

Afghanistan pharmaceutical sector development: problems and prospects

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Abstract

Objective: To provide an up to date comprehensive overview of the Afghanistan pharmaceutical sector situation and its future development needs and priorities.

Methods: The methods employed for researching and writing this paper were based on (i) structured interviews and workshop with Afghanistan pharmaceutical sector stakeholders, (ii) site visits, (iii) sector data review of relevant reports and documents, and (iv) use of sector assessment tool methodology. A full review of sector policy, regulation and management was conducted covering the complete pharmaceutical supply chain.

Results: The International Donor Community (IDC) in recent years has provided major assistance for the development of the Afghanistan health sector with some tangible successes. However, for several reasons the Afghanistan pharmaceutical sub sector suffers from major deficiencies in terms of implementation of policy, regulation and management. There are significant governance, structural and capacity weaknesses at both the central and provincial level. The consequence of this has been a pharmaceutical market and supply system contaminated with substandard, falsified, counterfeit and diverted medicines. The accessibility, affordability and availability of medicines are highly variable across the country.

Conclusions: Reports on the Afghanistan pharmaceutical sector have hitherto been scarce in the international literature and the quality and availability of sector data is generally low. The sector for several reasons is one of the least developed in the world, operates in a chaotic faction and suffers from many weaknesses that cover the entire spectrum of sector activities. The market presence of substandard and counterfeit medicines is likely to be significant and should be considered a public health menace demanding urgent attention. A number of sector development interventions are required to address both institutional and market weaknesses.

Keywords: Medicines policy, medicines regulation, medicines pricing, counterfeit medicines, pharmaceutical situation; Afghanistan.

Introduction

General background

The Islamic Republic of Afghanistan is a landlocked central Asian country consisting of 34 provinces and with a population of approximately 28 million. It is classified by the UN as a Least Developed Country (LDC), is in a state of ongoing conflict and can be described as both a fragile¹ and failed state². The poor health, socioeconomic and governance status of Afghanistan is summarised by a number of indicators presented in Table 1.

Pharmaceutical sector background

The first Afghanistan pharmaceutical sector assessment after the fall of the Taliban regime was conducted by the World

Health Organization (WHO) in 2002, and highlighted severe infrastructural damage, lack and low quality of essential medicines, widespread irrational medicines usage and reliance on medicines donations by the international community³. The WHO classifies Afghanistan as belonging to a group of countries (including Iraq, Palestine, Sudan, and Somalia) that have ongoing emergency situations and that require emergency supply of medicines with as much quality control as possible. These countries require major assistance for pharmaceutical sector strengthening and provision of adequate pharmaceutical public health.

The Afghanistan pharmaceutical sector is currently, and for the foreseeable future, managed and publicly financed via a dual administrative system: (i) the General Directorate for

Table 1. Afghanistan Governance, Socioeconomic and Health Indicators

| Indicator | Value | Year |
|--|-------|------|
| Failed State Index (rank out of 177) ² | 6 | 2010 |
| Corruption perceptions index (rank out of 178) ³ | 176 = | 2010 |
| Human Development Index rank ⁴ (rank out of 169) | 155 | 2010 |
| Gross national income (PPP \$US per capita) ⁵ | 1,100 | 2008 |
| % population living on < 1 \$US / day (national poverty line) ⁶ | 42 | 2009 |
| Crude birth rate (per 1,000) ⁵ | 47 | 2008 |
| Crude death rate (per 1,000) ⁵ | 20 | 2008 |
| Life expectancy at birth (total years) ⁷ | 42 | 2008 |
| Under-5 mortality rate (per 1,000 live births) ⁷ | 257 | 2008 |
| Maternal mortality rate (per 1,000 live births) ⁷ | 14 | 2008 |
| Adult mortality rate (per 1,000) ⁷ | 479 | 2008 |
| Health system performance rank ⁸ | 168 | 2004 |
| Total health expenditure (as % of GDP) ⁷ | 7.3 | 2008 |
| Public health expenditure per capita (\$US) ⁷ | 10 | 2008 |
| Total health expenditure per capita (\$US) ⁷ | 48 | 2008 |
| Health expenditure, public (% of total public expenditure) ⁵ | 3.7 | 2008 |
| Health expenditure, public (% of total health expenditure) ⁷ | 21.2 | 2008 |
| Total pharmaceutical expenditure (as % of total health expenditure) ⁸ | 15 | 2004 |

Note: PPP = Purchasing Power Parity

Pharmaceutical Affairs (GDPA), a directorate of the Ministry of Public Health (MoPH), which also oversees sector provincial management via a system of Provincial Pharmacy Officers (PPOs) located in Provincial Public Health Departments (PPHDs); and (ii) the International Donor Community (IDC), principally the World Bank, US Agency for International Development (USAID) and European Commission (EC), which finances and oversees the provision of medicines supplied via the Basic Package of Health Services (BPHS) by International Donor Community (IDC) contracted Non-Governmental Organisations (NGOs).

The corner stone of Afghanistan health and pharmaceutical sector development since 2003 has been the implementation of a BPHS¹⁰ which includes a defined set of cost-effective interventions aimed at addressing the principal health problems of the population, with an emphasis on the most vulnerable groups, women and children, but with provisions made for the eventual incorporation of interventions targeting other vulnerable groups. More recently in 2005, the Essential Package of Hospital Services (EPHS) has been created in an attempt to develop a functional referral system for more severe cases of disease¹¹.

Since 2002 there has been a significant increase in the quantity of both donated and privately imported medicines entering Afghanistan following the involvement of the international community in this country's health sector. The profile of the Afghanistan pharmaceutical market can only be described in general terms as there is a lack of accurate collected data¹²; and where such data has been collected it is largely done on an ad hoc and non-repeated basis. For example, only one comprehensive baseline pharmaceutical sector indicator study, designed in accordance with WHO recommended

Table 2. Afghanistan Pharmaceutical Sector Key Stakeholders Interviewed

| | Afghanistan Stakeholders | | International Donor Community (IDC) Stakeholders |
|----|---|----|---|
| 1 | Deputy Minister, Ministry of Public Health (MoPH) | 1 | Task Manager Health and Disability Sector, Delegation of the European Commission (EC) |
| 2 | Director, General Directorate for Pharmaceutical Affairs (GDPA) | 2 | Project Manager, EC Afghanistan Provincial Public Health Project |
| 3 | Senior Officer, Essential Drug Department GDPA | 3 | Team Leader, EC Support for Institutional Development of the Afghanistan MoPH Project |
| 4 | Director, National Medicines Quality Control Laboratory Kabul | 4 | Health, Population and Nutrition Officer, US Agency for International Development (USAID) |
| 5 | Director, MoPH Central Medical Stores Kabul | 5 | Project Manager, USAID Techserve / Strengthening Pharmaceutical Systems Afghanistan program |
| 6 | Dean, Kabul University Pharmacy Faculty | 6 | Afghanistan Public Health Specialist, World Bank |
| 7 | MoPH Technical Advisory Board for Pharmaceutical Affairs (TAB) | 7 | HIV/AIDS Adviser, World Bank Afghanistan HIV/AIDS Control Program |
| 8 | General Director, Avicenna Pharmaceutical Industry Kabul | 8 | Project Manager, Johns Hopkins University Afghanistan MoPH Support Project |
| 9 | Local Pharmacies (N = 10) | 9 | Health Cooperation Planning Officer, Japan International Cooperation Agency (JICA) |
| 10 | Local Health Facilities (N = 3) | 10 | Medical Officer, WHO Representative Office Kabul |
| 11 | Afghan BPHS NGOs (N = 3) | 11 | Team Leader, Afghanistan Blood Transfusion and Diagnostic Facility Project, French Development Agency |
| | | 12 | International BPHS NGOs (N = 2) |

Table 3. Principal Documents and Reports Reviewed

| | Title | Theme |
|----|--|-------------------|
| 1 | Baghdadi G, Chomilier C, Graaff P. Pharmaceutical Situation in Afghanistan. WHO Preliminary Assessment (14-23 January 2002) | Sector Assessment |
| 2 | Mansoor, B, Najib, Mohd. Baseline Drug Indicator Study, A comparative Cross-Sectional Study in SCA Health Facilities in Afghanistan, Part II Results and Next Steps. Swedish Committee for Afghanistan (2003) | Sector Assessment |
| 3 | Afghanistan Private Pharmacies Survey. Management Sciences for Health (August 2004) | Sector Assessment |
| 4 | Understanding markets in Afghanistan: A study of the market for pharmaceuticals. Afghanistan Research and Evaluation Unit (December 2005) | Sector Assessment |
| 5 | 2006 Afghanistan Health Survey. Ministry of Public Health, Islamic Republic of Afghanistan (2006) | Sector Assessment |
| 6 | 2007 Afghanistan National Health Services Performance Assessment. Johns Hopkins University (2007) | Sector Assessment |
| 7 | Afghanistan National Medicines Policy (2003) | Policy |
| 8 | Drug donation guidelines. HealthCare and Promotion Department, Ministry of Public Health, Islamic Republic of Afghanistan (2003) | Policy |
| 9 | International Donor Community Afghanistan Health Sector Strategic Planning Retreat Report (October 2007) | Policy |
| 10 | Afghanistan Donor health sector review: 'Building on early gains: the role and structure of government in further strengthening Afghanistan's health sector' (October 2007) | Policy |
| 11 | Draft Terms of Reference for General Directorate of Pharmaceutical Affairs (2007) | Policy |
| 12 | Afghanistan National Essential Drug List (December 2007) | Policy |
| 13 | Provincial Pharmacy Officer Job Description. General Directorate for Pharmaceutical Affairs Ministry of Public Health, Islamic Republic of Afghanistan (2007) | Policy |
| 14 | Afghanistan Health and Nutrition Sector Strategy (HNSS) 2008-2013. Ministry of Public Health; Ministry of Agriculture, Irrigation & Livestock Ministry of Public Health, Islamic Republic of Afghanistan (2008) | Policy |
| 15 | Workshop Report for Pooled Procurement of Essential Drugs. Management Sciences for Health (July 2003) | Medicines Supply |
| 16 | Inventory of drugs available in Kabul. Ministry of Public Health, Islamic Republic of Afghanistan (2004) | Medicines Supply |
| 17 | Procurement Procedure of Goods, Services, Medicine-Medical Items for the Procurement Department of Ministry of Public Health. Oxford Policy Management (February 2005) | Medicines Supply |
| 18 | Concept Paper for the General Directorate of Planning & Procurement, Ministry of Public Health; Procurement Reform in the Ministry of Public Health, Afghanistan, JICA (February 2006) | Medicines Supply |
| 19 | Assessment of the Pharmaceutical Logistics Management Capacity of REACH Grantee NGOs - Rural Expansion of Afghanistan's Community-based Healthcare Program (MSH / REACH, USAID), (July 2006) | Medicines Supply |
| 20 | MIAR (Monthly Integrated Activity Report) – Facilities with at least 1 stock out by province. Ministry of Public Health, Islamic Republic of Afghanistan (March 2006-March 2007) | Medicines Supply |
| 21 | Strengthening Logistics System in Urban Kabul Project. JICA (August 2007) | Medicines Supply |
| 22 | Terms of Reference for EC NGO BPHS Contractors concerning drug provision (2007) | Medicines Supply |
| 23 | Coordinated Procurement and Distribution System (CPDS) Governance Framework. General Directorate of Pharmaceutical Affairs Ministry of Public Health, Islamic Republic of Afghanistan (March 2010) | Medicines Supply |
| 24 | Drug Quality Assessment Study Afghanistan 2007. Ministry of Public Health Islamic Republic of Afghanistan (2007) | Regulation |
| 25 | National Licensed Drugs List. General Directorate of Pharmaceutical Affairs, Ministry of Public Health, Islamic Republic of Afghanistan; Essential Drug Department, Avicenna Pharmaceutical Institute (December 2007) | Regulation |
| 26 | Procedure for application for inclusion of medicines on the essential drugs list of the Ministry of Public Health of Afghanistan. General Directorate of Pharmaceutical Affairs, Ministry of Public Health, Islamic Republic of Afghanistan; Essential Drug Department, Avicenna Pharmaceutical Institute (2007) | Regulation |
| 27 | Procedure for application for inclusion of medicines on the essential drugs list of the Ministry of Public Health of Afghanistan. . General Directorate of Pharmaceutical Affairs, Ministry of Public Health, Islamic Republic of Afghanistan; Essential Drug Department, Avicenna Pharmaceutical Institute (2007) | Regulation |
| 28 | Procedure for application for inclusion of medicines on the licensed drugs list of the Ministry of Public Health of Afghanistan. . General Directorate of Pharmaceutical Affairs, Ministry of Public Health, Islamic Republic of Afghanistan; Essential Drug Department, Avicenna Pharmaceutical Institute (2007) | Regulation |
| 29 | Afghanistan National Medicines Law (2006) | Legislation |
| 30 | Regulation on 'import and production of medicines and medical devices' (2005) | Legislation |
| 31 | Regulation on 'pharmacies' (2006) | Legislation |

Table 4. Afghanistan Pharmaceutical Sector Functional Analysis Scheme (adapted from WHO National Medicines Policy scheme)¹⁴

| | Policy Objectives | | | Responsible Organisation |
|--|-------------------|---------|--------------|--------------------------|
| | Access | Quality | Rational Use | |
| Policy Components: | | | | |
| Selection of essential medicines | X | (X) | X | 1 |
| Affordability | X | | (X) | 1 |
| Financing | X | | | 1 |
| Supply systems | X | X | (X) | 1,2,3 |
| Regulation and quality assurance | | X | X | 2,3 |
| Rational use | | | X | 1,3 |
| Research | X | X | X | 1 |
| Human resources | X | X | X | 1 |
| Monitoring and evaluation | X | X | X | 1,2,3 |
| Stakeholder coordination | X | X | X | 1,2 |
| Policy Output Indicators: | | | | |
| Public health medicines needs met | | | | |
| Pharmaceutical market efficiency & effectiveness | | | | |

Notes

X = direct link and (X) = indirect link between policy components and policy objectives

Responsible organisation (in a model country): 1 = Ministry of Public Health (MoPH) Pharmaceutical Policy Department, 2 = National Medicines Regulatory Authority (NMRA), 3 = Provincial pharmaceutical management system

methodology¹³, has been conducted in recent years; in 2003 by the Swedish Committee for Afghanistan¹⁴. Other sector data and reports, where they exist, tend to be focused on specific sub sectors (particularly medicines procurement and distribution which is perhaps justifiable given the health sector priority of BPHS implementation) thus several sector knowledge gaps exist. In this context, the objectives of this paper are to provide (i) a descriptive comprehensive overview of the pharmaceutical sector situation in Afghanistan, and identify (ii) future sector development needs and intervention priorities.

Methodology

The following methods were used to collect the data for this project. These methods are also discussed in a 2007-08 report by the author (JH) to the European Commission¹².

Structured interviews and workshop with Afghanistan pharmaceutical sector stakeholders

Table 2 lists the various stakeholders interviewed. Following interviews, a workshop was conducted with all stakeholders to

present the initial review findings and to obtain feedback and further clarifying information so as to assist completion of the review.

Sector data review

A thorough review, listed in Table 3, of (a) all local available relevant health and pharmaceutical sector documents and reports (particularly from the MoPH and IDC), and (b) regional and international pharmaceutical sector reports and publications was conducted so as to inform the analysis and recommendations made by the EC Identification Mission.

Use of sector assessment tool methodology

Assessment was carried out based on available WHO sector assessment tools^{13, 15} according to the scheme illustrated in Table 4, and which is adapted by the authors from the WHO National Medicines Policy (NMP) scheme¹⁶ which matches NMP components against the NMP objectives of medicines access, quality and rational use.

Apart from the above, in order to obtain a ‘grass roots’ feeling of the Afghanistan pharmaceutical sector situation, a number of facility visits were conducted to public and private health facilities, pharmacies, distributors, local pharmaceutical manufacturers, medical stores and medicines quality control facilities. Following the above steps, a full review and analysis of Afghanistan pharmaceutical sector policy and its implementation was conducted, covering sector administration, management, regulation, financing and pricing, supply system and market characteristics.

Results and discussion

A summary of key findings is presented in Table 5 in accordance with the sector overview scheme presented in the results and discussion section. Results are discussed under each sector area heading.

Medicines Supply and Market Profile

Afghanistan has a dual public and private sector medicines supply system. The public system concerns the provision (procurement, import, storage, distribution and dispensing) of the Basic and Essential Packages of Health Services by the Ministry of Public Health and the International Donor Community, principally the World Bank, USAID and EC who have divided geographic management responsibility of the 34 Afghan provinces between them and contracted national and international Non Governmental Organisations to implement medicines supply.

The number of participants in the private supply system is larger at every point in the supply chain compared to other economic sectors in Afghanistan. There is an oversupply of importers (~200 licensed), distributors (~ 200 known licensed and unlicensed) and pharmacies (~13,000 known licensed and unlicensed), as well as many grocery stores and street vendors

Table 5. Summary of Sector Key Findings

| 1. Medicines Supply and Market Profile |
|---|
| <ul style="list-style-type: none"> • Dual public and private sector medicines supply system • Public sector BPHS/EPHS scheme jointly operated by Afghan MoPH and IDC and implemented by NGOs • Private supply system extremely complex, chaotic, inflated and under regulated • Weak availability of market data • Illegal imports likely to account for >50% of the total pharmaceutical market |
| 2. Medicines Policy and Legislation |
| <ul style="list-style-type: none"> • International standard NMP in place since 2003 but relatively few of its provisions implemented • Legislative gaps and inconsistencies exist in comparison to model national medicines legislation • Provisions for inspection, enforcement and sanctions are weak |
| 3. Sector Administration and Management |
| <ul style="list-style-type: none"> • Sector command versus market economy management conflict • MoPH GDPA undergoing continuous restructuring • Weak decentralised sector management • Sector professional human resource shortfall • Weak sector stakeholder national and international coordination |
| 4. Informing Policy – Sector Monitoring and Evaluation (M&E) |
| <ul style="list-style-type: none"> • Pharmaceutical sector M&E system is very limited • Existing M&E system oriented toward medicines inventory management |
| 5. Medicines Regulation |
| <ul style="list-style-type: none"> • Prescriptive and rigid medicines registration system • All batch imports are required to be tested • National MQCL is dilapidated, not internationally accredited and suffers from serious resource and operational deficiencies • Rigid batch import control system leads to supply delay, diversion and wastage • No pharmacovigilance system in place |
| 6. Medicines Financing, Reimbursement and Pricing |
| <ul style="list-style-type: none"> • Weak central medicines accounting and budgeting system • 70% of medicines needs are provided via the private sector with the balance by the BPHS/EPHS scheme (although the latter provides a greater proportion of essential medicines compared to the private sector) • Large provincial variations in medicines availability and per capita BPHS medicines expenditure • No health insurance or patient co-payment system is planned • Lack of enforcement of medicines price margins and an unofficial retail external reference price system exists with medicines from Pakistan and Iran |
| 7. Rational Medicines Usage |
| <ul style="list-style-type: none"> • Irrational medicines usage widespread • Weak availability of objective medicines information and implementation of NMP RMU provisions |
| 8. Local Pharmaceutical Industry Development and Trade Policy |
| <ul style="list-style-type: none"> • Pre-existing local production based severely damaged but beginning to re emerge • Basis exists for production and export of herbal ingredients |

Table 6. Observed Deficiencies in the Afghanistan Pharmacy Sector

| |
|---|
| <ul style="list-style-type: none"> • Many pharmacies are unlicensed; • Many pharmacies operate without a qualified pharmacist or even a pharmacy technician on site (one study showed that only 14% of dispensers are qualified pharmacists¹⁸); • Drugs are often sold as unpacked blisters (with no patient information leaflet), often they are expired; • Prescription only medicines are sold without prescription and often directly to children; • Rules on pharmacy physical conditions and coverage are frequently not observed (e.g. very often pharmacies are clustered together in central urban locations and there is a limited number of pharmacies in rural districts); • Pharmacies frequently do not stock the full range of essential drugs; • Pharmacy inspection is uncommon and haphazard and where it occurs it is conducted by a variety of inspectors from different authorities and not according to any particular inspection protocol); • There is no evidence of any enforcement (no reported cases exist of pharmacies being closed for infringement of regulatory requirements). |
|---|

that retail medicines. Many of these enterprises are unlicensed and thus are a major component of the large illegitimate supply chain.

The Ministry of Public Health (MoPH) is responsible for assuring good medicines warehousing and storage for both the public and private sector. However, except in the case of a few international donors, existing medicines storage conditions do not meet international standards. Distributors are licensed by the MoPH and a qualified person is a licensing requirement, but the extent to which this enforced is not clear. Good Distribution Practice Guidelines (GDP)¹⁷ do not exist and thus are not applied in country. The MoPH has a regulation on pharmacy supervision, but despite adequate legal provisions many deficiencies exist with respect to the operation of pharmacies and these are summarised in Table 6.

The Afghanistan medicines supply system is seriously under-regulated with weak provincial management leading to a chaotic supply situation. Afghanistan is not alone in having a lack of medicines supply chain oversight as in many countries Good Manufacturing Practices (GMP) inspection receives more attention and resources than inspection of distribution channels¹⁹. Medicines importation control is a difficult business in view of the extensive porous borders Afghanistan has with neighbouring countries. Ensuring the quality and provenance of medicines, in accordance with standards established by WHO/GDP¹⁷, is also problematic but a task that should be considered to be a regulatory priority. Thus there is a need to strengthen supply chain oversight through providing appropriate legal provisions, inspection, enforcement and sanctions and adoption of Good Governance for Medicines (GGM) practices²⁰. Despite supply chain chaos, complexity and oversight weaknesses, there has been some success with the IDC-supported BPHS/EPHS programme for essential medicines provision since its implementation in 2003, and recent efforts have been made

to establish a BPHS/EPHS coordination mechanism via the Governance Framework on Coordinated Procurement and Distribution System (CPDS)²¹.

In the absence of accurate data, it estimated that (i) the private sector accounts for 70% of the total pharmaceutical market (of which 95% consists of imported medicines from many sources in the region), and (ii) 30% of the market consists of international drug donations which are provided largely through the BPHS/EPHS essential medicines scheme, the balance provided through international humanitarian pharmaceutical assistance^{12,22}. Illegal imports, which can also contaminate the legitimate supply chain, probably account for greater than 50% of the total pharmaceutical market^{12, 22}; a major contributory factor that Afghanistan has lengthy porous borders, particularly the borders with Pakistan and Iran. The MoPH estimates that the number of unregistered far exceeds registered medicines on the market¹².

Although identification of substandard and counterfeit medicines in the Afghanistan market is a straight forward task and cases can readily be identified¹², for a number of reasons the estimation of the prevalence of substandard, counterfeit (falsified), adulterated and diverted medicines in Afghanistan is extremely difficult. Difficulties in estimating prevalence are due to weak Post Market Surveillance (PMS), a chaotic and complex supply chain and an absence of clear and internationally harmonised definitions of counterfeit and substandard medicines.

One recent study²³ was conducted in Afghanistan to examine medicines quality and which concluded that medicines provided publicly by the IDC through the BPHS were generally of an acceptable standard; however the sample size from the private sector was too small to draw any conclusions concerning private sector substandard medicine prevalence. Given the estimated high proportion of illegal imports a high prevalence of substandard (and counterfeit) medicines cannot be ruled out and PMS efforts need to be enhanced. The Afghan conflict situation is likely to provide fertile ground for pharmaceutical crime activity, particularly given the close association between organised crime and medicines counterfeiting²⁴. Counterfeiting is also perhaps a disincentive for research-based and branded medicines manufacturers to register their products in Afghanistan.

In 2010, the WHO conducted a questionnaire-based survey of several EMROⁱ and SADCⁱⁱ countries²⁵, including Afghanistan, with the objective of reviewing the counterfeit medicine situation so as to provide a more informed basis for developing and implementing counterfeit medicine policy and action.

Conclusions applicable to most countries surveyed, including Afghanistan, were a need for (i) specific legislation that empowers National Medicines Regulatory Authorities (NMRAs) and criminalises medicines counterfeiting, (ii) strengthened cooperation and information-sharing among the various key players at national, regional and global levels, and (iii) strengthened weak market control systems. Thus, in order

to tackle the problem in Afghanistan a number of actions are required, several of which will require IDC assistance for implementation.

Medicines Policy and Legislation

Afghanistan is in possession of a National Medicines Policy (NMP) dating from 2003 and which has been designed in accordance with the WHO national medicines policy model scheme and guidelines¹⁶. Aside from the creation of an Essential Medicines List (EML), last updated in 2007, and the supply of essential medicines via the BPHS/EPHS, other NMP provisions (e.g. rational medicines usage policies) are underrepresented in the MoPH pharmaceutical sector management programme, the latter effectively being the NMP implementation plan²⁶. While medicines supply management is an important policy area and which hitherto has been seen as a priority area in view of the emphasis on BPHS implementation, other areas of NMP equally deserve and require attention for implementation.

The sector legislative and regulatory framework is provided by a framework Medicines Law (2006) and Regulations covering local manufacturing, import, procurement, distribution and retail. The Afghanistan Medicines Law omits several regulatory areas that would normally be included in a model national medicines law and includes a number of areas that normally would not be included¹². For example, the law makes no provision for medicines intellectual property issues (IPR) issues, i.e. patent and brand name protection, data exclusivity and issues relating to Trade Related Intellectual Property Rights (TRIPS) flexibilities. Provisions for implementation and enforcement of the law and sanctions for violations are weak. There is scope to align the existing medicines legislation in accordance with regional and international standards and practices and to introduce stronger provisions concerning implementation, enforcement and sanctions.

Sector Administration and Management

Health sector stewardship is defined by the WHO as being one of the four essential functions of the health system in addition to service provision, resource generation and financing^{27, 28}. The Ministry of Public Health General Directorate for Pharmaceutical Affairs is responsible for pharmaceutical sector stewardship (sector policy and regulation) but also, as a legacy of the Soviet occupation period, continues to perform a command style of sector management and consequently conducts a range of commercial activities outside of its stewardship role and not related to medicines policy and regulation such as manufacturing, operating a pharmacy retail chain, wholesaling, warehousing and importing. This situation is in conflict with market economy based systems being introduced by the IDC and has a detrimental impact on activities that are within its terms of reference.

The MoPH, and particularly its GDPA, is continuing to undergo a long period of restructuring with regular organisational changes often driven by political reasons and consequently remains unsettled and not modelled in conformance with the

ⁱ East Mediterranean Regional Office of the WHO

ⁱⁱ SADC – Southern African Development Community. Inter-governmental organisation of 15 southern African states

Table 7. Afghanistan Pharmaceutical Sector Performance Indicators

- a. MoPH HMIS (Health Management Information System) - MIAR (Monthly Integrated Activity Report) – healthcare facilities with at least 1 drug stock out (assessed by province);
- b. Balanced Score Card (BSC) performance assessment of BPHS delivery (indicator relevant to the pharmaceutical sector is 'Indicator 7: Drug availability index'*;
- c. USAID assessment of the pharmaceutical logistics management capacity of NGO grantees (utilising an Inventory Management Assessment Tool).

* measures the continuous availability of a set of essential drugs in health facilities. This indicator is included in the BSC system adopted by the Afghanistan MoPH as a tool to measure and manage BPHS performance delivery³⁰. The median score for this indicator in 2004 was 69% and which had risen to 85% by 2006, thus indicating an increase in public sector essential drug availability.

tasks necessary to conduct its sector stewardship function. In comparison to other MoPH directorates, the GDPA has lacked IDC support which has contributed to both its unsettled organisational situation and lack of development. Afghanistan is a highly decentralised country and effective management of its pharmaceutical sector is reliant on the Provincial Pharmacy Officer system which is principally tasked with ensuring public sector medicines supply via the BPHS/EPHS programme in the provinces. An examination of the PPO task description and PPO-GDPA reporting system was conducted and revealed several inadequacies, particularly an absence of any provincial regulatory function as well as coordination activity with the IDC system that provides the BPHS/EPHS.

In 2004, the WHO estimated that a third of countries have no medicines regulation or a regulatory capacity that hardly functions⁸; it is certain that Afghanistan belongs in this category, particularly given the findings from the EC sector survey¹² which highlight major regulatory gaps and weaknesses as evidenced by the chaotic nature of its pharmaceutical market. Concerning sector human resources, Afghanistan has one pharmacy faculty training 120 pharmacists annually and which recommenced operations in 2001 following a long hiatus due to many years of conflict. Afghanistan health sector human resource development strategy is skewed towards recruitment of doctors and thus there is a major shortfall in qualified pharmacists and pharmacy technicians against the background of a rapidly expanding private pharmaceutical sector¹² which hinders effective sector functioning.

A necessary measure for effective and efficient sector management is sufficient coordination with sector stakeholders at both the national and international (particularly the Asia region) levels. An examination of national sector coordination between the various stakeholders revealed that this was very weak (even between the different IDC parties), and also at the international level, although Afghanistan is a member of the regional Economic Cooperation Organisation (ECO)ⁱⁱⁱ (which offers a framework for pharmaceutical regulatory cooperation) and the South Asian Association for Regional Cooperation

(SAARC)^{iv}. The Afghanistan pharmaceutical sector largely operates in an international void against the background of a global pharmaceutical market, a situation which is not conducive for its development.

Afghanistan is judged to be the second most corrupt country in the world³ and evidence suggests that the Afghanistan health and pharmaceutical sector is particularly adversely affected by corruption^{12, 22, 29}. Transparency International claims that in some countries up to two thirds of hospital medicines supplies are lost to corruption and fraud and it is estimated that 10–25% of global spending on public medicines procurement is lost to corruption³. This leads one to conclude that there is a pressing need to introduce medicines good governance measures in Afghanistan which can potentially be achieved via adopting the WHO Good Governance for Medicines (GGM) programme²⁰ in this country.

The Afghanistan pharmaceutical sector possesses a satisfactory enabling policy (and to a lesser extent legislative) framework and thus sector development now needs to focus on a number of areas which all require long term IDC support:

- (i). capacity building (e.g. human resource development);
- (ii). institution building. It is necessary to build an international standard medicines regulatory structure and function as a priority and which operates in accordance with the principles of good regulatory practices. Medicines policy and regulation functions require significant rationalisation and development to meet international norms and standards. This can be facilitated by benchmarking pharmaceutical regulatory structure and activities against those of other countries in the region and elsewhere. Further GDPA institution building efforts will require a functional separation of sector administration from service delivery;
- (iii). sector coordination (with corresponding authorities) strengthening at both the national and international levels; and
- (iv). introduction of medicines good governance.

Informing Policy – Sector Monitoring and Evaluation (M&E)

Sector Monitoring and Evaluation (M&E) is a vital stewardship function (i.e. generation of intelligence) which permits evidence-based policy making. However, pharmaceutical Sector M&E (and supporting sector management information systems), within the framework of overall health sector M&E and national health accounts is extremely limited in Afghanistan. Existing sector performance indicators tend to be directed towards medicines inventory management and are summarised in Table 7. In addition to the national level drug inventory Monitoring & Evaluation system, one international donor (USAID) employs a detailed Basic Package of Health Services inventory management assessment tool, while other donors employ no assessment tool at all.

ⁱⁱⁱ Afghanistan, Azerbaijan, Iran, Kazakhstan, Kyrgyzstan, Pakistan, Turkey, Turkmenistan, Tajikistan and Uzbekistan

^{iv} Afghanistan, Bangladesh, Bhutan, India, the Maldives, Nepal, Pakistan and Sri Lanka

Other sector data, where it is available, tends to be collected on an ad hoc basis by the IDC and contracted NGOs, however many sector areas outside of medicines inventory management are not monitored or evaluated (e.g. medicines quality, safety, usage and pricing). The failure of sector data coordination occurs due to the fact that the sector is currently managed jointly by the Afghan authorities and several international donors. The actual assimilation and utilisation of available sector data by the MoPH GDPA is hard to determine. Thus, as is often the case in developing countries, local data is sparse and the majority of policy decisions tend to be based on data which is gathered, modelled and published by international agencies³¹.

There is much scope to adopt a unified, standardised and comprehensive pharmaceutical sector M&E system (which should be incorporated into the overall health sector M&E system) to serve the purposes of both the MoPH and the IDC. The introduction of regular pharmaceutical sector baseline studies can complement and feed into this system.

Medicines Regulation, Registration and Quality Control

The Afghanistan Licensed Drug List (LDL)³² is determined jointly by the MoPH and IDC, is based on the WHO Model List of Essential Medicines (MLEM) and prescribes which medicines can be registered in Afghanistan as well as included in the Afghanistan Essential Medicines List (EML). A full medicines registration dossier, that should include both clinical efficacy and safety evidence and pharmacoeconomic data³³, is required to be submitted for all LDL applications. Thus there are no provisions for abbreviated medicines registration in the case of an existing reference product on the Afghanistan market. Limited provisions exist concerning intellectual property issues (i.e. data exclusivity, patent protection, registration of brand and trademark names).

The Ministry of Public Health Medicines Quality Control Laboratory (MQCL) is responsible for medicines Quality Control (QC) and carries out testing for registration, batch import QC, and ostensibly for Post Market Surveillance (PMS) purposes. As there is no capacity to conduct Good Manufacturing Practice (GMP) inspections and a lack of recognition of international manufacturing authorisations and GMP certificates, the MoPH relies on a system of testing every imported batch (except for batches imported by some international donors who have obtained a MoPH testing waiver), although the capacity and capability of the national Medicines QC laboratory to do such is far from adequate. The MQCL is not internationally accredited, is operating in a dilapidated condition, suffers from serious resource (staff and equipment) and operational deficiencies, and is inadequate in all respects to be able to conduct medicines testing according to international standards¹². The ultimate organisational position of the MQCL is yet to be determined.

Medicines import and export is regulated according to a batch import licensing system; however customs control procedures are reported by several stakeholders as being detrimental, inefficient and non transparent¹². The rigid import license

process and requirement for all batches to be QC tested by the central MQCL often results in delays of approximately three months for medicines to be imported into Afghanistan; often large amounts of import batch stock are damaged or misappropriated (diversion, 'system leakage') while in customs clearance; no customs risk analysis procedure is applied to imported medicines and there is no central customs bonded warehouse²². There is no system of medicines export and transit licensing. Importers are licensed by the MoPH and licenses can be obtained by general traders (i.e. not just specialist medicine distribution companies that employ a qualified person).

The Afghanistan medicines regulation system is underdeveloped, weakly implemented and not internationally harmonised. There are a number of weaknesses and gaps and principally there is a need to harmonise the medicines law and its regulations with existing international models, adopt internationally harmonised medicines registration procedures, invest in an adequate medicines QC infrastructure and implement a pharmacovigilance system.

Medicines Financing, Reimbursement and Pricing

It is difficult to make an accurate assessment of the public medicines financing situation in Afghanistan for a number of reasons: (i) no national health account system exists, (ii) there is no central compilation of medicines financing statistics or national medicines budget formula in operation, (iii) public health financing is derived and applied by a number of funders, i.e. Ministry of Public Health and International Donor Community, and (iv) medicines financing data is not routinely collected and where it exists it is of a limited nature. Thus there is a need for the IDC to assist and involve the MoPH in assessing medicines needs and monitoring sector financial flows.

The public Basic and Essential Packages of Health Services medicines budget is ~ 4 USD per capita per year¹². The best available statistics suggest that 70% of the country's medicines needs are provided via the private sector with the remainder being supplied by the 100% publicly funded essential medicine BPHS/EPHS scheme (90% funded by IDC with the Afghanistan Ministry of Finance contributing the balance); however the proportion of essential medicines provided by the public BPHS/EPHS scheme which is estimated to have 80% population coverage (as a % of total essential drugs supplied) is proportionately higher. It is estimated that an average of 20% of the BPHS/EPHS budget across all donors is spent on medicines¹², although there is a wide variation in per capita medicines expenditure between provinces and between donors (as a result of variations in medicines financing policies between the donors and which are not centrally coordinated).

Large variations occur in medicines availability and per capita BPHS medicines expenditure between the provinces for reasons that are not entirely clear and may be partly related to donor and MoPH incoordination in terms of estimating medicines needs. In spite of the public BPHS/EPHS system 'out of pocket' payments

for medicines constitute a significant part of private household expenditure³⁴. Anecdotal evidence suggests that patients meet a substantial part of their medicines needs from the private sector for a number of reasons; e.g. perception of product quality source, lack of availability in public health facilities, long waiting times, ability to obtain medicines without the need for a prescription. Thus fundamental medicines availability issues in Afghanistan require major attention.

Afghanistan Medicines legislation makes provision for controlling medicines prices via defining import, wholesale and retail margins, for both publicly and privately supplied medicines. Despite the existence of legislation governing medicines price margins, observance of regulated margins is not followed in practice and are hardly inspected or enforced. Very often pharmacies set retail prices by referring to the retail price of medicines in either Pakistan or Iran. The BPHS/EPHS medicines list is based on the MoPH EDL and inclusion of a medicine on the list requires the submission of pharmacoeconomic data³⁵, however the appropriateness and capacity of the Afghanistan authorities to employ pharmacoeconomic analysis in medicines assessment has to be seriously questioned. Strong arguments exist against blindly applying developed country pharmacoeconomic models and techniques in LDCs as they can in the first instance effectively manage scarce resources by applying effective pricing policies, differential pricing and by improving transparency and accountability within the medicines system³⁶.

It is unrealistic in the long term to expect the IDC to continue to fund Afghanistan's essential medicines needs so a system needs to be put in place whereby all regulatory-approved essential medicines, irrespective of source, come under the provisions of a national medicines financing and reimbursement system and with the introduction of international reference prices.

Rational Medicines Usage (RMU)

Irrational medicines prescribing, dispensing and consumption have been reported as being widespread in Afghanistan and include overuse of antimicrobials and injections and the dispensation of half treatment courses^{9, 14}. Medicines are widely available without prescription and a serious problem exists with diagnosis and prescription by unqualified persons posing as doctors in private clinics and working in private pharmacies as well as by street vendors²². It has been noted that consumers cannot always afford complete courses of therapy and that generic medicines are perceived to be of low quality leading to the prescription of high doses and multiple products in the same therapeutic category⁹. The usage of traditional and herbal medicines in Afghanistan medical practice continues to be a major part of health care delivery although utilised traditional remedies may or may not be clinically appropriate²².

The availability of objective medicines information is particularly weak although a few public education campaigns on medicines usage are in existence²². The Afghanistan National Medicines Policy makes provision for implementing several RMU policy

measures, e.g. creation of impartial medicines information resources (such as a national medicines information centre and a national medicines formulary) and national clinical protocols, but aside from the creation of the EML so far none have been implemented due to capacity and resource constraints. There is a real need for the implementation of a range of RMU policy measures including professional curricula development, medicines utilisation review and household consumption studies, health facility Drugs and Therapeutics Committees (DTCs), objective medicines information (for prescribers, dispensers and consumers), clinical protocols, and Good Pharmacy Practice guidelines.

Local Pharmaceutical Industry Development and Trade Policy

Only a decade ago Afghanistan was producing the majority of its medicine needs inside the country and was even developing an export market. As a result of the many recent conflicts in its history, Afghanistan's pharmaceutical industry, which was strong in the period between the 1970s to the early 1990s, has been severely damaged. There are currently two credible foreign-owned manufacturers and a pre-existing major state-owned manufacturer (the latter existing in a dilapidated condition but attempting to revitalise its production base in accordance with international manufacturing standards). In addition there are a large number of small scale 100 percent Afghan-owned pharmaceutical manufacturers, the number of which is growing.

Afghanistan also produces many herbal ingredients that are exported for use in herbal medicines; 28.6 million US\$ of 'medical plants' were exported in 2010 accounting for 7% of total exports³⁷. Thus the development of herbal medicine local production appears rational as the country is a reservoir of potentially valuable herbal active substances with cultivation experience.

The MoPH considers the development of local production and import substitution to be a major pharmaceutical sector strategic objective, but no state incentive schemes exist for supporting local essential medicines production. Due to its land-locked location the costs of importing bulky essential drugs can be prohibitive and above international reference prices and its porous borders make it difficult to control imports. Thus there is real justification for developing a local pharmaceutical industry that can contribute to supplying the country's essential medicines needs and which will require introducing effective import substitution policy measures.

Conclusions

The Afghanistan pharmaceutical sector for several reasons is one of the least developed in the world, operates in a chaotic fashion and suffers from many weaknesses that cover the entire spectrum of sector activities. The market presence of substandard and counterfeit medicines is likely to be significant and should be considered a public health menace demanding

urgent attention. As a result of International Donor Community assistance, there are signs of improvement in Afghanistan healthcare delivery (particularly the contribution of the Basic Package of Health Services / Essential Package of Hospital Services programme), although the country still remains at the bottom of the world health league. However, the IDC focus on providing its health sector development support to the BPHS/EPHS programme has meant that pharmaceutical sector development has been relatively neglected.

Afghanistan pharmaceutical sector development needs and intervention priorities can be described under the separate headings of institutional and market. Institutional needs and priorities cover strengthening (i) sector stewardship, good governance and full National Medicines Policy implementation, (ii) organisational capacity and resources, (iii) sector Monitoring & Evaluation, and (iv) national and international sector coordination. Market needs and priorities cover strengthening (i) medicines regulation - ensuring medicines quality, safety and efficacy, (ii) supply chain regulation, (iii) the drug financing, reimbursement and pricing system, (iv) rational medicines usage, and (v) local pharmaceutical industry.

The sector is currently being financed and managed jointly by the Afghanistan government and the IDC; a situation that is likely to continue for the foreseeable future and which should coexist with an ongoing IDC-supported Afghan MoPH and GDPA capacity building programme and sector infrastructural investment that will address the numerous challenges that the sector faces.

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