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MINISTRY OF PUBLIC HEALTH
GENERAL DIRECTORATE OF PHARMACEUTICAL AFFAIRS

Afghanistan Medicines Quality Assurance Assessment – A Qualitative Survey

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Strengthening
Pharmaceutical
Systems

Afghanistan Medicines Quality Assurance Assessment – A Qualitative Survey

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About SPS

The Strengthening Pharmaceutical Systems (SPS) 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.

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ACRONYMS AND ABBREVIATIONS

API	Avicenna Pharmacy Institute
API	Active Pharmaceutical Ingredient
BHC	Basic Health Center
BPHS	Basic Package of Health Services
CHC	Comprehensive Health Center
DH	District Hospital
DFID	Department for International Development (U.K.)
EC	European Commission
EDL	Essential Medicines List
EPHS	Essential Package of Hospital Services
EU	European Union
FDQCD	Food and Drugs Quality Control Department
GDPA	General Directorate of Pharmaceutical Affairs
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
HLRD	Health Laws and Regulation Directorate
JHU	Johns Hopkins University
LDL	Licensed Drug List
MoPH	Ministry of Public Health
MRA	Medicines Regulatory Authority
MSH	Management Sciences for Health
NGO	Nongovernmental organization
NMFB	National Medicines and Food Board
NMP	National Medicine Policy
NMQCL	National Medicines Quality Control Laboratory
PrH	Private Hospital
Ph. Int.	International Pharmacopoeia
PrPh	Private Pharmacy
QA/QC	Quality Assurance/Quality Control
QATF	Quality Assurance Task Force
RH	Regional Hospital
SCMS	Supply Chain Management System
SH	Special Hospital
SOP	Standard Operating Procedure
SPS	Strengthening Pharmaceutical Systems (Program)
USAID	U. S. Agency for International Development
USD	U. S. Dollar
USP	U. S. Pharmacopoeia
WB	World Bank
WHO	World Health Organization

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The successful completion of this medicines quality assurance assessment survey is the result of the combined efforts of several individuals, and public and private sectors agencies based in Afghanistan. The survey received tremendous support from HE Minister of Public Health (Dr. Sayed Mohammad Amin Fatemi), HE Deputy Minister of MoPH for Administrative Affairs (Dr. Sadrudin Sahar), and General Director of Pharmaceutical Affairs (Pharmacist Jamahir Anwari).

Annex A shows the officials that took part in the data collection process. All these individuals, the agencies, and their officials and representatives provided invaluable support to the process. Niranjana Konduri, Angelica Perez, Martha Embrey and Susan Brock reviewed the draft report; and provided very useful technical comments and observations. The public and private sectors organizations which were directly involved in the assessment include:

- Afghan National Police
- Aga Khan Health Service in Afghanistan
- Association of Afghanistan Pharmacists
- Association of Doctors and Health Workers of Afghanistan
- Avicenna Pharmaceutical Institute
- Basic Health Centers
- Central Medicine Stock Directorate
- Central Statistics Organization
- Comprehensive Health Centers
- Customs Directorate, Ministry of Finance
- European Union
- Food and Drugs Quality Control Department
- General Directorate of Pharmaceutical Affairs (GDPA)
- Global Express and Logistics Company
- Health Directorate of the Afghan National Army
- Health Laws and Regulations Directorate
- Health Management Information System of the Ministry of Public Health
- Health Net Transition Psychosocial Organization
- Human Resource General Directorate of the Ministry of Public Health
- International Committee of the Red Cross (ICRC)
- Japan International Cooperation Company
- Médecine Sans Frontières
- Ministry of Finance
- Ministry of Higher Education
- Ministry of Telecommunication
- Ministry of Public Health
- National Security Department
- Pharmaceutical Enterprise
- Private Hospitals
- Private Importers

- Private Retail Pharmacies
- Private Wholesale Pharmacies
- Procurement Department
- Provincial Health Directorates
- Provincial Hospitals
- Quality Assurance Task Force
- Regional Hospitals
- Specialty Hospitals
- Strengthening Pharmaceutical Systems Program
- Swedish Committee Afghanistan
- Tech-Serve Project Afghanistan
- United Nation Population Fund
- World Health Organization

Commentary

The Ministry of Public Health (MOPH) of Afghanistan is committed to ensuring that all medicines available in the country, whether of domestic or foreign origin, and used for treatment purposes are effective, safe, of good quality, and affordable. To achieve these objectives, there is a need to put in place a system which ensures that all medicines are screened for quality.

During the past three decades, like other sectors, Regulatory functions and Quality Assurance System have been found to be weak. In addition, the lack of a strong regulatory system for medicines in the country and the existence of long borders which are uncontrollable, are contributory factors to the manufacture and importation of ineffective, unsafe, and sub-standard or counterfeit medicines. This has led to waste of resources and also prolonged the period of treatment and emergence of anti-microbial resistance and death of many citizens.

To strengthen the system, it is important to know the state of medicines in the country, and the opportunities and challenges in the sector, and design public health policies and strategies.

Therefore, the General Department of Pharmaceutical Affairs (GDPA) of MOPH conducted a general assessment at the national level in April 2011 with the financial and technical support of SPS/MSH. The interpretation and analysis which is presented in the document under the name “Afghanistan Medicines Quality Assurance Assessment – A Qualitative Survey”, comprises valuable and in-depth information about structures and systems for medicines quality assurance in the country.

Information obtained from the survey indicates that regulation and control of medicines is weak in both public and private sectors. There are no structures, procedures and policies which regulate the quality assurance of medicines in the country. In addition, there is no Good Manufacturing Practice or other accepted guidelines in the country. Afghanistan follows eight different pharmacopeias.

The MOPH is committed to strengthening the quality assurance system throughout the country, based on the recommendations made in this report, by establishing national programs and developing a national strategy which includes Quality Assurance, Registration, Inspection, Sampling, and establishing small-scale QA laboratories in major areas of the country.

I hope that various departments of the MOPH and other partner Ministries, government agencies, donors and NGOs will synchronize their activities in the provision of good quality health services, based on the findings of this survey.

The MOPH acknowledges the contribution of all stakeholders involved in this assessment and is also grateful to the technical and financial support of Management Sciences for Health’s (MSH) Strengthening Pharmaceutical Systems (SPS) Program, which operates with the financial assistance of U.S. Agency for International Development (USAID). I am looking forward to seeing more such programs implemented by this particular project.



H.E. Dr. Suraya Dafil

MOPH Acting Minister

EXECUTIVE SUMMARY

Introduction

The Afghanistan Ministry of Public Health (MoPH) with technical assistance from the Strengthening Pharmaceutical Systems (SPS) Program carried out a qualitative survey of medicines quality assurance assessment in Afghanistan.

This survey was undertaken to assess the entire pharmaceutical sector, both public and private, to establish existing capacities for the medicines regulation and control framework. The findings of this qualitative survey, together with the findings of the separately carried out quantitative medicines testing survey, will lead to the development of policies and strategies for a sustainable medicines quality assurance system for Afghanistan.

Methodology

The medicines quality assurance assessment was designed to achieve a fair representation of both public and private major institutions in the supply chain of pharmaceutical products at different levels. Secure urban and rural areas of the country were visited.

Predefined indicator data collection tools were used to guide the data collection process of the assessment.¹ To maximize resource utilization and avoid duplication, a set of tools was adapted from the Rapid Assessment of Medicines Quality Assurance and Medicines Quality Control Study, sponsored by USAID and the United States Pharmacopeia (USP) in March 2007. A set of data collection tools was extracted and developed for target groups in both public and private sectors at both the national and provincial levels, as well as for development partners. At the Ministerial level, a team of officials from the relevant agencies was assembled and the national level data collection tool was administered. The respondents represented top policy officials of the health, pharmaceutical and laboratory services. This ensured the validation of information provided by individuals.

At the provincial level, the data collection tool was administered to proportionally selected health facilities in the medicines supply chain – 90 private retailers, 8 public retailers, 22 private wholesalers, 1 public wholesaler, and 39 private importers. The development partners' data collection tool was administered to 35 Non-governmental Organization (NGOs) and 17 government agencies that play a direct role in the supply of medicines in Afghanistan.

Key Findings

The assessment shows weak capacity for existing medicines regulation and control in both the public and private sectors. There are no developed structures, procedures, and policies to properly regulate the pharmaceutical sector for quality assurance; and no national Good Manufacturing Practice (GMP) guidelines or any officially accepted guidelines for use in the country. Afghanistan follows pharmacopeial standards of eight different countries.

From 2007 to 2009, authorities approved 1190 items of medicinal products for importation. The number of applications for registration and importation of pharmaceutical products are unknown but totally in 2007, 2008 and 2009 respectively 297, 357 and 536 pharmaceutical products are registered

¹ Rapid Assessment of Medicines Quality Assurance and Medicines Quality Control, March 2007, Sponsored by USAID & USP

within the GDPA and allowed them for importation. Every 3 years the registered manufacturers (In Afghanistan the foreign manufacture are registered firstly and then its products are registered) who registered their products in Afghanistan should pay 5000 AFs (approximately USD 100) per each registered item. The capacity to handle the number of applications received was also lacking. Currently, there is a backlog of approximately 1100 applications.

The total number of generic pharmaceutical products officially registered in the country for human use is about 3,700, as of the end of 2009. In emergency situations, unregistered medicines are allowed into the country under the authorization of HE Minister for Public Health.

Two directorates, the General Directorate of Pharmaceutical Affairs (GDPA) and Health Laws and Regulation Directorate (HLRD), jointly carry out the functions of a Medicines Regulatory Authority (MRA). About 659 medicine importers are registered with the GDPA. Most importers have agencies in the provinces that also serve as medicine wholesalers.

A total of 11,720 retail pharmacies were registered in the country. Out of those, 10,400 registered with HLRD prior to June 2007 and the other 1,320 registered with GDPA between June 2007 and January 2010. Prior to June 2007, the registration of retail pharmacies was the responsibility of the HLRD, which has since been shifted to the GDPA.

There is a medicines law which requires revision to facilitate medicines regulation in accordance with current dynamics of the pharmaceutical sector. The 11-page National Medicines Policy covers only some thematic areas and those areas are covered inadequately. Standard operating procedures (SOPs) for licensing of practitioners or pharmaceutical establishments are non-existent.

Afghanistan has only one school for training pharmacists or pharmacy technicians. There are no mechanisms to license pharmaceutical practitioners and no continuous professional development program or requirement in place. There is no professional program with postgraduate training.

As of December 2010, there are estimated 868 pharmacists and 769 pharmacy technicians in the public/NGO sector.² There is no clearly separate information about the number of pharmacists and pharmacy technicians in the NGO sector. There is no data on the number of pharmacists working in the private sector. Afghanistan has one school for training pharmacists and an Institute of Health Science in Kabul where pharmacy technicians graduate from after two years of education.

The Food and Drugs Quality Control Department (FDQCD) carries out some basic tests. The facility has serious resource challenges: human, material, equipment, and financial.

The country has no mechanism or system for monitoring the quality of medicines, adverse medicine reactions, or product recall, which are critical post-marketing surveillance activities. There is no system in place for pharmacovigilance. No properly developed structures and systems are in place for the receipt and vetting of medicines promotion and advertising materials.

Conclusion

There is weak capacity for existing medicines regulation and control for both public and private sectors, and no functional medicine regulatory authority in Afghanistan. Structures, procedures, and

² General Directorate of Human Resource & General Directorate of Pharmaceutical Affairs of the MoPH.

policies to properly regulate the pharmaceutical sector for quality assurance are lacking. There is no GMP inspectorate or national GMP guidelines. Although policies, legislation, and regulations do exist, implementation is weak due to insufficient budgets, infrastructure, and technical human resources. Afghanistan does not have a mechanism or system for monitoring the quality of medicines, adverse medicine reactions, and medication errors. There is no system for pharmacovigilance.

INTRODUCTION

Medicine product quality and integrity have been identified as major concerns in several countries, especially in developing countries where assessments were performed.³ Adequate medicines legislation and regulations, a competent Medicines Regulatory Authority (MRA), and appropriate medicine information are required to ensure the safety, efficacy, and quality of medicines.⁴

All MRA functions must work in concert to provide effective public health protection. Key functions are: licensing, product quality assessment and registration, inspection of manufacturing facilities and supply channels, laboratory control, and post-marketing surveillance for quality assurance, adverse medicine reactions monitoring, and pharmaceutical promotion and advertisement control.

Legal structures are the foundation of medicines regulation. In some countries, medicines laws may not cover certain aspects of pharmaceutical activity. For example, the production of certain medicines for domestic use may not require compliance with Good Manufacturing Practice (GMP) or clinical survey data may not be the mandatory standard for medicines registration. Many MRAs do not provide documented standard procedures for registration; others do not have written guidelines and checklists for inspection. All these result in a regulatory gap and inconsistent enforcement of laws that leads to less clarity and a lack of coherence in the medicines regulatory process.

Since pharmaceuticals frequently are very expensive and therefore prone to counterfeiting and substandard production, the establishment of a viable and sustainable market protection through regulatory processes is essential. These processes must be capable of detecting unacceptable products to help provide a deterrent to unscrupulous manufacturers and suppliers.

Previous studies of the pharmaceutical sector of Afghanistan provide some insight into the medicines supply situation in the country. However, there are gaps in the scope and approach to assessing the entire pharmaceutical sector. The Strengthening Pharmaceutical Systems Program's (SPS) survey aimed to assess the pharmaceutical sector, both public and private, to establish the existing capacities for the medicines regulation and control framework, leading to the development of strategies for a sustainable medicines quality assurance system for Afghanistan.

The Afghanistan Medicines Quality Assurance Assessment – A Qualitative Survey included five key objectives which were to—

- Determine whether or not a functional and operational MRA exists and, if so, how it carries out its responsibilities;

³ SEAM Conference 2001. Roundtable #6: Ensuring Drug Product Quality. www.msh.org/seam/conference2001/roundtable6.html

⁴ Paterson, A. and A. Karimi. 2005. *Understanding Markets in Afghanistan: A Survey of the Market for Pharmaceuticals*. Kabul: Afghanistan Research and Evaluation Unit.

- Examine what approaches and mechanisms are used to assure the quality of medicines and pharmaceutical products sold;
- Identify strengths and weaknesses of medicines quality assurance;
- Identify opportunities and threats for medicines quality assurance;
- Make recommendations to the MoPH policy makers and authorities responsible for designing and developing the appropriate medicines quality assurance system.

GENERAL OVERVIEW OF AFGHANISTAN PHARMACEUTICAL SECTOR

The Health Sector of the Islamic Republic of Afghanistan in Brief

The Islamic Republic of Afghanistan has experienced a continuous state of civil war that has grossly affected national development and health indicators.⁵ Afghanistan had an estimated population of 25.5 million as of October 2009, which was predominantly rural (77.1 percent). Life expectancy for both males and females is 44 years.

Total annual government health expenditure is 162 million U.S. Dollars (USD), of which, USD 135 million comes from international aid in 2009. The country is endowed with several public sector health facilities of varying levels, from basic health centres to specialty hospitals. The majority of health facilities are comprehensive health centers (CHCs) (372) and basic health centers (BHCs) (779). There are 174 private hospitals in Afghanistan (Annex B).

As of December 2010, there are estimated 868 pharmacists and 769 pharmacy technicians in the public/NGO sector.⁶ There is no clearly separate information about the number of pharmacists and pharmacy technicians in the NGO sector. There is no data on the number of pharmacists working in the private sector. Afghanistan has one school for training pharmacists and an Institute of Health Science in Kabul where pharmacy technicians graduate from after two years of education.

Production and Importation of Pharmaceuticals

Before 1992, there was a developed pharmaceutical production capacity for pharmaceuticals in Afghanistan. Those pharmaceuticals that were imported from abroad mostly came through the state-owned enterprise, Avicenna Pharmaceutical Institute (API). At that time, there were few licensed private importers, however a large uncontrolled import of medicines from Pakistan and Iran existed in mujahidin-controlled areas in the 1980s and early 1990s.

When the government system began to collapse in the early 1990s, private individuals came to dominate pharmaceutical imports. The number of players in the private import of medicines increased during the conflict and the Taliban period. Medicines are now imported into Afghanistan via various routes— Europe, India, China, South-East Asia, Iran, Pakistan, and the Middle East.⁷

There is no pharmaceutical manufacturing plant for active pharmaceutical ingredients in the country. There are 13 manufacturing plants for finished dosage forms. Most of these are in the private sector. There is no export of pharmaceuticals. A research-based pharmaceutical industry is nonexistent.

⁵ <http://www.unfpa.org/emergencies/afghanistan/factsheet.htm> and <http://www.who.int/countries/afg/en/>

⁶ General Directorate of Human Resource & General Directorate of Pharmaceutical Affairs of the MoPH.

⁷ Anna Paterson and Asif Karimi. December 2005. Case Survey Series. Understanding Markets in Afghanistan: A Survey of the Market for Pharmaceuticals. Funding for this research was provided by the UK Department for International Development (DFID). Afghanistan Research and Evaluation Unit

There has been a dramatic increase in the quantity of donated and privately imported medicines entering Afghanistan since 2002, according to the MoPH and World Health Organization (WHO) sources. Furthermore, it is expected that Afghanistan will continue to rely on donations of medicines for a number of years to come.

The Afghanistan Pharmaceutical Market

Total government expenditure and per capita expenditure for the pharmaceutical sector are not known. Similarly, the total value of domestic pharmaceutical production, and imports and exports of active pharmaceutical ingredients and finished pharmaceutical products, is not known. This is attributed to the lack of a database or credible source for collecting this information. However, the GDPA estimates that annually the private sector and NGOs respectively hold medicines worth USD 80 million and USD 20 million respectively. Other sources estimate that the private sector accounts for between 70 and 80 percent of total pharmaceuticals consumption and the annual market may be worth up to USD 200 million.⁸

According to WHO (2002), the MoPH is not in a position to adequately control the quality of medicines entering the market. Regular and periodic testing of medicines is critical to controlling the quality of medicines in the country. A well-equipped laboratory with adequate equipment and well-trained human resources can contribute significantly to an efficient registration and licensing process. Afghanistan's FDQCD is operating under challenging conditions in a dilapidated structure. The facility is not internationally accredited and operates without any formal international quality control laboratory cooperation.⁹

Major technical and financial assistance would be required to reconstruct and restructure the pharmaceutical sector into one that would offer the appropriate level of services critically needed by the population. Building up the pharmaceutical sector would take years and would require long-term commitment from any partner involved in the country.¹⁰ However, since 2002, there has been a number of positive sector developments, particularly concerning the introduction of the donor-funded BPHS/EPHS providing essential medicine coverage to the population and the implementation of basic policy and regulatory systems and structures.

The U. K. Department for International Development (DFID) (2005) states that in Afghanistan, profit margins at the point of import, wholesale and retail are technically capped by the government at between 8 to 15 percent. But almost all players admitted that this was not followed in practice. However, many medicines on the market are cheap, but of low quality, as market players opt for cheap products to meet the demand of poor Afghanistan customers. The number of players is larger at every point in the supply chain than in other markets studied.

The EC states in its 2008 report that the Basic Package of Health Services (BPHS)/Essential Package of Hospital Services (EPHS) system has made several achievements since it was established in 2003, but the system is highly complex and suffers from lack of coordination

⁸ Ibid.

⁹ Jonathan Harper and Abdurrahman Shahab. Draft Afghanistan Pharmaceutical Sector Identification Mission Report, Intervention Scenarios for EC, November 2007 – January 2008.

¹⁰ Baghdadi, G. et al. *Pharmaceutical Situation in Afghanistan*

among the government, the MoPH, and the international donor community that funds it.¹¹ There are weaknesses in providing essential medicines through the BPHS/EPHS scheme. It is not clear what level of coverage the system is supposed to achieve in terms of supplying essential medicines to the population in need. At least 70 percent of essential medicines are provided through the private sector in spite of the BPHS/EPHS system.

Irrespective of the clear inadequacies that exist in the pharmaceutical policy and regulation system in Afghanistan, particularly with respect to a lack of enforcement, what the government and the international development community operating in Afghanistan both do not yet realize is that there is an increasing global threat from pharmaceutical crime.¹² Unsubstantiated reports suggest that Afghanistan is a “pharmaceutical dustbin” of substandard, counterfeit, adulterated, and diverted medicines as well as a transit point for such medicines for the entire region. Afghanistan’s adverse economic and geopolitical situation makes it a strong target for pharmaceutical crime.

The MoPH Commitment to Strengthening the Pharmaceutical Sector

The Afghanistan pharmaceutical sector suffers from a serious lack of sector information sharing among key sector stakeholders, and there is an absence of a formal sector policy making forum between the MoPH and development partners. The existence of a dual public and private system of essential medicine provision is not sustainable.”¹³

The MoPH has the responsibility to ensure that each medicine being distributed in the country is safe, effective, and of standard quality. The Ministry has for some time now demonstrated strong commitment to strengthening the pharmaceutical sector. For example, the MoPH has continuously supported the pharmaceutical and laboratory services despite its budgetary challenges. Furthermore, the Quality Assurance Task Force (QATF) was established at the MoPH to lead the process of developing appropriate strategies for medicines quality assurance for the country.

MoPH Assessments Supported by Major Foreign Stakeholders

MSH-Supported Pharmaceutical Sector Assessment

In 2002, Management Sciences for Health (MSH) selected 16 samples from a random selection of private pharmacies in Kabul and sent them for testing in Baltimore, Maryland, USA. The results of these tests were surprisingly positive, with only one sample failing to meet acceptable standards.¹⁴ The MSH report stressed that this sample did not represent a very broad selection, and there were clearly opportunities for more research.

¹¹ Harper, J. and A. Shahab. Draft Afghanistan Pharmaceutical Sector Identification Mission Report, Intervention Scenarios for EC, November 2007 – January 2008.

¹² Harper, J., and B. Gellie. 2006. *Counterfeit Medicines-Survey Report*. Strasbourg, France: Council of Europe.

¹³ Jonathan Harper and Abdurrahman Shahab. Draft Afghanistan Pharmaceutical Sector Identification Mission Report, Intervention Scenarios for EC, November 2007 – January 2008.

¹⁴ MSH Afghanistan Pharmaceutical Sector Assessment, 2002

WHO-Supported Pharmaceutical Sector Assessment

Also in 2002, a WHO team conducted a preliminary assessment of the pharmaceutical situation in Afghanistan. Selected sites in Kabul were visited including pharmaceutical manufacturing plants, warehouses, and a quality control laboratory.

According to the WHO survey, “the overall pharmaceutical situation in Afghanistan has deteriorated dramatically during the last 20 years, leading to a lack of most of the essential drugs in public health facilities.” The health infrastructure was seriously damaged and some buildings were completely destroyed, making it difficult for the staff to maintain professional standards. Though not well substantiated, the report states that the consumption of low-quality and ineffective medicines procured from the private and public facilities was widespread. There was a large influx of donated medicines to the country.

DFID-Supported Pharmaceutical Sector Assessment

The DFID supported a survey of the pharmaceutical sector in 2005 to gain insight into the experiences of Afghan business people in the private pharmaceuticals market. The scope of the assessment was very narrow, conducted in a small number of provinces.

The report states that there had been a dramatic increase in the quantity of both donated and privately imported medicines entering Afghanistan since 2002.¹⁵ In addition, there was widespread smuggling of medicines. According to DFID, the proportion of smuggled medicines may have been as high as 80 percent of all medicines sold in the private sector. The pharmaceuticals market was in chaos, and there was a bewildering array of products on sale.

There were more medicines importers and wholesalers, and more pharmacies, grocery stores, and street vendors selling pharmaceuticals than in 2002. Low quality and counterfeit medicines containing insufficient or no active ingredients were also found in the market. The report concluded that inspection, sampling, and testing facilities were inadequate to secure basic standards of medicines on the market.

Johns Hopkins University-Supported Pharmaceutical Sector Assessment

In 2007, the MoPH assessed the standard of medicine quality in BPHS health facilities with technical support from the Johns Hopkins University Bloomberg School of Public Health and the Indian Institute of Health Management Research.¹⁶ The results of this survey showed that “Afghanistan does not face a large problem of substandard medicines at the present time. The small sample size from the private sector, however, precludes one from drawing sweeping conclusions about the extent of substandard medicines in the for-profit private pharmaceutical market. These findings should not provide a false sense of security, especially in the absence of effective regulation.” The scope was limited to a sub-section of the public sector health care delivery system.

¹⁵ Paterson et al. *Understanding Markets in Afghanistan*.

¹⁶ Peters, D., A. A. Noor, L.P. Singh, et al. 2007. A balanced scorecard for health services in Afghanistan. *Bulletin of the World Health Organization* 85:146-151.

EC-Supported Pharmaceutical Sector Assessment

The EC carried out an assessment of the pharmaceutical sector in 2007–2008. The report examined all aspects of Afghanistan pharmaceutical sector functioning—market operations and financing, policy and regulation conduct, pharmaceutical donor activities in the sector as well as drawing on international comparisons.

The report states that the Afghanistan pharmaceutical market situation was completely out of control in all respects. Afghanistan was far from meeting international pharmaceutical regulatory and policy standards and practices or from guaranteeing medicine quality, safety, and efficacy. The report further pointed that some of the government’s policies actively encourage pharmaceutical crime. Based on interview information, the EC study stated that Afghanistan was a receptacle for substandard, counterfeit, adulterated, and diverted medicines; however, the assessment did not attempt to determine if medicines complied with standards through product quality testing.

Need for this Further Survey in Medicines Quality Assurance

Further studies in the area of medicines quality assurance, carried out with support from development partners, were necessitated by observed gaps in previous assessments of the pharmaceutical sector. The results of the various studies had conflicting conclusions, some of which were drawn from unsubstantiated positions. The MSH report stressed that the survey sample did not represent a broad selection, and there was clearly scope for more research in this field and that it was possible that fake medicines were targeted at more remote and poorer areas.

The WHO assessment was limited to a small number of manufacturing plants, warehouses, and the control laboratory - all located in Kabul. The DFID survey was conducted to gain insight into the experiences of Afghan business people in the private pharmaceuticals market. The scope of the assessment was very narrow, conducted in a small number of provinces.

The JHU survey results suggested that Afghanistan did not face a large problem of substandard medicines. The small sample size from the private sector, however, precluded one from drawing sweeping conclusions about the extent of substandard medicines in the for-profit private pharmaceutical market. The survey cautioned that the findings should not provide a false sense of security, especially in the absence of effective regulation.

The EC report, while providing detailed sector information and analysis, was not intended as a full pharmaceutical sector survey of Afghanistan, as ideally such a survey needed to be agreed to and performed with the input from all sector stakeholders. The report examined all aspects of Afghanistan pharmaceutical sector functioning—market operations and financing, policy and regulation conduct, pharmaceutical donor activities in the sector as well as drawing on international comparisons.

An assessment of the medicines control, regulatory, and licensing system needed to be carried out to determine what was actually in place and what needed to be done. The assessment also needed to fairly represent both urban and rural Afghanistan, and types of health facilities. For

this reason, the MoPH/GDPA and MSH/SPS Afghanistan felt an assessment of the country's medicines quality assurance system was warranted to provide a more objective way forward to develop strategies for an Afghanistan quality assurance system.

METHODOLOGY

Survey Planning and Implementation

The medicines quality assurance assessment was jointly carried out by the General Directorate of Pharmaceutical Affairs (GDPA) and SPS Program. The Quality Assurance Task Force (QATF), mandated by the MoPH, led the planning and implementation process with technical assistance from SPS Afghanistan and a team of external consultants. Approval for this survey was secured from the MoPH and USAID.

Survey Design

This analysis is based on collected information on quality assurance structures and processes, based on the rapid assessment of medicines quality assurance and medicines quality control. The design of the medicines quality assurance assessment was based on a framework of key variables for quality assurance.¹⁷ These included regulatory authority, policies and laws, regulatory activities, such as medicines registration and inspection, and post-marketing surveillance for quality assurance.

For the purpose of broad participation and collective ownership, 35 development partners and NGOs who directly participated in the medicines supply chain in Afghanistan were interviewed. Nearly two-thirds (20) of them are based in Kabul. Respondents are workers who have between 1 and 17 years of experience. Twenty-eight (80 percent) of the respondents are directly involved in the supply of medicines in their respective organizations.

Predefined indicator data collection tools were used to guide the data collection. The tools were adapted from the Rapid Assessment of Medicines Quality Assurance and Medicines Quality Control (Annexes E, F and G).

Data was collected mainly by pharmacists who had in-depth knowledge in medicines supply in Afghanistan. They were trained on the theoretical and practical aspects of the survey methodology, to ensure understanding. This was especially necessary as the documents and data collection tool were translated into Dari. The interviews were conducted in Dari or English as appropriate. The completed data collection tools were then translated into English for entry and analysis. The data were reviewed for consistency and accuracy by a team of consultants. All the necessary queries and questions were compiled and sent back to the QATF, which provided answers and clarifications.

¹⁷ Rapid Assessment of Medicines Quality Assurance and Medicines Quality Control, March 2007, Sponsored by USAID & USP

RESULTS OF THE MEDICINES QUALITY ASSURANCE ASSESSMENT

Regulatory Authority

A central administration office oversees key pharmaceutical activities and functions such as product assessment and registration, licensing of persons and pharmaceutical establishments or premises, inspection, development and implementation of technical standards, advertising and promotion, and post-marketing surveillance. This is a joint responsibility of the GDPA and HLRD of the central MoPH.

The professional qualifications of the Directors for the GDPA and HLRD are Bachelor's of Science and Medical Degree, respectively. The number and quality of professional staff members working at the central level are woefully inadequate (Table 1). There are no professionals with post-graduate training and there is no continuous professional development program in place for practitioners.

Table 1. Professional Staff Working on Medicines Quality Assurance at MoPH

Qualification	Pharmaceutical sciences	Medical sciences	Other sciences
Post-graduates	0	0	0
Graduates	30 (GDPA) 10 (HLRD)	1 (HLRD)	0
Technicians	10 (GDPA) 11 (HLRD)	0	0
Nurses and Administrators	0	1 (HLRD)	1 (HLRD)
Total	51	2	1

Two directorates, the GDPA and HLRD, jointly carry out the functions of a MRA. Their key functions include—

- Issuance of licenses for pharmaceutical production companies, importation of medicines, retail pharmacies, wholesale pharmacies, and medicines import companies (GDPA);
- Issuance of licenses for pharmaceutical practitioners to register wholesale and retail pharmacies (the GDPA for first time registration; the HLRD for renewal of agreement between owner and pharmacist);
- Registration of medicine import companies (the GDPA);
- Permission to import vaccines, narcotic and psychotropic medicines, and donated medicines (the GDPA);
- Supervision and monitoring of the pharmaceutical establishments and production of complementary medicines (the GDPA);
- Post-shipment inspection of imported medicines (the GDPA); and
- Inspection of retail pharmacies, wholesale pharmacies, importing company, and local production companies (the GDPA and the HLRD).

MRA government budget allocations for the last three years are not readily known. While it is reported that there is a unit/team for the assessment/evaluation and registration of medicines quality and cost-effectiveness, medicines safety and efficacy are not being assessed.

The GDPA has a technical board consisting of—

- General Director;
- Manager of Procurement and Registration Department;
- Manager of Supervision and Monitoring Department;
- Manager of Planning Department;
- Manager of Narcotic and Psychotropic Medicine;
- Faculty Representative the Faculty of Pharmacy of Kabul University; and
- Faculty Representative from the Pharmacology Department/Faculty of Medical University.

The board's responsibilities are to evaluate the cost of imported medicines, medicines production, and importation, and to identify medicine-related problems for submission to the National Medicines and Food Board (NMFB). In all, five officers/professionals are responsible for routine medicines registration within the MRA. These graduates of the Faculty of Pharmacy all hold a Bachelor of Science and have between 2 and 10 years of work experience in the field.

National Medicine Law

The first Afghanistan medicine-related law, enacted on August 27, 1976 was the “Law for Generic Medicines.” A new medicine law was enacted on February 24, 2007 to regulate production, importation and retail sale of medicines and medical supplies in the country. This was later revised on November 19, 2008.

The medicines law covers product registration, pharmaceutical establishment licensing, control of medicine importation, inspection services, monitoring for quality and adverse drug reactions, control of medicine promotion and advertising, and medicine quality testing/control. Not covered by the law are the control of medicine exportation and clinical trials.

The law provides for the establishment of the NMFB that consists of—

- The Minister of Public Health—Head
- General Director of Pharmaceutical Affairs—Deputy Head
- Director of Avicenna Pharmaceutical Institute—Member
- Two Lecturers of the Faculty of Pharmacy—Members
- One Representative of the Pharmacology Department of Kabul Medical University—Member
- One Representative of Procurement and Registration Department—Member
- Head of Pharmacy Enterprises—Member
- Head of Food and Drug Department—Member
- One Internal Medicine Specialist from a Hospital selected by the Minister of Public Health—Member

- Head of Legislation Implementation Ensuring Department (LIED)—Member
- One Surgical Specialist from a Hospital selected by the Minister of Public Health—Member
- Representative of the National Union of Drug Importers—Member
- Representative of the National Union of Drug Producers—Member
- Head of Monitoring and Evaluation Department—Member
- Head of Environmental Health Department—Member
- Head of Public Nutrition Department—Member
- Focal Person for Food and Drug Section of the National Office of Norms and Standards—Observer
- Representatives of the World Food Programme, Food and Agriculture Organization, the World Health Organization and UNICEF—Observers
- Focal Person for Food Control of the Ministry of Agriculture, Irrigation and Livestock—Observer
- Representative of the Ministry of Commerce—Observer
- Representative of Chamber of Commerce—Observer
- Representative of Traditional Treatment Union—Observer

The duties and responsibilities of the NMFB are very limited in scope. These include—

- Approving the Licensed Drugs List (LDL);
- Monitoring API's activities according to the relevant legislative document;
- Determining inclusion or exclusion of medicines from the LDL after the relevant department expresses their professional opinion;
- Reviewing the LDL once each year by the NMFB selected committee; and
- Making decisions regarding other relevant issues not provided for by law or other relevant legislative documents.

The current law provides for the inclusion of interest areas such as rational use of medicines, prescription format, and pharmacovigilance. Established periodic, regular and systematic approaches to national medicines policies review should allow for changing trends in medicines supply systems to be met adequately through a less cumbersome review processes.

The current law also has several defects in the definitions of some technical terminologies, possibly due to translation difficulties. For example, in the law, “active ingredient” is referred to as “effective substance”. Furthermore, “a pharmacist” is referred to as “a person who possesses higher education in the field of pharmacy”. The law has no provision for the registration of pharmacists in the country.

National Medicine Policy

The current National Medicine Policy for Afghanistan was promulgated in the year 2003. Areas briefly covered (though inadequately) by the 11-page policy include supply and control; efficacy, safety and quality; rational use; advertising and promotion; information; accessibility; financing, policy development; and selection. Areas not covered by the policy include the local manufacture procurement; donation; storage inventory management; distribution; pricing;

intellectual property rights; new and emerging diseases and medicines; human resource; research and development; technical cooperation and assistance development; implementation; monitoring and evaluation.

The medicine policy as currently presented does not follow the WHO's recommended format, which provides for specific policy direction lines for medicines quality assurance. A review of the policy and the development of an accompanying national pharmaceutical master plan are therefore needed.

Regulatory Activities

Medicines Registration

There are no established SOPs for the registration of medicines in the country. Key information required for the registration of medicines in Afghanistan include applicant information, manufacturer information, detailed formulation (e.g., dosage, form, strength, name and content of each ingredients, therapeutic indication), complete batch manufacturing record, packaging material, labeling detailed information, the product registration status in other countries, stability survey data, certificate of analysis, and registration and use in country of origin.

The registration system of Afghanistan is: that first of all the manufacture of the medicinal product should be registered and then its products are registered based on registered proforma. The intended marketed name, bioavailability/bioequivalence and clinical trials data are not required for registration of medicines. Based on the medicines law of Afghanistan, all the medicines are registered by their generic name only, not by brand name.

The registration fee for a generic product through registration of proforma is 5,000 Afghanis (approximately USD100) per item. However, the costs of registration application for newly branded or innovative products, changes to an application, or renewals are not available. Similarly, the specific budget allocated for medicines registration is non-existent.

Since 2007, there has been a continuous increase in the number of registered generic products—297 in 2007; 357 in 2008 (20 percent increase); and 536 in 2009 (50 percent increase) but the number of application for registration of medicinal product is not known. Three companies applied for change of names. The number of applications for registration of new branded or innovative products is unknown. In 2008, only one registration certificate of foreign manufacturer (In Afghanistan the foreign manufacture are registered firstly and then its products are registered) was renewed. This increased to 4 in 2009, and 10 certificates were under consideration or investigation at the end of 2009. No certificate was suspended or revoked in the last three years.

The registration validation period for companies is forever. Once a company is registered in the country (with GDPA), there is no need to renew the license.

The registration validation period for companies is forever. Once a company or medicine is registered in the country (with GDPA), there is no need to renew the license.

The total number of generic pharmaceutical products for human use officially registered in the country is about 3,700 out of about 1,800 in the LDL. Unregistered pharmaceutical products are formally permitted into the country by the MoPH in emergency situations. In general, it takes about six months between application submission and the date of issuance of the registration certificate to register a pharmaceutical product. There is no fast-track registration system in place.

The current registration system is completely paper-based. Guidelines on registration of foreign manufacturers and their medicines are available and freely accessible in hard copies in the form of terms and conditions for registration at the GDPA/Procurement and Registration Department of the MoPH. These are not available on the Internet.

Licensing of Practitioners and Pharmaceutical Establishments

There is no specific unit/team in charge of issuance, variation, suspension, and revocation of licenses for practitioners or pharmaceutical establishments; rather functions are split between the GDPA and the HLRD. The GDPA is responsible for issuance of licenses for medicine production and import companies and wholesale pharmacies and the HLRD handles licenses for pharmacy practitioners. There are no provincial or local authorities that issue licenses for establishments operating at provincial/district levels. Standard Operating Procedures (SOPs) for licensing of practitioners or pharmaceutical establishments are non-existent. Afghanistan has one school for training pharmacists and an Institute of Health Science in Kabul where pharmacy technicians graduate after two years of education.

By law, any Afghan over 18 year of age who does not have a criminal record and who meets all other legal requirements may obtain a license to engage in the manufacture, importation, and exportation, wholesale and retail sale of medicines. The individual must hire a pharmacist or pharmacy technician to oversee the technical management of the operations. Pharmacists have priority over pharmacy technicians in these activities.

The only key regulatory requirement for the approval of a retail pharmacy outlet license is the completion of a certified training program as a pharmacist or pharmacy technician. There are no restrictions on outlet locations based on population size or the sale of a specified list of medicines. Based on the medicines law, there should be a minimum distance of 200 meters between retail pharmacies. There are no fees for obtaining a license for a pharmaceutical establishment, except for the payment of royalties in accordance with the medicine law. The amount of royalty paid varies according to the type of establishment. Fees for retail pharmacies are charged in accordance with the category of business (Figure 1).

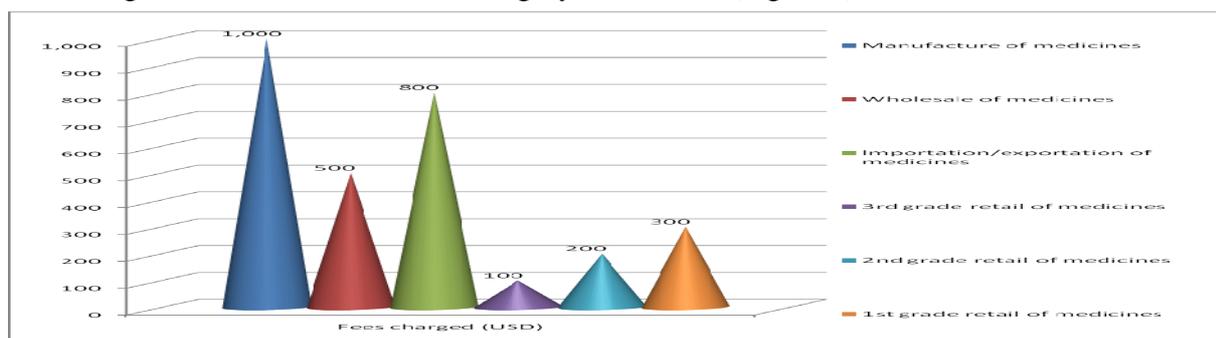


Figure 1. Royalty charges for the manufacture, wholesale, importation, and retail of medicines

In accordance with Article 19 of the Medicines Law, retail pharmacies shall be classified according to the amount of capital, their location and area as follows:

- First Class (First Grade) Retail Pharmacy:
 - Has a capital of at least one million (1,000,000) Afghanis;
 - Has an area of at least (53) square meters;
 - Located in the center of cities, densely populated areas and at a proximity of up to (500) meters of hospitals.
- Second Class (Second Grade) Retail Pharmacy:
 - Has capital of at least five hundred thousand (Afs. 500,000);
 - Has an area of at least (43) square meters;
 - Located in other areas of the capital and provinces.
- Third Class (Third Grade) Retail Pharmacy:
 - Has capital of at least three hundred thousand (Afs.300,000);
 - Has an area of at least (38) square meters;
 - Located in the remote areas, districts and villages.

Manufacture and Distribution of Medicines

There are no pharmaceutical manufacturing plants for the manufacture of active pharmaceutical ingredients in Afghanistan. Thirteen manufacturing plants manufacture finished dosage forms. Most (12/13) of these are in the private sector. Afghanistan does not export pharmaceuticals and a research-based pharmaceutical industry is non-existent.

In 2008, only one manufacturer/producer license was issued; the same in 2009. Two manufacturer/producer licenses were suspended in 2009 and two others were under consideration/investigation for possible suspension (Figure 2). No manufacturer/producer license was renewed, revoked, or pending. In 2008, only one illegal manufacturer/producer was identified. Prequalification inspection for GMP compliance of the manufacturing sites is not a precondition for licensing a manufacturing plant in Afghanistan.

About 659 Kabul-based medicine importers are registered with the GDPA. An additional 230 medicines importing companies/agencies/branches exist in the provinces. Of these, an estimated 150 importers are functional and actively importing medicines from other countries into Afghanistan. Most of the representatives of importers in the provinces also serve as wholesalers of medicines. Total annual value of medicines import is estimated at USD80 million and USD20 million for the private and NGO sectors respectively.

A total of 11,720 retail pharmacies were registered in the country. Out of those, 10,400 registered with HLRD prior to June 2007 and the other 1,320 registered with GDPA between June 2007 and January 2010. Prior to June 2007, the registration of retail pharmacies was the responsibility of the HLRD, which has since been shifted to the GDPA.

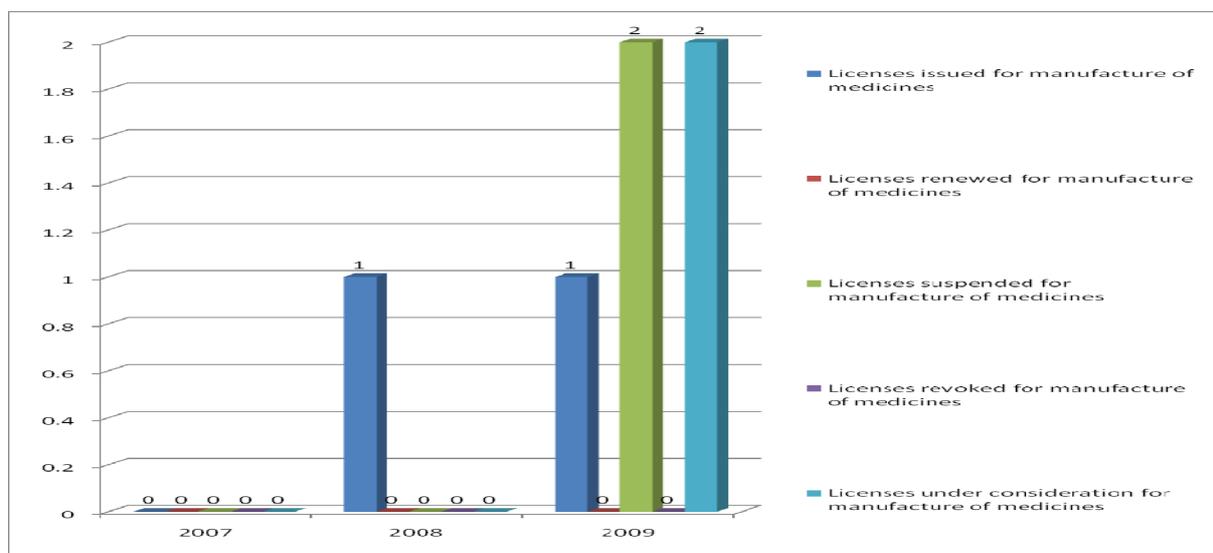


Figure 2. Licenses for the manufacture of medicines

The number of wholesaler/distributors/importers and exporters licenses that were issued fluctuated from 62 in 2007 to 50 in 2008 and 53 in 2009 (Figure 3). No license was renewed, suspended, revoked, or under consideration/investigation during this period.

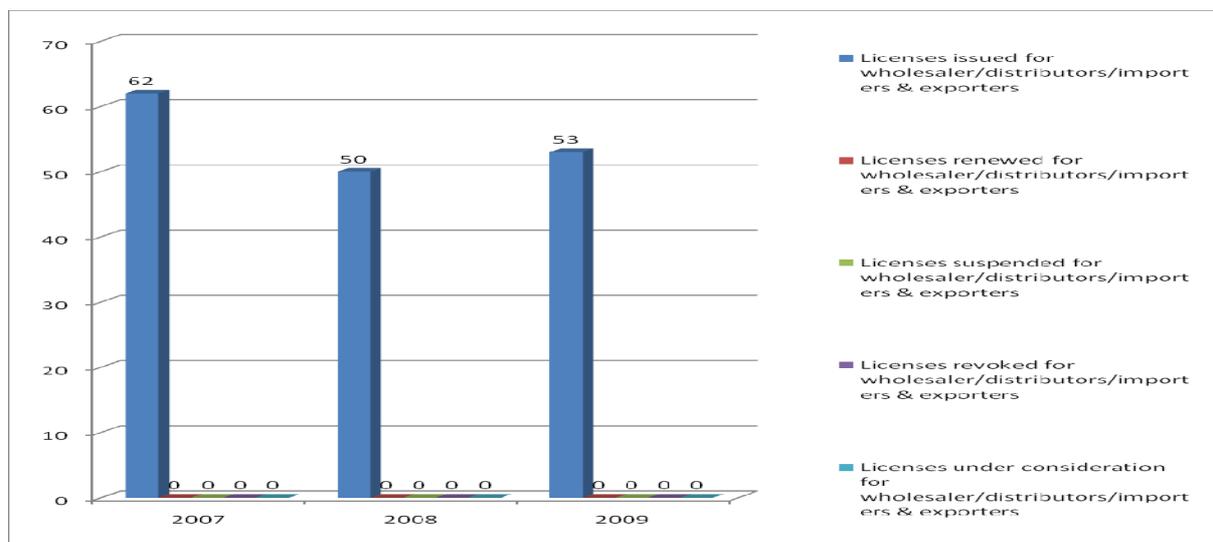


Figure 3. Licenses for the wholesale, importation, and exportation of medicine

The number of retail licenses issued was 354 in 2007, 425 in 2008, and 341 in 2009 (Figure 4). No retail license was renewed, suspended, revoked or under consideration/investigation during this period. According to the Supervision and Monitoring Department of the MoPH, illegal or unlicensed pharmaceutical establishments that sell pharmaceutical products exist in the country, but the total number of such facilities is not known.

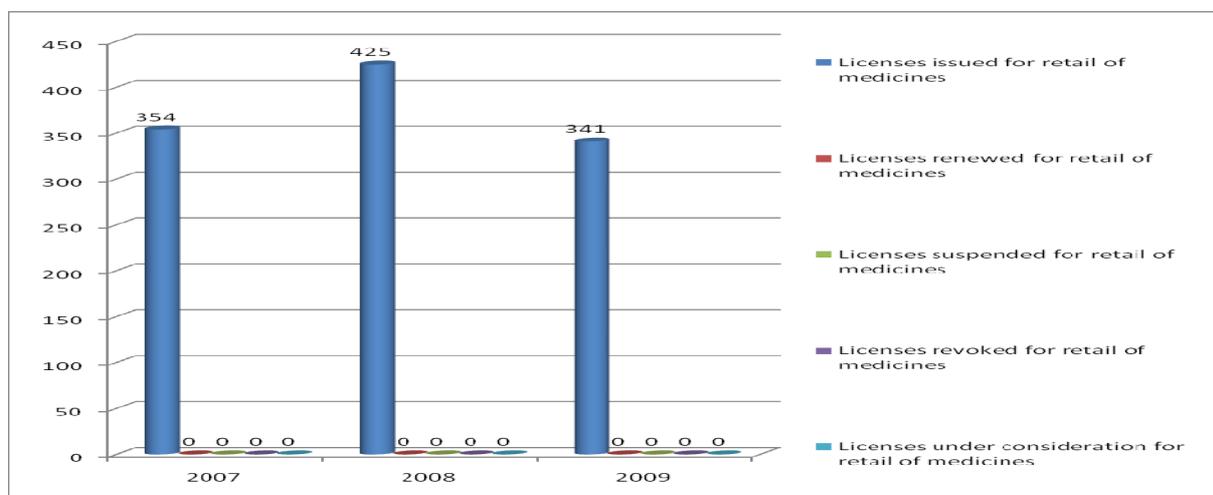


Figure 4. Licenses for the retail of medicines

There is no advisory or expert committee of appointed members from relevant agencies to make decisions on licensing. Typically a committee of agencies would include the national MRA, local authority, professional associations and other relevant stakeholders. The GDPA technical committee which includes representatives from the Faculty of Pharmacy and Medical University can only make decisions on the importation of medicines.

National Inspections of Services

There are no provisions in the medicine law/regulations defining the powers and status of GMP inspectors. Furthermore, there is no GMP inspectorate. There is no established relationship of GMP inspector(s) to the unit/division in charge of licensing of manufacturers and product registration unit/division. No national GMP guidelines exist in the country; there are also no manuals or SOPs for GMP inspectors.

The application of GMP guidelines/standards for manufacturing plants is compulsory and required by law (*Resolution on the Manufacture and Importation of Drugs and Medical Equipment – English Version*). Exact records on the number of inspections carried out per year for routine GMP inspection are not available. There is no checklist for GMP inspections. However, it is reported that about 12-13 inspections are carried each year in the country's manufacturing plants. There are no records on plants inspected for complaints. No administrative and regulatory measures have been taken against GMP noncompliant manufacturing plants in the past three years. There are no plans to increase the number of manufacturing plants to comply with GMP standards.

The medicines supply/distribution chain is also inspected regularly by the GDPA and HLRD. There are prepared checklists used for the registration and routine monitoring of facilities involved in the supply of medicines. As seen in Annex C, these include medicine manufacturing factories, governmental retail pharmacies, private retail pharmacies, private wholesale pharmacies, private hospital pharmacies, and import companies. Private wholesale pharmacies

and medicine import companies are inspected two to four times each year on average. The number of medicines samples collected and passing quality testing during distribution chain inspections was—

- In 2007, six samples were collected during inspection and all six samples (100 percent) passed;
- In 2008, eight samples were collected during inspection and four (50 percent) passed; and
- In 2009, thirty-nine samples collected during inspection and twelve (31 percent) passed.

Some administrative and/or regulatory measures are taken against practices related to producing and/or selling poor quality products. Written warnings were sent to 2 manufacturing, wholesale, and retail companies in 2007, 8 in 2008, and 9 in 2009. One license was suspended in 2009. In the same year, one product was recalled.

The GDPA and HLRD do not charge fees for inspection services for both GMP and distribution chain. The main constraints/challenges faced in carrying out inspection services are identified as low government budget allocations, limited numbers of qualified inspectors, lack of continuing education/training, lack of SOPs or guidelines, and limited access to relevant information on inspection.

Importation of Medicines

As part of this assessment, 39 out of 200 functional private importers of medicines from across the secure areas of the country were randomly visited, 28 of which are based in Kabul. Of the 39 private importers visited, 38 (97 percent) were duly licensed by the national authorities for the importation of medicines. The only unlicensed importer was located in Takhar Province. Of the total outlets visited, 31 (79 percent) of the attendants present at the time of the visit were the actual license holders.

As a result of weak control and enforcement in Afghanistan, medicines suppliers often go out of their way to conduct business outside their authorized scope. It was difficult to properly classify operations as solely import or wholesale, as importers also act as wholesalers for locally manufactured products. Twenty-nine (75 percent) importers are supplied directly by foreign manufacturers, while 4 (10 percent) importers are supplied by foreign wholesalers. Six (15 percent) importers acquired their medicines from other importers, and one importer from Kandahar was also supplied by a local manufacturer.

None of the medicines suppliers, either private or public, was prequalified by the importing companies. No pre-shipment inspection was carried out by the companies before accepting any consignment. Post-shipment inspection is carried out by the GDPA by sampling the medicines for analytical testing and checking the pro-forma invoices. No international agency is involved in the post-shipment inspection. All the wholesale outlets keep invoices which are used to trace the sources of medicines purchased.

Only 1 (3 percent), a Herat-based importer, had a cold storage facility. No other importing outlet has any form of cold storage for thermolabile medicines. All the wholesalers have incoming medicines receiving areas but they are not clearly separated from issuance (distribution) areas, and there are no quarantine areas or rooms. None of the wholesalers had basic laboratory testing facilities or SOPs for receiving and storing medicines. Inventory control systems are in place, though not well developed.

Most importing companies (77 percent) have paper-based inventory control systems. Only 11 (28 percent) use computer-based inventory control system, with two of them combining both paper-based and computer-based systems.

Expired medicines were found at only 1 (3 percent) - a Takhar-based importing outlet. All the other importing companies had no expired medicines on the premise at the time of visit. Air ventilation at most of the premises for importing medicines was inadequate. Only two outlets located in Herat had air conditioning; the remaining outlets were not air-conditioned.

Twenty-four (62 percent) of the importing company premises had been inspected by the national medicines authorities. The inspections were conducted to check for the presence of a pharmacist, storage procedures, expired products, the company license, the import license, poor quality medicines, tax documents, and the pricing list.

Pharmaceutical Distribution

Wholesale Level: Private Sector

Twenty-two out of 48 private wholesalers/distributors were proportionally selected from across the country for this survey. Out of these, 17 (77 percent) were duly licensed by the national medicines authorities as wholesalers. The unlicensed wholesalers were located in Baghlan, Herat, and Kabul Provinces. The outlets are essentially licensed as private retail outlets for medicines, but also sell medicines wholesale. Of the twenty-two outlets visited, 11 (50 percent) of the attendants present at the time of visit were the actual license holders.

Most wholesalers (64 percent) are supplied by local manufacturers, in addition to supplies from import companies. Importers supply 14 wholesalers (45 percent) and foreign wholesalers supply 10 (41 percent) with their medicines. Five (23 percent) of the wholesalers visited purchased their medicines directly from foreign manufacturers.

One wholesaler from Herat is supplied by an unlicensed dealer. It is not clear whether the supplier is prequalified by a national or international agency. All the wholesale outlets keep invoices which are used to trace the sources of medicines purchased. Only one Kabul-based wholesaler has cold storage facility. All the other wholesale outlets did not have any form of cold storage for thermolabile medicines.

All the wholesalers have incoming medicines receiving areas that are not clearly separated from issuance (distribution) areas. Four had quarantine areas or rooms. None of the wholesalers has basic laboratory testing facilities or SOPs for receiving and storing medicines. Proper inventory

control systems are generally lacking at the wholesale outlets. Only 4 (18 percent) out of the total number have some form of tools for inventory control.

Most (95 percent) wholesale outlets have paper-based inventory control systems. Only 5 (23 percent) use computer-based inventory control system, with 4 of them combining both paper-based and computer-based systems. Expired medicines are found at 7 (32 percent) of wholesaler outlets. Two of these are unlicensed wholesalers. None of the wholesale outlets has appropriate air ventilation or air conditioning.

Sixteen (73 percent) of the premises had been inspected by the national medicines authorities within the past year. The purpose of the inspections were to check for cleanliness of the outlet, existence of a refrigerator and thermometer, low quality, unlicensed, counterfeit and expired medicines, technical supervision, and wholesale license. The survey found that three of the inspected outlets were unlicensed wholesalers, which ironically did not get licensed or closed down by the national authorities.

Wholesale Level: Public Sector

The only Kabul-based public wholesaler, Pharmaceutical Enterprise, was identified and visited for this survey. The premise is licensed by the national medicine authorities. The outlet attendant at the time of visit is a government employee. The supply sources are both local manufacturing companies and foreign manufacturers. The medicine suppliers are not pre-qualified. There is no pre-shipment inspection carried out by the outlet before accepting any consignment. However, post-shipment inspection is carried out by the GDPA, which samples some medicines for analytical testing and also checks the invoices.

The wholesale outlet keeps all invoices, which are used to trace the sources of medicines purchased. The premise does not have cold storage facilities for thermolabile medicines. An incoming medicines receiving area is available but the outlet lacks a quarantine area, basic laboratory testing facilities, and SOPs for receiving and storing medicines. The inventory control system used is paper-based. No expired products are found on the premise. Air ventilation is inappropriate and there is no air conditioning. The outlet is inspected by the national medicines authorities to check on medicines quality.

Retail Level: Private Sector

A total of 90 private retailers of medicines in secure areas of the country – Herat, Badakhshan, Baghlan, Paktia, Kabul, Kandahar, Balkh, and Nangarhar Provinces – were visited for this survey. In Kabul, twenty (20) retailers were visited, and 10 retailers were visited in each province. All the retailers completed the data collection tool. Of the 20 retailers visited in Kabul, 15 (75 percent) are licensed by the national licensing authority. The other 5 (25 percent) retailers do not have licenses to sell medicines (Figure 5). Both Badakhshan and Kandahar had one retailer each without a license. Most of the attendants who presented at the time of visit are not

the license holders. Half of the private retailers visited in Balkh are license holders, but in Kandahar none of the attendants were holders of the license.

The sources of medicines for retailers are local manufacturers, local wholesalers, importers, and unlicensed suppliers. Local wholesalers are the biggest direct suppliers of medicines to retailers. Several retailers acquire their medicines from unlicensed sellers in Nangarhar (Figure 6). With the exception of one retail pharmacy each in Balkh, Kandahar, and Kabul, all the retailers visited keep all documents or papers, such as invoices, that can be used to trace the sources of medicines purchased. The retail outlet in Kabul which does not have documents is also not licensed.

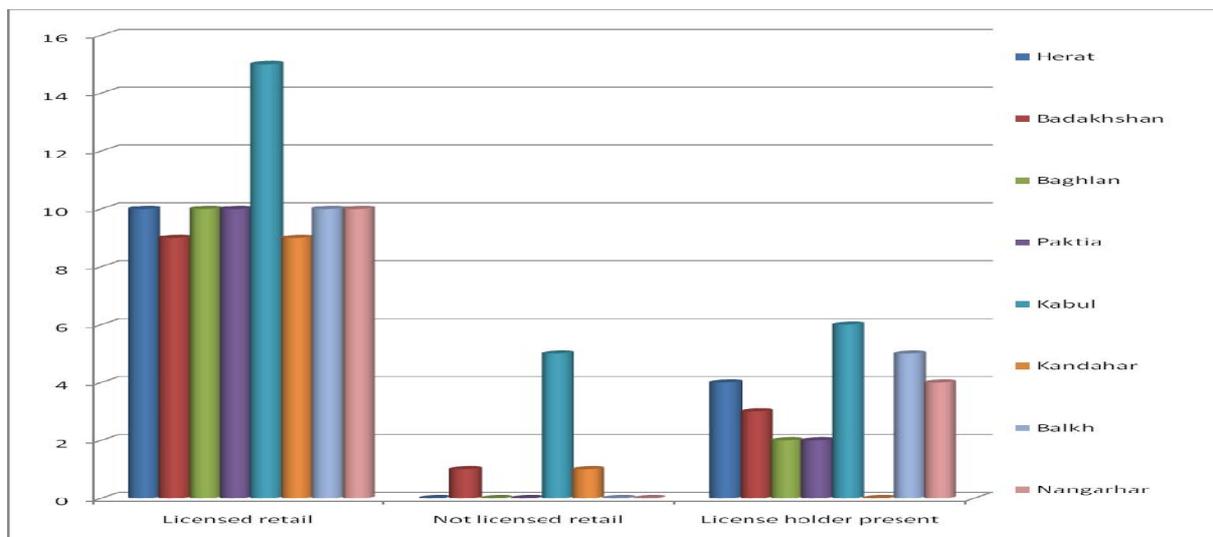


Figure 5. Private sector medicines retail licenses

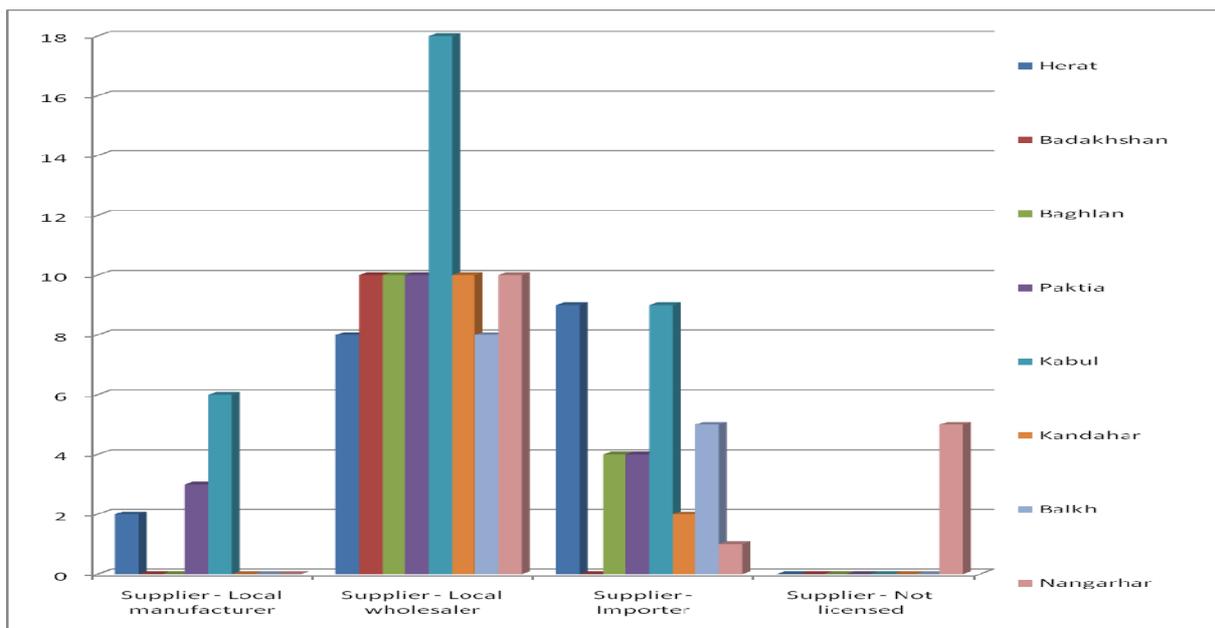


Figure 6. Source of supply of medicines to retailers in the provinces

As illustrated in Figure 7, expired medicines are found in all the retail pharmacies, with the exception of the retail pharmacies at Balkh. All the unlicensed retail outlets in Kabul also have expired medicines on their premises.

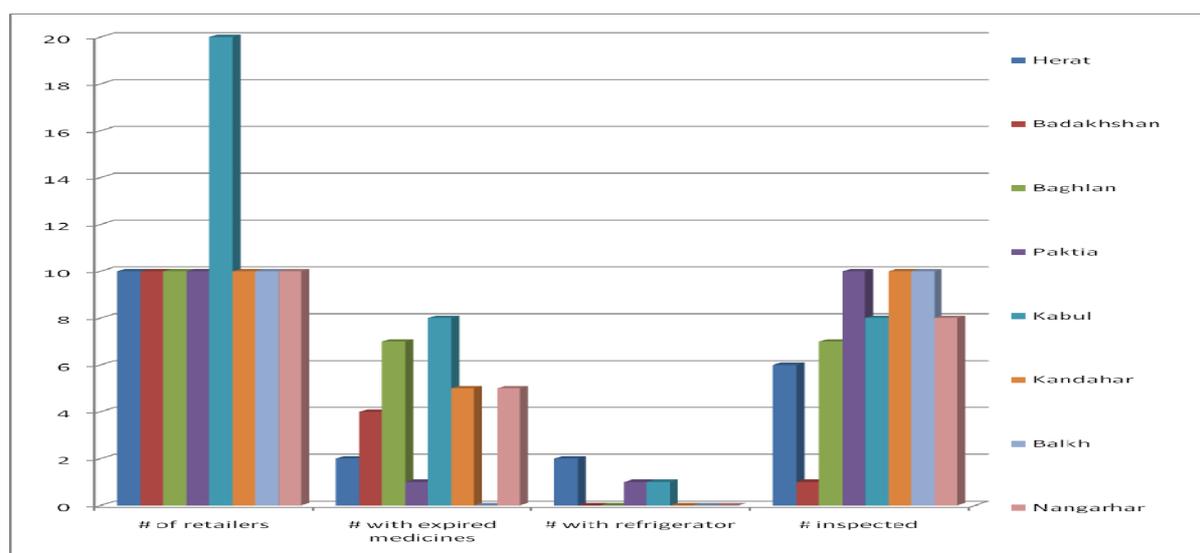


Figure 7. Expired medicines at retail pharmacies in the provinces

Refrigerators to store medicines requiring cold temperatures are seriously lacking in the retail outlets. Only two outlets in Herat and one outlet each in Paktia and Kabul have refrigerators. Therefore, it is clear that thermolabile medicines cannot be properly and safely stored in the retail outlets.

Most of the premises are inspected by the GDPA inspectors, with the exception of those in Badakhshan province. The number of inspections varies among the provinces. In some cases, retail facilities are visited by the local authorities. Generally, the inspections are performed to check for expired, low quality, counterfeit and unlicensed medicines, cleanliness of the outlet, presence of pharmacist, presence of identity cards, outlet paint quality, presence of emergency services, nighttime duty shift staff, and valid documents.

Retail Level: Public Sector

Eight public retail outlets in six provinces – Kabul (3), Nangarhar (1), Herat (1), Takhar (1), Balkh (1), and Baghlan (1), were visited. All these retail outlets are licensed by the national licensing authority, and the attendants present at the time are all government employees.

The only source of medicines supply is local wholesalers. There are no records of supply from local manufacturers or importers. All public retailers visited keep all documents or papers, such

as invoices, that can be used to trace the sources of medicines purchased. Only one outlet in Kabul had expired medicines at the time of the survey.

Refrigerator to store medicines requiring cold temperature are available at six out of eight of the public retail outlets visited. One outlet in Baghlan and another in Kabul (incidentally the one that had expired medicines on the premise) did not have cold storage abilities.

With the exception of the retail outlet at Badakhshan, all the outlets were inspected by the national authorities during the preceding year. The main purpose of the inspections is to check and control cleanliness of the outlet, low quality medicines, expiry of medicines, unlicensed products, costs of medicines, stock management, and staff uniforms.

Quality Control Laboratory Testing

The MoPH has a national laboratory (the FDQCD) with 14 functional and semi-functional units/divisions— registration, physical testing, chemical testing, biochemistry testing, herbal medicine testing, cosmetics, microbiology (semi-functional), toxicology (semi-functional), pharmacology (semi functional), pharmaco-dynamics (semi-functional), virology (semi-functional), research (semi-functional), instrument room, and reagents room.

The number working at the national laboratory and their technical capacity is woefully inadequate. There is no staff member with post-graduate training and no Continuous Professional Development (CPD) program in place for practitioners.

The national laboratory has the capacity to carry out identification of active pharmaceutical ingredients, hardness (for solid form), loss on drying, melting range, residue on ignition, disintegration, dissolution, assay for content of active pharmaceutical ingredients, impurities (ordinary), water content, viscosity, pH, total ash, titration, and density. However, the laboratory is unable to perform sterility, pyrogen, bacterial endotoxin, bioavailability, bioequivalence, or heavy metals testing. Equipment is available for the various pharmacopeial testing methods, however much of it is not functional.

Afghanistan has no national pharmacopeia. Eight pharmacopeias from other countries are used by the national laboratory, though these have not been officially adopted. The pharmacopeias are: British Pharmacopoeia, USP, Ph. Int., Japanese Pharmacopeia, German Pharmacopeia, Iranian Pharmacopeia, Indian Pharmacopeia, and European pharmacopoeia. This survey found that the total number of active pharmaceutical ingredient samples tested rose from 120 in 2007 to 150 in 2009. All the samples passed the analytical testing (Figure 8).

Several thousands of finished pharmaceutical products were tested over the period under review. The number however dropped in 2009. As seen in Figure 9, some medicines failed routine quality testing. About 24 samples of finished products were not routinely tested due to lack of the necessary equipment and reagents.

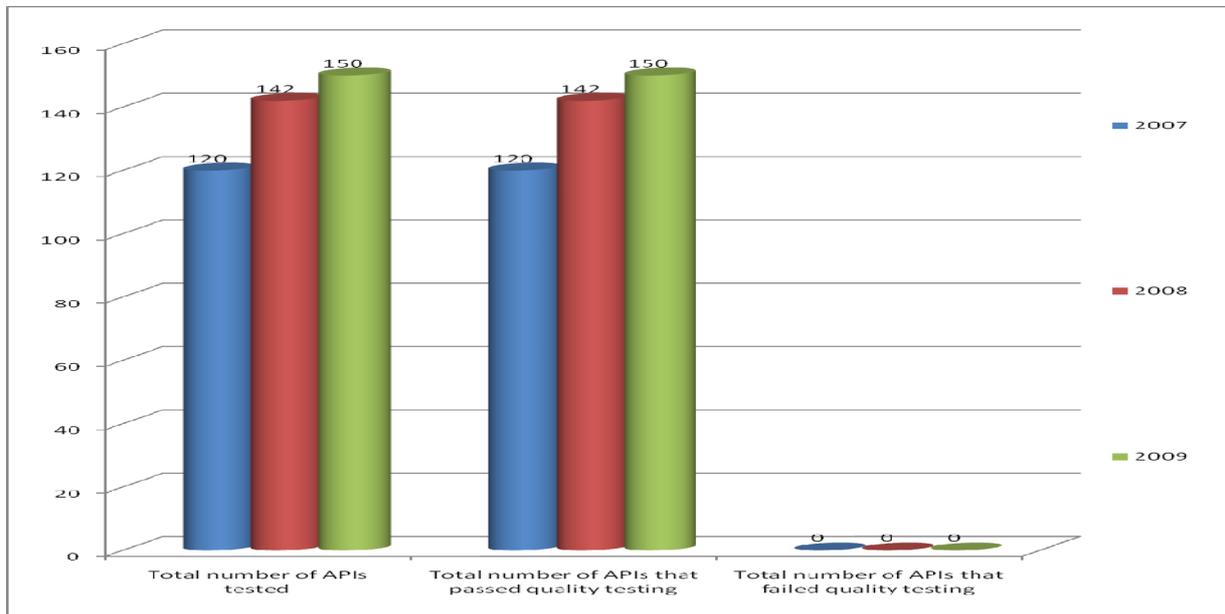


Figure 8. Routine analytical testing of active pharmaceutical ingredients

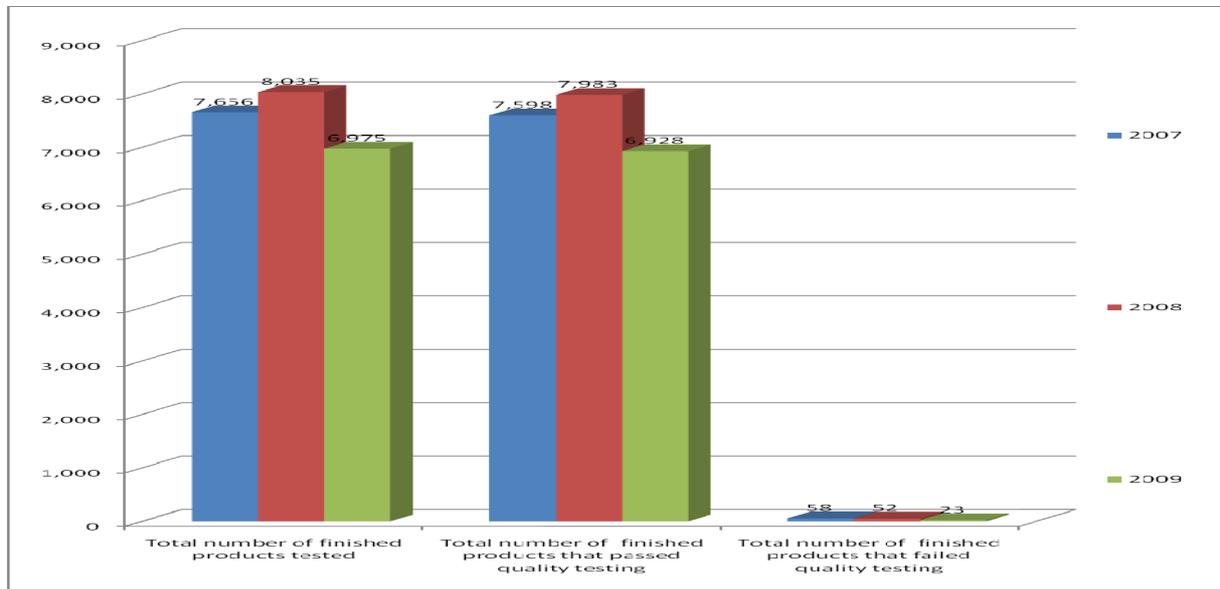


Figure 9. Routine analytical testing of finished pharmaceutical products done by the national laboratory

Antibiotics, antipyretics, anti-inflammatory agents, and antihypertensive medicines were the most common medicines groups that the laboratory tested in the last three years. Samples of medicines and active ingredients are brought in by private pharmaceutical production companies,

the GDPA and the HLRD of the MoPH. Ironically, the purpose for the quality testing of the medicines and active pharmaceutical ingredients is not clear. There are no data to show if the purpose is for quality monitoring, manufacturing in-process control, or administrative or regulatory action.

The laboratory charges a fee of USD24 per sample tested, using pharmacopeial methods. Revenue generated from laboratory charges is delivered to the government treasury. There is no specific budget allocation for the laboratory's operation and there are no allocations for laboratory equipment/instrument maintenance. The main sources of monies that trickle in for the day-to-day operations of the laboratory are from the government and donors. The annual costs for the salaries of the 44 laboratory technical and administration staff is about USD31,310.

Since its establishment, the laboratory has received financial or in-kind support from a few international agencies. For example, in 2004, the WHO donated USD83,000 for laboratory equipment, and in 2007, the Government of Finland donated USD300,000 for equipment and USD100,000 for the reconstruction of the laboratory.

Constraints and challenges faced by the FDQCD in conducting the various tests/assays in the laboratory include—

- Low government budget allocations;
- Limited numbers of qualified professionals;
- Lack of continuing education/training;
- Limited number of adequate laboratory equipment/instruments;
- Unavailability of certain reference standards/substances;
- Unavailability of pharmacopeia specifications or methods;
- Unavailability of certain reagents, solvents, and indicators;
- Irregular electricity supply; and
- Dilapidated building.

Despite the numerous constraints and challenges, the laboratory is reportedly managed according to Good Laboratory Practices (GLP). These practices include the existence and use of—

- A sample receiving/collection notebook;
- A laboratory notebook;
- An analytical work book or work sheet;
- A laboratory equipment log book;
- Safety rules and measures;
- Appropriate laboratory clothes, gloves, and goggles;
- Appropriate and separate storage room for reference substances, toxic and poisonous materials, and flammable chemicals;
- Standard operating procedures for testing and other activities; and
- An air-sucking chamber.

Working reagents, references, solutions, solvents, and samples in the laboratory are appropriately labeled (at least their name, concentration, date of preparation, initials of preparer, and count). Since its establishment, the laboratory has never participated in any international or regional assessment of professional and technical competency. Furthermore, the laboratory has never been requested to test a certain product's quality by an international agency or neighboring country. No complaints were ever received regarding testing results in the past three years.

Post-Marketing Surveillance Activities

Post-market surveillance covers monitoring the quality of medicines being distributed, adverse drug reactions, and medication errors. Surveillance also includes the control of medicines promotion and advertising.

The country does not have an established mechanism or system for monitoring medicines quality or recalling products, though there was one product recall in 2009. The country does not have any mechanism or system for monitoring problems related to the quality of medicines, adverse drug reactions, and medication errors. There is no system in place for pharmacovigilance and no provision for it in the national medicines policy. Though the national medicine policy has a chapter on advertising and promotion of medicines, there are no properly developed structures or systems to review or approve medicines promotion and advertising materials.

Development Partners, NGOs, and Government Agencies Participation

For the purpose of broad participation and collective ownership, representatives from 35 development partners and NGOs who directly participate in the medicines supply chain in Afghanistan were interviewed. Nearly two-thirds (20) of them are based in Kabul.

The organizational representatives who responded have between 1 and 17 years of work experience. Twenty-eight (80 percent) of the respondents were directly involved in the supply of medicines in their respective organizations.

Public sector and private organizations and agencies were asked their opinions about the systems and structures for quality assurance of medicines in country. Some of the challenges of medicines quality assurance that were identified include long and complex custom procedures and tax payment process, corruption in the public importation of medicines, inadequate control of the country's borders, poor enforcement of medicines law and regulation, lack of training, and high cost laboratory and analytical testing.

The interviewees identified several areas of collaboration with the MoPH. These include the implementation of BPHS/EPHS concept in accordance with the MoPH policies; supply of medicine to health facilities; donation of medicines; technical and professional coordination of medicine-related activities; inspection of medicines outlets; collection and disposal of expired medicines in accordance with national guidelines; collaboration in immunization, emergencies, epidemics, human resource development and projects financing. Annex D includes a summary of their responses.

CONCLUSION

The capacity for existing medicines regulation, control and enforcement for both public and private sectors is weak in Afghanistan. Developed structures, procedures, and policies to properly regulate the pharmaceutical sector for quality assurance are lacking. Medicines suppliers often go out of their way to conduct business outside their scope. There are no national GMP guidelines or any officially accepted guidelines for use in the country. Afghanistan officially follows pharmacopeial standards of several different countries.

Insufficient budgets, infrastructure and human resources, and lack of proper documentation on medicines quality assurance contribute to inefficiency in the analysis, decision making, and action process.

Despite existing challenges in the pharmaceutical sector, the MoPH staff, other government agencies, and development partners are highly committed and willing to work towards developing a sustainable medicines quality assurance system. The political commitment to the medicines quality assurance development process is demonstrated by the tremendous support received from the Minister of Public Health, the Deputy Minister of Public Health, Directors of the Ministry including the GDPA and HLRD.

RECOMMENDATION

The way forward for an improved quality assurance system for Afghanistan is a collective responsibility of all stakeholders. Based on the findings of this assessment, SPS makes the following recommendations—

1. Medicines regulation and control for both public and private sectors are critical to assuring the quality of pharmaceutical products. This can be achieved through improved structures, procedures, and policies. The formation and appointment of a medicines quality assurance technical advisory committee to support the NMFB could assist the development of strategies for a sustainable medicines quality assurance system for Afghanistan.
2. The national medicines quality control laboratory currently has human resource, managerial, structural and funding constraints. The laboratory should be developed and properly empowered to carry out mandatory analytical testing of medicines before registration and routine analysis after registration as necessary. The needed logistical support should be provided to the national laboratory to carry out this important medicines quality assurance activity. An effective product quality sampling and testing strategy should be developed that considers the use of simple methods to complement the pharmacopeial method testing that is done in the FDQL in Kabul. The complementary testing approach (discussed in the sampling and testing study report) could be implemented in selected provinces and points of entry for imported medicines to screen for potential counterfeit and/or grossly substandard products.
3. Record keeping and data management was also found to be deficient. Informed management decision is critical to sustainable medicines quality assurance. This would also ensure optimal utilization of resources through a reliable national planning process for continuous improvement in the pharmaceutical sector. There is need to establish a robust system for the collection, storage and utilization of data on the pharmaceutical sector.
4. The numbers and quality of professional and technical human resource for planning and implementing medicine quality assurance decisions are woefully inadequate. It is necessary to promote advocacy for the establishment of schools for the training of pharmacists and pharmacy technicians in the country. In the long term, this would improve on the availability and accessibility of local human resource in the country. The gaps to be filled and the number of years it will take to do so could be determined through a needs assessment.
5. The continuous professional development is critical to ensuring that providers are always abreast with quality assurance issues. As pertains in other countries, continuous professional development could be made a requirement for re-licensure on periodic basis. The necessary policy guidelines should be developed and implemented. Training institutions need to be identified and duly accredited. Proper documentation and reporting mechanisms should be put in place.

6. There is an obvious lack of proper regulation of providers and premises. The necessary legislative instrument should be put in place to properly regulate all practitioners in the pharmaceutical sector. The duly empowered regulatory body would ensure that in the public interest the right caliber of personnel to provide high quality services across the supply system. The body would also ensure that all outlets meet established requirements for medicines storage, distribution, transportation, and use.
7. Despite the wide spread perception about substandard medicines on the Afghanistan market, there is no mechanism or system for monitoring of quality of medicines, adverse medicine reactions and product recall as a critical post-marketing surveillance. The need to establish a pharmacovigilance system could therefore not be overemphasized. This should be integrated into the appropriate regulatory body to ensure cohesive control and sustainability.
8. A functional and sustainable medicines quality assurance system requires regular inflow of funds. Sustainable funding mechanisms are needed to support or sustain the medicines quality assurance system in Afghanistan. Local initiatives should be explored and encouraged as a major source of funding. Internally generated funds from the very operations of the relevant public institutions could be of immense support.

ANNEX A. NAMES AND AGENCIES OF DATA COLLECTION TEAM MEMBERS

Name	Title	Organization
Yusuf Inua	QA Consultant	MSH/SPS
Mohammad Zafar Omari	Country Team Leader	MSH/SPS-Kabul Afghanistan
Wahidullah Karwar	QA Advisor	MSH/SPS-Kabul Afghanistan
Abdul Zahir Siddiqui	RMU Advisor	MSH/SPS-Kabul Afghanistan
Abdul Tawab Khetab	Procurement Advisor	MSH/SPS-Kabul Afghanistan
Lotfullah Ehsas	RMU Officer	MSH/SPS-Kabul Afghanistan
Kamila Sultani	Director of Food and Drug Labs	MoPH
Khalil Khakzad	GDPA/MoPH Activities Coordinator	MoPH/GDPA
Zekria Fatehzada	Supervision and Evaluation Manager	MoPH/GDPA
Shaperi	Pharmacist	MoPH/GDPA/API
Salih Mohammad	Pharmacist	MoPH/GDPA
Mohibullah	Pharmacist	MoPH/GDPA/API
Abdul Rahim	Pharmacist	
Mohmmd Sabir	Pharmacist	MoPH/GDPA
Mahmood	Pharmacist	MoPH/GDPA
Nazir Ahmad	Planning Manager	MoPH/GDPA
Merza Mohammad Ayoobi	Deputy Director of Pharmaceutical Enterprise	MoPH/GDPA
Nasir	Pharmacist	MoPH/GDPA
Said Razashah Masomi	Manager of Pharmaceutical Establishment Department	MoPH/GDPA
Khalil	Pharmacist	MoPH/GDPA/API
Belal Ahmad	Pharmacist	MoPH/GDPA/API
Dawod Shah	Deputy Manager for Procurement and Registration	MoPH/GDPA/API
Mohammad Zarif	Manager of Narcotic and Psychotropic Medicines Department	MoPH/GDPA
Samiullah	Pharmacist	MoPH/GDPA
Ishaq	Pharmacist	MoPH/QC Labs
Mohammad Zaman	Pharmacist	MoPH/QC Labs
Abdul Hadi	Pharmacist	MoPH/GDPA
Abdul. Basir	Pharmacist	MoPH/QC Labs
Nangialai	Pharmacist	MoPH/GDPA
Nazir Ahmad	Pharmacist	MoPH/GDPA
Nasir Ahmad	Pharmacist	Nangarhar Provincial Health Directorate
Ezatullah	Pharmacist	MoPH/GDPA
Abdul Zahid	Pharmacist	MoPH/GDPA/API
Mohammad Monir	Pharmacist	MoPH/GDPA/API
Karimullah	Pharmacist	Khost Provincial Health Directorate
Said Sharif	Pharmacist	MoPH/GDPA
Sabrulhaq	Sampling Manager	MoPH/GDPA
Nasim	Pharmacist	MoPH/GDPA
Ajmal	Pharmacist	MoPH/GDPA
Hashmat	Pharmacist	MoPH/GDPA

Name	Title	Organization
Zabiullah	Pharmacist	MoPH/GDPA
Mohammad Naser	Pharmacist	MoPH/GDPA/API
Abdullah	Pharmacist	MoPH/GDPA
Ghulam Qader	Pharmacist	Balkh Provincial Health Directorate
Hamidullah	Pharmacist	MoPH/GDPA
Khalilullah	Pharmacist	MoPH/GDPA
Haji Dor Mohammad	Pharmacist	Kandahar Provincial Health Directorate
Aziz Ahmad	Pharmacist	MoPH/GDPA
Hedaytullah	Pharmacist	MoPH/GDPA
Said Mohammad Sajadi	Pharmacist	MoPH/GDPA/API
Amir Mohammad	Pharmacist	Baghlan Provincial Health Directorate
Nasir Ahmad	Pharmacist	MoPH/GDPA
Shabir Ahmad	Pharmacist	MoPH/GDPA
Najmudin	Pharmacist	Badakhshan Provincial Health Directorate
Ghulam Omar	Pharmacist	MoPH/GDPA
Shakila	Pharmacist	MoPH/GDPA/API
Karima	Pharmacist	MoPH/GDPA/API
Mohammad Asif	Pharmacist	Herat Provincial Health Directorate

ANNEX B. AFGHANISTAN DEMOGRAPHIC DATA

Item	Value	Source
Total Area	652,864 km ² .	Central Statistics Organization (CSO)
Number of Provinces	34	CSO
Number of Districts	354	CSO
Total Population—October 2009	25.5 million	CSO
Urban Population	5.5 million (22.9%)	CSO
Rural Population	18.5 million (77.1%)	CSO
Migrant Population	1.5 million	CSO
Life Expectancy— Males and Females	44 years	CSO
Literacy Rate (National Survey 2007)	26 %	CSO
Gross Domestic Product Per Capita – 2008	USD426	CSO
Infant Mortality Rate (Per 1000 Live Births)	111/1,000	MoPH/HMIS
Maternal Mortality Rate (Per 100,000)	1,400/100,000	MoPH/HMIS
Total Annual Government Health Expenditure	USD162 million	MoPH/HMIS
Total Annual Value of International Aid to Health Sector (2009)	USD135 million	MoPH/HMIS
Real Growth Rate (2007 Est.)	7.5%	CSO
Inflation Rate (2005 Est.)	16.3%	
Unemployment Rate (2005 Est.).	40%	CSO
Number of Special Hospitals	22	MoPH/HMIS
Number of Provincial Hospitals	30	MoPH/HMIS
Number of Regional Hospitals	5	MoPH/HMIS
Number of District Hospitals	60	MoPH/HMIS
Number of Comprehensive Health Centers (CHC)	372	MoPH/HMIS
Number of Basic Health Centers (BHC)	779	MoPH/HMIS
Number of Private Hospitals	174	MoPH/HMIS
Number of Sub Health Centers	305	MoPH/HMIS
Number of Mobile Clinics	47	MoPH/HMIS
Number of Other Facilities	79	MoPH/HMIS

ANNEX C. MOPH ROUTINE EVALUATION CHECKLISTS FOR PHARMACEUTICAL ESTABLISHMENTS

MoPH Routine Supervision and Evaluation Checklist for Medicine Import Companies

Date / /

Name of the company, name of manager and deputy of the company and phone number	Location	Evaluation date	Official document of imported medicine	Price list	Near to expiry and expired medicine	Is the existing medicine related to this company or related to other companies	Location and condition of stock	Technical responsible of the company	Other issues	Contentment of the company responsible
Company name										
Name of manager and phone #										
Name of deputy and phone #										
Company name										
Name of manager and phone #										
Name of deputy and Phone #										

MoPH Routine Supervision and Evaluation Checklist for Private Hospital Pharmacy

Date / /

#	Hospital Name	Location	Hospital manager identification	Pharmacist identification			Clean- liness	Uniform	Unlicensed medicine	Donated medicine (NGOs or donors medicine)	Expired medicine	Existence of the vaccinates	Remarks
			Name and phone #	Name	F/Name	Pharmacist ID card							
1													
2													

MoPH Routine Supervision and Evaluation Checklist for Private Wholesale Pharmacies

Date / /

#	Name of the wholesale pharmacy	Location	Owner identification and phone #		Pharmacist identification			Clean- liness	Near to expiry and expired medicine	Medicines did not receive from official import companies	Condition and location of stock	Existence of purchase document for present medicine in the wholesale pharmacy	Remarks
			Name	F/Name	Name	F/Name	Job location						
1													
2													

MoPH Routine Supervision and Evaluation Checklist for Private Retail Pharmacies

Date / /

	Pharmacy name	Location	Owner identification		Pharmacist identification			Clean- liness	Uniform	Unlicensed medicine	Helping medicine	Expired medicine	Existence of reservation room in the pharmacy	Remarks
			Name	F/Name	Name	F/Name	Job location							
1														
2														

MoPH Routine Supervision and Evaluation Checklist for Governmental Retail Pharmacies of Pharmaceutical Enterprise
Date / /

#	Stock name	Location	Responsible identification			Medicine procurement resources	Cleanliness	Uniform	Expired medicine	Availability of unlicensed/NGOs or donors and counterfeit medicine	Remarks
			Name	F/Name	Profession						
1											
2											

**MoPH Routine Supervision and Evaluation Checklist for Medicine Manufacturing
Factories**

Date / /

Factory name	
Name of the manager and deputy manager and phone numbers	
Location	
Name of technician responsible and his job location	
Name of lab responsible and his job location	
General condition and cleanliness of factory	
Status of laboratory	
Status and condition of production line	
Condition and cleanliness of stock	
Analysis of produced medicine	
Price list of produced product	
Analysis and control documents of raw material	
Supervision and evaluation date	
Other	
Satisfaction of the factory responsible from evaluation process	

ANNEX D. DETAILS OF DEVELOPMENT PARTNERS, NGOS, AND GOVERNMENT AGENCIES PARTICIPATION

For the purpose of broad participation and collective ownership, thirty-five development partners and NGOs who participated directly in the medicines supply chain in Afghanistan were interviewed. Most (20) of them were based in Kabul. The representatives of the various organizations who responded were workers who had 1 to 17 years of experience. Twenty-eight (80 percent) of the respondents were directly involved in the supply of medicines in their respective organizations.

Several areas of collaboration with the MoPH were identified. These include the implementation of BPHS/EPHS concept in accordance with the MoPH policies; supply of medicine to health facilities; donation of medicines; technical and professional coordination of medicine-related activities; inspection of medicines outlets; collection and disposal of expired medicines in accordance with national guidelines; collaboration in immunization, emergencies, epidemics, human resource development, reproductive health, and tuberculosis control; policy planning and implementation and projects financing.

Major Quality Assurance Challenges Identified by Development Partners

Based on their own experiences and anecdotal evidence, respondents outlined various challenges in the supply of medicines at the various levels. The major challenges identified by the development partners and NGOs were—

- Long and complex custom procedures and tax payment process;
- Entrance of low quality, unlicensed, counterfeit and near expiry medicines into the country;
- Import of medicines by unlicensed suppliers and dealers;
- Corruption in the importation of medicines;
- Inadequate control of the country's borders;
- Inadequate quality control laboratories;
- Establishment of too many medicine import companies;
- Lack of professional staff in the pharmaceutical sector;
- Lack of price of medicine control;
- Importation of same type of medicines with different brand names from several companies and countries;
- Poor enforcement of medicines law and regulation;
- Lack of training;
- Dispensing of medicine to the patient by non-professional people;
- High import tax on medicines;
- Lack of security;
- High cost laboratory analytical testing;
- Lack of standards for the supply of medicine;
- Low public awareness and education about the medicines;
- Lack of coordination among national and international organization;

- Incomplete prescriptions;
- Poor local production capacity;
- Lack of standard system for the disposal of expired and deteriorated medicines; and
- Lack of credit systems.

Achievements Identified by Development Partners

Some achievements were listed by the development partners and NGOs interviewed. These were—

- Publication of the LDL, EDL, and national formulary;
- Capacity building of staff;
- Introduction of computer in stocks management;
- Establishment of BPHS and EPHS;
- More functional GDPA organizational approach;
- Establishment of law and regulation in the pharmaceutical sector; and
- Establishment of system for strengthening capacity in the pharmaceutical sector.

Stakeholders were of the view that there is need to improve the system by appointing representatives of the various health professional associations on the national medicines and food board. There should also be total and full coordination amongst all stakeholders in solving of technical problems.

There is also need to develop the pre-service and in-service capacity for pharmacy professional staff. The media should be involved in the public education and awareness creation on medicine use. One comprehensive medicines register should be established for the country. Furthermore, the registration system should be changed entirely from paper-based to computer-based.

Collaboration with Government Agencies

Some officials from critical ministries and government agencies were interviewed to collect their views about the way forward for medicines quality assurance in Afghanistan. This is also to build bridges for future collaboration for purposeful government machinery mobilization. Seventeen (17) government agencies which were directly involved in the medicines supply chain in Afghanistan participated. The majority (9) of them were based in Kabul.

The ministries and agencies included the ministry of finance, ministry of food, ministry of communication, police, national security, national army customs, central medicines directorate, public health directorates, and procurement department. The officials who responded had 1–35 years of work experience in their various organizations. Sixteen (94 percent) of the respondents were directly involved in the supply of medicines in their respective agencies.

Areas of on-going collaboration with the MoPH were identified. These included the implementation of BPHS/EPHS concept in accordance with the MoPH policies; control of medicine and food on the markets; withdrawal of low quality and expired medicines; collaboration with provincial health directorates; enforcement of the medicines law, regulation

and policy; quarantine of medicines that fail quality test; checking of smuggling and substandard medicines; procurement of medicines and medical equipment; importation and disposal of medicines; donation of medicine by foreign organization; collaboration during national emergencies.

Major Quality Assurance Challenges Identified by Government Agencies

Based on their own experiences and anecdotal evidence, the officials outlined various challenges in the supply of medicines in the country. The major challenges identified by the government agencies were—

- Lack of coordination between private sector and public sector;
- Lack of MoPH commitment to ensure that medicine importers certify the quality of medicine;
- Lack of comprehensive standards and guidelines for medicines supply;
- Law enforcement in the supply of medicines;
- Medicines smuggling;
- Lack of quality control mechanisms;
- Lack of active participation of pharmacists in import, procurement, and distribution of medicines;
- Lack of QC laboratories in the provinces;
- Customs favoritism for international NGOs;
- Availability of low quality, unlicensed, counterfeit and expired medicines on the market;
- Dispensing of medicines without prescriptions;
- Poor border control;
- Irrational prescribing; and
- Corruption in the pharmaceutical sector.

Achievements Identified by Government Agencies

Some achievements were listed by the development partners and NGOs interviewed. These were—

- Reduction in availability of counterfeit and smuggled medicines;
- Publication of LDL and EDL;
- Establishment of medicine production factories by private sector;
- Approval by Ministries of Finance for building standard medicine stocks in five zones and at customs;
- High availability of medicines;
- Establishment of some small production companies;
- Reduction in custom clearance and process time;
- Existence of law, specific guidelines and policy;
- Establish of patient registration database;
- Encouragement of the private sector to investment;
- Strengthening of the procurement system; and
- Availability technical training in procurement.

Most officials were of the view that there should be proper coordination amongst all stakeholders in the pharmaceutical sector. They also felt that the procurement and importation of medicines should be centralized and carried out by the government (GDPA). The registration process should be made more transparent, and efforts should be made to curb corruption in the sector. A medicines information system should be developed to inform practitioners and the general public alike.

Please Note: Questions 1 – 9 to be completed by Central Statistics Department

Country Information

1. What is the area of Afghanistan? (*Square Kilometers*)

2. What is the number of provinces in Afghanistan?

3. What is the number of districts in Afghanistan?

Demographic Data

4. What is the total population of Afghanistan as at October 2009?

5. What is the population distribution of urban versus rural in Afghanistan?

6. What is the life expectancy for males?

7. What is the life expectancy for females?

8. What is the literacy rate?

9. What is the gross domestic product per capita (year)?

Please Note: Questions 10 – 21 to be completed by MoPH/HMIS Department

Health System Data

10. What is the infant mortality rate (per 1000 live births)?

11. What is the maternal mortality rate (per 100,000)?

12. What is the total Government health expenditure?

13. What is the total value of international aid for the health sector?

Number	Health Facility	Public	Private	NGO
14.	Special Hospitals			
15.	Provincial Hospitals			
16.	Regional Hospitals			
17.	District Hospitals			
18.	Comprehensive Health Centers			
19.	Basic Health Centers			
20.	Private Hospitals			
21.	Others (specify)			

Please Note: Questions 22 – 28 to be completed by GDPA

Pharmaceutical Sector Data

22. What is the total Government expenditure on medicines?

23. What is the per capita expenditure on medicines?

24. What is the total value of domestic pharmaceutical production?

25. What is the total value of imports of finished medicine products?

26. What is the total value of imports of Active Pharmaceutical Ingredients (APIs)?

27. What is the total value of exports of finished medicine products?

28. What is the total value of exports of APIs?

Please Note: Questions 29 – 36 to be completed by Ministry of Higher Education and HR Department of MoPH

Health and Pharmaceutical Human Resources

No.	Item	Public	Private	NGO
	Medical Schools			
	Pharmacy Schools			
	Pharmacy Polytechnics			
	Nursing Schools			
	Medical Doctors			
	Pharmacists			
	Nurses			
	Other Health Professionals (specify)			

Please Note: Questions 37 – 161 to be completed by GDPA

Pharmaceutical Sector Status

No.	Establishment	Public	Private	NGO
37.	Pharmaceutical manufacturing plants for APIs			
38.	Pharmaceutical manufacturing plants for finished dosage forms			
39.	Pharmaceutical manufacturing plants for packaging finished dosage forms			
40.	Pharmaceutical manufacturing plants for packaging materials			
41.	Research-based pharmaceutical industry			
42.	Pharmaceutical exporters			
43.	Pharmaceutical importers			
44.	Pharmaceutical wholesalers/distributors			
45.	Pharmaceutical Retailers			
46.	Medical Stores			
47.	Other (specify)			

Medicines Regulation

48. Does a medicine-related law/act/regulation exist?

- 1 Yes
- 2 No (*If No go to Q61*)

49. What is the title of the first medicine-related law/act/regulation?

50. Which year was the medicine-related law/act/regulation enacted?

Which of the following aspects does the medicine-related law/act/regulation cover:			
No.	Item	Yes	No
51.	Medicine product registration?		
52.	Pharmaceutical establishment licensing?		
53.	Control of medicine importation?		
54.	Control of medicine exportation?		
55.	Inspection services?		
56.	Monitoring for quality and Adverse Drug Reactions (ADR)?		
57.	Control of medicine promotion and advertising?		
58.	Medicine quality testing/control?		
59.	Control of clinical trials?		
60.	Others (specify)?		

61. Does a National Medicine Policy (NMP) exist?

- 1 Yes
- 2 No (*If No go to Q85*)

62. Which year was the NMP promulgated?

Which of the following aspects does the NMP cover:			
No.	Item	Yes	No
63.	Legislation, regulation and quality assurance		
64.	Local manufacture of medicines		
65.	Local manufacture of complementary medicines		
66.	Selection of medicines		
67.	Procurement of medicines		
68.	Donation of medicines		
69.	Storage of medicines		
70.	Inventory management		
71.	Distribution of medicines		
72.	Rational use of medicines		
73.	Medicines information		
74.	Therapeutics committees		
75.	New, emerging and re-emerging diseases and medicines		
76.	Financing and pricing of medicines		
77.	Global trade in pharmaceuticals		

78.	Advertising and promotion of medicines		
79.	Human resource development		
80.	Research and development		
81.	Technical cooperation and assistance		
82.	Policy implementation		
83.	Monitoring and evaluation		
84.	Others (specify)?		

85. Does a Medicine Regulatory Authority (MRA) exist?

- 1 Yes
- 2 No (*If No go to Q88*)

86. What are the key functions of the MRA?

87. What is the Government budget allocation for the MRA for the last three years?

Year	Amount (USD)
2009	
2008	
2007	

Pre-Marketing Quality Assessment

88. Does the MRA have a unit/team for the assessment/evaluation and registration of medicines?

- 1 Yes
- 2 No (*If No go to Q93*)

What aspects of the following does the unit/team assesses:

No.	Item	Yes	No
89.	Quality?		
90.	Safety?		
91.	Efficacy?		
92.	Cost-effectiveness?		

93. Does the MRA have a medicines evaluation committee consisting of appointed members from relevant disciplines whose role is making decision on product registration?

- 1 Yes
- 2 No (*If No go to Q103*)

What is their background:

No.	Category	Yes	No
94.	A Clinician from a major teaching hospital?		
95.	A Pharmacologist from teaching institution or major hospital?		
96.	A Regulatory Personnel from the MRA?		
97.	A General or Community Practitioner?		

98.	A Community Pharmacist?		
99.	A manufacturing or GMP Expert?		
100.	A Pediatrician?		
101.	A Representative from Consumer Associations?		
102.	Other (specify)?		

103. What is the present total number of officers/professionals responsible for routine medicine registration within the MRA?

104. What are their professional qualifications?

105. Are Standard Operating Procedures (SOPs) for medicine product registration available?

1 Yes

2 No (*If No go to Q107*)

106. What are the titles of the SOPs?

What key information is required for the registration:			
No.	Item	Yes	No
107.	Applicant information?		
108.	Manufacturer information?		
109.	Intended marketed name?		
110.	Detailed formulation (e.g., dosage, form, strength, name and content of each ingredients, therapeutic indication)?		
111.	Complete batch manufacturing record?		
112.	Packaging material?		
113.	Labeling detailed information?		
114.	The product registration status in other countries?		
115.	Stability survey data?		
116.	Bioavailability/bioequivalence data?		
117.	Clinical trials data?		
118.	Other (specify)?		

119. Do the same requirements apply for both branded/innovative and generic pharmaceutical products?

1 Yes

2 No

120. Please briefly explain.

No.	Item	Cost (USD)
121.	Application for registration of new branded/innovative product	
122.	Application for registration of a generic product	
123.	Application for change of application	
124.	Application for renewal	
125.	Other (specify)	

126. Is there a specific budget for medicine registration?

- 1 Yes
- 2 No (*If No go to Q128*)

127. What is the source?

Number of applications received for registration:				
No.	Item	2009	2008	2007
128.	Total number			
129.	Registration of new branded/innovative product			
130.	Registration of a generic product			
131.	Change of application			
132.	Other (specify)			

Number of medicines registration certificates issued, renewed, suspended or revoked:				
No.	Item	2009	2008	2007
133.	Issued			
134.	Renewed			
135.	Suspended			
136.	Revoked			
137.	Under consideration/investigation			
138.	Not-yet evaluated			
139.	Other (specify)			

140. What is the total number of pharmaceutical products for human use officially registered in the country?

141. What is the total number of **generic** pharmaceutical products for human use officially registered in the country?

142. What is the estimated total number of unregistered pharmaceutical products for human use available in the country?

143. Does the country allow the import of unregistered pharmaceutical products?
1 Yes
2 No
144. Please briefly explain.

145. What is the registration validation period? (*mark one answer only*)
1 2 years
2 3 years
3 4 years
4 5 years
5 > 5 years
146. What is the time (averagely) between application submission and the date of issuance of the registration certificate for registering a pharmaceutical product? (*mark one answer only*)
1 < 6 Months
2 6 – 12 months
3 1 – 2 years
4 > 2 years
147. Does a fast-track registration system exist?
1 Yes
2 No (*If No go to Q149*)
148. What are the conditions or requirements for a product to be eligible for fast-track registration?

149. Are guidelines or instructions on medicine registration available and freely accessible?
1 Yes
2 No (*If No go to Q152*)
150. Are guidelines or instructions on medicine registration available: (*mark all that apply*)
1 On the internet
2 World Wide Web (WWW)
3 In hard copies
151. Please specify the URL address.

152. What is the current registration system?
1 Paper-based
2 Computer-assisted

Regulatory Functions

153. Is there a central administration office that oversees key pharmaceutical activities and functions such as product assessment and registration, licensing of persons and pharmaceutical establishments or premises, inspection, development and implementation of technical requirements, advertisement and promotion, and post-marketing surveillance?
1 Yes
2 No (*If No go to Q162*)
154. Please state the name of that central administration.

155. What are the professional qualifications of the director?

156. What are the professional qualifications of the deputy directors?

Professional qualifications and the number of people working at central administration:				
No.	Qualification	Pharmaceutical sciences	Medical sciences	Other sciences
157.	Post-graduates			
158.	Graduates			
159.	Technicians			
160.	Other (specify)			
161.	Total			

Please Note: Questions 162 – 223 to be completed by GDPA and Health Laws and Regulations Directorate of MoPH

Licensing of Practitioners and Pharmaceutical Establishments

162. Is there a unit/team in charge of issuing, variation, suspension, and revocation of license for practitioners or pharmaceutical establishments?

- 1 Yes
- 2 No

163. What is the number of officers/professionals responsible for routine licensing?

164. List their professional qualifications:

165. Is the national MRA the only agency that issues the licenses for practitioners or pharmaceutical establishments in the country?

- 1 Yes
- 2 No

166. Are there provincial or local state authorities which also issue licenses for those establishments operating at provincial/state level?

- 1 Yes
- 2 No

167. Are there SOPs for licensing of practitioners or pharmaceutical establishments?

- 1 Yes
- 2 No (*If No go to Q169*)

168. What are the titles of the SOPs?

Key professional qualifications required to obtain a license to engage in or operate the following pharmaceutical activities:

No.	Practice/activity	Professional requirement
169.	Manufacturing	
170.	Importing/exporting	
171.	Wholesaling	
172.	Retail selling/pharmacy	

For retail pharmacy outlets, what are the key regulatory requirements to be met for license approval:

No.	Item	Yes	No
173.	Specified location e.g. based on population heads?		
174.	Specified list of medicines to abide with for sale?		
175.	Completion of certified pharmacy or dispensing training program?		
176.	Other (specify)?		

Number of manufacturer/producer licenses issued, renewed, suspended or revoked:

No.	Item	2009	2008	2007
177.	Issued			
178.	Renewed			
179.	Suspended			
180.	Revoked			
181.	Under consideration/investigation			
182.	Not-yet assessed			
183.	Other (specify)			

184. Is pre-qualified inspection for GMP compliance of the manufacturing site a pre-condition for licensing of a manufacturing plant?

- 1 Yes
- 2 No

Number of wholesaler/distributors/importers and exporters licenses issued, renewed, suspended or revoked:

No.	Item	2009	2008	2007
185.	Issued			
186.	Renewed			
187.	Suspended			
188.	Revoked			
189.	Under consideration/investigation			
190.	Not-yet assessed			
191.	Other (specify)			

What are the main requirements and qualifications to be met for license approval of a pharmaceutical wholesaler or distributor?			
No.	Item	Yes	No
192.	In compliance with regulatory requirements e.g. based on outcomes of the inspection		
193.	specified location		
194.	Professional qualification – e.g., pharmacist as technical manager		
195.	Adequate facility with proper air ventilation and air conditioning		
196.	Appropriate storage areas (cold, cool, and room temperature rooms)		
197.	At least 80 percent of the transport means are in good working conditions		
198.	Other (specify)?		

Number of retail pharmacies (of all categories, if different) licenses issued, renewed, suspended or revoked:				
No.	Item	2009	2008	2007
199.	Issued			
200.	Renewed			
201.	Suspended			
202.	Revoked			
203.	Under consideration/investigation			
204.	Not-yet assessed			
205.	Other (specify)			

Estimated total number of illegal (or unlicensed) pharmaceutical establishments for preparations for human use that engaged in the manufacture, import, export or retail sale of pharmaceutical products in the country:				
No.	Item	2009	2008	2007
206.	Manufacturer/producer			
207.	Wholesaler/importer/exporter			
208.	Retail pharmacy			
209.	Other (specify)			

A license validation applied to the following establishments:						
No.	Description	2 years	3 years	4 years	5 years	>5 years
210.	Manufacturer/producer					
211.	Wholesaler/importer/exporter					
212.	Retail pharmacy					

213. What is the average time span between application submission and the date of issuance of the license for retail pharmacy?
- 1 < 6 months
 - 2 6 – 12 months
 - 3 1 – 2 years
 - 4 > 2 years
214. Are guidelines or instructions on retail pharmacy licensing available and freely accessible?
- 1 Yes
 - 2 No (*If No go to Q217*)
215. Are guidelines or instructions on retail pharmacy licensing available: (*mark all that apply*)
- 4 On the internet
 - 5 World Wide Web (WWW)
 - 6 In hard copies
216. Please specify the URL address.
- -----
217. Does the MRA apply fees for service to the applicant of an application to obtain a license to operate a pharmaceutical establishment?
- 1 Yes
 - 2 No (*If No go to Q222*)

No.	Type of license	Fees charged (USD)
218.	Manufacturing pharmaceutical product	
219.	Wholesaling/distributing	
220.	Importing/exporting	
221.	Retail pharmacy	

222. In addition to the MRA staff persons in charge of licensing, is there an advisory or expert committee consisting of appointed members from relevant agencies whose role is making decision on licensing?
- 1 Yes
 - 2 No (*If No go to Q224*)
223. Which agencies are represented on the advisory or expert committee appointed to make decision on licensing?
- 1 National MRA
 - 2 Local authority
 - 3 Professional association
 - 4 Others (specify) -----

**Please Note: Questions 224 – 273 to be completed by QC Laboratories of MoPH
Laboratory Control and Testing**

224. Does a National Medicines Quality Control Laboratory (NMQCL) exist?
- 1 Yes
 - 2 No (*If No go to Q232*)

225. How many units/divisions does the NMQCL have?

226. Please list the name(s) of each unit/division:

Professional qualification and the number of people working at NMQCL:				
No.	Qualification	Pharmaceutical sciences/Pharmacy	Chemistry	Other (specify)
227.	Post-graduates			
228.	Graduates			
229.	Technicians			
230.	Other (specify)			

231. What are the types of tests or assays the laboratory can perform for pharmaceutical compounds? (*mark all that apply*)

- 1 Identification of APIs
- 2 Hardness (for solid form)
- 3 Loss on drying
- 4 Melting range
- 5 Residue on ignition
- 6 Disintegration
- 7 Dissolution
- 8 Assay for content of API
- 9 Sterility
- 10 Pyrogen
- 11 Bacterial endotoxin
- 12 Bioavailability
- 13 Bioequivalence
- 14 Impurities (ordinary impurities)
- 15 Water content
- 16 Heavy metals
- 17 Others (specify) -----

232. Does a national pharmacopeia exist?

- 1 Yes
- 2 No (*If No go to Q236*)

233. What is the name of the national pharmacopeia?

234. Which year was the national pharmacopeia first published?

235. What is the current edition of the national pharmacopeia?

236. List the name(s) of all pharmacopeias officially accepted for use in the country:

 Functioning laboratory equipment and instruments: Specify in the table below all equipment and instruments the laboratory possesses and provide the information required:

No.	Description of equipment/instrument	Model or type	Quantity	Year introduced in the laboratory	Functioning status
	<i>e.g., dissolution tester</i>	<i>Pharma Test PTZIE</i>	<i>1</i>	<i>1996</i>	<i>Working - requires calibrating</i>
237.					
238.					
239.					
240.					
241.					
242.					
243.					

244. What is the estimated maximum number of samples (including APIs and finished products) the laboratory is able to test per year?

Tests (with report of results) that were performed by the laboratory on APIs:				
No.	Item (APIs)	2009	2008	2007
245.	Total number of samples tested			
246.	Total number of samples that passed quality testing			
247.	Total number of that failed quality testing			

Tests (with report of results) that were performed by the laboratory on finished medicine products:				
No.	Item (finished medicine products)	2009	2008	2007
248.	Total number of samples tested			
249.	Total number of samples that passed quality testing			
250.	Total number of that failed quality testing			

251. Specify the most common medicines groups (e.g., antibiotic, antipyretic, anti-inflammatory, etc.) that the laboratory has tested in the last 3 years:

252. List the sources or agencies that have sent medicines samples or APIs and requests for testing?

Purposes for quality testing of medicines samples:				
No.	Purpose	2009	2008	2007
253.	Quality monitoring			
254.	Manufacturing (in process control)			
255.	Request from pharmaceutical company			
256.	Request from individuals			
257.	Administrative or regulatory action			
258.	Other (specify)			

259. Does the laboratory charge fees for testing services?
 1 Yes
 2 No (*If No go to Q261*)
260. What is the average fee the laboratory charges per sample testing using pharmacopeial method? (USD)

261. What is the total annual budget for the laboratory operation, including salaries of staff? (USD)

262. What is the total annual budget for the laboratory equipment/instrument maintenance? (USD)

263. Specify the major sources of budget for the laboratory operations/activities:
 1 Government
 2 Fees for services
 3 Donation (grants and aides)
264. Has the laboratory received any financial or in-kind support from any international agencies since its establishment?
 1 Yes
 2 No (*If No go to Q266*)
265. What is the estimated value(s) of support or type of equipment received? (USD)

266. What are the main constraints/challenges faced in conducting the various tests/assays in the laboratory? (*mark all that apply*)
 1 Financial constraints – low Government budget
 2 Limited numbers of qualified professionals
 3 Lack of continuing education/training
 4 Limited number of adequate lab equipment/instrument
 5 Unavailability of certain reference standards/substances
 6 Unavailability of pharmacopeial specifications or methods
 7 Unavailability of certain reagents, solvents, and indicators
 8 Others (specify) -----
267. Indicate if the laboratory management is with regard to some aspects of Good Laboratory Practices (GLP): (*mark all that apply*)
 1 Existence and use of sample receiving/collection notebook
 2 Existence and use of laboratory notebook

- 3 Existence and use of analytical work book or work sheet
 - 4 Existence and use of lab equipment log book
 - 5 Existence (in written document) of safety rules and measures applied
 - 6 Existence and use of appropriate lab clothes, gloves, goggles, etc.
 - 7 Existence and use of appropriate and separate storage room for reference substances, toxic and poisonous materials, and inflammable chemicals
 - 8 Working reagents, references, solutions, solvents, and samples are appropriately labeled (at least their name, concentration, date of preparation, initial of preparer, count, as necessary)
 - 9 Existence and use of standard operating procedures for testing and other activities
 - 10 Existence and use of air-sucking chamber
 - 11 Others (specify) -----
268. Has the laboratory participated in any international or regional assessment for professional and technical competency?
- 1 Yes
 - 2 No (*If No go to Q270*)
269. Describe the event and the year:

270. Has the laboratory ever been requested to test a certain product's quality by an international agency or neighboring countries?
- 1 Yes
 - 2 No (*If No go to Q272*)
271. Describe the event and the year:

272. Has the laboratory received any complaints regarding its testing results in the past three years?
- 3 Yes
 - 4 No (*If No go to Q274*)
273. Describe the event and the year:

Please Note: Questions 274 – 338 to be completed by GDPA and Health Laws and Regulations Directorate of MoPH

Inspection Services (GMP and Pharmaceutical Supply/Distribution Chains)

274. Are there provisions in the medicine law/regulations defining the powers and status of GMP inspectors?
- 1 Yes
 - 2 No
275. Is there a GMP inspectorate?
- 1 Yes
 - 2 No (*If No go to Q280*)

No.	Type of inspection	Total number (2009)
276.	GMP inspection	
277.	Distribution chain inspection	
278.	Other (e.g. investigational)	

279. Does the same Inspector perform both GMP inspection and distribution chain?
 1 Yes
 2 No
280. What is the relationship of GMP inspector(s) to the unit/division in charge of licensing of manufacturers and product registration unit/division?

281. Do national GMP guidelines exist?
 1 Yes
 2 No (*If No go to Q284*)
282. What is the name of the national GMP guidelines?

283. Which year was the national GMP guidelines introduced?

284. List the name(s) of all GMP guidelines (e.g. WHO, ASEAN) officially accepted for use in the country:

285. Are there manuals or SOPs for GMP inspectors?
 1 Yes
 2 No (*If No go to Q288*)
286. List the name(s) of manuals or SOPs for GMP inspectors:

287. What date(s) was/were the manuals or SOPs for GMP inspectors published?

288. What is the status of application of GMP guidelines/standards for manufacturing plants?
 1 Voluntary
 2 Compulsory (required by law)
289. What is the average number of inspections carried out per year for routine GMP inspection?

Information on current GMP inspection-related activities:				
No.	Number of plants and type of inspection	2009	2008	2007
290.	Total number of manufacturing plants in the country			
291.	Number of plants inspected and compliant to GMP			
292.	Number of plants inspected for renewal of license			
293.	Number of plants inspected because of complaints			
294.	Number of plants inspected as follow-up			
295.	Other (specify)			

Number of administrative and regulatory measures taken against GMP non-compliant manufacturing plants:				
No.	Measures taken	2009	2008	2007
296.	Written notice of warning			
297.	Fines			
298.	License suspended			
299.	License revoked			
300.	Production suspended			
301.	Other (specify)			

302. Is there a plan to increase the number of manufacturing plants to comply with GMP standards?

- 1 Yes
- 2 No (*If No go to Q305*)

Current target to increase GMP compliance				
No.	Item	2009	2008	2007
303.	Number of GMP noncompliant manufacturing plants			
304.	Number of GMP compliant plants			

305. Are there inspections in the medicine supply/distribution chain?

- 1 Yes
- 2 No (*If No go to Q307*)

306. What is the average number of inspections planned per year?

307. Are medicines samples collected by the inspector(s) during inspections?

- 1 Yes
- 2 No (*If No go to Q320*)

Total medicines samples collected and tested for:				
No.	Type of inspection	2009	2008	2007
308.	GMP inspection			
309.	Distribution chain inspection			
310.	Other (e.g. investigational)			
311.	Total			

Total medicines samples that passed quality testing for:				
No.	Type of inspection	2009	2008	2007
312.	GMP inspection			
313.	Distribution chain inspection			
314.	Other (e.g. investigational)			
315.	Total			

Total medicines samples that failed quality testing for:				
No.	Type of inspection	2009	2008	2007
316.	GMP inspection			
317.	Distribution chain inspection			
318.	Other (e.g. investigational)			
319.	Total			

Number of administrative and/or regulatory measures taken against practices related to producing and/or selling poor quality products:				
No.	Measures taken	2009	2008	2007
320.	Written notice of warning to manufacturer, wholesaler, and retailer			
321.	Fines			
322.	License suspended			
323.	License revoked			
324.	Pharmaceutical product recall by MRA			
325.	Pharmaceutical product withdrawal by the distributor or producer			
326.	Other (specify)			

327. Does MRA charge fees for inspection services for both GMP and distribution chain?
 1 Yes
 2 No (*If No go to Q331*)

Average fees charge for the type of inspection:				
No.	Type of inspection	Per hour (USD)	Per day (USD)	Per plant facility (USD)
328.	GMP inspection			
329.	Distribution chain inspection			
330.	Other (e.g. investigational)			

331. Is there a mechanism or system for monitoring of quality of medicines as post-marketing surveillance activity?

- 1 Yes
 2 No (*If No go to Q333*)

332. Briefly describe the mechanism:

333. Is there a product quality and adverse medicine reactions reporting mechanism or system?

- 1 Yes
 2 No (*If No go to Q335*)

334. Briefly describe the mechanism:

335. Is there a product recall mechanism or system?

3 Yes

4 No (*If No go to Q337*)

336. Briefly describe the mechanism:

337. What are the main constraints/challenges faced in carrying out inspection services? (*mark all the apply*)

1 Financial constraints – low Government budget

2 Limited numbers of qualified inspectors

3 Lack of continuing education/training

4 Lack of SOP or guidelines

5 Limited access to relevant information on inspection

6 Others (specify) -----

338. What is your opinion of the current system of medicine registration in terms of process (transparency, effectiveness), application time, availability of clear instructions, and fees?

Thank you

Please Note: Questions 339 – 372 to be completed in the Provinces

Retail Medicine Premise or Pharmacies

339. Is the premise licensed by the relevant medicine authority?
 1 Yes
 2 No (*If No go to Q3*)
340. Is the license for the premise still valid?
 1 Yes
 2 No
341. Is the outlet attendant at the time of visit the person who holds the license?
 1 Yes
 2 No
342. What are the main sources of the medicines sold in the outlet? (*mark all that apply*)
 1 Direct from local manufacturing companies
 2 From main domestic wholesaler(s)
 3 Others (specify) -----
343. Has the outlet kept all documents or papers, such as invoices, that can be used to trace the sources of medicines purchased?
 1 Yes
 2 No
344. Any expired-date products found on the premise?
 1 Yes
 2 No
345. Does the outlet have a refrigerator to store medicines requiring cold temperature?
 1 Yes
 2 No
346. Have medicines been kept out of direct sunlight?
 1 Yes
 2 No
347. Has the premise been inspected by the Inspector(s) from medicines authority?
 1 Yes
 2 No (*If No go to Q14*)

Inspections to the retail premise:			
No.	Number of inspections	Purpose of inspection	Month and Year
348.			
349.			
350.			
351.			

Wholesaler/Distributor

352. Is the premise licensed by the relevant medicine authority?
 1 Yes
 2 No (*If No go to Q16*)

353. Is the license for the premise still valid?
1 Yes
2 No
354. Is the outlet attendant at the time of visit the person who holds the license?
1 Yes
2 No
355. What are the main sources or suppliers of the medicines sold by the wholesaler? (*mark all that apply*)
1 Direct from local manufacturing companies
2 Direct from foreign manufacturers
3 From foreign or international distributors/suppliers
4 Others (specify) -----
356. Are the sources or suppliers of medicines pre-qualified?
1 Yes
2 No (*If No go to Q21*)
357. Who pre-qualified the sources or suppliers of medicines?
1 National agency
2 International agency
358. List the name(s) of the agencies:

359. Was pre- or post-shipment inspection carried out by the company before accepting any consignment?
1 Yes
2 No (*If No go to Q23*)
360. Who carried out the pre- or post-shipment inspection?
1 QA/QC personnel of the company
2 National medicines regulatory authority official
3 Sub-contracting private entity
361. Has the company kept all documents or papers, such as invoices, which can be used to trace the sources of medicines purchased?
1 Yes
2 No
362. Does the premise storage facility have cold and cool rooms?
1 Yes
2 No (*If No go to Q26*)
363. Does the storage facility have the following critical components? (*mark all that apply*)
1 Incoming medicines receiving area
2 Quarantine area or room
3 Basic laboratory testing facilities or room
4 SOPs for receiving and storing medicines
5 Inventory control system

364. What inventory control system is used?
 1 paper-based
 2 Computer-based
365. Are any expired-date products found in the premise?
 1 Yes
 2 No
366. Does the premise have appropriate air ventilation?
 1 Yes
 2 No
367. Does the premise have appropriate air conditioning?
 1 Yes
 2 No
368. Has the premise been inspected by the Inspector(s) from medicines authority?
 1 Yes
 2 No (*If No go to Q34*)

Inspections to the wholesale premise:			
No.	Number of inspections	Purpose of inspection	Month and Year
369.			
370.			
371.			

372. What is your opinion of the current system of medicine registration in terms of process (transparency, effectiveness), application time, availability of clear instructions, and fees?

Thank you

Please Note: Questions 373 – 382 to be completed by development partners and government agencies

373. How long have you been working with this organization?

374. How long have you been working in your current position?

375. Does your work relate in any way to the supply or management of medicines?

3 Yes

4 No (If No go to Q5)

376. Please explain how your work relates to the supply or management of medicines:

377. Please explain the type or nature of collaboration existing between your ministry/agency/organization and the MoPH?

378. Please explain the type or nature of collaboration existing between your ministry/agency/organization and other relevant ministry/agency/organization in relation to the supply or management of medicines?

379. In your opinion, what are the main **challenges** in the importation, exportation, regulation, procurement, storage, distribution, and use of medicines in Afghanistan?

380. In your opinion, what are the main **achievements** in the importation, exportation, regulation, procurement, storage, distribution, and use of medicines in Afghanistan?

381. What do you think your ministry/agency/organization can do to improve the general supply or management of medicines in Afghanistan?

382. What is your opinion of the current system of medicine registration in terms of process (transparency, effectiveness), application time, availability of clear instructions, and fees?

Thank you