharmacy, clinical pharmacology, medicine or a similar discipline, and their practical experience in at least one of these disciplines as well as in biopharmaceuticals.

6.1 Provide information below on the type and number of regular and part-time staff involved in product assessment and registration of pharmaceutical products (do not include committees):

Position	Full-time	Part-time
<i>Administration/management staff</i>		
<i>Staff engaged in evaluation and registration activities:</i>		
Physicians all types		
Pharmacists		
Chemists		
Microbiologists		
Pharmacologists/clinical pharmacologists		
Toxicologists		
Others (specify):		
Total		

6.2 Is there an established organization Chart / organogram for the medicine regulatory agency/ authority (MRA)?

Yes No

If yes, when was it last updated?

6.3 Are the key technical and scientific personnel been identified based on their authorities and responsibilities?

Yes No

If yes, when was it last updated?

6.4 Are the job descriptions for the following staff 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...)? Yes No

If yes, give details?

6.5 Are all the staff working in product assessment and registration have job descriptions?

	All have	Some have	Needs to be developed
Tick appropriate box	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6.6 Are there established necessary competencies (education, training, skill and experience) for the key personnel to perform the assigned work? Yes No

If yes, get copies or summarize below:

6.7 Is the MRA or institution performing medicine assessment and registration able to select and recruit its own staff and dismiss staff following documented procedures based on its own written

criteria (experience, minimum educational background, advanced training, etc.)?
 Yes No
 If yes, give reference to the document that gives such power:

6.8 Is there an initial and periodic staff appraisal system established to review performance and competencies identify academic and training needs; and agree on performance targets?
 Yes No
 If yes, give details:

6.9 Is there an induction or orientation program for newly recruited staff?
 Yes No

6.10 Is there a human resources/staff development plan (training, career structure, etc.)?
 Yes No
 If yes, give reference to the document:

 Indicate the number of people planned and trained in the previous years

	Year : 2009		Year : 2010		Year: 2011	
	Planned	Trained	Planned	Trained	Planned	Trained
Product assessment and Registration						

6.11 Is there budgetary provision for staff training?
 Yes No
 If yes, give details:

6.12 How does the salary of the technical staff working in product assessment and registration compare to the salaries of people with the same qualifications/functions but working in the private sector?

Tick one appropriate box	Similar	Higher	Lower	Comments
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

6.13 What is the staff establishment in GDPA and the vacancy rate?

Category	Establishment	Positions filled
Support staff		
Technical / professional staff		

6.14 What is the number of staff who have resigned or dismissed or retired compared to number of staff recruited in the past three years?

Category	# resignations/ dismissals/ retirement			# Recruited		
	2009	2010	2011	2009	2010	2011
Support staff						
Technical / professional staff						

6.15 Complete the information in table below to determine the turnover rate.

	2007	2008	2009	2010	2011
Number of staff (technical) who left employment (resignation, termination or dismissal, retirement)					
Total number of technical employees on last day of reporting period					
TYD turnover %					

6.16 What are the main reasons for resignations/dismissal?

6.17 Complete the following tables to assess the available expertise (education, experience and training) for the assessment of different parts of the application for all types of authorized pharmaceutical products.

a. Education and experience

	Education			Experience			
	Diplomas	Relevant bachelor's degree	Masters or PhD in relevant fields	Less than 1 year	1 – 3 years	3 – 5 years	More than 5 years
#							

Relevant qualifications refer to pharmacy, medicine, pharmaceutical sciences, pharmaceutical chemistry / chemistry. If other qualifications, please give details:

b. Training

	Training (internal)			Training (external)* within or outside country		
	Product assessment – quality (API and FPP)	Product assessment–bioequivalence/efficacy	Other give details	Product assessment – quality (API & FPP)	Product assessment – bioequivalence/ efficacy	Other give details
# of staff participated						
# of trainings per year						

6.18 Is there internal planning of human resource utilisation for performing any upcoming and periodical reviews of the applications?

Yes No

If yes, give details:

<p>6.19 Are the manufacturer's or licence holder's representatives ever involved in assessment work at any level/stage, including expert committees?</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If yes, give details:</p>												
<p>6.20 Are there are lines of authority reflecting the independence of decision-making in the MA system from manufacturers, supply systems or government?</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If yes, give details:</p>												
<p>6.21 Is there adequate office, working environment and storage space for MAs files?</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Comments</p>												
<p>6.22 Is there adequate equipment for MAs functions e.g. computers?</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Comments</p>												
<p>6.23 Is there adequate storage with sufficient security to give applicants confidence – against theft and unauthorized copying; fire and water proof?</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Comments</p>												
<p>6.24 Which of the following is used for archiving?</p> <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 35%;"></th> <th style="width: 35%;">Tick all that applies</th> <th style="width: 30%;">Comments</th> </tr> </thead> <tbody> <tr> <td>Electronic storage</td> <td></td> <td></td> </tr> <tr> <td>Paper storage</td> <td></td> <td></td> </tr> <tr> <td>Other, specify</td> <td></td> <td></td> </tr> </tbody> </table>		Tick all that applies	Comments	Electronic storage			Paper storage			Other, specify		
	Tick all that applies	Comments										
Electronic storage												
Paper storage												
Other, specify												
<p>6.25 Is the register of authorized medicines easily accessible in an electronic format for easy maintenance, updating and searching for relevant information?</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If yes, give details:</p>												
<p>6.26 Is there ready access to internet for evaluators?</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>												

Comments
Key findings and gaps

Documented evidence to be studied

1. *GDPA's organogram/organization charts*
2. *Internal procedures for recruiting, training and qualifying staff and records*
3. *Procedure for assessing the impact of training activities*
4. *Procedure for assessing the competencies of the staff*
5. *Code of conduct/code of ethics*
6. *List of staff with their qualification*
7. *Training plan*
8. *List of trainings performed*
9. *Job descriptions*
10. *Curriculum Vitae*
11. *Recruitment plan*

Section 7: Financing

<p>7.1 Is there a specific budget for the registration unit? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If yes, what was the budget of the unit during each of the last five years (US\$)</p> <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="width:25%;">Budget section</th> <th style="width:10%;">2007</th> <th style="width:10%;">2008</th> <th style="width:10%;">2009</th> <th style="width:10%;">2010</th> <th style="width:10%;">2011</th> </tr> </thead> <tbody> <tr> <td>Capital budget</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Salaries</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Miscellaneous</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Total</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>							Budget section	2007	2008	2009	2010	2011	Capital budget						Salaries						Miscellaneous						Total					
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Total																																				
<p>7.2 What was the source of the budget in the last 5 years (select from the drop down list)?</p> <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="width:35%;">Source</th> <th style="width:10%;">2007</th> <th style="width:10%;">2008</th> <th style="width:10%;">2009</th> <th style="width:10%;">2010</th> <th style="width:10%;">2011</th> </tr> </thead> <tbody> <tr> <td>Government</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Fees</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Other (specify e.g. donors)</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>							Source	2007	2008	2009	2010	2011	Government						Fees						Other (specify e.g. donors)											
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<p>7.3 What was the estimated expenditure of the unit in the last five years?</p> <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="width:35%;">Estimated expenditure</th> <th style="width:10%;">2007</th> <th style="width:10%;">2008</th> <th style="width:10%;">2009</th> <th style="width:10%;">2010</th> <th style="width:10%;">2011</th> </tr> </thead> <tbody> <tr> <td>Local currency</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>USD</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>							Estimated expenditure	2007	2008	2009	2010	2011	Local currency						USD																	
Estimated expenditure	2007	2008	2009	2010	2011																															
Local currency																																				
USD																																				
<p>7.4 Is there a fee system for the regulatory services provided? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If yes, indicate below the main services for which fees were charged and fee amount</p> <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="width:70%;">Types of registration services on which fees are levied</th> <th style="width:30%;">Fees charged USD</th> </tr> </thead> <tbody> <tr> <td>1. Evaluation of applications for new marketing authorizations</td> <td></td> </tr> <tr> <td>2. Registration of domestic product</td> <td></td> </tr> </tbody> </table>							Types of registration services on which fees are levied	Fees charged USD	1. Evaluation of applications for new marketing authorizations		2. Registration of domestic product																									
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Situational Analysis of the Medicine Evaluation and Registration System of Afghanistan

	3. Generics / OTC products	
	4. Retention fees, renewals	
	5. Other (specify)	
<p>7.5 Do the fees charged reflect the costs i.e. fee setting based on the proportion of the costs of work of the application (nature and amount of data to be analysed e.g. NCE vs generics, orphan medicines)? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Comments</p>		
<p>7.6 Is the fee schedule published and easily available to the public? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If yes, collect copy of the current fee schedule and indicate below how the public have access to the fee schedule (i.e. at offices, website etc)</p>		
Key findings and gaps		

Section 8: General information/statistics

8.1 How many applications have been received in the last five years?

No of applications received	2007	2008	2009	2010	2011
New applications for registration of products containing new active pharmaceutical ingredients					
New applications for registration of generic/well-established multi-source products					
New applications for registration by fast-track Procedure					
Applications for amendments or changes in product data after approval					
Applications for renewal					
Applications for export certificate					
Other (specify):					
Total					

Comments:

8.2 How many applications have been processed in the last five years?

No of applications processed	2007	2008	2009	2010	2011
New applications assessed and marketing authorization issued					

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Ingredients					
New applications assessed and marketing authorization refused					
New applications assessed, application withdrawn before decision					
No of applications assessed and approved for amendments or changes in product data after approval					
No of applications assessed and refused for amendments or changes in product data					
Export certificates issued					
Applications for export certificates refused					
Other (specify):					
Total					

Comments:

8.3 How long does the MRA spend on key activities for evaluation and registration?

Activity	Number of days**	Comments
Registration of a new medicine		
Registration of a generic product		
Renewals		
Variations / Amendments		

***Average number of days spent by the MRA for decision-making calculated as period between the date of submission of application for MA and the date of approval / date of issue of registration certificate.*

Review sample of the approved products (e.g. 10%) of products registered in past three years for each category, and state the average period from receipt to approval or issue of registration certificates.

Key findings and gaps

Summary of key findings (observations) in the assessment

General
Section 1: Legal Provisions
Section 2: Technical Standards and Criteria

Section 3: Organization and Structure
Section 4: Processes and Procedures
Section 5: Transparency
Section 6: Human Resources
Section 7: Financing
Section 8: General Information/Statistics

References

Assessment of medicines regulatory systems in sub-Saharan African countries: An overview of findings from 26 assessment reports, World Health Organization 2010

Marketing authorization of pharmaceutical products with special reference to multisource (generic) products: a manual for National Medicines Regulatory Authorities (NMRAs) – 2nd edition, World Health Organization 2011

Measuring Transparency in Medicines Registration, Selection and Procurement: Four Country Assessment Studies, World Health Organization 2006

Sauwakon Ratanawijitrasin and Eshetu Wondemagegnehu. Effective drug regulation: A multi-country study, World Health Organization 2002,

WHO Data Collection Tool for the Review of Drug Regulatory Systems, World Health Organization 2007

ANNEX C. GLOSSARY

The terms listed below are defined specifically for the purposes of the situational assessment.

Accountability

Being required to account for one's conduct and actions, usually to an individual or group but ultimately to the public. Both individuals and organizations may be accountable. There is some overlap between accountability and transparency (see below).

Active pharmaceutical ingredient (API)

A substance or compound that is intended to be used in the manufacture of a pharmaceutical product as a therapeutically active compound (ingredient)

Advertising

For the purposes of this manual, advertising is considered a part of promotion.

Applicant

The person or company who submits an application for marketing authorization of a new pharmaceutical product,

Authorized person

A person (among key personnel of a manufacturing establishment) responsible for the release of batches of finished products for marketing in some other GMP guides and legal texts, the term qualified person is used to describe analogous functions.

Bioequivalence

Two pharmaceutical products are bioequivalent if they are pharmaceutically equivalent and their bio availabilities (rate and extent of availability), after administration in the same molar dose, are similar to such a degree that their effects can be expected to be essentially the same.

Comparator

In this manual, the term comparator is used to mean "the pharmaceutical product with which the new product is intended to be interchangeable in clinical practice". In any particular market, the comparator should be the first in this list that is available. The product for which efficacy, safety and quality have been fully established (often the innovator);

Container labelling

All information that appears on any part of a container, including that on any outer packaging such as a carton

Drug

Any substance or pharmaceutical product for human or veterinary use that is intended to modify or explore physiological systems or pathological states for the benefit of the recipient

Drug master file

A drug master file (DMF) is a master file that provides a full set of data on an API. In some countries, the term may also comprise data on an excipient or a component of a product such as a container.

Dossiers

Set of documents or data to support product applications / registrations

Medicine regulatory authority

A national body that administers the full spectrum of drug regulatory activities, including at least or all of the following functions:

- marketing authorization of new products and variation of existing products
- quality control laboratory testing
- adverse drug reaction monitoring
- provision of drug information and promotion of rational drug use
- good manufacturing practice (GMP) inspections and licensing of manufacturers, wholesalers and distribution channels
- enforcement operations
- monitoring of drug utilization
- control of clinical trials

Essential drugs

Essential drugs are those that satisfy the health care needs of the majority of the population. As indicated by the Expert Committee on the Use of Essential Drugs [12], each country may generate its own list of essential drugs.

Evaluation report

A critical summary and interpretation of the data, with conclusions, prepared by or on behalf of the drug regulatory authority.

Excipient

Any component of a finished dosage form other than the claimed therapeutic ingredient or ingredients

Expert advisory body

A standing advisory board (or committee) of independent experts, including academic experts and practicing health care professionals

Expert report

In European Union usage critical summary and interpretation of the data, with conclusions, prepared by or on behalf of an applicant.

Finished pharmaceutical product

A product that has undergone all stages of production, including packaging in its final container and labelling

Formulation

The composition of a dosage form, including the characteristics of its raw materials and the operations required to process it.

Generic products

The term generic product has somewhat different meanings in different jurisdictions. Use of this term is therefore avoided as much as possible, and the term multisource pharmaceutical product (see below) is used instead. Generic products may be marketed either under the approved non-proprietary name or under a brand (proprietary) name. They may be marketed in dosage forms and/or strengths different from those of the innovator products. Where the term generic product is used, it means a pharmaceutical product, usually intended to be interchangeable with the innovator product, which is usually manufactured without a licence from the innovator company and marketed after expiry of the patent or other exclusivity rights. The term should not be confused with generic names for APIs.

Guidelines

Guidelines are departmental/institutional documents that are used to interpret the legislation and/or a regulation. Although they may be derived from the legislation, they are often used to advise on how to comply with a regulation. The legal status of these guidelines can vary from one country to another but in any case they will not have the same level of empowerment as a legislative act.

Innovator pharmaceutical product

The innovator pharmaceutical product is generally that which was first authorized for marketing (normally as a patented product) on the basis of documentation of efficacy, safety and quality (according to requirements at the time of the authorization). When a substance has been available for many years, it may not be possible to identify an innovator pharmaceutical product.

Interchange ability

An interchangeable pharmaceutical product is one that is therapeutically equivalent to a comparator (reference) product.

Legislation

The term "legislation" refers to written laws, often referred to as Acts or Statutes, which are enacted by Parliament (the legislative arm of Government).

Manufacture (manufacturing)

All operations of purchase of materials and products, production, quality control, release, storage, shipment of finished products and the related controls.

Marketing authorization

An official document issued by the competent drug regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality. It must set out, inter alia, the name of the product, the pharmaceutical dosage form, the quantitative formula (including excipients) per unit dose (using INNs or national generic names where they exist), the shelf-life and storage conditions, and packaging characteristics. It specifies the information on which authorization is based (e.g. "The product(s) must conform to all the details

provided in your application and as modified in subsequent correspondence”). It also contains the product information approved for health professionals and the public, the sales category, the name and address of the holder of the authorization, and the period of validity of the authorization.

Once a product has been given marketing authorization, it is included on a list of authorized products - the register - and is often said to be “registered” or to “have registration”. Market authorization may occasionally also be referred to as a licence or product licence.

Marketing authorization holder

The person or company in whose name the marketing authorization has been granted. This party is responsible for all aspects of the product, including quality and compliance with the conditions of marketing authorization. The authorization holder must be subject to legislation in the country that issued the marketing authorization, which normally means being physically located in the country.

Master file

A master file is a dataset that is:

- submitted by someone other than a finished product applicant, e.g. the supplier of an active ingredient or the supplier of a packaging component
- a common feature of more than one product, e.g. sterility test procedures; or some other matter that is conveniently dealt with by means of a master file
- An applicant for a new marketing authorization or for a variation may make reference to a master file, but must have the permission of the person or company that submitted the master file

Multisource (generic) pharmaceutical product

Multisource pharmaceutical products are pharmaceutically equivalent products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable.

New chemical or biological APIs (new APIs)

New chemical or biological APIs are those not previously authorized for marketing for any pharmaceutical use in the country in question. Those provisionally authorized at the time of the initial market inventory are not new pharmaceutical ingredients.

New drug

Any drug that does not match the definition of well-established drugs (see below).

New pharmaceutical product

A pharmaceutical product that contains a new API, a new combination of marketed APIs, or a new multisource (generic) product. It may be available either on prescription or without prescription.

Periodic review

The regular process, usually occurring every five years, by which the validity of a marketing authorization is renewed and information on a product is reviewed (validated), consolidated and sometimes expanded.

Pharmaceutical equivalents

Products are pharmaceutical equivalents if they contain the same amount of the same active substance(s) in the same dosage form; if they meet the same or comparable standards; and if they are intended to be administered by the same route. Pharmaceutical equivalence does not necessarily imply therapeutic equivalence, as differences in the excipients and/or the manufacturing process can lead to differences in product performance.

Pharmaceutical product

Any preparation for human or veterinary use that is intended to modify or explore physiological systems or pathological states for the benefit of the recipient

Product information

A document defining information that may be supplied with or about a pharmaceutical product by or on behalf of the marketing authorization holder the minimum information in the product information should be defined by the DRA. The content of the product information is agreed between the marketing authorization holder and the DRA at the time the market authorization is issued.

Promotion

All informational and persuasive activities by marketing authorization holder, manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal products.

Provisional marketing authorization

Temporary authorization following the initial market inventory, and pending full approval based on evaluation of quality, safety and efficacy.

Quality control

Quality control is concerned with sampling, specifications and testing, and with the organization, documentation and acceptance/rejection procedures which ensure that the necessary and relevant tests are actually carried out and that starting materials, intermediates and finished products are not accepted for use, sale or supply until their quality has been judged to be satisfactory.

Register

A list of all the pharmaceutical products authorized for marketing in a particular country. The register is maintained by the drug regulatory authority of the country in question.

Registered drug products

Pharmaceutical products that have a marketing authorization

Registration

See marketing authorization.

Regulations

Regulations are prepared under the authority of an Act, referred to as the “Enabling Act”. The regulations are enacted by the body to whom the authority to make regulations has been delegated in the Enabling Act, such as the Governing Council or a minister, etc.

Renewal

The word “renewal” has been avoided in this manual because its meaning is not consistent between Member States. See periodic review and retention fee.

Retention fee (for marketing authorization)

A fee paid to maintain marketing authorization, usually annually. Product details are not normally reviewed when retention fees are paid. (See also periodic review)

Specification - expiry, check or shelf life

The combination of physical, chemical, biological and microbiological test requirements that an active ingredient must meet up to its retest date or a drug product must meet during its shelf-life.

Specification - release

The combination of physical, chemical, biological and microbiological test requirements that determine whether a drug product is suitable for release at the time of its manufacture

Stability

The ability of an active ingredient or a drug product to retain its properties within specified limits throughout its shelf-life the chemical, physical, microbiological and biopharmaceutical aspects of stability must be considered:

Starting material

Any substance of a defined quality used in the production of a pharmaceutical product, but excluding packaging materials.

Staff turnover

The number of permanent employees leaving the company within the reported period versus the number of actual Active Permanent employees on the last day of the previous reported period (physical headcount)

Therapeutic equivalence

Two pharmaceutical products are therapeutically equivalent if they are pharmaceutically equivalent and, after administration in the same molar dose, their effects with respect to both efficacy and safety are essentially the same, as determined from appropriate bioequivalence, pharmacodynamics, clinical or in vitro studies.

Tracking

Keeping a record of the progress of an application at all stages

Transparency

The term transparency means (1) defining policies and procedures in writing and publishing the written documentation, and (2) giving reasons for decisions to the affected party. There is some overlap between transparency and accountability (see above).

Unregistered drug products

Pharmaceutical products that do not have a marketing authorization

Validation

The demonstration, with documentary evidence, that any procedure, process, equipment, material, activity, or system actually leads to the expected results.

Variation

A change to any aspect of a pharmaceutical product, including but not limited to a change to formulation, method and site of manufacture, specifications for the finished product and ingredients, container and container labelling, and product information.

Well-established drugs

APIs (not products) which:

- have been marketed for at least five years in countries that undertake active post marketing monitoring
- have been widely used in a sufficiently large number of patients to permit the assumption that safety and efficacy are well known
- have the same route of administration and strength, and the same or similar indications as in those countries

Because this definition refers to active pharmaceutical ingredients and not products, it does not take into account possible sensitivities to excipients and other factors that are relevant to therapeutic equivalence

Well-established drug products

Pharmaceutical products which contain well established drugs, and which

- have been marketed for at least five years in countries that undertake active post marketing monitoring
- have been widely used in a sufficiently large number of patients to permit the assumption that safety and efficacy are well known
- have the same route of administration and strength, and the same or similar indications as in those countries

WHO-type certificate of pharmaceutical product

A certificate of pharmaceutical product of the type defined in the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

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About SPS

The Strengthening Pharmaceutical Systems (SPS) Associate Award Program strives to build capacity within developing countries to effectively manage all aspects of pharmaceutical systems and services. SPS focuses on improving governance in the pharmaceutical sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to and appropriate use of medicines.