Health Partners
AFGHANISTAN

ASSESSMENT OF THE PHARMACEUTICAL-MANUFACTURING INDUSTRY IN AFGHANISTAN

FINAL REPORT

HEALTH PARTNERS INTERNATIONAL OF CANADA (HPIC)
CAPACITY BUILDING AND ACCESS TO MEDICINES PROJECT (CBAM)

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Table of Contents

List of Tables 3

List of Acronyms 4

Executive Summary 7

1.0 Introduction 10

2.0 Rationale of the Assessment 11

3.0 Goal and Objectives of the Assessment 13

4.0 Methodology of the Assessment 13

5.0 Findings of the Assessment 17

5.1 Manufacturing Units 17

5.2 MoPH and Line Departments 28

5.3 Other Ministries 41

5.4 Faculty of Pharmacy, Kabul University 44

5.5 Pharmaceutical Associations 47

5.6 International Development Partners 51

5.7 Health Facilities (hospitals and pharmacies, both public and private) 59

5.8 Implementing Partners 64

5.8.4 Discussion 67

6.0 Conclusions 68

7.0 Recommendations 70

List of Tables Given in Annex 2

Table 1: List of Respondents Covered Under the Study

Table 2: List of Human Resources at Pharmaceutical Enterprise

Table 3: List of Equipment at Avicenna Pharmaceutical Industry

Table 4: List of Products Manufactured at M1

Table 5: List of Equipment at M1

Table 6: List of Equipment at M2

Table 7: List of Products Produced by M2

Table 8: List of Machinery and Equipment at M3

Table 9: List of Equipment Available at QC Laboratory, MoPH

Table 10: Minimum List of Equipment Required in an Ideal National QC Laboratory

Table 11: Course Curriculum of Pharm. D. at Kabul University

Table 12: List of Equipment Available at Faculty of Pharmacy, Kabul University

Table 13: List of Minimum Required Equipment/Apparatus for Pharm. D. Course in India for Intake of 30 Students

Table 14: Department List of Minimum Equipment Required for D. Pharm. (Two-year Diploma Course in India)

Table 15 A: List of Medicines in Demand (Pharmaceutical Enterprise)

Table 15B: List of Medicines in Demand Shared by Government Pharmacy

List of Acronyms

AADA : Agency for Assistance and Development of Afghanistan
ABC : Analysis of Benefits and Costs
ACCI : Afghanistan Chamber of Commerce and Industries
ACTD : Afghanistan Centre for Training and Development
AISA : Afghanistan Investment Support Agency
ALOS : Average Length of Stay
AMS : Afghanistan Mortality Survey
APHI : Afghan Public Health Institute
API : Avicenna Pharmaceutical Industry
ARI : Acute Respiratory Infection
ASMO : Afghanistan Social Marketing Organization
BP : British Pharmacopeia
BPHS : Basic Package of Health Services
CBAM : Capacity-Building and Access to Medicines Project
COMPRI-A : The Communication for Behavior Change: Expanding Access to Private Sector Health Products and Services in Afghanistan
DG : Director General
DTCs : Drug and Therapeutics Committees
EDL : Essential Drug List
EPHS : Essential Package of Health Services
FDI : Foreign Direct Investment
FGD : Focus Group Discussion
GAIN : Global Alliance for Improved Nutrition
GAVI HSS : Global Alliance for Vaccine and Immunization, Health System Strengthening
GDAA : General Directorate for Administrative Affairs
GDP : Gross Domestic Product
GDPA : General Directorate for Pharmaceutical Affairs
GDPP : General Directorate of Policy and Plan
GMPs : Good Manufacturing Practices
GLPs : Good Laboratory Practices
GoA : Government of Afghanistan
GTZ : German Technical Cooperation
HNTPO : Health Net Transcultural Psychosocial Organization
HPIC : Health Partners International of Canada
HR : Human Resource
IIHMR : Institute of Health Management Research, Jaipur, India
IGICH : Indira Gandhi Institute of Child Health, Kabul
ISAF : International Security Assistance Forces
ISO : International Organization for Standardization
JHU : Johns Hopkins University
LDL : Licensed Drug List
MNCs : Multi-National Corporations
MoPH : Ministry of Public Health, Afghanistan

MSH : Management Sciences for Health
NGOs : Non-governmental Organizations
OPD : Out-patient Departments
OPSC : Office for Private Sector Coordination
PE : Pharmaceutical Enterprise
PMEC : Pharmaceutical and Medical Equipment Committee
PPP : Public-Private Partnership
QC Lab : Quality Control Laboratory
ORS : Oral Rehydration Solution
RCH : Reproductive and Child Health
SOPs : Standard Operating Procedures
SPS : Strengthening Pharmaceutical System
STGs : Standard Treatment Guidelines
TB : Tuberculosis
TOR : Terms of Reference
UNDP : United Nations Development Program
UNFPA : United Nations Population Fund
USAID : The United States Agency for International Development
UNICEF : United Nations Children's Fund
USP : United States Pharmacopeia
VED : Vital, Essential and Desirable
WHO : World Health Organization

Executive Summary

The goal of the Capacity-Building and Access to Medicines (CBAM) project is to support the Ministry of Public Health (MoPH) in Afghanistan in ensuring greater and more equitable access to priority pharmaceuticals and medical supplies for all Afghans. The project has a special focus on women and children.

The pharmaceutical manufacturing and production industry plays a significant role in Afghanistan's ability to provide effective, quality medicines to the population. The pharmaceutical manufacturing industry is a complex system with many key players, which can be privately or publically, locally or internationally owned. Government regulates the industry. If quality is not assured, the population may suffer dire consequences.

The goal of this assessment is to determine the current capacities, strengths and weaknesses of the pharmaceutical-manufacturing industry in Afghanistan. The assessment reviews all sectors of the industry in the country, including the private, public and non-profit sectors. The objectives are to identify:

- *The manufacturing interests and operations that currently exist in Afghanistan.*
- *Enhanced opportunities for pharmaceutical-manufacturing industry development in Afghanistan.*
- *Past successes and failures to guide future recommendations.*
- *Strategies on how to implement essential changes.*

Overall, the assessment aims to improve understanding of the needs and opportunities that currently exist within the industry and to identify possibilities for developing local pharmaceutical manufacturing in Afghanistan.

The assessment was cross-sectional in design and qualitative in nature. The respondent categories include manufacturing units (both public and private), line departments of the MoPH, other government ministries, the Faculty of Pharmacy at Kabul University, international development partners, health facilities, implementing partners and various associations. A total of 36 respondents were interviewed and four onsite visits were made to manufacturing facilities.

The multiple difficulties being faced by manufacturing units are different for private and public sectors. The private sector laments the lack of land in an industrial area dedicated to pharmaceutical manufacturing, as well as a lack of electricity and incentives. They also state that the duty for importing raw materials is higher than for finished products. Despite these challenges, they continue to manufacture pharmaceutical products and maintain a positive outlook; some even plan to expand production in the near future.

Comparatively, the public sector is almost negligible. The only public manufacturing unit — Avicenna Pharmaceutical Industry (API) — is run by Pharmaceutical Enterprise (PE), under the MoPH.

API, once a vibrant pharmaceutical-manufacturing facility that produced 120 products, is currently manufacturing only five. There has been low motivation among staff due to poor salaries, a lack of raw materials and no initiative on the part of the MoPH and GDPA to address challenges. Staff also feels threatened by the possibility of privatization.

Despite this, the PE director said the plant aims to manufacture 50 per cent of all medicine produced in Afghanistan; the remaining 50 per cent would be produced by the private sector. However, PE has no vision document regarding this objective.

The international partners of the MoPH are not playing an active or direct role in the pharmaceutical-manufacturing sector. SPS is not supportive of the MoPH and GDPA in this sector. SPS feels the need for pharmaceuticals in Afghanistan is too low to support the optimum production capacities of a dedicated industry in the economy of scale, and that importing medicine is a better option. In addition, SPS maintains that most private and public manufacturing units have no GMPs and SOPs.

However, SPS continues to provide assistance to the MoPH/GDPA on the technical and policy side of activities, as they require. According to SPS, the major issues related to pharmaceuticals in Afghanistan are: too few staff for the regulatory body, limited professional competency, poor-quality products and lack of standardization of medicines. Further, there is no strict national GMPs enforcement.

The Faculty of Pharmacy at Kabul University is the only institution that teaches pharmacy in the country. However, the educational inputs pertaining to pharmaceutical manufacturing and quality control, including laboratory equipment for practical courses, are below par. Consequently, the country has an acute shortage of skilled and competent professionals in the pharmaceutical-manufacturing industry and in quality control.

At the time this report was written, the public health facilities were receiving drug supplies on a quarterly basis through the MoPH central medicine warehouse. The quantities they received were sufficient to last a maximum of one week (in the case of big hospitals, like the IGCH). Public health facilities generally wait between 20 to 30 days to receive drug supplies.

On the other hand, private facilities have a very simple and quick medicine-procurement procedure: the direct purchase of medicine from wholesalers. They do not experience medicine shortage. Rather, it is generally available to them in abundance, except for insulin and cancer-treatment drugs.

Various pharmaceutical associations also stated that the rules, regulations and procedures regarding the sale or production of pharmaceutical products in the country are quite cumbersome and time-consuming. The sale or production of medicine in Afghanistan is only permitted after the MoPh (QC Lab) issues its certification.

Based on the above findings, the assessment team made the following recommendations for the various categories of stakeholders:

Government of Afghanistan

(1) The GoA needs to develop a clear vision and roadmap for reviving the pharmaceutical sector, followed by strong advocacy measures both within the MoPH, line ministries and other related stakeholders.

(2) Clear intra and inter departmental communication and co-ordination must be developed.

(3) *Attractive incentives to promote pharmaceutical production must be introduced and clearly communicated to all stakeholders and investment-generating agencies, such as AISA. Incentives should include:*
   a. *Clear policy and action level guidelines*
   b. *One-window operations to promote investment in this sector*
   c. *Other incentives, such as provision of land, tax holidays, relaxation or exemption of duties for machinery imports in order to establish or expand operations*
   d. *Duty-free import of raw materials*
   e. *Tax reduction on net profits.*

(4) *The Faculty of Pharmacy at Kabul University must be improved, new Schools of Pharmacy in other universities must be established and a master's level program should be developed.*

(5) *AISA should attract and promote foreign investment through joint ventures or MNCs working in the region. Measures should be developed to reduce time consumed at international borders and to make this process hassle-free.*

(6) *English translations of all relevant acts, rules and regulations should be available to bring greater transparency and to attract foreign investment.*

Ministry of Public Health

(1) *At the outset, the MoPH should emphasize the pharmaceutical-manufacturing sector as a priority in its new strategic vision document. The ministry should develop a realistic vision, then document and share it with all stakeholders, including MoPH bodies and different concerned ministries, international partners, and public and private manufacturing units.*

(2) *There needs to be increased co-ordination between AISA, the Ministry of Economy and the Ministry of Commerce in order to attract and to promote investment in the pharmaceutical sector. Steps may be taken to revive API only after general consensus among the various ministries of Public Health, Economy and Finance. There must also be efforts to strengthen the GDPA and QC Lab.*

(3) *It also needs to develop and communicate SOPs and GMPs for pharmaceutical-manufacturing units progressively, considering the local environment and other factors.*

(4) *To address core grievances in the manufacturing units, the ministry should develop a mechanism for the expeditious processing of requests from manufacturers regarding the import of raw materials, as well as product testing.*

(5) *Attempts should be made to meet regularly with manufacturers in order to develop a better understanding of their issues, problems and planning and to solve/address these in a consistent manner.*

International Partners

(1) *Once pharmaceutical production becomes a documented priority, international partners should assist in developing the capacity of MoPH and GDPA staff, in particular technical staff, to enhance production.*

(2) *Based on a training-needs assessment, they should identify, in each sector of pharmaceutical production, areas where skill-building is required. They should also assist the MoPH in developing SOPs and GMPs for manufacturing units.*

Manufacturing Units

(1) Manufacturing units should adopt and use newer technology, build the capacity of their technical staff and strengthen in-house quality assurance of their products.
(2) Wherever possible, they should try to increase the range and quantity of their products and keep prices and quality competitive.
(3) They should follow SOPs as mandated by the MoPH once they are finalized.
(4) Manufacturing units should work closely with the government to phase in necessary incentives.
(5) They should continue to lobby relevant authorities and to advocate for their needs in a positive manner in view of gaining the support of authorities.

1.0 Introduction

The goal of the Capacity Building and Access to Medicines (CBAM) project is to support Afghanistan's Ministry of Public Health (MoPH) so that it may ensure greater and more equitable access to priority pharmaceuticals and medical supplies for all Afghans, especially women and children. The pharmaceutical manufacturing industry plays a significant role in Afghanistan's ability to provide effective, quality medicines to the population.

The CBAM project is committed to conducting an assessment of the current status of the said industry in Afghanistan, which is a complex system with many key players. It consists of facilities that manufacture medicine and medical supplies, as well as businesses that supply raw materials, pack finished products and sell the final products. These businesses can be privately or publically, locally or internationally owned. The Government of Afghanistan (GoA) regulates the industry. This industry is a major stakeholder, and the health of the population may suffer dire consequences if quality is not assured.

The objectives of the assessment are to identify:

- Manufacturing interests and operations that currently exist in Afghanistan.
- Enhanced opportunities for the development of the pharmaceutical industry in Afghanistan.
- Past successes and failures to guide future recommendations and strategies on how to implement essential changes.

Overall, the assessment is aimed at improving understanding of the needs and opportunities that currently exist within the industry and identifying possibilities for the development of local pharmaceutical manufacturing operations in Afghanistan.

This assessment explores various aspects of the industry and includes, but is not limited to, the following areas:

- The role of the GoA, including laws, regulations and control of the industry, as well as human and physical resources in Afghanistan.
- Current international initiatives, laws, regulations and standards, as they apply to Afghanistan.
- Private and public investments.
- Distribution mechanisms.
- The three phases of pharmaceutical production: Primary production (manufacturing active pharmaceutical ingredients and intermediates); secondary production (finishing dosage forms from excipient, non-active ingredients and active ingredients), tertiary production (packaging finished products or repackaging bulk finished products).[1]
- Herbal and alternative medicine production.
- Regional development in pharmaceutical production and manufacturing.

The results of this assessment were shared with the stakeholders at a two-day meeting in June. The goal of the meeting was to come up with recommendations for the future of the industry in the country.

finalizedfinalized1 How to Develop and Implement a national drug policy, photocopied sheet

2.0 Rationale of the Assessment

HPIC visited the Avicenna Pharmaceutical Institute (API), private industry stakeholders and stakeholders at the MoPH to discuss the need to assess the industry as part of the CBAM project.

HPIC learned that Afghanistan once had a very good pharmaceutical industry. In the 1970s, the country was able to produce most of the medicine that the population required and was developing an export market.

However, just like many other industries in Afghanistan, the pharmaceutical industry was negatively impacted by decades of war.

Today, less than 5 per cent of the total pharmaceuticals needed in the country are produced locally. Of these, the majority is produced in liquid or suspension, topical-solution and ointments forms. The more modern technology needed to produce tablets, capsules, injections and infusions is lacking.

Currently, most pharmaceuticals in Afghanistan are imported, and there is growing concern about their quality, especially those from Pakistan.[2]

According to the Terms of Reference (TOR) (Annex 1) developed by HPIC, the GoA aims to produce locally up to 50 per cent of the required essential medicines by 2013. A new branch of the MoPH, dedicated to the relationship between government and the private sector, was created to increase the quality and quantity of health-care services and supplies. This new branch is called the Office for Private Sector Co-ordination (OPSC). It demonstrates the importance that the GoA and the MoPH place on private-sector development and co-operation[3], as well as on the pharmaceutical-manufacturing industry and other health-care-related industries. It was consulted for this assessment.

Furthermore, this assessment is aimed at contributing to the decisions of industry and government leaders in determining the future of pharmaceutical production. It is expected that, with greater understanding of the industry among government and interested partners, Afghanistan can create a local industry that is responsive to the population's needs and makes high-quality medicines readily available in the country.

The TOR also states that, before 1992, Afghanistan had developed pharmaceutical-production capacity through the state-owned Avicenna Pharmaceutical Institute (API), and Hoechst Pharma Company, a public-private venture, as well as with many small-scale enterprises. After the end of the Soviet invasion and during the civil unrest that followed, most multinational corporations pulled out of Afghanistan. With the fall of the Taliban Government in 2001, a few multinationals returned. Some bilateral and multilateral aid initiatives reestablished a pharmaceutical-production industry in Afghanistan. Current and past attempts include:

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[2]European Commission (Nov 2007-Jan 2008), "Afghanistan pharmaceutical sector identification mission report: Intervention scenarios for EC."

[3] USAID, Afghanistan (October 2007-september 2008), "COMPRI-A Social Marketing Project: Annual Progress Report."

- Hochpharma, previously called Hoechst Pharma, which is incorporated into Sanofi-Aventis; it was reportedly privatized in c. 2008, but the GoA still holds 15 per cent.
- American Afghan United Incorporated Pharmaceuticals began recently and has a factory in Kabul. It is 100 per cent foreign-owned and has been developing generic tablet medication (seven products to start) for sale in the local market as an alternative to imports.
- Baz International Pharmaceutical Company Ltd., was launched by the Swiss Business Humanitarian Forum, the European Generic Medicines Association and the UNDP Country Office in Kabul. It plans to produce urgently needed medicine for the local market.
- Khalid Irshad Pharmaceuticals is the first Afghan pharmaceutical company to achieve ISO 9001:2000 accreditation in May 2009. It manufactures water treatment solution and oral rehydration salts as part of the COMPRI-A/ASMO project.
- COMPRI-A is a four-year project, funded by USAID, intended to build capacity in the private sector and to produce affordable health and family planning products for low-income groups, including oral contraceptive pills, injectable contraceptives, condoms, water purification solutions, and oral rehydration salts, among other products. It is planning to launch Iron Folate tablets. The COMPRI-A project has now ended and has been replaced with a local organization called ASMO, who is continuing the work of the project.

The TOR states that API is owned by the GoA, specifically by the Ministry of Finance, which receives all profits. However, it is on a list of state-owned enterprises slated for privatization. Prior to the 1990s, API was producing approximately 120 generic medicines; however, war and conflict dramatically reduced its production capabilities. It reopened operations officially in 2007 and is only producing a limited number of products.

There are also small and privately owned pharmaceutical-manufacturing enterprises starting in Afghanistan — about 12 to 14, according to recent data— which are contributing to the industry's growth.

After the completion of the assessment, HPIC worked with stakeholders to develop an action plan. HPIC is also working with the international pharmaceutical industry to identify key contacts in Canada or regionally.

Research conducted previously in Afghanistan suggests that, "(t)here is good justification (both for economic and public health reasons) for building local capacity in the production of essential generics, herbal/traditional medicines, infusion solutions and medicinal gases."[4]

[4] European Commission (Nov 2007-Jan 2008). "Afghanistan pharmaceutical sector identification mission report: Intervention scenarios for EC."

3.0 Goal and Objectives of the Assessment

Goal:
The goal of the assessment is to determine the current capacities, strengths and weaknesses of the pharmaceutical-manufacturing industry in Afghanistan. The assessment reviewed all sectors of the manufacturing industry in the country, including private, public and non-profit sectors.

Objectives:

1. Conduct an information review of any documents and sources of information pertaining to the Afghan pharmaceutical-production industry, as well as relevant regional information, international guidelines and literature.
2. Conduct an assessment of the pharmaceutical-manufacturing industry in Afghanistan, including the following (others to be identified throughout assessment process):
    - role of the GoA
    - role of pharmaceutical associations in Afghanistan, such as the Afghanistan Medicine Services Union
    - current international initiatives, such as COMPRI-A/ASMO
    - private and public investments
    - regulations and laws of the industry
    - licensing regulations
    - import and export regulations
    - international laws, regulations and standards
    - regional development in pharmaceutical production and manufacturing
    - the three phases of pharmaceutical production:
        - primary production (manufacturing active pharmaceutical ingredients and intermediates)
        - secondary production (finishing dosage forms from excipients (non-active ingredients) and active substances)
        - tertiary production (packaging finished products or repackaging bulk finished products)[5]
    - production of herbal and alternative medicine
    - distribution mechanisms
    - quality control mechanisms
    - controlling contraband pharmaceuticals
    - human and physical resources
    - opportunities and barriers.
3. Compile data in a report, including recommendations for how industry, government and non-government players in the pharmaceutical production industry can move forward to increase access to pharmaceuticals for the people of Afghanistan.

4.0 Methodology of the Assessment

[5] How to Develop and Implement a national drug policy (Ref: HPIC ToR)

4.1 Methodology

The following qualitative techniques were used for data collection:

- in-depth interviews
- key-informant interviews
- group discussions
- pharmaceutical manufacturing site visits

These techniques were selected, in view of HPIC's timeline and information requirements.

In-depth interviews: These were helpful in understanding the views and opinions of respondents, who represented the various stakeholders. The following categories of stakeholders were covered using in-depth interviews:

MoPH

- Director, GDPA Procurement and Registration
- Pharmaceutical Enterprise
- Director, Food and Drug Quality Control Department
- General Director Administrative Affairs
- Adviser, Private Sector Co-ordination Office
- General Directorate of Policy and Planning
- Afghanistan Public Health Institute
- Law Enforcement Department

Teaching Institution

- Faculty of Pharmacy, Kabul University

Manufacturers

- Representatives of government and private pharmaceutical manufacturing units

Health Providers

- Director, Indira Gandhi Institute of Child Health
- Director, Wahaaj Hospital
- Chief of Pharmacy, Indira Gandhi Institute of Child Health
- Chief of Pharmacy, Ibn-Sina Emergency Hospital
- Private pharmacies

International Development Partners

- World Bank
- USAID
- European Commission
- UNFPA
- UNICEF

Key-Informant Interviews: key-informant interviews were conducted to understand the current state and issues related to manufacturing units and to gather suggestions to enhance the production of pharmaceutical products in-house.

International partners

- MSH
- Compri-A (now known as, Afghanistan Social Marketing Organization (ASMO))

Association representatives

- Wholesale dealer representative
- Afghanistan Medicine Service Union
- Afghanistan Pharmacist Association
- Afghanistan Pharmaceutical Production Association (*Anjumane Sanate Dawasaje*)

Other Core Ministries

- Ministry of Economy
- Afghanistan Investment Support Agency
- Afghan Chamber of Commerce and Industry
- Ministry of Finance

Implementing Partners

- BPHS – ACTD, HNTPO
- EPHS HNTPO, AADA

Focus Group Discussion: A discussion was held with the Afghanistan Pharmaceutical Production Association (*Anjumane Sanate Dawasaje*) to understand the views of the manufacturing units as a whole, as well as the various issues and problems they face.

4.2. Target population, selection of sites and respondents

The in-depth assessment was cross-sectional in design and qualitative in nature. It focused on of the current status of a pharmaceutical-manufacturing unit, with emphasis on the support required to enhance in-country production in the near future. The assessment was done in Kabul since the majority of these units are situated there.

Selection of respondent categories:
HPIC's Afghanistan office provided a list of respondent categories. In addition, IIHMR proposed that the Afghanistan Chamber of Commerce and Industries be included in the sample. One person was identified and interviewed in-depth for each respondent category. If a proposed respondent was not available, the person referred by him or her was interviewed.

In the case of private manufacturing units, a focus group was conducted with members of their association. Three manufacturing units, identified by HPIC, were visited and their key staff interviewed. During these visits, information was collected on available HR (technical and non-technical), building and equipment (with functional status).

4.3 Introduction to tools, development process and involvement of stakeholders

To understand the basic issues related to manufacturing units and the role of each stakeholder, a checklist and in-depth discussion guidelines were prepared by a team of experts from IIHMR.

The tools were prepared after an exhaustive literature review, provided by HPIC, as well as related material on the Internet. The draft tools were shared with HPIC. Feedback from HPIC was received, discussed and incorporated with consensus. HPIC approved the final versions of the tools before the fieldwork was begun.

4.4 Team formation and orientation

The assessment team consisted of five members with good research skills and pertinent experience. The team leader was supported by a pharmacy professor, with nearly four decades of experience. They were supported by three other team members; among them, two were local consultants with the Afghanistan Centre for Training and Development. The assessment team had an orientation session to ensure that all were on the same page regarding the assessment objectives, the tools and methodology.

4.5 Data collection and feedback

Initially, all team members worked together and thereafter split into two teams. The HPIC team facilitated most of the meetings. De-briefing sessions were held every evening to discuss key findings. Interview data was entered the same day. During the entire assessment, periodic meetings were held with the HPIC team to share key findings. HPIC gave useful suggestions for the assessment focus and approach.

4.6 Data control and confidentiality

Confidentiality was maintained at all levels. No details were shared with anyone other than the core team members and HPIC. The overall findings will be shared with the MoPH, as clearly indicated in the assessment goals.

4.7 Data management and analyses

The assessment team conducted in-depth discussions, key-informant interviews and focus group discussions in the local languages (Dari/Pashto), Urdu and English. Local staff translated interviews conducted in the local languages into English and entered them into the database. The international team members entered the English interviews.

The transcriptions were then discussed among team members to ensure that all points were included. Key content analysis of the findings was conducted (as there was only one respondent for most of the respondent categories), except in the case of the manufacturing units. Major and minor themes were identified, and information was grouped according to these themes, which were primarily based on assessment objectives, tools of enquiry and information collected.

4.8 Limitations of the assessment

1. Initially, the private manufacturing unit representatives were reluctant to open their facilities to the assessment team. However, the assessment team was successful in conducting an informal focus group discussion with them to apprise them of the assessment objectives and to get information while assuring confidentiality.
2. The assessment was purely qualitative in nature.
3. The assessment was limited to Kabul since, according to the GDPA, the pharmaceutical industry is only present here and quite insignificant outside Kabul.
4. Language was a barrier for international team members, but this hurdle was overcome by partnering with locals.

5.0 Findings of the Assessment

Overall, 36 respondents were included in the assessment (See Annex 2; Table 1). The results of the in-depth interviews, focus groups and observations of the manufacturing units are presented here. The key issues confronting the manufacturing sector, as well as suggestions from both the stakeholders and the assessment team, are included. The findings for the various stakeholders are presented in the following order:

- manufacturing units
- MoPH and line departments
- health facilities (hospitals and pharmacies)
- pharmaceutical associations (in-depth interviews and group discussion)
- different government ministries
- international partners
- Faculty of Pharmacy, Kabul University
- international development partners
- implementing partners (BPHS/EPHS NGOs)

5.1 Manufacturing Units

The team set out to assess the three phases of pharmaceutical production. There was a complete lack of primary production, that is, the manufacturing of active pharmaceutical ingredients and intermediates.

Most units in Afghanistan are involved in secondary production (formulation, finished dosage forms from active pharmaceutical ingredients with excipient or non-active ingredients).

Some secondary manufacturers are also in tertiary production (packaging finished products or repackaging bulk finished products). As per the GSPA, except KIP and KP, all other manufacturing units are engaged in secondary production.

One public and three private manufacturing units were covered in the assessment. The only public manufacturing unit was Avicenna Pharmaceutical Industry (API), which operates under Pharmaceutical

Enterprise (PE) of the MoPH. Three private units were also visited to assess HR, facilities, machinery and equipment. To ensure confidentiality, these units were assigned the codes M1, M2 and M3.

5.1.1 Pharmaceutical Enterprise

Pharmaceutical Enterprise has 200 staff (See Annex 2: Table 2). PE's director would like to see 100 per cent of the essential medicines produced domestically in the next five years. He envisions 50 per cent of the essential medicines being produced by the domestic private sector, and 50 per cent being produced by the public sector. However, his vision, its specific aims and objectives are not articulated in any written documents.

PE stated that a national pharmaceutical manufacturing policy exists and serves as a guideline for all units and that it is available from the GDPA. (In discussions later, the GDPA clarified that there is no specific policy document. The GDPA said there is a list of 700 essential drugs and separate list of 1,300 licensed drugs. According to the GDPA, drugs can be manufactured or imported only according to these lists.)

However, in order to realize its vision, PE wants the GoA to give it 1,000 hectares of land for a pharmaceutical industrial park. PE imported machinery from China with the intention of building an IV-fluid manufacturing industry, however, it cannot be housed in the API building. The Ministry of Construction deemed the building unsafe due to damages it incurred during the civil war.

Commenting on the current capacity of the public manufacturing unit, the PE stated that API is currently manufacturing eight products; it intends to increase the number of products to 20 in the near future. When asked to name the products, the PE director suggested the assessment team collect this information from API. However, in subsequent interviews, neither API nor PE were able to share this information. PE said the number of staff is sufficient, but all of them need more skills training. There are currently no specific plans for training.

PE reported that the major issues related to pharmaceutical manufacturing in Afghanistan are:

- lack of separate land for the industry
- lack of electricity
- lack of technically competent and trained staff.

Suggestions to improve manufacturing units, though not prioritized, are:

- promote more public sector industries
- allocate land for pharmaceutical manufacturing units
- establish an IV-fluids and gases industry (IV fluids and gas cylinders are heavy and bulky, and require much space for storage and transport to health facilities)
- promote the establishment of local industry in the private sector.

PE said it was open to other suggestions from the assessment team.

5.1.2 Public Manufacturing Unit - Avicenna Pharmaceutical Industry (API)

API is the only public manufacturing unit in Afghanistan. Its facility offers sufficient space for manufacturing. However, the building is old and under-utilized. At the time of the visit, only part of ground floor was in use while the first floor remained unutilized. Only about 20 per cent of the available space was being used.

API's top management said the production capacity of the unit had been adversely affected by the war. Most of the equipment is damaged, so the space cannot be utilized to its utmost. Building safety is also questionable. According to management, for safety reasons, the Ministry of Construction was not in favor of any construction, additions or alterations to the premises to accommodate the newly purchased IV-fluid machinery.

Moreover, as per WHO recommendations, the plant should be GMP-compliant, free of environmental and occupational contamination, which justifies PE's demand for land to rebuild the whole unit in conformity with international standards.

API's equipment is very old and mostly obsolete. Much of it was purchased, on average, 25 years ago (See Annex 2, Table 3). Some machines are not being used because staff does not have the skills or knowledge to operate them. Other machinery is not functional. API's technical staff could not explain what exactly was broken. It seems no efforts have been undertaken to fix the machinery. When asked why the equipment was not repaired, staff said the GoA was not keen on making further investments in the unit since it could be privatized.

API has 35 staff; 15 are pharmacists. API reported it made 120 products before the war of 1992. Now, due to lack of support and facilities, products have been reduced to five.

The fact that API and PE each presented the assessment team with different statistics regarding production indicates a lack of co-ordination and communication.

API's products are syrups, ointments and solutions, namely: Syrup Diphenhydramine, Analgesic ointment (methylsalicylate with camphor), Ointment Ichthamol, Ointment Zinc Oxide and Solution Povidone.

Production policies and procedures are the same as those applied by the MoPH and GoA, administered through the GDPA. The MoPH administers the Regulation on Manufacturing and Importing Medicines and Medical Appliances, in addition to the Public Health Law and the Medicine Law.

These regulations are not available in English. However, their availability in English would allow for more transparency, especially for foreign investors or partners willing to participate in developing the pharmaceutical sector in Afghanistan.

Although, GMPs do figure in these regulations, the exact GMP requirements are not fully specified. It is left up to the discretion of GDPA officials to ascertain whether the building, equipment and processing meet GMP criteria.

At API, the assessment team observed that no gloves, masks or head covers were being used inside the production plant. Bare hands were used to cap syrup bottles, a practice which can contaminate

medicine. Storage at the facility was sufficient and well-demarcated for incoming raw materials and outgoing finished products.

An informal discussion with API staff indicated a lack of support from the top management of PE and GoA for:

- addressing their problems
- reviving the unit
- helping to provide raw material for producing medicine
- prevailing low salaries
- repairing of machinery/equipment.

API staff said the cost of production is relatively high for their products compared with the smuggled products from the porous borders with Pakistan and Iran. For example, a bottle of Diphenhydramine syrup, produced by API, costs about 20AFS; a smuggled product costs about 10AFS in the local market.

API staff fears this problem is one of the reasons that the GoA is not supporting API's revival and considering privatizing API. Based on subsequent discussions with representatives of the Ministry of Economy and Ministry of Finance (See Section 5.3), the assessment team believes this fear is not unfounded.

Based on the information above, the assessment teams believes that API could become viable and manufacture a number of products in-house, provided the GoA and the related departments take the initiative to revive it, rebuild the infrastructure, provide the latest-available machinery, offer specialized technical training and skills-development of key professionals, and ensure a supply of raw materials and related supplies.

Annex 2 is an illustration (and not a recommendation) of machinery to procure. It would be better to create a list of required equipment once a decision is taken by the GoA in favour of reviving API. This would avoid purchasing technology that would become outdated, since the allocation of land, the development of an industrial infrastructure, and the construction of buildings will take considerable amounts of time.

As a matter of caution, the purchase of equipment should be considered only after the GoA and the Ministry of Economy and Finance come to a general agreement on API. A consensus at the level of the GoA is essential. This is strongly suggested in order to prevent the repetition of the instance with the PE, which purchased IV-fluid manufacturing machinery that is now sitting idle without a proper storage facility.

The product price is major concern, as they it might be more than similar products available on the market. In general, public sector units are not able to offer competitive prices, like the private sector, because of higher HR and other costs (See Annex 3). Public sector units can be viable only with adequate protection from the government in terms of purchases by the public sector or substantial subsidies for the importation of raw materials.

Contrary to the views strongly expressed by the Ministry of Economy, the GoA has to decide whether or not it will follow through and extend protection to its only public manufacturing unit. All of these points

must be considered carefully at the high levels of government before any decision can be made about reviving API or enhancing its capacities.

5.1.3 Private Manufacturing Units

The assessment team held discussions with the Afghanistan Pharmaceutical Production Association (*Anjumane Sanate Dawasaje*) before starting on-site visits. Manufacturers said they were reluctant to show their units to the team due to past bad experiences. However, the team managed to conduct a focus group with them (refer to 5.1.4) on the agreement that they would remain anonymous. Since the GDPA does not specify exact norms pertaining to space and location, the private units are situated in residential areas and have limited space; they have chosen production capacities accordingly. The observations and general assessments of these units follow.

5.1.3.1 Code M1

M1 is situated in a residential area. It has a staff of 10. Five of them are pharmacists, trained in oral formulations, such as syrups, suspensions and topical solutions, so this is the focus of their production. Two pharmacists work in production, one is in the QC Lab and two are in packaging.

M1 manufactures 27 products (See Annex 2, Table 4). Its current production capacity is 3,000 bottles/day. It is in the process of procuring land in an industrial area and intends to set-up a new unit there once the land has been confirmed.

The company imports raw materials from India, Iran, China, Pakistan, Korea and Indonesia. It takes three to four months to receive these raw materials (from the initiation of the process). According to M1 staff, the letter of credit (LC) system in banks is very weak, so there is a delay in the supply of money. An LC is a bank certificate, which assures payment upon receipt of the goods by the party. Sometimes, M1 staff has had no work for a month due to delays in the delivery of raw materials. The result has been a reduction of 20 per cent in M1's production this past year.

According to M1, if there were access to free land, a tax-exemption policy and a subsidy on machinery, then it would be able to implement GMPs. Staff said that, due to lack of space and other restrictions, it is not possible to adhere strictly to GMPs. However, it has SOPs for every product manufactured (as it is an ISO-accredited unit). It has its own QC Lab for testing raw materials and manufactured goods. The facility has a storage area, whose capacity and conditions meet the unit's needs. Raw materials and finished products have separate storage areas. M1 staff was reluctant to share its budget.

M1 had a range of equipment in good condition. (See Annex 2, Table 5). All of it was in working order and operating at a standard level. It was all being used. It can be reasonably expected that private manufacturers have to ensure the optimum operation of plants and machinery. Some machines were under guarantee and repaired as needed by engineers from India and the United Arab Emirates (Dubai).

M1 has two sales agents distributing medicine to pharmacies; a wholesaler also distributes M1's medicine to pharmacies all over the country.

5.1.3.2 Code M2

M2 is currently located in an industrial area, but it rents additional space in a shoe factory. It has 35 staff, three are pharmacists. Two pharmacists are in production, and one is in quality control. There is also a doctor on staff, who does technical work. The others are operators. M2's expertise is in the production of tablets, capsules and suspensions, namely tab. Amoxicillin (250mg, 500 mg), tab. Ampicillin (250 mg), tab. Cotrimoxazole (400mg), Cap. Cephalexin (500mg), Cotrimoxazole suspension, Amoxicillion suspension, and tab. Paracetamol.

M2 has sufficient space for its current production needs. It also wishes to have land in an industrial area in order to scale-up production in the near future. It has sufficient equipment (See Annex 2, Table 6). All of it was in use, in working order, and operating at a standard level. It is currently producing 13 million tablets/year and 60,000 suspensions in bottles/month. Turnover for the past two years is about US$700,000.

M2 buys raw materials from China, India and Pakistan. It takes three to four months to receive the raw materials. In the past, production has stopped for up to three months due to the slow delivery of raw materials. As a result, production was reduced by at least 25 per cent.

M2 staff said they knew about GMPs but did not implement them in a true spirit. However, they document SOPs for product manufacturing and post them in each work area. M2 has its own QC Lab, but admits it does not have sufficient resources or machinery to check every product. They reported that the MoPH QC Lab also does quality control of products, before and after manufacturing.

The M2 facility has a storage area and is trying, as much as possible, to adhere to the appropriate storage conditions, taking special precautions for humidity control. Machines are regularly maintained. Some personnel were trained in China and maintain the machines made in China. M2 has its own sales and marketing department for Afghanistan.

5.1.3.3 Code M3

M3 is located in a private residential area. It has a staff of 30; three are pharmacists. Its technical expertise is in the production of ointment (salicylate), syrup (Mucaine), suspensions, drops, lotion and cream. It is currently manufacturing 52 products (See Annex 2, Table 7). In the past two years, they produced two million bottles of cream and ointment/year.

M3 purchases raw material from Iran, China, Malaysia, Indonesia, India and Pakistan. Importing these materials requires a 20-day hold at customs for procedural reasons (sampling and QC certification). Due to this delay, production dropped by 60 per cent this past year. In addition, the lack of appropriate storage systems at customs for the raw materials has led to the deterioration of substances.

There was a prevailing lack of GMP compliance in this unit. M3 staff indicated that, in principle, all manufacturing units must follow GMPs. However, the company said it needs land in an industrial area in order to build a facility and install equipment that is GMP-compliant. According to them, there should be a standard location and standard machinery to manufacture medicines.

It has no documented SOPs for product manufacturing. It has its own QC Lab but with only limited capacity in terms of space, HR and equipment. As such, its QC Lab is for internal purposes only and has no legal status because products can be marketed only after the MoPH QC Lab certifies the samples in any case. The facility has a storage area but there is no separate storage for raw materials and finished products.

M3 has a sufficient amount of equipment (See Annex 2, Table 8) to manufacture its range of products. It undertakes regular maintenance of machinery after every production. An engineer on staff is self-motivated and builds machinery as well. He takes care of regular maintenance. M3 has its own agencies and medical representatives to sell its medicine and maintain good relations with pharmacies, wholesalers and hospitals. It also sells medicine to the MoPH for health facilities in Kabul.

5.1.4 Focus Group Discussion with Manufacturing Unit Representatives

Representatives from the three private units said current laws are not very conducive to production. According to them, the importation law applies QC testing to each individual item used in the production of any medicine.

In other words, the government's QC mechanism demands that all companies, from which raw materials are purchased, first be registered with the MoPH. Once a raw material reaches customs, a sample is taken. The consignment comes in only after it is approved. Once a final product is ready, it is tested through the government's QC mechanism. This process, manufacturers say, is time- and resource-consuming.

For example, the drug cotrimoxazole (which has two ingredients and 20 excipients), manufactured in Afghanistan, requires 22 chemicals for production. Therefore, manufacturing units have to register all 22 companies with the MoPH, which is very time-consuming, as well as very cumbersome.

Manufacturers opined that the QC Lab should test only the final product, not each of the individual ingredients. The manufacturers voiced a strong opinion on this: "Burn our units if they fail in QC post-production but at least simplify the process of manufacturing".

Further, the price-control section of the GoA's pharmaceutical department decides the price of each medicine, based on the invoices submitted by each unit for costs involved in producing it. Here, the problem is that manufacturers often bear hidden costs, and a GoA department's price doesn't take these into consideration.

Manufacturers suggest they should be free to fix prices, as they face stiff competition from four sources: locally produced medicine, medicine imported from neighbouring countries, smuggled products and medicine supplied by UN agencies but which find their way through illegal channels into the local market.

They added that they face the problem of fake medicines on the market, which are produced in neigbouring countries. They claim this is done purposefully to destroy the image of a good local brand and to promote the sales of a competitor. A representative said they already presented this problem to the GDPA.

Manufacturing units say they would need to be allocated land to truly implement GMPs. They identified two plots of government land and submitted a proposal to the GoA, but nothing has moved on this proposal for the past three years. They would be willing to invest in building new units if the GoA gives them land first.

They noted that some units located in residential areas pay as high as 10AFS/unit of electricity, whereas industrial units pay 6AFS/unit of electricity.

The lack of skilled HR (QC testing and production) in the country is a big issue, they said. There are no SOPs by the government to fix anything (like water filtration). They reported that some time back, 24 investors applied to set up units but none of them could get a licence to do so.

They also suggested that Afghan pharmaceutical companies be allowed to manufacture products with accountability (i.e. they would be fined if a sample fails the QC test). In this model, the GoA could take samples from a batch of medicine, and then at any time from the market, to test quality. This would eliminate the current method of testing raw materials and facilitate production.

They suggested that perhaps API (or some other agency) could be appointed to act as the national body to purchase, test and provide all raw materials/chemicals to manufacturers. This would do away with the current cumbersome process of pre-testing imported raw material. (Manufacturers are even willing to pay a fee to facilitate the process.) This would ensure ready availability of raw materials for manufacturers and a substantial savings in time previously spent waiting for the sample results from the MoPH QC Lab.

Another concern was that they sometimes require only very small quantities of raw materials and suppliers are not willing to file a registration application and enter into the Afghan bureaucracy for such small amounts. They suggested reducing bureaucratic procedures by having an MoPH QC Lab dedicated to testing final products only, and not raw materials.

Currently, the process is to apply to the government for the launch of a product. Then, the MoPH staff takes a sample. Follow-up is with six different departments of the pharmaceutical sector. Sometimes there is a further delay, as the head of a department is not available and the process cannot move forward. Overall, they want a simplification of the process to save time. They also suggested training key personnel in manufacturing and QC, with special emphasis on GMP compliance.

5.1.5 Comparison of Public and Private Manufacturing Unit

Table: Comparison of Manufacturing Units

Topic/head	Public	Private
Space	Huge infrastructure	Limited space, mostly in residential areas
HR	202 staff in Pharmaceutical Enterprise. API, 15 pharmacists out of 35 staff	M3= 3 pharmacists out of 30 staff, M2= 3 pharmacists out of 35 staff, M1= 5 pharmacists out of 10 staff
Equipment	Old, obsolete and mostly non-functional	New, automatic or semi-automatic, almost 100 per cent functionality
Number of Products	API=5	M1 = 27, M2 =7 and M3 = 52

It emerges clearly from the above table that the situation at PE is not encouraging. The PE director's vision is not well documented and has not been clearly conveyed to API staff. He stated that API would manufacture 20 products in the near future, but API was not aware of this plan, nor of the names of the 20 proposed products. In the meantime, API staff feared that they would not be able to continue with the current five products, as the supply of raw materials and syrup bottles was inconsistent. This reflected a failure in communication within the organization (PE).

API staff was not motivated due to low salaries, poor management support, and the erratic supply of raw materials and product packaging. They feared that API would soon be privatized since the GoA was not enthusiastic about increasing production.

API staff said prior to the civil war, they were manufacturing about 120 products. If management support — in terms of the ready availability of raw material — were ensured and the issue of non-functional machinery were properly addressed, they could produce not 120 but 240 products, they said.

It is pertinent to mention here that PE had imported more than US$7-million worth of IV-fluids manufacturing machinery, and had taken steps to procure sufficient land to construct a building to house this machinery. PE did not share any other information about this machinery.

However, the assessment team was informed that the machinery is not in country. It is at a customs port. It is not certain when this machinery will start manufacturing IV fluids, but it is feared that by the time it starts operating, it may be old technology.

Conversely, private manufacturers are using their plants, machinery and HR at optimum levels. Despite such a vast availability of space, HR and equipment, API is producing far less than the private sector, which has fewer resources.

5.1.6 Discussions on Manufacturing Units

All these units can be described as small-scale. The SOPs were followed at M1 and M2. In general, manufacturing units in the private sector:

- Are in private residential areas with limited space.
- Have relatively new and modern machinery, as compared with the public-sector unit, API. Most of them are semi-automated or automated.

- Have technical staffs, which consist of qualified pharmacists with bachelors degrees in pharmacy.
- Have a small in-house QC Lab with very basic facilities and equipment.
- Manufacture 52 (M3), 30 (M1) and 7 (M2) products. M3 had three pharmacists, while M1 and M2 had 5 and 3 pharmacists respectively.
- Are very keen on increasing their manufacturing base provided the government allots them a plot of land in an industrial area. As other option, they are also willing to buy-out, partially or fully, or share the unutilized space at API.
- Are willing to make their own investment and bring in technical expertise for manufacturing all kinds of drugs (including injectables and IV fluids) provided the GoA gives them infrastructure support, such as land in an industrial area.

It was also interesting to note that expertise was available for designing and building pharmaceutical machinery, as was observed in one of the units (M3). The engineer in question appeared to be competent in assembling and repairing the pharmaceutical machinery.

The MoPH/Director Pharmaceutical Enterprise could access this expertise in order to repair API's non-functional machinery and to increase the production base accordingly. However, repairs should be accompanied by a warranty and a long-term maintenance contract. This reveals the need to have inter-sectoral coordination and to build on the strengths of partners.

5.1.7 Issues of Manufacturing Units

The difficulties being faced by the units were of a procedural nature. According to them, if an agency imported a finished product for marketing, it was mandatory to register that product. The MoPH QC Lab tested all imported products for quality. Only after the lab issued its certification could the product be sold on the market.

However, manufacturing units must register not only active pharmaceutical ingredients but also excipients imported for use in a formulation. These substances must be tested by the MoPH QC Lab and receive certification before they being released from customs.

This procedure takes a long time and quite often leads to an absence of supplies at the unit, thereby affecting production. Manufacturers propose that either a branch of the MoPH QC Lab be situated at customs or that they be entrusted and held accountable for bringing good-quality substances to the market. The manufacturers also want their own in-house QC Labs to be responsible for conducting the quality analysis of their final products, and then to be held accountable for their medicine, rather than the MoPH.

Other major hurdles perceived by manufacturers for local production include:

- a shortage of technically trained and competent manpower
- unavailability of land for establishing a pharmaceutical industry
- unavailability of a subsidy for electricity
- the absence of a chemical industry for ready-availability of raw materials
- a lack of incentives for locally produced products (like protectionism)
- price competition from smuggled and illegal products.

5.1.8 Suggestions from Manufacturing Unit Representatives

Suggestions from private industry to improve local production are presented for each of the following stakeholders:

GoA:

- provision of land/industrial zone for pharmaceutical-manufacturing industry
- availability of technically trained and competent labour
- addressing the security issue
- purchase of locally produced medicines by the GoA for public health facilities or suitable incentives for local products

MoPH:

- expansion of essential drug list and licensed drug list (to increase sales)
- support for suitable price approval to compete with imported products
- supply raw materials through a government agency, such as API
- ban the import of medicines that are currently produced locally (to eliminate competition)

Ministry of Finance:

- provide subsidies for imported machinery and equipment
- simplify procedures and eliminate duties on raw material

AISA/Other Ministries:

- GoA should arrange symposia and exhibitions
- e-business and training sessions

5.1.9 Recommendations by the Assessment Team

If the MoPH wants self-sufficiency in pharmaceutical manufacturing within the country, it must have a clear, well-defined pharmaceutical manufacturing policy (through: "Indicators for Monitoring National Drug Policies, 1999, WHO"[6]), duly approved by the Cabinet with sufficient incentives and safeguards for the promotion of the local industry.

The GoA should also clarify the role of the public sector in achieving this objective. In view of globalization, liberalization and privatization, the GoA must consider whether it would like to remain in pharmaceutical production and decide the future operations for PE and API.

If the GoA, specifically the Ministries of Economy and Finance, are in agreement with the revival of API, including the purchase of API-produced medicine for its public sector health facilities, it must respect the minimum equipment requirements for manufacturing (Annex 2, Table 9) and in-house quality control (Annex 2, Table 8).

[6] http://apps.who.int/medicinedocs/en/d/Jwhozip14e/

As well, the staff working for PE/API is not experienced in manufacturing tablets, capsules, ophthalmic solutions, injectables, etc., and would need extensive and rigorous training, for at least six months, in each area. There should be at least three trained pharmacists (in manufacturing, QA and QC) in a unit currently manufacturing tablets, capsules, solutions (internal and external) and powders, who can ensure these products are well produced and act as master trainers for other pharmacists in manufacturing.

In the event that the GoA wants to invest in the revival of API, it must hire manufacturing consultants to ensure that the building, equipment, utilities, etc., are in conformity with the country's GMPs (refer to Annex 3). These consultants would be in a better position to determine the following: a conceptual plan (including building plans), design engineering, procurement, installation and HR training.

Regarding GMPs, every country is sovereign, and it is under the purview of each government to analyze, judge and decide what kind of standards they would like to enforce. Even WHO's recommendations are not binding on all countries.

If the policy of the GoA is to promote indigenous industry as a priority, then GMPs shall be enforced gradually so that local industry can stand on its own. The regulations may be made tougher gradually, keeping pace with the level of industrialization.

If this is not the priority and there is liberal policy for the promotion of foreign investment, then strict GMP norms can be imposed immediately and to the same standard as they are in developed countries, in order to prevent the establishment of second-hand or outdated plants in the country. The GoA has to weigh this policy option, in consultation with the GDPA, Director, QC Lab and MoPH.

The assessment team suggests that the option of banning the importation of medicine that is currently produced locally be considered very carefully in view of the quantity of the product being manufactured and its regular availability. Similarly, the expansion of EDL/LDL also requires further careful consideration to prevent the proliferation of irrational fixed-dose combinations (FDCs).

Industries seem justified in demanding that the GoA provide separate land/industrial area with a built-in infrastructure (such as water, electricity, drainage and transportation facilities, etc.), address the security issue, give incentives on the promotion of industries in the form of subsidized/free land, and give subsidies and tax exemptions on imported machinery and raw materials. Steps must be taken to prevent the entry of smuggled and illegal pharmaceuticals without quality assurance through porous borders.

Regarding the demand of the industry for technically trained and competent HR, refer to discussions and recommendations under section 5.4 (Faculty of Pharmacy, Kabul University).

In addition, efforts should be made to improve security to encourage investors.

5.2 MoPH and Line Departments

In this sub-section, different departments within the MoPH are discussed. These departments include the General Directorate of Pharmaceutical Affairs (GDPA), the QC Lab, the Office of Private Sector Co-ordination, the General Directorate of Administrative Affairs, the General Directorate of Policy &

Planning, Law & Legal Affairs, and the Afghan Public Health Institute. PE and its unit, API, were covered in the pharmaceutical manufacturing section.

5.2.1 General Directorate of Pharmaceutical Affairs (GDPA)

The director of the GDPA has six directors below him: Psychotherapeutic Drugs, Policy & Planning, Registration, Production, Information & Education, and Research & Development. The GDPA 164 drug inspectors, 160 are based in Kabul; four inspectors are in the provinces. All are them are qualified pharmacists.

The GDPA reported that there is no vision document on pharmaceutical manufacturing by the MoPH. After 1992, API was almost non-functional. It was producing as many as 120 medicines before 1992 and had even started exports. According to the GDPA, the World Bank gave PE US$7 million to repair/renovate API, but no improvements are visible. They lamented a lack of vision and no activities planned to develop one.

The GDPA has a pharmaceutical policy for importing, manufacturing, distributing and selling medicine. As per the policy, all drugs (either for importing or producing) should be on the Essential Drug List (EDL, which includes about 700 medicines) or Licensed Drug List (LDL, which includes about 1,300 medicines).

An agency (supplier/manufacturer) should obtain a manufacturing licence from the MoPH, and all foreign companies, including raw-material suppliers and import companies, must be registered with the MoPH.

The various licences include: import licence, pharmacy licence, manufacturing licence and wholesale licence. In order to receive a licence, the applicant must be at least 18 years old; he must not have a criminal record or a human-rights violation record. Afghan citizenship is not required.

Various laws related to the pharmaceutical industry include: public health law, medicine law, registration for pharmacists, regulation on manufacturing and importing medicine and medical equipment. English versions of these regulations are not available, which makes it difficult for foreign investors to understand the specific provisions facilitating or hindering pharmaceutical manufacturing in the country.

Once the agency explains its procedure for importing finished pharmaceutical products and importing raw material for local manufacturing, it receives a licence from the GDPA, under the MoPH. Then, the agency submits a Performa invoice of the material to be imported. Quality analysis of a sample is done at the custom port. Once it receives certification by the MoPH QC Lab, the material is allowed to enter the country. The timeline for such a process is usually between four and five working days.

There is no active pharmaceutical-ingredient manufacturer in Afghanistan. However, the GDPA has licensed up to 12 manufacturing units for formulation, and some are also working as tertiary units (re-packaging).

Currently three Pharmaceutical units are in operation but there is no exact information about the others. Herbal and alternative medicine units are not registered with the GDPA and are not required to share their annual production with the GDPA. Therefore, the GDPA had no data on them.

However, the assessment team believes the GDPA should monitor and keep a record on the activities of herbal and alternative-medicine units. As well, they should be rquired to submit information on their annual production, product volume and sales to the GDPA. This would improve the national database on pharmaceutical manufacturing.

The GDPA reported that GMPs were enforced for all imported products. They are also essential for local units, but they are not imposed as strictly as they should be.

Imported products and those manufactured locally are submitted to quality analysis at the MoPH QC Lab. After deemed satisfactory, permission is granted for their importation and manufacturing. This process takes about four to five working days. The labs do not have their own pharmacopeia, but mainly BP, USP and other pharmacopeial standards are acceptable.

As per their policy, every drug should have a generic name. The GDPA monitors the pharmaceutical-manufacturing units once or twice per month and whenever there is a complaint. They inspect the unit and in-house QC Lab. They usually do not take samples for testing during these visits.

The current capacity of the industry in the country is very low; it contributes about 4 to 5 per cent of medicines to the country. Despite the many challenges, such as years of war and poor government support, some local units still manage to produce. They have formed associations and organized meetings to help to resolve their problems. They have many demands and expectations of the GDPA.

The GDPA says the challenges of the manufacturing units are:

- severe damage to API's infrastructure due to the war
- taxation
- availability of smuggled and illegal medicines (through porous borders)
- lack of competent human resources
- no land in industrial areas
- high prices for electricity for units in residential areas
- no chemical industry to supply raw materials readily.

In order to support local industry, the GDPA was moving cautiously on strict GMP enforcement. It suggests:

- easing laws and regulations for manufacturers
- providing land and basic amenities
- promoting MNCs and joint ventures to enhance the professional competencies of HR

Finally, the GDPA emphasized the importance of more education (full time and of longer duration) for staff. According to GDPA staff, the small workshops they attended did not enhance their knowledge and competence in regulatory affairs. They all have a pharmacy degree but they lack knowledge of industry, particularly pertaining to GMPs. Therefore, they are unable to guide industry on ways to meet GMPs.

5.2.2 Quality Control Laboratory, MoPH

The QC Lab is an independent body under direct supervision of the MoPH; it is the only government food and drugs testing laboratory in the country. It has 20 pharmacists; the Acting Minister of Public Health had approved 20 more pharmacists for this laboratory. Apart from site and chemical analysis, it tests herbal medicines, cosmetics and raw materials. It also has toxicology and microbiology laboratories. At the time of the assessment, the microbiology laboratory was not active because of a lack of instruments. The complete list of available equipment is attached (Annex 2, Table 9). An ideal list of available equipment is attached for comparison (Annex 2, Table 10). The QC Lab had no specific allocated budget for the past 10 years; it expects to have a budget allocated this year.

The QC Lab director said they had provisions related to GMPs, specified under the Regulation on Manufacturing and Importing Medicines and Medical Appliances. The director did not have a copy of this document at the time of the interview. An English translation does not exist, therefore, it could not be ascertained to what extent GMPs are being imposed.

He said Afghanistan has no local pharmacopeia but the Afghanistan National Standardization Authority was in the process of setting standards. However, whenever manufacturers send medicine (for QC testing), they specify the pharmacopeia. So, samples are analyzed according to the stated pharmacopeia.

The QC Lab tests both raw materials and finished products. Private manufacturers are required to give only the main active ingredients and excipients, and not all substances added to the formulation. Policies are the same for both public and private manufacturers. However, the director felt that government units should have different (more demanding) policies so as to set a better example for others to follow.

Testing proceeds as follows: Once the sample is received, it goes to the registration section, where they check the seal and sign. They check the number of samples, and assess everything according to SOPs. Then a certificate for the analysis is issued. When asked to share the SOPs, the director said analyses are conducted according to the pharmacopeia specified on the product label. Therefore, the QC Lab does not have specific SOPs. Rather, they consider the pharmacopeia documents to be equivalent to SOPs. They send it to the QC Lab, where the sample is checked according to the category and the method (pharmacopeia).

The director explained that there is no privately authorized laboratory because of a lack of capability, building space, human resources, reagents, references and standardization. Further, he felt this responsibility is too critical and government cannot outsource it to private industry.

The table given below reveals sample failure results for the past two years. The QC Lab director said samples are analyzed as per the respective pharmacopeial standards stated on the product label (e.g., USP, BP, IP etc). The director was quite confident about the accuracy of the results. The failure ratio shows that the quality of samples is fairly good.

Table: Sample Failure Ratio for 2008-09

Year	Total sample received	Sample not analyzed	Sample failed	Failure ratio
2008	7,352	149	64	1.52%
2009	10,090	69	22	0.21%

The QC Lab does not have an animal house to do pyrogen testing to improve HR competency their pharmacist needed refresher training in different fields.

QC Lab staff goes with GDPA staff to check equipment, raw materials and finished products of local private manufacturing units seeking to register with the government. The QC Lab is the final authority regarding permission for production.

The QC Lab inspects local manufacturing units (both private and public) twice per year. Lab staff said the general quality of medicines manufactured in Afghanistan is not bad. However, they felt that both the number of products and amounts produced are too low.

They said the quality of imported medicine on the market was not very good, attributing the entry of sub-standard products to porous borders. They suggested that the GoA short-list three companies for each medicinal category to ensure quality and fair competition.

In order to improve the situation of local units, it was suggested that the GoA:

- provide land and tax exemptions for five years
- motivate investors
- ensure that units follow SOPs and other standards
- revoke licences if units produce sub-standard medicine.

5.2.3 General Directorate of Administrative Affairs (GDAA)

The main aim and objective of the GDAA is to provide medicine and medical equipment to central and provincial hospitals. It has a staff of 16; six are devoted to medicine and medical supplies (one central technical manager, one provincial technical manager, two biomedical engineers and two administrative staff). Each staff member has a clearly defined role.

Procurement estimates are based on yearly demand estimates, submitted by each hospital/facility. Hospitals specify their needs (in terms of what they want: medicine and quantity required). The Ministry of Economy has an annual budget of 25 million AFS (approximately US$50,000) for medicine procurement. Thereafter, global tenders/notices are issued.

The procurement department decides the criteria: the expiry date of the medicines must be adequate; drug companies must be of international standard, follow GMPs, and have ISO accreditation; after procurement, the QC Lab should sample, test and approve all medicine.

The expiry date varies from product to product and depends on the nature of the drug. For example, vaccines, sera, and some antibiotics have a short period of stability and must be stored under cold chain. Other products are fairly stable. Therefore, it is up to the procurement department to specify the remaining shelf life of the product at the time of reception.

In general, the department insists that a product must reach a store within at least 75 per cent of the time remaining from the date the product was manufactured to its expiry. An explicit statement to this effect is included in the tender document. Upon receiving tenders from all national and international companies, the contract is awarded to the company with the lowest price.

Then, the selected company supplies all the approved medicines and places it in the CMS. Payment is made by the Ministry of Finance, which transfers payment directly to the contractors' accounts. Most of the health facilities in Afghanistan are covered under BPHS/EPHS through NGOs. However, in some of the provinces, procurement is decentralized and provincial health offices call for tenders (following the same process).

There is a provision for additional medicine and supplies for hospitals, in case they are required, for up to 200,000 AFS (about US$4,000). For example, two months earlier, the "hospital of infectious diseases" received medicine, totaling 150,000AFS (about US$3,000).

In an emergency situation, the GDAA can procure medicine and supplies from the local market totaling 400,000AFS (about US$8,000). Should the value of medicines to be procured be above 400,000AFS, they call for tenders. The GDAA said its purchase prices are almost the same as open-market prices, i.e., the prices found in pharmacies or given by suppliers in Kabul. In other words, if the price of Paracetamol in the open market is 10AFS (about US$0.50), they will accept an offer from a contractor for the same medicine at the same price. They reported to have not received any complaints regarding the quality of medicines in past two years.

The MoPH has a big central warehouse with AC and a refrigerator to stock all types of medicine. The warehouse's inventory system is not computerized, and USAID and UNFPA are working to computerize the system. It currently operates with a card system: each product has a card on which all transactions are recorded.

As well, warehouse staff informs the MoPH of products nearing one year from the date of expiry. Accordingly, the MoPH sends these medicines to the provinces for timely consumption and use. Each hospital must send an official to collect their quota of medicine each quarter.

They said they are unaware of the work done by local private pharmaceutical manufacturing units but suggested that these units improve the standard of their production and quality. In order to boost local production, they suggested the GoA:

- provide security
- ease rules and regulations
- remove taxation on machinery and raw material
- provide electricity & land for construction
- provide qualified human resources.

Staff said the growth of local units would not have any effect (positive or negative) on the role of the GDAA, as they are basically concerned with procurement, and that will continue.

5.2.4 Office of Private Sector Coordination (OPSC)

The OPSC is a newly established body, which came into existence in February 2009. It has two staff members: one is director; the other is an administrative assistant. The director said the OPSC was working to build trust and understanding between the private hospitals, pharmaceutical manufacturing units and government. He said the OPSC may facilitate meetings between the private manufacturers associations and the Ministry of Finance, Water and Power, in view of tax relief or access to resources, such as land and electricity.

He feels the MoPH is not able to complete all of its obligations single-handedly, with regards to pharmaceutical production, and should support private industry. The OPSC is to act as a bridge between the public and private sectors.

Currently, there is no incentive from the GoA for setting up and running a pharmaceutical-production facility under the Public Private Partnership (PPP) model. The OPSC is also trying to convince the MoPH to extend support to the private sector. However, as this office is new, with insufficient staff, it has not yet had any success.

According to the OPSC, 90 per cent of medicines purchased in Afghanistan are imported. If Afghanistan were to produce these drugs locally, then they would be easily accessible and cheaper in price.

It was very difficult for OPSC staff to state how much time and resources are required to set up and run manufacturing units under the PPP model in Afghanistan. It did not conduct any feasibility studies due to the great cost and time involved in conducting them. As well, no MNC/international company had shown interest in the PPP model to date. However, he noted, the Compri-A (now ASMO) project does run under the PPP model with the support of USAID. In this project, he said, Khalid Irshad manufactures ORS and chlorine solution for water purification.

The OPSC suggested promoting pharmaceutical manufacturing by providing:

- land, buildings, infrastructure and financial support
- knowledgeable HR and equipments
- security and a stable policy environment for investors
- government-funded financial assistance for industry
- simple and transparent procedures and regulations with incentives in order to promote investment in the private sector.

5.2.5 General Directorate of Policy & Planning

This directorate plays a very important role in setting the policies of the MoPH and planning their implementation. The IIHMR team met with one of the advisers to the Director General of Policy & Planning to get his perspective.

The MoPH is in the process of finalizing a strategic plan for 2010-15. One point on the 10-point plan is related to providing an environment that facilitates the production of quality medicine in the country. It includes the production of vaccines, pharmaceuticals and equipment needed for production. The details will become clear only once political leadership approves the plan.

He was unaware of any policies to attract investment in the country and did not have any suggestions of how to attract investment.

About 4 per cent of the gross domestic product is allocated to the health sector, and he did not know if further allocation is made to the pharmaceutical sector.

However, he said, investment in this sector would create jobs for Afghans and help to produce quality drugs in the country, which would lead to the long-term sustainability of the industry and reduce Afghanistan's dependency on foreign countries. Conversely, he felt that some investors might abuse the incentives. In the absence of effective monitoring, this could lead to poor-quality manufacturing.

He also feared that, due to the prevailing political uncertainties and the insecure environment, Afghanistan was not a favorable destination for foreign investment at the moment. He felt that Public Private Partnership could be a solution. He said the GoA would have to initiate the process and invite private partners to invest. An initiative on the part of the GoA would make private investors feel more secure in their investment. The government can provide incentives by offering land to build new units and by guaranteeing to buy their products for a certain number of years. The government should also assist these units in whatever other ways are necessary.

The Policy & Planning Directorate can strengthen local manufacturing by developing procedures for testing and importing raw materials, he said. It can help strengthen the MoPH in terms of quality assurance, good quality testing and personnel for product testing.

He feels that the vision a self-sufficient pharmaceutical production industry in Afghanistan is far-fetched and will require considerable effort long-term.

5.2.6 Afghan Institute of Public Health (APHI)

APHI is a premier department of the MoPH and functions as its think-tank. It aims to facilitate evidence-based decision-making at the MoPH and to work towards raising awareness among the population about healthy lifestyles and the proper use of pharmaceutical products.

The DG of APHI offered a list of MoPH priorities:

- maternal and child health
- control of communicable diseases
- capacity-building of human resources
- improvement of pharmaceutical production
- improvement in the quality of pharmaceutical imports
- environmental health

- evidence-based decision-making
- surveillance and surveys to facilitate evidence-based decision-making

Based on the priorities of the MoPH, the priorities of the APHI are:

- evidence-based decision-making
- providing leadership based on solid evidence
- raising awareness among the population about healthy lifestyles

The priority for APHI in the pharmaceutical sector is to monitor the quality of imports, since much poor quality medicine is entering the country illegally. To address this issue, prompt sample checks at the level of entry, and inspections of distributors and outlets must be a top priority. Further, co-ordination with other ministries, such the Border Police (within the Ministry of the Interior), needs to be developed to monitor the entry of poor-quality drugs to Afghanistan from other countries.

The quality of medicine being procured under BPHS, mostly from international sources, is relatively better. The major problem lies with the public hospital sector in Afghanistan, including in the capital city, where most of the procurement is from local distributors. He was unsure if proper quality checks take place when a hospital orders from local producers.

He does not believe Afghanistan is in a position to have good-quality pharmaceutical production in the next decade. Therefore, the focus of MoPH and related ministries should be on ensuring proper quality of the medicine currently produced locally.

He said the following conditions are required for the local production of high-quality pharmaceuticals:

- A pharmaceutical production policy, followed by a strategic plan.
- This plan would give way to an action plan for the pharmaceutical sector.
- The first priority in the action plan should be training highly competent personnel for the sector by improving education programs for specialists in pharmaceuticals, chemistry, manufacturing, business, etc. Develop a program that allows students a chance to gain practical experience with companies in the geographic region, such as Iran and India.
- Promote the message across all branches of the MoPH and other related government departments that the pharmaceutical sector is one of the top priorities of the MoPH. Ensure that the action and strategic plans are understood by all in order to get co-operation from all departments and to ensure improvement in the sector.
- The private industry should have a greater role in promoting production in the country. Therefore, a better understanding of the private sector and their needs would be important: facilitate the process for licensing, offer assistance in the form of reduced taxing, ensure expeditious product testing, facilitate the importing of raw materials and equipment. It may require a revision of the current policy, which should be undertaken as a priority.
- There is a strong need to stop the illegal entry of medicine in order to help to create demand for locally produced pharmaceutical products.

5.2.7 Law & Legal Affairs

The interview with the director of Law & Legal Affairs did not generate any information. He said all questions should be addressed to the GDPA. The director was unable to provide the English versions of

the relevant rules and regulations concerning medicines. However, the assessment team found that none of the rules and regulations were contradicted by the GDPA.

5.2.8 Discussion

The current procedures and practices prevailing under the GDPA and the MoPH QC Lab require that all imported medicine and raw materials be sampled first.

Then, after the certification by the QC Lab, the raw material or product can be brought or sold in the country. The officers of these organizations do the sampling. The focus of these two organizations is totally devoted to these activities. As a result, it seems the GDPA has no time to do random QC analysis of products in the various pharmacies and to prevent the smuggling of medicine into the local market. In this way, the monitoring of counterfeit and sub-standard drugs gets diluted.

In most countries, it is the responsibility of the importing agency and manufacturing units to ensure the quality of their products. Afghanistan must provide units with the reasonable autonomy and accountability regarding the quality of their products. This would force all manufacturers to strengthen their in-house QC Labs. In view of the current dearth of qualified HR and the low production, private industry could be allowed to have their raw materials and finished products tested expeditiously by an authorized yet autonomous QC Lab. Currently, the private sector has not been granted this capacity.

Local manufacturers believe the procedure of getting QC clearance for all medicinal ingredients is quite long and cumbersome. The GDPA and QC Lab officials say sample analysis takes four to five working days; manufacturers say it can take more than a month in some cases. In this way, the raw material remains at custom ports for long periods of time and the marketing of finished products is delayed until the QC certification is issued. The other major issue is that there is only one central QC Lab with limited capabilities.

The regulations should be suitably amended to match global procedural requirements, which make industry responsible for efficacy, safety and quality and impose strict penalties for laxity and any violation of the rules. Industry representatives are prepared for this type of system.

The QC Labs at all manufacturing units could be licensed by the MoPH and reduce the time lag at all stages of manufacturing. These laboratories would be subject to Good Laboratory Practices (GLPs) with SOPs and strict accountability. The MoPH would have the authority to renew or revoke these licences, as well as issue penalties for failure to adhere to GLPs/SOPs. This would allow the MoPH QC Lab and the GDPA to focus more on monitoring the quality of medicine on the market and other development issues, such as adverse drug reactions/pharmacovigilance and the gradual enforcement of GMPs.

At a minimum, the pre-testing of raw materials by the MoPH QC Lab can be dispensed with, and manufacturers can be held responsible for the QC of the raw materials they import. The assessment team does not agree with the director of the MoPH QC Lab, who suggested that the production for each medicinal category (e.g., antibiotics, vaccines, etc.) be restricted to three manufacturers for fear that a cartel could be formed.

It appears that the creation of the OPSC, within the MoPH, is just a pretense, given its tiny staff of two. The OPSC should take a more proactive role. It should create a brochure and give input to the Afghanistan Investment Support Agency (AISA, for more information, see section 5.3.1) on how to attract investment in the industry.

The OPSC, in consultation with the MoPH, should identify a list of priority medicines for Afghanistan on the basis of prevailing morbidities and mortalities. The GoA could then use this information to develop local industry. The MoPH shall also impress upon other related ministries (Ministry of Industry, Ministry of Finance, Ministry of Economy, Ministry of Chemicals and Petro-Chemicals) the importance of developing a basic chemical industry, which is necessary in developing a pharmaceutical-manufacturing industry.

The GDAA is working towards making medicines available at various health facilities. It is intriguing that the GDPA procures medicine at market prices. Normally, procurement prices of the public sector, through open tenders, are just 5 to 10 per cent of the market price. The table below is a comparison with one of the states in India (Tamil Nadu).

Table: Difference in Price of Medicines (generic) Procured Through Open Tender

Generic Name of Drug	Tender Rate (Rs.)	Unit	Maximum Retail Price Printed on pack / strip (Rs.)
Albendazole Tab IP 400 mg	11.00	10 tablets	250.00
Alprazolam Tab IP 0.5 mg	1.40	10 tablets	14.00
Arteether 2 ml Inj	9.39	1 Injection	99.00
Amlodipine Tab 5 mg	2.50	10 tablets	22.00
Cetrizine 10 mg	1.20	10 tablets	35.00
Ceftazidime 1000 mg	52.00	1 Injection	370.00
Atorvastatin Tab 20 mg	18.10	10 tablets	170.00
Diclofenac Tab IP 50mg	2.20	10 tablets	25.00
Diazepam Tab IP 5 mg	1.90	10 tablets	29.40
Amikacin 500 mg	6.95	1 Injection	70.00

Note: US$1= Indian Rupees 45/-.

It is well reported in WHO circles that pooled procurements should result in substantial savings. The assessment team feels that the GDAA needs to assess procurement prices vis à vis retail prices. If there is no significant difference in price between bulk and pooled procurements, there is a problem of transparency in the system. The GDAA should have professionals to draft a procurement plan and to develop a list of medicines and medical supplies, along with the proper quantification of requirements.

The WHO[7] identifies 12 guiding principles for good pharmaceutical procurement, which it has grouped into four categories, explained below. It also identifies the officials/authorities within the GoA, who could be assigned these responsibilities.

A. Efficient and Transparent Management

1. Different procurement functions and responsibilities (selection, quantification, product specification, pre-selection of suppliers and adjudication of tenders should be divided among different offices, committees and individuals, each with the appropriate expertise and resources for the specific function. Selection of medicines by the Faculty of Medicine and officials of the MoPH, quantification of drugs requirement shall be based on consumption data and morbidity pattern of the country, product specification by the GDPA, pre-selection of suppliers and adjudication of tenders by the GDAA or any other designated central procurement agency (CPA) authorized by the GoA.

2. Procurement procedures should be transparent, following formal written procedures within the GDPA/CPA throughout the process and using explicit criteria to award contracts.

3. Procurement should be planned properly on the basis of needs ascertained on the basis of past consumption data, taking into account the quantum required during stock-out periods. Prevailing and expected morbidities and procurement performance should be monitored regularly; monitoring should include an annual external audit. It is up to the MoPH to allocate these responsibilities to appropriate GDs/directors.

B. Drug Selection and Quantification

4. Public sector procurement should be limited to an essential drugs list or national/ local formulary list.

5. Procurement and tender documents should list drugs by their International Nonproprietary Name (INN), or generic name (Action GDAA in consultation with GDPA).

6. Order quantities should be based on a reliable estimate of actual need obtained from health facilities, based upon their past-consumption data adjusted to stock-out periods, surplus and avoidable wastages with due consideration to expected increase or decrease in demands on account of changing patterns in morbidities and mortalities.

C. Financing and Competition

7. Mechanisms should be put in place to ensure reliable financing for procurement. Good financial management procedures should be followed to maximize the use of financial resources.

8. Procurement should be effected in the largest possible quantities in order to achieve economies of scale; this applies to both centralized and decentralized systems.

[7] Operational Principles for Good Pharmaceutical Procurement WHO/EDM/PAR/995, Geneva, 1999.

9. Procurement in the public health sector should be based on competitive procurement methods, except for very small or emergency orders.

10. Members of the purchasing groups should purchase all contracted items from the supplier(s) which hold(s) the contract.

D. Supplier Selection and Quality Assurance

11. Prospective suppliers should be pre-qualified, and selected suppliers should be monitored through a process, which considers product quality, service reliability, delivery time and financial viability.

12. Procurement procedures/systems should include all assurances that the drugs purchased are of high quality, according to international standards.

Professional pharmaceutical management should do ABC (Analysis of Benefits and Costs) and VED (Vital, Essential and Desirable) analysis. This needs to be incorporated in the system. In line with WHO guidelines for pre-qualification of products, the GDAA shall also undertake this kind of exercise to ensure the supply of quality medicines at competitive prices. The GDAA can also enter in a rate-contract with pre-qualified suppliers/manufacturers, and hospitals/health facilities managers can be authorized to procure medicines from them at the contracted price. This would eliminate the supply of unnecessary medicine at these facilities and prevent the accumulation of expired/near-expiry medicines.

The Directorate of Policy & Planning has identified 10 strategic directions for 2010-15, including providing an enabling environment for quality pharmaceutical production in the country, but the blueprint for achieving this is completely absent.

APHI states that the improvement of both pharmaceutical production and the quality of pharmaceutical imports are key priorities of the MoPH. They feel that, due to the porous borders, poor-quality medicines infiltrate into the market and often find their way into the hospital supply. Therefore, apart from tightening measures through Border Police (under the Ministry of the Interior), regular quality checks of the available pharmaceuticals need to be conducted rigorously to ensure the population's safety.

Therefore, there is a need to periodically monitor the quality of medicine available on the market. The MoPH QC Lab and the GDPA need to focus their activities more on these aspects with due vigilance rather than do routine testing of imported raw materials and pre-marketing testing of locally produced products.

The pharmaceutical sector has been identified as one of the six pillars of the MoPH. This must be communicated to all ministries, particularly to AISA, which can work to attract investors with the help of OPSC-produced materials.

5.3 Other Ministries

5.3.1 Afghanistan Investment Support Agency (AISA)

AISA is the premier national body to encourage investment in Afghanistan. It was established in 2003, with the technical assistance of German Technical Cooperation (GTZ). AISA is an independent body that sustains itself through client fees. Its main role is to encourage foreign and domestic investment. Their core areas of interest are: mines and minerals, agriculture, cold storage, food and fruit processing, packaging, herbal medicine and textiles (cotton export).

AISA reported that it did not prioritize the pharmaceutical industry since it had not received a proposal from the MoPH. "So far, the pharmaceutical industry has not been assigned any priority as no proposal for this sector has been received from the MoPH," they reported.

AISA said it had asked all ministries to send their proposals for investment programs in their respective sectors so that necessary brochures could be produced. The MoPH should have taken a lead, said AISA, and formed a separate department to cover the pharmaceutical industry, as well as other health-related organizations and services, such as hospitals, diagnostic laboratories, etc.

According to AISA, investment laws are very liberal, and domestic industries can simply submit an investment proposal and ask for land. However, international companies must file their documents from their country of origin, with documents certified by the Ministry of Foreign Affairs. Further, AISA encourages investment by facilitating the allotment of land (in an industrial zone set up by the GoA).

It provides: visas for experts, dispute resolution, assistance in getting over inter-governmenal hurdles, advisement to other ministries on how to support investment, rationalization of custom duty and a conducive environment for investment.

At this point, there are no subsidy and tax-holiday schemes in Afghanistan. However, key incentives for investment in Afghanistan include accelerated depreciation, tax concessions on raw materials and the exemption of duties on capital goods. AISA is also organizing seminars, conferences and workshops, both within and out of the country.

According to the director, getting a licence takes between four to five working days, after the required documents are in place. The international company first presents its application to the Afghan embassy (in its country of origin). Then, the embassy refers it to Afghanistan's Ministry of Foreign Affairs, which presents it to AISA. Once the appropriate ministry grants the licence, the company proceeds with setting up the industry. In other words, in the case of an application for the pharmaceutical industry, the MoPH would grant the licence through the GDPA, and the company would be subjected to appropriate regulations.

However, no international or multinational company has yet shown interest in investing in Afghanistan's pharmaceutical sector. Reasons include lack of land in an independent industrial area, insecurity and the fear of competition from products produced in neighbouring countries. AISA suggested the GoA should

provide good security and free land, with the necessary infrastructure, such as electricity, water, drainage, etc., to promote the industry.

5.3.2 Ministry of Economy

Interactions were held with the director of the Health, Education and Culture Department of the Ministry of Economy, since this ministry's policies help to direct growth in the various economic sectors.

Commenting on the perceived vision of MoPH regarding self-sufficiency in pharmaceutical production in the country, the director stated: "It is out of the question to achieve the vision of Pharmaceutical Enterprise, i.e. 50 per cent production of essential medicines in-house (by API by the year 2013), as the GoA policy is to facilitate the production of pharmaceutical products by the private sector and not by the Government (API)".

The director listed the key financial incentives/concessions available to local pharmaceutical units:

- a government loan to set up manufacturing units
- tax-free holiday for three to five years
- 60 per cent price concession on land purchases
- no tax on imported machinery
- work permits for foreign technical experts.

He said there are special industrial areas for the pharmaceutical sector: for one is in Pule Charkhi; another is in Karte-Nau; a third is in Parwan; and the fourth is in Jalalabad. At the moment, a 15-20 per cent tax is imposed on these companies' net profits but the government is considering reducing it to 7-8 per cent. However, the Ministry of Economy is not offering financial incentives/concessions to rehabilitate struggling local pharmaceutical units, he said.

Commenting on the foreign direct investment policy in the pharmaceutical sector, he said that if any foreign firm wants to invest, the same conditions apply as for private local investors. However, foreigners cannot buy land; they can take only lease it for 30-50 years.

If the firm wants to partner with the government, then different conditions may apply. For example, if the government invests more than the foreign company, then government conditions are applied.

The director said the health budget is a combination of foreign aid and government funds, though he did not have specific details. Last year, the total health budget was US$181 million: US$160 million was foreign aid and US$21 million were government funds.

He also said private manufacturing units should be free to decide the price of their own products. The manufacturing units should also try to improve the quality of their medicines. He considered the volume of production to be very low.

He offered the following suggestions to improve the pharmaceutical-manufacturing sector:

- The GoA should encourage investment in public and private projects.
- Manufacturing units should produce good-quality medicines; they tend to start by producing good products but the quality eventually slips.

- A mechanism should be put in place to monitor counterfeit medicines in the Afghan marketplace.

5.3.3 Ministry of Finance

During the meetings with the Ministry of Finance, the assessment team was told that the ministry does not have any special package for attracting new investment in any sector in the country. As well, the Income Tax Act does not have any special provisions to attract investment in any industry. The tax holiday that had been offered previously expired, and the GoA has not renewed it. Under the prevailing laws, only the following provisions exist to facilitate industry:

- **Unlimited carryover losses**, where a company can carry over losses to the subsequent financial year and any profits (in the subsequent year) can be used to balance books.
- **Accelerated depreciation law,** available to industrial units, where faster depreciation is allowed to recover the cost of investment.

Besides these two provisions, there is no other special promotion scheme available to attract investment.

5.3.4 Discussion

From the discussions with the representatives of various ministries, it appears that there is a lack of:

- clarity of vision among ministries
- co-ordination and communication between ministries
- knowledge about financial incentives/concessions available
- special packages/provisions to attract investment in this sector

In addition, the representative of the Ministry of Economy felt that the pharmaceutical manufacturing (public sector) was not on the GoA's agenda. He was concerned about the GoA's interest and support for this sector. Quality and quantity of medicines produced by local units, as well the ready availability of fake medicines were other key issues. Lack of security was also mentioned as reason for almost no local or foreign investment. Questions were raised regarding the capacity of the MoPH QC Lab to test all types of medicines in-house.

As well, the Ministry of Economy stated that there are four industrial zones allotted to the pharmaceutical sector, whereas industry representatives are completely unaware of this allocation and are crying out for land. Even the MoPH is not aware of this.

5.3.5 Recommendations of Respondents

- The Ministry of Economy and AISA strongly suggested that the MoPH should send proposals for attracting investment with brochures for the pharmaceutical sector and other health-related sectors (i.e., hospitals, diagnostic laboratories, medical devices and other medical supplies).
- The quality of medicines produced by local manufacturing units should be improved and maintained.
- The industry must be told about the availability of land in the four industrial areas, as mentioned by the Ministry of Economy.
- The GoA should control entry and availability of counterfeit medicine.

- There must be strict and transparent rules to curb corruption at all the levels.
- The GoA must provide security to investors and their families.

5.3.7 Recommendations of the Assessment Team

- The vision of various departments of the MoPH, including the pharmaceutical sector, should be documented and shared with all the ministries. A Cabinet-approved pharmaceutical policy should clear all inter-ministerial doubts and conflicts. The policy should specifically settle the question regarding the involvement of the public sector (PE/API) in the production of pharmaceuticals.
- There should be greater co-ordination between different ministries to streamline investment in the pharmaceutical sector, complemented by proper information and communication among stakeholders.
- The GoA can consider partnering with some leading MNCs to guide both the public and private pharmaceutical manufacturing sector.
- A Chemical and Pharmaceutical Industrial Park/Zone with necessary infrastructure, including adequate safeguards for environmental protection, should be created. Pharmaceutical production is based on basic chemicals and the ready availability of quality chemicals; raw material is a basic requisite for a viable pharmaceutical industry. (A list of some commonly required chemicals as excipients in formulations is in Annex 4.)
- The MoPH has to come up with a special package and get it endorsed by the Council of Ministers or through a Presidential decree where provisions, such as tax holidays and subsidized facilities, are offered to potential investors.
- The MoPH has to communicate both within the ministry and across other government agencies that pharmaceutical production within Afghanistan is one of its top priorities. So far, PE's vision is only limited to a few individuals, and most of the stakeholders, even within MoPH, think it is unrealistic. Therefore, there is need to document this vision and to communicate it extensively. Once this is done, it has to be followed by advocacy for a special package and implemented.
- Relevant ministries/departments should try to reduce taxes (at various levels, i.e. import of machinery, repair parts, raw materials, etc.).
- The government should provide security to the investors and in the proposed industrial park.
- The MoPH should support the Ministry of Higher Education/Faculty of Pharmacy at Kabul University to formulate a separate pharmaceutical manufacturing-oriented curriculum (including quality assurance) with adequate knowledge, skills and attitudes pertaining to the manufacturing and quality control of medicines.

5.4 Faculty of Pharmacy, University of Kabul

5.4.1 Findings

The Faculty of Pharmacy at Kabul University offers a Doctorate in Pharmacy (Pharm. D.) consisting of five years (10 semesters) (Annex 2, Table 11 for course curriculum). Earlier, it offered a four-year B.Sc. course, but it was replaced by the doctorate. There are no diploma-, graduate- or post-graduate-level programs in pharmacy at Kabul University. This is the only Faculty of Pharmacy in the whole country, and no other courses related to pharmaceuticals are offered anywhere else in Afghanistan. The

eligibility for admission is decided through an entrance exam, written only by those who have passed 12th standard. The annual intake is 100 students.

Upon evaluation of this course, it is evident that:

- About 30 per cent of teaching time is spent on manufacturing and QC aspects.
- Faculty agreed that the materials and chemicals/reagents for laboratory work are very low, and that the quantities available are not sufficient. They give practical classes only for a few liquid and powder preparations. Therefore, students gain very little practical experience compared with what exists in other countries.
- They have only one disintegration test apparatus and there is no dissolution-testing machine. There is no separate machine room to learn and practice pharmaceutical operations. They also give limited exposure on semi-solid dosages forms (ointments/suppositories).
- They are unable to provide exposure to sterile preparations (injections, drops, etc.) requiring aseptic technology.
- Students do analysis only for aspirin and paracetamol, and limited tests for iron, lead and arsenic. The international exposure for faculty is very limited.
- Only few faculty members had an opportunity to be trained for a short period outside Afghanistan.
- The students get very limited first-hand exposure in manufacturing and testing drugs in pharmaceutical companies during the last semester (one four-week internship in a local pharmaceutical factory).
- There are no partnerships between the faculty and local pharmaceutical companies.

The faculty is satisfied with the theoretical part of the program, but not with the practical instruction from a manufacturing point of view. They said their program could not compete with the quality of practical work they had seen during short-term training sessions in other countries, such as Germany, India and Japan.

Afghanistan lacks a basic chemical industry and, therefore, reagents and a chemical supply for practical work at the university is very low. They said the chemical shortage had to be addressed for the benefit of practical instruction. Teacher–training and international academic exchange programs for instructors would improve their competencies. The faculty would welcome support from the MoPH or external donors towards acquiring good chemicals, reagents, and equipment to set up a laboratory, as they have seen in other countries.

Since the industry in the country is very small, less than 10 per cent of graduates find jobs in the industry. The faculty does not believe that the current program provides sufficient knowledge or skilled labour to advance local manufacturing. The faculty agreed that the current curriculum is oriented towards community pharmacy and supply chain. The focus is not on industry.

5.4.2 Discussion

Since India has achieved importance in pharmaceutical manufacturing in the sub-continent, it is worthwhile to compare the two countries' university programs. A comparison demonstrates that the educational inputs pertaining to pharmaceutical manufacturing and quality control (i.e. course content,

lab work, practical experience with pharmaceutical machinery & equipment) at Kabul University are far below standard (Annex 2, Table 12).

Therefore, all major stakeholders appear justified when they complain of an acute shortage of skilled and competent HR at all levels of the industry in Afghanistan. The annual intake of students at the Faculty of Pharmacy at Kabul is 100. In India, it is capped at 30 students per institution offering the Pharm D. program (Annex 2, Table 13). In India, intake is set according to the equipment available. The faculty-to-student ratio is far poorer in Kabul than in India.

A school that offers a two-year diploma program in pharmacy in India has more equipment than what is available at Kabul University for the five-year Pharm D. program (Annex 2, Table 14).

Moreover, there is only one pharmacy program in Afghanistan and exams are handled more or less internally. The same teachers who have taught the candidates for five years conduct the evaluations. In India, external examiners come from different institutions, ensuring a fair and independent evaluation process of students without personal preference or bias.

Therefore, it is recommended that Afghanistan have more pharmacy schools (perhaps located in different provinces) with fewer students in order to allow better opportunities for teacher-student interaction. This would also offer more educational opportunities for students unable to pursue studies in Kabul.

The classes offered at Kabul University and India, on the basis of weekly teaching load, are compared in a table below. The percentage of time devoted to practical training at Kabul is very low compared with India, which explains why the HR competence in manufacturing and QA is equally low in the Afghanistan. Also, practical classes at Kabul seem like somewhat a formality, given the non-availability of chemicals and reagents to conduct them properly.

Table: Comparison of Theory and Practical Classes at Kabul University and India*

	Number of classes at Kabul University for Pharm. D. (ten semesters)	**Number of classes in India for Pharm. D. (five years, yearly scheme)**
Theory (classes)	268	72
Practical (classes)	72	74
Tutorial (classes)	-	27
Percentage of practical classes	**21.2% (72/340)**	**42.8% (74/173)**

* The Pharmacy Council of India (PCI) regulates all institutions running Pharm. D. course in India. It is necessary for all institutions to comply with the Education Regulations (ER) framed by the PCI.

5.4.3 Recommendations of the Assessment Team

If Afghanistan wants to improve pharmaceutical manufacturing and quality control capabilities, it has to make an appropriate investment in education. The Faculty of Pharmacy at Kabul University can either change current course content on professional pharmacy or start a new course with an appropriate focus on pharmaceutical sciences. Professional pharmacy and pharmaceutical sciences are globally

recognized as two distinct streams. Alternatively, the faculty may consider starting a course in pharmaceutical manufacturing and quality control in pharmaceutical chemistry, in either the Faculty of Pharmacy or the Department of Chemistry (which is in the Faculty of Science).

Pharmacists coming out of Kabul University have very poor knowledge about the manufacturing industry. Their curriculum is not oriented toward manufacturing technology. As well, students do not gain experience during their internships either since manufacturing units do not have sufficient capacity to produce tablets, capsules, injections, IV fluids, sterile drops and new drug delivery systems.

If the GoA wishes to achieve self-sufficiency in pharmaceutical production, it may direct Kabul University to either suitably amend its curriculum or mandate the university's chemistry department to set up a separate division for pharmaceutical chemistry and technology.

It is very important to produce competent pharmaceutical scientists and chemists in order to strengthen the local production according to GMPs. It is very difficult to set up efficient industries without adequately and competently trained HR. Pharmacists not properly trained in drug manufacturing and testing cannot fulfill the production needs of the country. All stakeholders (government officials, industry, associations, international donors & partners) are in agreement that the current curriculum is unable to generate competent and qualified HR for manufacturing, QA and QC.

5.5 Pharmaceutical Associations

This sub-section presents the results of discussions with the Pharmaceutical Wholesalers Association, Afghanistan Medicine Services Union and Afghanistan Pharmacists Association.

The Pharmaceutical Wholesalers Association primarily looks at safeguarding the interests of wholesalers. It meets government agencies periodically to ensure that importation and distribution of medicines go smoothly. The Afghanistan Medicine Service Union looks after the interests of both manufacturers and wholesalers.

The Afghanistan Pharmacists Association promotes the interests of pharmacists in all spheres of pharmaceutical activity in the country. Their views are critical since they work in the field and face the day-to-day challenges in executing the tasks related to drug supply and local manufacturing. The results of discussions with the Pharmaceutical and Medical Equipment Committee, which operates under the Afghanistan Chamber of Commerce and Industry, are also presented in this section.

5.5.1 Wholesale dealers

There are regulations to start a wholesale dealership in the pharmaceutical sector. The first step is to apply to the GDPA (MoPH). Then, the GDPA team visits the applicant in their place of work. After an evaluation of the premises and available HR, the GDPA gives them a licence, which has a one-time start-up fee of 60,000AFS (about US$1,200). The Ministry of Finance charges each wholesaler between 10,000 and 30,000AFS (about US$200-$600) per year, depending on their sales.

Regarding regulations that affect day-to-day business, the MoPH issues licences for importing EDL and LDL medicines only. Both lists include a total of 2,000 drugs. However, there is great demand on the

market for other drugs, not approved by the GDAA, which are being sold illegally. According to those interviewed, about 5,000 drugs are available on the market, indicating that 3,000 are making their way through illegal sources. As well, wholesalers have to apply to the MoPH to import narcotics and psychotherapeutic medicine. The MoPH then refers these applications to the Ministry of Narcotics, which sends it to Geneva. Thereafter, they receive clearance, but this is a very long process.

Wholesalers buy or import medicine from Pakistan, Iran, China, India, Bangladesh and other Arab countries. They also buy locally manufactured medicines, but these fulfill only 1 per cent of the demand/needs. Their customer base consists of the whole of the Afghanistan, the MoPH, the Ministry of Hajj or Augaf, private hospitals, NGOs, pharmacies and calls for tender, published in various newspapers.

They described the supply chain as follows: the medicines come first to the distributor, then to the wholesaler and then to the retailer. They said there is no gap between demand and supply as they import so many medicines, but there is a shortage of insulin and anti-cancer drugs.

The 25 medicines most in demand are: Ceftriaxone, Augmentin, Amoxicillin, Azithromycin, Clarithromycin, Cefalaxin, Ceftadine and Ciprofloxacin, Metronidazole, Analgesics, such as Diclofenac, Parcetamol, Ibuprofen, Orphenadrine, Nimuselide, Antacids, Antihistamines, Vitamin A, Vitamin E, Multivitamins, B-Complex, Cetrazine, Loratidine, Omeprazole, Ranitidine and Aluminium hydroxide.

For the past three years, they have not received any complaints about drug quality; they were imported only after quality control testing by the MoPH QC laboratory. However, some medicines are smuggled into the country without QC checks.

They suggested the following to help enhance accessibility of medicine:

- presence of pharmacies in the entire country, without any terms and conditions
- wholesale dealerships in the provinces, and relaxation of regulations (i.e. the minimum-space requirement for wholesale premises)
- expand the EDL and LDL
- the MoPH should allow the combination of omeprazole and Domeperidone.

5.5.2 Afghanistan Medicine Services Union (AMSU)

AMSU co-ordinates with the GoA to address problems related to pharmaceutical manufacturing and distribution. They said the regulations indicate that a manufacturer should have the following documentation to set up and run a unit:

1. Investment plans
2. Standards to which to adhere
3. Technical HR staff
4. A production list

Once these requirements have been met, the MoPH grants permission. The final product should also be sent to the MoPH QC Lab. They felt these regulations are not encouraging, since they do not extend any tax-free offers, bank loans, free land or other business incentives and subsidies to local manufacturers and MNCs.

There is a board in the MoPH for medicines, and members meet twice per month with the minister. The MoPH also has a technical board, which has a representative from the AMSU. AMSU also meets regularly among its own members, about every two months.

They reported no demand-and-supply gap, as the MoPH procures too many medicines, and there is no lack of the medicines in the open market. They felt the current capacity of the local industry is very poor, producing only 1 to 5 per cent of medicines needed. Their suggestion to improve local manufacturing is to promote the establishment of local units. The process of receiving permission for the import of psychotherapeutic and narcotic drugs should be made easier; the EDL and LDL lists should be expanded (like in neighbouring countries); the tax-submission process should be eased; and there should be four more QC Labs in the country to shorten the time for QC analysis.

5.5.3 Afghanistan Nationwide Pharmacists Association

The Afghanistan Nationwide Pharmacists Association was established in 2004. The 1,500 members of the association are graduates of the pharmacy faculty. The role of this association is to:

- Help and advise the MoPH on in-country drug production, import, quality control and distribution of medicines, through various commissions of the association (scientific, inspection, pharmacy affairs, publication, administration and cultural commissions).
- Protect the rights of the Afghan pharmacists through various commissions of the association as stated above.

They do not have regular meetings with MoPH representatives. Their meetings take place based on the needs of the association or the MoPH. For example, three months ago they had a meeting with the MoPH and MSH/SPS regarding the assessment of the private pharmacies and drug stores of Afghanistan. They have a policy document and brochures specifying their roles. Currently, it was not possible to fill all of the expected roles due to the lack of technical competence. They were not aware of the regulations to set up and run a manufacturing unit.

When asked to comment on the current capacity of the manufacturing units, they said the pharmaceutical manufacturing industry in the country can be divided into two categories. Previously, there were two government industries, Avicenna and Hoechst, which produced 60 per cent of the total demand in the country (40 per cent, Avicenna and 20 per cent, Hoechst). Hoechst is now closed, and the production at Avicenna has dropped to less than 1 per cent of the total demand in the country.

They said private manufacturing companies should be called “small laboratories of drug production”.

“We can’t call them drug manufacturing companies. Because they are not following GMPs, they lack professional personnel, appropriate space and are producing just syrups. The amount of the drug they are producing can’t be counted in the percentage, that is, the amount is less than the 0.0001 per cent of the country’s total drug demand.”

Despite this, he felt there was a surplus of medicines on the national market, compared with the true demand, and the quality of the medicines was questionable.

They suggested that pharmaceutical production could be increased in the country by allocating land to the pharmaceutical industry (far from residential areas), offering government support to local investors that would facilitate the process of setting up a company, reducing bureaucratic processes, offering subsidies on land and power, promoting joint ventures with MNCs and reviving Avicenna and Hoechst through semi-privatization and joint ventures with foreign investors.

5.5.4 Afghanistan Chamber of Commerce and Industries

ACCI was established with a vision to solve problems in the private sector. It has 21 committees, including a Pharmaceutical and Medical Equipment Committee (PMEC). The PMEC was formed just eight months ago. It works to bring all private investors in the pharmaceutical industry together to address their challenges (taxation, issues with government). PMEC meetings are held on a needs basis.

There seemed to be a general lack of understanding about regulations: the time required to get licences and to set up a manufacturing unit for local and international investors and MNCs. This department was also unaware of how many MNCs/investors have shown interest in setting up units. They reported that there was no support from the government for MNCs or local producers. They stated that manufacturing units are very few and most medicines are imported and/or smuggled into the country. As well, they claim that the MoPH QC Lab is not able to do QC completely. For example, they said: "When the government wanted to check Swine flu medicine, they had to send it to WHO in Geneva to check it".

Concerns were also voiced about the quality of medicines: "If you buy a Pakistani or Indian brand here, their efficacy is low (as compared to when bought in their country of origin)".

They suggested procuring the latest technology and affiliating with a good MNC to build the capacity of local manufacturing units.

5.5.5 Discussion

It emerged during the discussions that the various associations felt the rules, regulations and procedures were quite cumbersome and time-consuming. They felt that the quality of medicine imported through proper procedure, as well as those produced in-country, are good because they are tested by the MoPH QC Lab. These pharmaceuticals were only sold on the market after they received this lab's certification.

They also stated that the government should try to address the issue regarding the delay for the approval of medicines and raw materials, which remain stuck at the custom ports for many days. They suggested the government establish four QC Labs in different locations to speed-up the process.

The manufacturers said they should be allowed to buy raw materials without testing and have the QC Lab test their final products only in order to save some time in the production process. They are unhappy that a government body decides the market price of their products, which cuts their ability to compete with other companies. They feel the government should deregulate these bodies and open the sector to the market.

They shared that the EDL and LDL need to be revised, as there is a demand for more types of medicines on the market than those listed. Further, the MoPH should allow combinations of different drugs to be imported and sold, as it is cheaper and good for consumers. They also stated that the procedure to import narcotics and psychotherapeutic medicine needs to be simplified and shortened.

5.5.6 Recommendations of the respondents

- The MoPH should establish four QC Labs at the custom ports to reduce time required for sample testing (of both raw materials and medicines).
- The GoA should revise the EDL and LDL. The process to receive permission to import psychotherapeutic and narcotic drugs should be made easier.
- The GoA should address the issue of availability of counterfeit medicines in the market by taking random samples for testing.
- Land should be allocated to the pharmaceutical industry (far from residential areas); subsidies should be offered for land and electricity; joint ventures with MNCs should be promoted
- Allow manufacturers to produce medicines and then submit to the government agency for testing (exempting raw-material testing to save time).

5.5.7 Recommendations of the assessment team

- The government could form a committee to discuss the issue of allowing manufacturing units with due accountability to bring in raw material and manufacture medicines; the QC Lab and the MoPH would check only finished products.
- Revision of the essential and licensed drug lists may be considered on a merit basis only, in view of discouraging unsafe combinations.
- Allocate land to the pharmaceutical industry (far from residential areas); offer subsidies for land and power; promote joint ventures with MNCs.
- The MoPH may consider establishing QC Labs at the custom ports to reduce the time required for sample testing (of both raw materials and medicines).
- The GDPA and MoPH QC Lab shall conduct regular random sampling of available products in government and private health facilities, pharmacies and medicine storage units.

5.6 International Development Partners in Afghanistan

The assessment team conducted interviews with international development partners to get their opinions of the health and pharmaceutical sectors.

The major development partners in Afghanistan include:

- The World Bank
- United States Agency for International Development
- European Union

Other partners in the reconstruction of Afghanistan include the World Health Organization and UNICEF. International partners also include Management Sciences for Health and Compri-A (now ASMO).

5.6.1 The World Bank

Since 2002, the World Bank is involved in rebuilding the health sector and has pushed contracting out for performance-based partnership agreements (PPAs). It has systematically supported the MoPH in many sectors, including pharmaceutical management.

The World Bank believes that no centralized procurement system of drugs has worked anywhere. Therefore, in the BPHS contracts supported by the Bank, NGOs are free to purchase drugs from the global market, as long as they meet the MoPH criteria. This eliminates the requirement to purchase local pharmaceuticals.

There are issues in pharmaceuticals management in the country. On account of the porous borders with Pakistan and Iran, many drugs are entering the country illegally, preventing stringent quality standards from being applied in Afghanistan.

All World Bank-supported contracts are lump-sum contracts. The Bank passes resources to the MoPH, which enters into contracts with NGOs. Therefore, the onus of assuring the quality of the medicine is on the MoPH. The World Bank does not play an active role in this monitoring.

Strengthening the local pharmaceutical manufacturing industry is not yet on the World Bank's radar. However, the Bank maintains that it supports the MoPH in whatever direction it wants to take the health sector. The MoPH states it wants to promote the pharmaceutical sector and let the World Bank to decide on the support, but so far this has not been conveyed to the Bank.

Generally, the World Bank maintains that it is difficult to develop a strong pharmaceutical-production sector in Afghanistan given the high costs and poor-quality products. According to the Bank, it will be a while before this sector becomes self-reliant.

The first priority to develop such a sector is to prepare an environment for drug manufacturing, followed by the implementation of the manufacturing policy. Lastly, the sector has to come up with strategy on how to stay competitive.

5.6.2 The United States Agency for International Development

The United States Agency for International Development (USAID) feels that the Afghanistan Health System has come a long way since 2002. It went from being nonfunctional to functional and coherent. The major development partners' efforts have resulted in outlining and executing BPHS, EPHS and the EDL, along with many other milestones. Since the rebirth of the health system in 2003, major progress has been made in terms of coverage for the population and the number of health facilities that are functional. Quality leadership also had a major role in turning around the health system.

In the revised BPHS framework, development of the pharmaceutical sector is one of the 10 pillars that will help bring about a second-generation health system in Afghanistan. USAID is directly responsible for providing technical and financial assistance for operationalizing this sector. Efforts will be put into building capacity for procuring high-quality medicine and for developing a pharmaceutical strategy and

operations within the MoPH. It aims to work on identifying gaps in pharmaceutical management and putting legislation in place to bridge those gaps.

USAID does not have a position on pharmaceutical manufacturing but thinks it is a noble ideal. USAID feels it is not a function of the government to engage in pharmaceutical production but of the private sector. USAID regrets that the government's focus in pharmaceutical manufacturing is API. Up until now, pharmaceutical production in Afghanistan is not a concern of USAID.

USAID is most worried about the quality of medicine, irrespective of its country of origin. The product has to meet the gold standards set for quality, and the medicine manufactured in Afghanistan should be no exception to this. No laxity whatsoever should be given to quality, whether it is manufactured in the country or elsewhere.

The procurement of pharmaceutical products for the 10 provinces supported by USAID is done through a central agency, named TECHSERVE. They only procure drugs from IDA-approved companies, and there is a built-in quality-check mechanism.

The health sector of USAID does not support pharmaceutical manufacturing. However, the economic growth cell of USAID has interest in collaborating with pharmaceutical manufacturing associations.

When asked for suggestions on how to revive manufacturing in the country, USAID said the first priority would be a commitment to gold (GMP) standards from the start and the production of drugs identified on the essential drugs list. Having a good QC Lab is a priority to ensure that good-quality products are imported and manufactured.

5.6.3 The European Union

The European Union (EU) is one of the three major donors engaged in rebuilding the Afghanistan Health System. They also list EPHS and BPHS as a major achievement of the new GoA since 2002. Among other positive developments is the development of human resources, which will increase the capacity of the MoPH and result in a more efficient health system.

However, the staffing issues at the MoPH, especially in the field, remain an issue. Their capacity needs to be increased significantly. There is a need to reform administration and establish regulations for operations in the private sector. Primary care has improved, but less emphasis has been given to the development of secondary care.

There are issues with local companies supplying medicine to NGOs operating in the health system. Many of them are not registered and operate beyond the government's jurisdiction.

As well, poor-quality medicines are being brought in. This is the personal perception of the interviewee. Attention needs to be paid to this issue by orienting local companies in their procurement of quality products.

The EU supports NGOs operating in 10 provinces providing BPHS services. These NGOs are expected to adhere to clauses in their contracts pertaining to the purchase of quality medication. The EU office in Kabul has no regulatory mechanism in place to monitor the procurement of drugs by these NGOs.

The EU does not see any purpose to reviving the pharmaceutical-manufacturing industry in Afghanistan nor in setting up new production units.

It has, however, drafted a contract with an international company to work with the GDPA in setting up its pharmaceutical management and building the capacity of the GDPA staff; the contract was not signed at the time of this study, as it was waiting government approval.

When asked for suggestions about how to set up or revive a pharmaceutical unit, the EU suggested that it would be important to build the capacity of the local workforce and, as much as possible, use local raw material.

5.6.4 The World Health Organization

The WHO representative interviewed felt that, since 2002, a lot of progress has been made in the health sector. The BPHS and EPHS package, which are being implemented, have had a positive impact, and the coverage of health services has gone up to a respectable level. The MoPH has developed policies, strategies and guidelines, essential to run the health system. They have been able to secure firm commitments from the donors for running the health system for the next few years. There is a decline of about 30 per cent in child and infant mortality, and it is expected that the MMR will decrease significantly once the results of the Afghanistan Mortality Survey are out. Skilled birth attendance has gone up. However, there is still a lot of work to be done to make the system more responsive and effective.

One of the limitations of the pharmaceutical sector is its failure to install a system to check the quality of imported drugs. The perceived corrupt practices prevalent at all levels are supposedly responsible for the poor-quality imports and local products.

As of now, neither the government nor the WHO has support of the local production of drugs as a priority. There is a need to seriously assess the situation for local production, as it looks grim. The raw material and labour skills required are not available within the country. As expatriates would likely be involved in production, the cost would be high and production capacity would not be at the economy of scale.

The WHO representative also felt that the government itself should not engage in production. Rather, it should promote and encourage the private sector by providing the right kind of atmosphere, incentives and support.

The MoPH should work with AISA and the Ministry of Economy and Ministry of Finance to encourage private-sector investment in this area.

Manufacturers should start with routine government procedures and produce high-quality medicines that are easy to make and most-often consumed in the local population. Another area that needs attention is the MoPh QC Lab.

5.6.5 The United Nations Children Fund

The United Nations Children Fund (UNICEF) representative reported that most of the medicine in Afghanistan is imported from India, Bangladesh, Pakistan, Iran and Turkey.

In principle, the UNICEF representative agreed that the GoA should support the private sector and encourage local industry. He thought that machinery, technical know-how and skilled human resources would have to be imported but believed that, over time, reliance on outside assistance could be phased out. Some of the raw material needed for manufacturing may be available locally. He was not clear regarding UNICEF's role in reviving the pharmaceutical industry in Afghanistan. The private sector would have to assess the demand for drugs and start catering as per the needs of the local market.

He believed regulations must be strengthened and put in place for quality imports. He also advocated that the MoPH QC Lab, which acts as a reference laboratory, needs to be well equipped and new skilled labour needs to be in place for it to provide quality services.

UNICEF said it would only start buying locally produced drugs once they meet the gold standards of quality.

5.6.6 Strengthening Pharmaceutical System (SPS), Management Sciences for Health

SPS, led by Management Sciences for Health (MSH), started their operations 15-16 months ago. Currently, their priority is strengthening the pharmaceutical supply in Afghanistan (as per MoPh requirements). All their activities are aligned with the MoPH objectives and co-ordinated through the MoPH office.

The focus areas of SPS are:

- strengthening the rational use of medicines (setting up Drug and Therapeutics Committees in up to five hospitals and developing of Standard Treatment Guidelines)
- quality Assurance in all areas
- procurement and distribution of medicines
- capacity-building of doctors and pharmacists
- revision of the curriculum at the Faculty of Pharmacy, Kabul University, in tune with the Rational Pharmaceutical Management
- support research studies on the quality of medicines available in Afghanistan[8] (findings reveal that only 9 per cent of drugs failed according to pharmacopeia standards and the quality of medicines are not as bad as thought).

[8] The study report is yet to be finalized.

They founded the Co-ordinated Procurement and Distribution System, under the MoPH Deputy Minister. They also run a sister project for drug management, called TECHSERVE. It is under MSH, focusing mainly on TB and RCH medicines.

Most of the medicines from the EDL are in greatest demand, and they are mainly antibiotics and NSAIDS. It is a common problem to run out of stock of these drugs due to inadequate funding. MSH does not have any direct contact with the local pharmaceutical-manufacturing units.

However, their impression is that there are very few manufacturing units, which have very limited production capacity. The major issues related to pharmaceuticals in Afghanistan were: lack of sufficient funds to procure medicines for all, few staff for the regulatory body, limited professional competency, poor quality of products and no standardization of medicines. Further, there was no strict national enforcement of GMPs.

MSH said it had sufficient subject experts for SPS operation areas for its internal functioning. However, the system outside their own organization was very weak and old, with limited resources (technical and professional staff). Responding to change is very slow, as it requires political support, which is often not quick in coming, if at all. However, it has a very good relationship with the GDPA and MoPH.

The future plan of SPS is to encourage the private sector to improve the quality of medicines in the imports, wholesale and retail sectors (not the manufacturing sector). SPS does not support local pharmaceuticals units. However, they suggested ways to improve local units:

- improve regulations, especially GMPs, to strengthen manufacturing
- impose GMPs as mandatory to ensure the quality of locally manufactured medicines
- address security issues
- curb the supply of counterfeit medicines
- consider the economy of scale of production
- improve the technical qualification and competence of HR in pharmaceutical manufacturing
- improve the MoPH's monitoring and application of regulation standards.

5.6.7 Afghanistan Social Marketing Organization (ASMO)

ASMO is a local organization that implements a USAID-funded social marketing project. This initiative was started by Population Services International and then handed over to MSH, which handed it to ASMO.

ASMO has been independent since October 2010. Their mission aligns with the mission of the MoPH in that it also aims to reduce child mortality and increase contraception use. Their mission is to increase awareness, as well as the access to and use of reproductive and child health products. They are working to create an enabling environment for the private sector and the effective delivery of quality services. Their target population is women of reproductive age and women with children less than 5 years old.

It has five regional offices, in addition to its head office in Kabul. ASMO promotes three contraceptives: the male condom, oral contraceptive pills and injectable contraception (Depo-Provera). It also offers a water purification solution (Apacon) and three flavours of ORS. It plans to introduce Iron Folic Acid

tablets. The contraceptives are provided to them by USAID and transported by a Canadian company. Khalid Irshad Pharmaceutical prepared the ORS packets and water purification solution.

It said the only local manufacturing company it deals with is Khalid Irshad for ORS packets. According to ASMO, American – Afghan United Inc. has GMPs but other companies have low standards; they operate out of residential homes, and SOPs are lacking. It believes there have been significant improvements in local products, but Afghans still prefer foreign products.

According to ASMO, antibiotic, analgesic and multi-vitamins are most in demand. ASMO believes 95 per cent of the drugs are imported while only 5 per cent are produced locally. The EDL and LDL are the two guidelines to follow when importing medicine. Importers purchase medicine according to these lists, which have about 2,000 medicines. However, ASMO believes there are about another 2,000 medicines that are distributed in the market illegally due to market demand.

ASMO underlined issues, such as the challenges at customs, which impacted drug quality. Reportedly, manufacturers and importers have to declare the imported items here before bringing them to Kabul. There is no MoPH QC Lab at these customs stops, so a team from the Kabul-based lab must go to collect the drug samples for analysis. Only after the drugs are analyzed can manufacturers and importers bring their supplies into the country. Further, if the MoPH QC Lab is unable to test the sample, it is sent to lab in another country and the manufacturing unit or importer has to bear the cost.

Another issue was the availability of proper storage facilities, such as refrigerators, among wholesalers and retailers. Some products need temperature maintenance (e.g., oxytocin). A lack of these facilities compromises quality and end-users are unaware of this. ASMO also considers it ironic that duties imposed on raw materials are higher than those imposed on finished products. Another problem that was underlined is that the number of registered/qualified pharmacists (8,600) is less than the number of pharmacies (about 15,000) in the country.

Sharing their key strength, ASMO staff said their organization is the only one working with the private sector, providing grants to professional associations and doing capacity-building. Recently, MSH consultants conducted an assessment of the Afghanistan Medical Services Union (pharmaceutical sector). They awarded a grant to the Afghanistan Private Hospital Union for an exposure visit to Turkey.

ASMO's major achievements, from 2006 to 2009, include the sale of: 26 million condoms, 4 million cycles of oral pills, 12 million injections of Depo-Provera, 0.8 million bottles of chlorine (250 ml; 2.5 ml cleans 10 liters of waters), and 16 million ORS packets. They lobbied the government to engage private sector in health services and succeeded to convince the GDPP to establish the OPSC under the MoPH.

ASMO also supported a knowledge, attitude and practice study on contraception and water purification. Elaborating on expansion plans, staff said they would launch IFA tablets in 2011. They also plan to launch ORS packets with zinc and are in touch with Global Alliance for Improved Nutrition to launch a program for a micro-nutrient product. A consortium of Global Alliance for Improved Nutrition, a manufacturer and a research agency are assessing what micro-nutrients are available, the food habits of different ethnic groups, the production needs and price.

ASMO felt that government should not intervene in product pricing. To improve the local pharmaceutical sector, ASMO suggested that the GoA allocate land in an industrial area for manufacturing units, provide electricity and a water-drainage facility, develop skilled labour, expand the EDL and LDL, provide local raw material from reliable sources and establish four QC Labs to test medicine from Pakistan and Iran.

5.6.8 Discussion

International partners play a critical role in the health-care system. Their activities are aligned with the aims and objectives of the MoPH with regards to health. However, there is limited involvement with local pharmaceutical manufacturing. The partners felt that only some of the local units produced good-quality medicine, as most units do not have GMPs or SOPs.

According to them, antibiotic, analgesic and multi-vitamins are most in demand. They also highlighted the prominent issue of procedural delay due to lack of QC Labs at the custom ports. Further, if the MoPH QC Lab cannot test a sample, it is sent to a lab in another country and the cost is borne by the importer.

The lack of proper storage facilities (among wholesalers and retailers) compromises product quality. Duties imposed on raw materials are higher than those on finished products. The major issues related to pharmaceuticals in Afghanistan are: a funding crunch, meager staff of the regulatory body, limited professional competency, poor quality of products and no standardization of medicines. Further, there is no strict national GMP enforcement. They recognize that the GDPA is limited in its capacities; it has outdated procedures with a limited technical and professional staff.

5.6.9 Recommendations of the Partners

The international partners, though not directly associated with local manufacturing units, suggested that the GoA provide:

- skilled and competent labour
- land in an industrial area to pharmaceutical manufacturing units (ensuring electricity and a water-drainage facility)
- local raw material from reliable sources
- the application of regulations, especially GMPs
- four QC Labs at custom ports to testing medicine
- expanded EDL and LDL
- better security to attract investment
- a method to curb the supply of counterfeit medicine.

5.6.10 Recommendations of the Assessment Team

International partners should focus on:

- capacity-building of the GDPA and PE (they should be trained in English and be offered refresher courses in pharmaceutical manufacturing and business promotion)
- developing the skills of top management in leadership, strategic planning and team-building

- speeding-up the revision of the curriculum of the Faculty of Pharmacy, Kabul University, in tune with current GMPs as recommended by the WHO

- The GoA should consider the following:
    - developing and implementing GMPs
    - conducting periodic reviews of the EDL and LDL
    - strengthening the capacity of the MoPH QC lab and establishing a few more regional/provincial MoPH QC labs at the custom ports;
    - eliminating/reducing import duties on raw materials for pharmaceutical production
    - reviewing the role of MoPH QC labs and the GDPA
    - establishing licensed/authorized QC labs in the private sector with accountability.

5.7 Health Facilities (hospitals and pharmacies, both public and private)

5.7.1 Public hospital - Indira Gandhi Institute for Child Health (IGICH)

The IGICH covers the entire country. Patients come from all over because there are no other specialized children's hospitals in Afghanistan. The IGICH had a staff of 555, with about 150 doctors. Their average OPD/day was 700-1,000. Their IPD is 350 beds, with an occupancy rate of more than 85 per cent. The average length of stay (ALOS) is 2-3 days. In the emergency department, they receive as many as 200 patients per day. According to the IGICH, the major morbidities include seasonal diseases (pneumonia, diarrhea), burns, orthopedics (accident and falls), and malnutrition cases. The ALOS was higher for burns and orthopedics.

Sharing the mechanism of medicine procurement, an IGICH official stated that the MoPH has a moderate budget of 60,000AFS/quarter (about US$1,200) for the hospital. For procuring medicines, they compile a list of essential medicines at the hospital level and submit it to the MoPH, which forwards it to the central warehouse. Delivery takes an average of 15 days. However, most of the time, the central warehouse is able to provide only about 50 per cent of the medicines requested. When medicine is not available in the hospital, patients have to buy them from private pharmacies. There is no budget to buy from the market. The hospital has 10,000AFS in petty cash (about US$200), which is usually replenished when it runs out. However, there were no funds to replenish the petty cash last year.

In addition to the MoPH supply, they receive medicine from UNICEF, HPIC and the International Security Assistance Forces (ISAF). UNICEF provides only nutrition-related products and food (biscuits, corn, etc.). Whenever the stock is near completion, the IGICH sends UNICEF a request, and their stock is replenished within 15-20 days.

Regarding the ISAF, there was no formal procedure and timelines. They give supplies as gifts occasionally, with no consistency. In the past year, they gave supplies about five times. Sometimes, for poor patients, the doctors and other staff collect money among themselves and pay for their treatment.

The hospital reported that the MoPH had never checked the quality of medicine or products in the past year, even though the quality of medicine available in the country is a big issue. The quality of medicine provided by the MoPH and HPIC is good. They said European, Canadian and American medicines are of very high quality. Medicine from Pakistan, India and Iran are also good but there is big problem of fake

medicine from these countries. Despite this, the hospital did not report a supply of counterfeit medicine in the government pharmacy. Further, due to the poor perception of medicine produced locally, strengthened by the fact that raw materials come from India, Pakistan and China (also perceived to be of low quality), people do not like to buy them. Moreover, production is very low.

Hospital officials had visited a local pharmaceutical-manufacturing unit (Afghan-American) and two manufacturing units abroad (one in UAE and one in Iran) and, based on their observations, said there was no comparison. The units abroad had the latest and sophisticated machinery. Everything was automatic. Staff was highly educated (in the U.S. or U.K.), had high education and high skill level. They had special QC Labs, as well as survey and research departments. Local units had staff, who were trained for two to three months in India or Pakistan; their education and skill-set were low. Afghan-America had one person who was educated in the U.S. They felt that the major issues regarding local units were: lack of qualified staff, obsolete and redundant machinery, and the poor quality of raw materials.

Hospital staff suggested there was a need for:

- local capacity-building
- new buildings, with separate areas for manufacturing different types of products, such as injectables, serums and tablets, as well as an in-house QC Lab
- the latest machinery and technology
- raw material purchased from reliable companies
- better university programs for proper training
- government programs that supply land, electricity, loans and training for private manufacturing units.

5.7.2 Private hospital (Wahaj Hospital):

Wahaj Hospital attracts patients from all over the country. Their average OP/day is 150-200; the average IPD is 30-40/month, with ALOS of 3-5 days. According to officials, abdominal diseases (50 per cent), ARI, heart, orthopedics, cancer (10 per cent) and renal diseases were the major morbidities with which patients presented themselves.

Doctors/consultants submit their medicinal needs to the pharmacy department, which buys it from the local Parwan market. The most-consumed medicines are: Antacid (Omeprazole, Esomeprozole, Pantaprozole), Ceflriaxone, Dicolfenac, Augmentin, Amoxil, Clarithromycin, Azythromycin, Levofloxacin, Ciprofloxacin, Glimeperide, Captopril, and Xanax.

They have never experienced these medicines being out-of-stock as they are always available on the market. They also stated that MoPH representatives had never checked the quality of medicine or products in their pharmacy in the past year. Doctors address the problem of poor-quality and counterfeit medicine by prescribing only reliable brands. They also inform the pharmacy if they find anything wrong with a brand. They think that the quality of locally produced medicine is good but that the supply of counterfeit medicine is a big problem. Counterfeits of good brands make their way into the market very fast. While few patients are aware of the quality of medicine, they said they do not think people would like to buy locally manufactured medicine due to quality.

Hospital officials said two local manufacturing units, Afghan-America and Ariyana, produced about five medicines, but the quality is not good. Only about 10 per cent of their doctors are satisfied with this brand. However, they attribute this to the gifts they receive from the representatives of international companies, such as laptops, TVs and even cars.

They believe the major issues for local manufacturing units are: lack of land, electricity, human resources, chemical supply, security (in some cases, the Taliban abducts the family member of an investor for ransom), as well as the supply of fake medicine.

Commenting on the fake supply, a hospital official said: "Medicines, from A to Z, come from Iran. But there is a big difference in the efficacy of the medicines sold here and there (due to the availability of fake medicine on the market). For example, Isorbide costs 100AFS in Iran but here it is available for 10AFS? So, how this is possible (without the quality and efficacy being compromised)?"

In order to improve local manufacturing, they suggested that the GoA give land, electricity and security. They felt that investors would invest in machinery if they had more government support.

5.7.3 Public Pharmacies

The assessment team visited two big government hospital pharmacies and two normal-functioning private pharmacies.

5.7.3.1 Indira Gandhi Institute for Child Health

The IGICH pharmacy has 11 staff and receives its supplies from the MoPH (central warehouse). The delay in receiving a request for medicine is about 20 days. The delay is due to the absence of an MoPH or warehouse official. There is no delay in the country of origin. They shared the list of medicines in demand (Annex 2, Table 15B).

They reported that the MoPH has never checked the quality of medicine or products in their pharmacy in the past year. They believe that most of the medicines they receive, which were produced in Pakistan, China and India, are of poor quality. They said drugs coming from Europe, Canada and the U.S. were of better quality but price was a big factor.

They felt that about 90 per cent of patients are sensitized to quality, and the local population was more concerned about quality than price. They felt that the quality of locally produced medicine is low. Initially, they said, the quality of local products was good, but it deteriorated over time. People changed their perception of the local drugs and lost trust in them. As a result, they said, people do not like to buy local medicine.

They said they purchased Povidone but it was of very low quality. They did not think it could improve because the government wants favours and pharmacy/private health care providers want gifts (to sell products of a particular brand).

According to them, half of the patients come with a prescription, 30 per cent take the pharmacist's advice, and 10 per cent come without prescription or with an old one. They said a higher proportion of medicine is sold to patients without a prescription.

Corruption at all the levels must be eradicated to improve accessibility of medicine throughout the country, they said. To improve local manufacturing, there should be a mechanism for the quick clearance of raw material and QC testing for finished products only.

5.7.3.2 Ibn-Sina Government Emergency Hospital Pharmacy

This pharmacy receives its supplies from the central warehouse, through the MoPH. The delay to receive medicine is one month, if they follow up the request; otherwise, it takes several months. The top 20 medicines on their request list are: Antibiotics: Ceftriaxone, Ampecillin, Gentamycin, Ciprofloxacin, Ofloxacin, Levofloxacin, Moxifloxacin, Augmentin, Erythromycin, Azithromycin, Metronidazole, Analgesics: Voren, Ibuprofen, Meloxicam, Piroxicam, Paracetamol, Morphine Derivatives, and Anesthetics: Ketamine, Atropine, Suxamethoniumpentazocin, Thiopental, Diazepam.

They reported that the MoPH did not check the quality of medicines or products in their pharmacy in the past year, nor did they receive any complaints about quality. They felt the quality is not bad, though they admitted that it differs according to the country of origin. Price was again a big factor. MNC medicines are expensive, whereas medicine from China is cheap and of low quality. They believe consumers are not aware of quality. They said medicine is generally unaffordable as most Afghans are poor and jobless. The local population expected to have good quality medication for a fair price. They stated that some local medicines are good, but, in general, they do not sell local products in their pharmacy. They believe people would buy local medicine if the quality is good and the price is fair. In order to improve accessibility of medicine throughout the country, they suggested that security be improved, the network of government clinics be expanded and pharmaceutical industries be established in all provinces.

5.7.4 Private Pharmacies

According to the two private pharmacies interviews, the regulations to open and run a pharmacy require that an application be made to the MoPH to obtain a licence. The MoPH forwards this application to the rules and regulations department, which assesses the location (including the size) and grants a work permit. These pharmacists buy drugs from wholesale dealers. Delivery takes only one hour and there was no problem regarding the availability of medicine (from any country).

The top 20 medicines they order include: Antibiotics, Ceftriaxone, Ampecillin, Gentamycin, Ciprofloxacin, Ofloxacin, Levofloxacin, Moxifloxacin, Augmentin, Erythromycin, Azithromycin, Metronidazole, Analgesics: voren, brufen, meloxicam, piroxicam, paracetamol, morphine derivatives, and Anesthetics: ketamine, atropine, suxamethoniumpentazocin, thiopental, diazepam.

They said an MoPH representative did not check the quality of medicine or products in their pharmacy in the past year and they did not receive any complaints regarding the quality of medicine in the past year. They felt that the quality of medicines was not bad but it differed depending on the origin of the

medicine. For example, medicines from China were of low quality. They also felt that the consumers do not know much about the quality of medicine.

5.7.5 Discussion

The private pharmacies revealed that the rules and regulations to get a licence were quite simple and straightforward. Though there was some difference of opinion on the minimum space required (which has recently being increased).

According to ASMO (refer to 5.6.7), the number of registered pharmacists is less than the number of pharmacies in the country, and there is good number of pharmacies being run by unqualified persons.

Hospitals and pharmacies (both public and private) have concern regarding the quality of the medicine, especially from Pakistan, China, Iran and India. They were satisfied with the quality of medicines from Europe, the United States, Canada and Western countries, but felt they are expensive.

The top medicines in demand are: Ampecillin, Amoxil, Atropine, Augmentin, Azythromycin, Captopril, Clarithromycin, Ceftriaxone, Ciprofloxacin, Diazepam, Dicolfenac, Esomeprozole, Erythromycin, Gentamycin, Ibuprofen, Ketamine, Levofloxacin, Moxifloxacin, Metronidazole, Meloxicam, Morphine, Ofloxacin, Omeprazole, Paracetamol, Pantaprozole, Piroxicam, Suxamethoniumpentazocin, Thiopental and Voren.

The public health facilities have their own government mechanism of obtaining medicine through the MoPH central warehouse. They receive supplies on a quarterly basis. However, the quantity supplied is meager and fulfill their requirements for only one week (in the case of big hospitals, such as the IGICH). Their representatives lamented that the allocated budget for medicines was as just 60,000AFS (about US$1,200 USD) per quarter. Further, delivery takes at least 20 days to a month or more.

The private facilities have a very simple and quick supply procedure. Based on their internal needs-assessment, they buy medicine from wholesale dealers. The private providers felt that there is no drug shortage and medicines are available in abundance, with the exception of insulin and anti-cancer drugs. According to them, the capacity of local manufacturing units is too low; they lacked the proper resources: land, electricity, human resources, modern equipment and technology. The quality of local medicine is not perceived as good, and people have no trust in them. They felt that the government should make efforts to strengthen the local manufacturing units.

5.7.6 Recommendations of the respondents:

- An increase in medicine budget for public health facilities
- Better availability of medicine and quicker delivery of all requested medicines
- More competent human resources
- The government should provide: land, electricity, loans and training of staff for private manufacturing units

5.7.7 Recommendations of the assessment team:

- The government should increase the medicine budget for public health facilities by a significant amount.
- The MoPH and the central warehouse should try to minimize the delay in delivering medicine and consider computerizing the Drug Logistics System.
- The government should establish a few more pharmacy schools across the country.
- The government and international partners should try to revise the course curriculum of the Faculty of Pharmacy, Kabul University, in line with the current global standards or at least with the standards of the neighbouring countries.
- The government should support the private sector and provide basic amenities required to attract investment, such as land, electricity and long-term loans.
- The GDPA and QC Lab, MoPH shall do a regular random sampling of available products at all hospitals and pharmacies irrespective whether it is government or private for quality monitoring and enforcement of regulations.

5.8 Implementing Partners

In Afghanistan, most health services are contracted out to NGOs, both national and international, and they are responsible for providing primary healthcare services to a community. Some NGOs also provide hospital services at the provincial level. Three NGOs, one national and two international, were interviewed in view of capturing their viewpoint on the state of their services, their perception about quality of medicine and their procurement process. Half are engaged in BPHS and other half is in EPHS. However, one of the NGOs is both BPHS and EPHS.

The following NGOs were interviewed:

- Afghanistan Center for Training and Development – national BPHS Provider
- Health Net TPO – international NGO engaged in both BPHS and EPHS
- Agency for Assistance and Development of Afghanistan (AADA) – national NGO engaged in EPHS services

5.8.1 Afghanistan Center for Training and Development

The Afghanistan Centre for Training and Development (ACTD) provides BPHS to nearly 2 million people in five provinces: Paktya, Helmund, Badghis, Saripol and Samangan. It has been in the health sector since 2007; it has a staff of 1,500. It has achieved between 92 per cent and 97 per cent of the outpatient service targets, set by the MoPH.

The NGO is also heavily engaged in the development of civil society and the capacity-building of local resources and research.

The World Bank and USAID have granted ACTD support. Both of these agencies have different procurement mechanisms for drugs. Under the USAID contract, the procurement agency TECHSERVE procures medicine and supplies to ACTD, which in turn supplies field-level facilities. Under the World Bank contract, the NGO procures medication from local suppliers. They ask for bids for a specific brand from a specific company. Each company who submits a bid must have the appropriate documents, such as a registration certificate, and meet other criteria to be considered. Once these criteria are fulfilled,

the company with the lowest bid gets the sales contract. Normally, supplies are delivered to the NGO within a week of the order.

Over the past year, the NGO has not run out of stock as orders are placed in advance for each quarter, and the field facilities always have a buffer stock to cope with the needs. The drugs most commonly ordered include:

- Amoxicillin, 125mg syrup, 250 mg and 500 mg
- Analgesics; Paracetamol 500mg
- Ibubrufen
- Sulphacetamide
- Aminophyline
- Doxicillin
- Mebendazol
- Cough syrups
- Anti-malarial drugs
- Vitamin A
- Iron Folic Acid tablets

The NGO has not received any complaints from its field staff about the quality of medicine. However, the management feels that the country of origin of medication does make a difference in the quality. Some of the local medicine being produced in Afghanistan is also good. As of now, the NGO is not procuring any local medicines. However, they feel they could purchase local products if they are able to keep the cost competitive, offer a greater range of products, provide all the relevant information on their products and make them available in all regions. Currently, local medicine is available in Kabul and Hirat; their availability is limited beyond these cities.

5.8.2 Health Net TPO

Health Net TPO (HNTPO) is the biggest health NGO in Afghanistan and is presently working in four provinces: Ningharhar, Laghman, Paktya and Khost. It manages nine hospitals and 130 health facilities. Besides providing EPHS and BPHS, HNTPO is working on malaria and mental health. Their malaria program runs in 29 provinces, with funding from the Global Fund Round 5 and Round 8 grants. The NGO has a staff of about 2,600, including the field staff, and serves a population of nearly 3 million for BPHS and EPHS. Its goal is to provide health care to about two-thirds of the country.

Among the most common morbidities are communicable diseases and seasonal diseases, such as diarrhea and malaria. The HNTPO works with USAID and EC for BPHS and EPHS. USAID has a standard procurement mechanism through TECHSERVE, and all the drugs and related equipment are centrally procured. For EC-supported areas, procurement is done through various channels, depending on the amount. For procurement below 30,000 euros, there is a call for tenders. Procurements between 30,000 and 150,000 euros, goes to national tender. Any procurement above 150,000 euros goes to global tender and is processed at the Health Net TPO headquarters in the U.K. The local office also plays an important role in such procurements. All the local firms, which supply medicine to the NGO, has to conform to the pre-selection criteria set by the MoPH: the firm has to be registered, the product has to be registered and carry Quality Control Certification, issued by the MoPH QC Lab.

The NGO tenders for medicines every quarter, based on the demand from the field. It can take 30 days for a local bid, two to three months for a national-level procurement, and up to six months for the global bid.

The NGO said it sometimes faces small problems with medicine being out of stock, but it is usually not a problem.

The top drugs procured by Health Net TPO include: antibiotics (Amoxicillin, Tetracylcline), anti-amoebic, Analgesic, IV fluids and some disease-specific medicines.

The NGO feels that it is the prerogative of the private sector to engage in drug manufacturing. However, it perceives that there is a strong lobby for the import of medical products, which does not want the local manufacturing sector to flourish.

There is a lack of political commitment from the MoPH and the government to develop this sector. This commitment has to come from the top. As well, the right kind of legislation must be in place to encourage production. This has to include easy licensing, ease of import of raw materials, tax holidays and subsidized land to develop local units.

They said those who wish to engage in local production should have the right kind of agreement with the government and the ability to handle the government set-up efficiently.

5.8.3 Agency for Assistance and Development of Afghanistan (AADA)

The Agency for Assistance and Development of Afghanistan was formed in 2005, with the mission of health and prosperity for all. The NGO runs health programs in four provinces: Bamyan, Ghazni, Khost and Faryab. It has a staff of 1,200, and serves a population of about 1.6 million potential beneficiaries. Besides the health sector, the AADA works on community-development projects, agriculture and vocational training programs.

The NGO claims its services are used to their optimum level. Common morbidities include diarrhea, skin infections, malaria and mental health. They have psychosocial practitioners among its staff, who provide much-needed psychosocial support.

Since their contract is through USAID, most of the drugs are centrally procured through TECHSERVE, which they forward to field areas. However, they also have two relatively small contracts with Global Alliance for Vaccines and Immunizations, Health System Strengthening (GAVI HSS) and UNFPA, where procurement is done through a local office. They place orders for medicine with local agents, who are authorized by manufacturing companies and registered with the government.

They reported that, owing to the lengthy procurement mechanism of TECHSERVE, outages of medicine are common in the field. However, there are always provisions for an emergency purchase should a need arise. The quality of drugs supplied seems satisfactory, as there are no complaints from the field.

The most commonly procured drugs include antibiotics and analgesics. The NGO reported that the quality of the medicine supplied through TECHSERVE is good and the local procurement process is rated

middle to low level. The NGO believes that the quality varies according to origin, which is evident in their local procurement policy. The NGO has a policy of not procuring Iranian drugs; they purchase only from selected firms in Pakistan and China because of the possibility of spurious drugs coming from these places. The NGO is open to buying drugs from any company of Indian or European origin, as the quality of these drugs is perceived as good.

When asked to comment about local manufacturing units, the NGO responded that all local NGOs and government should be required by lay to buy local products first, before importing drugs. However, the local product must be competitive for both quality and pricing. The government would have to set up regulatory mechanisms to manage pricing though quality control should be managed by a third party. For local production, the first priority should be medicine that is most in demand, such as analgesics, antibiotics and I.V. fluids.

5.8.4 Discussion

In Afghanistan, most health services are contracted out to NGOs, both national and international. These NGOs are responsible for providing primary health-care services to community. The NGOs feel that it is the up to the private sector to engage in pharmaceutical manufacturing. However, they also feel that there is a strong lobby for pharmaceutical imports, which does not want the local manufacturing sector to grow.

There is a lack of political commitment both at the level of MoPH and the GoA to develop the pharmaceutical manufacturing sector. First and foremost, this initiative has to come from the top level; it must be followed-up with the right kind of legislation, which would include simple licensing, easy importing of raw material, tax holidays and subsidized land.

Another area that needs attention is increased transparency in the procurement of raw materials and product testing. Making them more explicit and efficient would ensure that all the drugs are expeditiously manufactured and marketed and improve people's perceptions of the agencies.

General:

Practically all stakeholders, including government officials, generally complained about the prevalence of corruption at all levels. The general perception of corruption in government departments can sometimes impede progress. Specifying guiding principles and setting up a transparent system with minimum discretionary powers will help to improve confidence in the government among entrepreneurs and the public.

6.0 Conclusions

This assessment analyzed the state of the pharmaceutical manufacturing sector and looked seriously at the possibility of reviving it in Afghanistan. During the course of the assessment, various stakeholders expressed their opinions honestly and frankly, and an effort was made by the assessment team to document their viewpoints as honestly as possible. The assessment team has tried to provide suggestions based on the findings.

The conclusions and recommendations have been grouped according to stakeholder.

Government of Afghanistan:

1. There is a clear lack of political will and energy to strengthen the pharmaceutical sector even though it is a clear priority for both the MoPH and GoA.
2. There is a lack of coordination and communication, both within the MoPH and among various other related ministries, about a shared vision for the future and a strategic direction to achieve the same. Therefore, a state of confusion exists at the MoPH and other ministries.
3. There is a lack of incentives and subsidies for potential investors, such as:
    a. land in industrial areas for manufacturing units
    b. percentage of tax imposed
    c. tax-free holiday
4. The facilities at the Faculty of Pharmacy, Kabul University, are inadequate (old syllabus and laboratories, and a need for refresher-training for faculty)

Ministry of Public Health:

1. Lack of clear vision (in terms of documentation and sharing) in the MoPH, line-departments and related ministries regarding the pharmaceutical manufacturing sector, international partners and public and private manufacturing units.
2. Poor visibility of the need to develop the pharmaceutical sector as a priority.
3. Limited capacities and capabilities of the GDPA, PE and QC Lab to effectively do their jobs.
4. Weak regulatory mechanism and even poorer implementation of regulatory mechanism.
5. Lack of implementation of SOPs and GMPs for manufacturing units
6. Lack of interest and initiatives to revamp API
7. Lack of efforts to attract and promote investment in the pharmaceutical sector
8. Procedural delays, i.e., the process to import raw materials and medicines is very cumbersome and time-consuming (due to the lack of MoPH QC Labs at the custom-ports).

International development partners:

1. Since this is not a stated priority of the MoPH, the donors at the moment are not much interested in supporting pharmaceutical production. However, they do support the technical aspect of Pharmaceutical Management. At this state, there is no direct interaction with manufacturing units (public or private). However, once the MoPH announces this as a priority area, development partners are likely to support this initiative.
2. Need for taking the lead in developing capacity of the GDPA, QC lab, among others.
3. Promote and use products produced by local manufacturing units.

Manufacturing units:

Public

- There is lack of direction and leadership strategies for the API and PE.
- There is lack of motivation among staff (due to salary and the indifferent attitude of authorities, i.e., GDPA). There is a fear of privatization that haunts employees of this unit.
- The majority of the equipment is old and obsolete. Some have not been used for long and have become redundant. No GMPs and SOPs are being followed at the moment due to various constraints, such as lack of land in a proper industrial area, proper infrastructure including water, electricity, drainage, transportation, security, etc. Currently, private sector manufacturing is being carried out in small residential buildings, with limited space, where GMPs norms are neither being followed nor implemented.
- No facilitation in supplying raw material and limited demand of products by the GDPA

Private

- They are using relatively new technology.
- In-house adoption of SOPs and guidelines by some units only. Some manufactured units are reluctant to show their units for unknown reasons.
- There is an application of QC measures in all the private sector outlets.
- The number of products is relatively large.
- There is a positive future outlook (planning to expand production base and products).

7.0 Recommendations

Based on the above, the following recommendations are presented for each stakeholder category.

Government of Afghanistan:

The GoA/MoPH should sensitize and stimulate policymakers to develop their own vision and roadmap, based on realities on the ground and their capabilities. As per WHO guidelines, policies and plans should be drawn by direct stakeholders and not by outsiders. The GoA should create an appropriate working group/task force for detailed situational analysis and consideration of various policy options and strategies to:

1. Develop a clear vision and roadmap for reviving the pharmaceutical sector
2. This needs to be followed by strong advocacy measures, both within MoPH, line ministries and other related stakeholders
3. There is need for clear intra- and inter-department communication and coordination among various stakeholders.
4. Introduce attractive incentives to promote pharmaceutical production, and these includes provisions, such as:
    a. Clear policy and action-level guidelines
    b. Single-window operations are needed to promote investment in this sector so that all services (allocation of land, power, permission for building and licence to manufacture) are provided at one place
    c. Other incentives, such as the provision of land, tax holidays, relaxation or exemption of duties for importing machinery to set up or expand operations, as well as import raw material, should be duty-free and taxes reduced on net profits
        i. The availability of land for industrial purposes in Pule Charkhi, Karte-Nau, Parwan and Jalalabad should be communicated to industry and industry representatives. They should be given an opportunity to reflect on whether it can serve their purposes. The GoA should make a decision that would satisfy the basic needs of investors in this sector.
    d. This needs to be clearly announced and communicated to all stakeholders and investment-attraction agencies, such as AISA, so that they start taking initiative in this regard.
5. There is a need to strengthen the Faculty of Pharmacy, Kabul University, to set up new Schools of Pharmacy in other major universities and to start Masters program in this area as well.
6. AISA should attract and promote foreign investment through joint ventures or MNCs working in the region.
7. Develop measures to reduce the delay at the border for the collection of test samples of raw materials and/or of pharmaceuticals. Reduce the waiting period for results of the analysis; this process should be made hassle-free.
8. In order to bring greater transparency and attract foreign investment, the relevant English versions of all acts, rules and regulations should be made available. The availability of these regulations in internationally accepted English could result in greater transparency for foreign investors/partners willing to participate in the development of Afghanistan's pharmaceutical sector.

Ministry of Public Health:

1. Emphasize pharmaceutical production as a priority in the new strategic vision document of the MoPH.
2. Develop a realistic vision document and share it with all stakeholders, including among the various MoPH bodies and different concerned ministries, international partners and public and private manufacturing units. There is a need to increase coordination, especially with AISA and the ministries of the economy and finance to attract and promote investment in pharmaceutical sector.
3. Initiate steps to revive API only after a clear mandate from the GoA, in particular from the MoE and MoF, with clear understanding that the procurement policies in the public sector would offer preferential support to the API to meet pharmaceutical requirements.
4. Strengthen the GDPA and PE in both management and technical aspects
5. Strengthen the QC Lab (in terms of human resources and enhanced skills through training and infrastructure support by providing more efficient equipment)
6. Introduce a provision of alternative autonomous / authorized QC laboratories, not directly under the control of the MoPH, so that manufacturers can get their samples tested and certified in time and market them promptly.
7. Develop and communicate SOPs and GMPs for pharmaceutical manufacturing units
8. Expedite the processing of requests from manufacturers regarding the import of raw material, as well as product testing
9. Interact regularly with manufacturers to understand their issues, problems and planning to solve/address them progressively.
10. Gradually make GMPs mandatory for all manufacturing units
11. Enhance the coordination and exchange of expertise between public and private sectors on a regular basis, especially regarding the repair and maintenance of machinery and equipment.

Set up a working group/task force to develop modalities on how communication within and between government ministries and sub-ministries can be improved and reinforced so as to bring a transparent system with guiding principles for the pharmaceutical manufacturing sector with a single-window approach.

International partners:

1. Once pharmaceutical production becomes a documented priority, take the lead in developing capacity of the MoPH and GDPA staff, in particular technical staff, to enhance production as a priority.
2. Identify areas where skill-building is required in each sector of the pharmaceutical manufacturing industry and work on areas, such as training of GDPA and manufacturing-industry staff in English, computers, strategic planning and team work, among others topics.
3. Assist the MoPH in developing SOPs and GMPs for manufacturing units.

Manufacturing units:

1. Ensure the adoption and use of newer technology.
2. Build capacity of technical staff by sending them for in-house on-the-job training in well-functioning GMPs-approved manufacturing units for skills development and hands-on experience.

3. Strengthen in-house staff in quality assurance of products by sending them for in-house on-the-job training in well-functioning GMPs-approved manufacturing units for skills development and hands-on experience.
4. Wherever possible, increase the range and quantity of products and keep the prices and quality competitive with products already available on the market
5. Make products available both in regional headquarters, such as Hirat, Mazar-e-Shareif, Jalalabad and Kandahar, as well as in the provinces in a progressive manner.
6. Follow SOPs as mandated by the MoPH once they are finalized.
7. Work closely with the government to provide needed incentives in a progressive manner.
8. Continue advocating needs in a positive manner, with relevant authorities to get their support.
9. Improve coordination with the MoPH and other Ministries to gain complete knowledge of available facilities and resources.

10 Recommendations for MoPH in Re-establishing the Pharmaceutical Manufacturing industry in Afghanistan

1. *The MoPH shall get a clear "Policy Mandate" from the GoA - whether pharmaceutical production is priority or not. A Cabinet approved Pharmaceutical Policy shall clear all inter-Ministerial doubts and conflicts. The MoPH need to present a strong case in form of vision favouring the local pharmaceutical production before the GoA, while addressing the concerns expressed by the other Ministries and stakeholders. Under this exercise, the MoPH shall develop a realistic vision on pharmaceutical production, document and share it with due regard to views and opinions expressed by the all stakeholders including within MoPH and different concerned Ministries, international partners and public and private manufacturing units. Other stakeholders to be involved in the development of the vision can be*

    - *Chambers of Commerce*
    - *AISA*
    - *ANSA*
    - *Private pharmaceuticals production sector*
    - *Associations of private pharmaceuticals producers*
    - *NGOs*
    - *United Nations Organizations*
    - *Donor Agencies*

    The proposed national pharmaceuticals policy shall include topics related to communication to ensure relevant compilation of communication strategy for pharmaceuticals production industry by the MoPH with identification of priority medicines as per the prevailing morbidity and mortality scenario in Afghanistan. Preferential industrial promotion incentives may be incorporated under the policy for manufacturers willing to set up industries for local productions of identified priority medicines.

2. *The MoPH shall also impress upon the GoA for considering and exploring the tie-up/joint-sector with some leading/well established internationally recognized pharmaceutical manufacturers / MNCs with public and/or private pharmaceutical manufacturing sector to start local production of*

pharmaceuticals in Afghanistan and also make available relevant English versions of all Acts, Rules and Regulations in order to bring greater transparency and attract foreign investment. The MoPH may avail the expertise of the international partners/donors in identifying the internationally recognized pharmaceutical manufacturer / MNCs interested in such joint ventures. Events shaping the global pharmaceutical industry provide an unprecedented opportunity for the least developed countries (LDCs) such as Afghanistan to attract investment in the pharmaceutical sector, including from other developing countries, as per the new UNCTAD report "Investment in Pharmaceutical Production in the Least Developed Countries - A Guide for Policymakers and Investment Promotion Agencies" (UNCTAD/DIAB/PCB/2011/5 or http://www.unctad.org/en/docs/diaepcb2011d5_en.pdf). With the right set of policies in place, Afghanistan can use the local production of pharmaceuticals to help in ensuring greater access to essential medicines. The publication finds that large research and development-based pharmaceutical transnational corporations (TNCs) in developed countries are facing the expiration of patents over a series of blockbuster drugs and have a dearth of new medicines in the pipeline to replace these medications. Under pressure to meet shareholder expectations, these TNCs are partnering more and more with profitable generic manufacturers in developing countries as part of a survival strategy. The report finds that counties interested in supporting foreign direct investment in local pharmaceutical production could consider measures such as reviewing procurement practices and regional options to ensure a market for locally made medicines; ensuring that factories have reliable infrastructure, especially clean water and power; investing in the upgrading of quality standards and supporting effective drug regulation; and providing for the duty-free import of active pharmaceutical ingredients and excipients.

3. *The MoPH with GDPA and Director QCL shall undertake regular interaction with pharmaceutical manufacturers to understand their issues, problems and initiate steps to solve/address them in a phase-wise manner (i.e. increased communication between the government and private sector). Enhanced coordination and exchange between public and private sector on regular basis including on repair and maintenance of machineries and equipments, especially lying non-functional at API can be a rewarding experience. During the site visit at a private sector industry, the assessment team came across a local engineering person (there can be many as well) who has locally fabricated pharmaceutical machineries for the industry and is competent to repair non-functional machineries. A huge amount of non-functional machineries lying at API can be made functional by utilization of local resources.*

4. *The MoPH shall specifically settle the question with the GoA on involvement of public sector (PE/API) on production of pharmaceuticals. As IV fluids and Gases occupy a high volumes in transportation, these areas may be considered as top priority manufacturing in the country and with approval of the GoA, PE may immediately initiate steps for commissioning of purchased imported IV fluid manufacturing machinery/plant or sell it out in a transparent manner to private sector for production of IV fluids in the country as soon as possible.*

5. *The Office for Private Sector Coordination (OPSC) under MoPH shall work proactively and aggressively in coordination with AISA, Ministry of Economy and Ministry of Commerce to promote investment in pharmaceutical sector in the country. As per AISA the MoPH has not provided them the required inputs in form of a draft brochure for attracting investment in the health sector. The OPSC shall initiate strong advocacy efforts on AISA in seeking attractive industry promotion incentives, such as provision of land at subsidized rates in a suitable industrial zone/park with basic infrastructure facilities (roads, electricity, water, drainage, telecommunication. etc.), tax holidays for 10 years/specified years, relaxation or exemption of duties for importing machinery to set-up or expand operations, as well as import of raw material should be made duty-free and reduce the tax on net profits for certain specified years. An integrated Chemical and Pharmaceutical Industrial Park/Zone with necessary infrastructure including adequate safeguards for environment protection should be created as the pharmaceutical production is based on basic chemicals and ready availability of quality chemicals as raw materials which are basic requisites for a viable pharmaceutical industry. Single window operations at AISA are needed to promote investment in this sector so that all services (allocation of land, power, and permission for building, industrial promotion incentives and license to manufacture) are provided at one place.*

6. *The MoPH through coordination between the Director, QCL and GDPA shall expeditious process the requests from manufactures regarding import of raw materials as well as testing of their products/ raw materials. The MoPH shall develop measures to reduce time consumed at border in bringing raw materials and make this process hassle-free. Although, the process of setting up 4 regional QCLs at 4 different ports is under the implementation by the MoPH, yet the MoPH shall also consider Introduction of a provision of alternative autonomous / authorized/ empanelled QC laboratories not directly under the control of MoPH, so that manufacturers can get their samples tested and certified in time and market them promptly. The principle of accountability in maintaining the quality assurance by the manufacturer through its own in-house QCL or an authorized/empanelled QC laboratory shall replace the prevailing system/practice, as this is perceived as major stumbling block by the local manufacturers. The MoPH may explore the establishment of system for "Prequalified Suppliers" to supply raw materials (Active Pharmaceutical Ingredients and excipients). Indeed, the GDPA and QC laboratory under the MoPH shall do a regular random sampling of available products at hospitals and pharmacies irrespective of whether it is government or private facilities and pharmacies premises where medicines are being stored for quality monitoring and enforcement of regulations. This is necessary in ensuring availability of quality medicines to patients to and to keep a regular check on products brought illegally through cross border trade.*

7. *The MoPH shall ensure the revision of essential and licensed drug list periodically on every two years on merit basis only (efficacy, safety, suitability and cost-effectiveness), keeping in view to discourage unsafe and irrational combinations. WHO also revises Model Essential Medicines Lists every two years. The cell responsible for finalizing EDL under MoPH may undertake this exercise periodically, considering the priority needs of the Afghanistan with due regard to its prevailing*

mortality and morbidity data. This cell shall resist the pressure of manufactures for enlarging the list, especially when rationality of such proposals is not established.

8. *The HR capacities in terms of technical competence in the manufacturing of pharmaceuticals in Afghanistan are very poor, as neither the current curriculum under the Faculty of Pharmacy, University of Kabul have a focus on modern manufacturing technologies nor the current level of pharmaceutical manufacturing practices can offer training opportunities to manpower for modern pharmaceutical technologies. The MoPH should enjoin upon the Ministry of Education / Faculty of Pharmacy, Kabul University to formulate a separate Pharmaceutical manufacturing oriented (including Quality Assurance) curriculum with adequate knowledge, skills and attitudes pertaining to manufacturing and quality control of medicines. The MoPH may avail the help of the international partners and donor agencies in revising the current course curriculum of Faculty of Pharmacy, University of Kabul or start a new curriculum in line with the current global standards or at least with the standards of the neighboring countries which have demonstrated capabilities in pharmaceutical manufacturing. As the current level of sophistication under the pharmaceutical industry is very low, facilitating visit of HR engaged in the industry in pharmaceuticals production plants for on job training in the neighboring and developed countries with proven pharmaceutical capabilities can enhance HR capacities to certain extent.*

9. *The MoPH shall establish the general committee and sub committees for development and implementation of industry standards including monitoring to be decided by the MoPH in consultation with the private sector. Developing and communicating SOPs and GMPs for pharmaceutical manufacturing units with due considerations to local environment and factors in a phased manner and gradually making GMPs mandatory over a period of time for all manufacturing units. The MoPH may seek assistance of International partners in developing SOPs and GMPs for manufacturing units and capacity building of GDPA and PE. The Draft GMP Guidelines are to be prepared by the GDPA/MoPH looking at the local capacities and capabilities to adopt stringent guidelines and preferably in consensus with local industry associations, so as to avoid disenabling environment at this primitive stage.*

10. *As regard to enhancing access to medicines within the available budgetary constraints, the GDAA may be mandated to follow WHO/inter-agency guidelines for procurement of pharmaceuticals at competitive prices or a Corporation for Procurement and Supply Management with integrated IT based MIS be created for medicines and health products (HPs). The MoPH may evolve or adopt IT based Procurement & Supply System in lines with the Tamil Nadu Medicines Service Corporation (www.tnmsc.com) for highly cost-effective procurement of quality medicines with supporting logistics system to eliminate shortages/stock-outs and expiry. The MoPH and the central warehouse should try to minimize the time-lag for supplying medicines and implement computerization of Drug Logistics and Supply System to facilitate timely re-ordering with due consideration to safety stocks and lead time.*

Post Script

There is a general perception of corruption in government departments, which can sometimes impede progress. Specifying guiding principles and setting up a transparent system with minimum discretionary powers will help to improve the confidence in the government among entrepreneurs and the public. This would also change any perceptions about financial irregularities.