Pharmaceutical situation in Afghanistan

Preliminary Assessment

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Afghanistan: facts and figures

Health and health systems

- Life expectancy at birth is 47.2 years for Afghan women and 45.3 years for men.
- In 1997 an estimated 25% of children died before their 5th birthday, with around 20% of deaths caused by pneumonia, diarrhoea or diseases that could be prevented by the use of vaccines.
- 23% of the population has access to clean water (5% in rural areas and 40% in urban areas).
- 80% of the health budget is provided by 20 international agencies.
- There is one physician for every 50,000 inhabitants.

Education

- 39% of boys and 3% of girls go to primary school.
- More than 90% of school-age girls do not know how to read.

Pharmacy

- Pharmaceutical services of the Ministry of Public Health operate with fewer than 15% of the staff in place six years ago.
- Total expenditure on medicines is estimated at US$ 0.25 per person per year.

Other

- Dozens of people are killed every day by landmines and other such devices spread over an area of more than 700 km² of territory. The number of landmines is estimated at 10 million.
- In some provinces, up to 95% of households earn their living from opium sales.
- There is one telephone line per 1000 inhabitants.
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Executive summary

A WHO team comprising staff members from the Department of Essential Drugs and Medicines Policy (WHO Headquarters Geneva), the Department of Emergency and Humanitarian Action (WHO Headquarters Geneva), and Essential Drugs and Biologicals (WHO Regional Office for Eastern Mediterranean, Cairo) conducted a preliminary assessment of the pharmaceutical situation in Afghanistan.

Key sites of the pharmaceutical sector in Kabul, such as the drug manufacturing plant, warehouses, and the quality control laboratory were visited. The team was impressed by their counterparts in the Ministry of Public Health (MOPH), who, after serving for many years under difficult conditions and with extremely limited resources, are still active, showing great professional commitment and profound dedication to their work. Meetings were held with senior government officials, including Her Excellency the Minister of Public Health, and representatives of WHO’s sister agencies and NGOs involved in the pharmaceutical sector.

The overall pharmaceutical situation in Afghanistan has deteriorated dramatically. The health infrastructure is seriously damaged: some buildings have been completely destroyed; others have broken windows, missing electrical wiring, etc., thus making it very difficult for the staff to maintain professional standards. Lack of essential drugs is very common in public health facilities, expensive brand-name medicines available in private pharmacies remain unaffordable for most Afghans. In addition, there is widespread consumption of low-quality and ineffective medicines procured both in public and private facilities. However, recent events have resulted in a huge influx of drug donations to the country, temporarily alleviating shortages.

Major technical and financial assistance will be required to develop pharmaceutical systems offering an appropriate level of services, which are critically needed by the population. WHO has proposed a US$ 25 million budget to the international community for the first year, which would allow medical stores to be established at the central and provincial levels, supplying safe essential drugs to the Afghans in Kabul, in the provinces, and also in remote areas where the majority of the population lives.

Several specific activities have been identified for immediate implementation. The main criteria for selecting an activity was (a) its importance as a basis for sustainable development of the sector, (b) whether it could serve to bring together key players under the overall guidance of the MOPH, (c) whether it could be initiated immediately, moving from assessment to action without undue delay, and (d) if it could be carried out without substantial additional funding. The areas identified for immediate action include:

- appointing an essential drugs focal point in the WHO Office in Kabul;
- developing national guidelines for drug donations;
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- reviewing and updating the national list of essential drugs;
- training key staff;
- initiating the process of developing a national drug policy;
- establishing a mechanism for testing drug samples in the region.

Building up the pharmaceutical sector will take years and will require long-term commitment from any partner involved in the country. WHO is committed to working closely with the Government of Afghanistan and coordinating the efforts of other United Nations agencies and NGOs involved in the development of the pharmaceutical sector.
Introduction

Essential drugs are a vital component of the health care delivery system. Interruptions and a non-continuous supply of essential drugs, substandard quality, and inappropriate use of medicines all contribute to reduced use, and even distrust, of health services by the general population. As a result, health outcomes will be affected negatively. A national essential drugs programme, based on a comprehensive national drug policy promoting the three main objectives of (a) improved access, (b) ensured quality, and (c) rational use by health care professionals and the general public has proven to be a cost-effective way of strengthening health services in general and pharmaceutical services in particular.

The national health authorities currently face two sets of challenges. Health services, including those for essential drugs, urgently need to be strengthened, while national resources, especially in terms of staff and funds, are very limited. The international community will increasingly be involved in supporting the health sector. This positive response will be most effective in leading to the development of sustainable systems if properly managed and coordinated from the outset by the MOPH.
Findings and recommendations

The overall pharmaceutical situation in Afghanistan has deteriorated dramatically during the last 20 years, leading to a lack of most of the essential drugs in public health facilities; expensive brand-name medicines that are unaffordable for most Afghans; and low-quality, ineffective medicines being widely used by the population. Major technical and financial assistance will be required to reconstruct and restructure the pharmaceutical sector into one that will offer the appropriate level of services critically needed by the population.

The following activities are recommended as a basis for setting up a comprehensive national essential drugs programme in order to secure the long-term development and sustainability of the pharmaceutical sector in Afghanistan. WHO, through its country office, is committed to offering the national authorities extensive assistance in introducing a national essential drugs programme in Afghanistan.

When a specific technical area is being developed, assistance should be presented as a package that includes initial assessment, follow-up visits, regular contact with WHO’s MOPH counterpart, training of Afghan counterpart(s), and coaching. Any consultant involved in supporting such a programme must understand that coaching is part of the technical assistance; a one-year plan should be developed, including the results expected by the end of the year, along with the various elements mentioned above. For this reason, any technical assistance can and should be initiated only if a counterpart is identified in MOPH.

1. General

The Avicenna Pharmaceutical Institute (API) is the body overseeing the pharmaceutical affairs in Afghanistan for MOPH. Its two main functions cover activities related to the importation and production of medicines and medical supplies. It is currently run by 90 staff, reduced from 750 following restructuring under the previous government. Its functions are distributed as follows:
Organigram 1: Avicenna Pharmaceutical Institute (API)

Trading
Import
Sales
Finance

Production
Import
Sales
Finance

Director
Planning

Planning

Administration

Personnel

Procurement

External relations

A general government decree was recently issued to restore the previous staffing levels. For the pharmaceutical services, this could mean a substantial increase in staffing. Thirty-five female pharmacists have already registered to return to API. This new influx of personnel may offer an opportunity to reallocate staff to different functions, including those related to the essential drugs programme.

Other pharmaceutical activities are carried out by bodies outside API but are still part of MOPH. These include the National Quality Control Laboratory (NQCL) and the Department of Rules, Regulations and Investigation (RRI). The latter is responsible for inspection and control in the private sector and has its own pharmacists.

Organigram 2: Ministry of Public Health and pharmaceutical services

MOPH

Deputy Minister
(administrative)

Deputy Minister
(policy and technical)

API

NQCL

RRI

Preventive

Curative

It should be noted that API staff, as is the case for most government staff, have not received a salary for the last six months. Very limited professional documentation and material is available and no computers were seen in the various offices visited. The general working conditions are far from optimal: there are broken windows, a lack of proper office equipment, and no heating system.
Recommendation 1: Create a Department of Pharmaceutical Services

MOPH is responsible for ensuring that a range of pharmaceutical services is delivered in the country. Some functions, including policy development, legislation, and overall supervision of pharmaceutical services, would typically fall under the Pharmacy Department of MOPH. Other functions, such as drug supply and drug regulation and control, could be the responsibility of autonomous bodies affiliated to MOPH.

The fact that the NQCL and RRI are separate from API is commendable as these functions should be completely independent from each other. The manufacturer, supplier, and other administrative services should not be part of the same body as the regulator because this could lead to conflicts of interest. It is therefore suggested that a Department of Pharmaceutical Services be created under MOPH. This department would provide the following services:

Organigram 3: Proposed new Department of Pharmaceutical Services

The main functions of the head of the Department of Pharmaceutical Services would be to coordinate the development of policies and ensure their implementation, identify staffing requirements in the various bodies dealing with pharmaceuticals in Afghanistan, define terms of reference for all staff, and ensure that training requirements are met both in university for new graduates as well as in continuing education for those who have already graduated and practising health professionals. The manufacturing unit, the distribution facilities, and the drug regulatory authority would be operationally and financially autonomous in order to ensure efficiency but would still be accountable to the Director of Pharmaceutical Services to ensure that they remain fully in line with MOPH priorities.

1 Nevertheless, a quality control laboratory is needed within API, as a unit independent from production.
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Recommendation 2: Move all pharmaceutical services to the site of the API manufacturing plant

The premises of the API manufacturing plant occupy a large area located 20 minutes away from the centre of Kabul. The premises are too large to implement modern standards for good manufacturing practices (GMP) in a cost-effective manner. It is therefore suggested that, after renovation of the premises, the Central Medical Store, the NQCL, and various other offices be relocated to the manufacturing plant. Transportation (bus) may have to be organized for the staff in view of the location of the premises.

Recommendation 3: Provide immediate training to key staff

It is important to build on the experience and effective systems in place in neighbouring countries. It is therefore suggested that the Director of the Pharmaceutical Institute visit Iran (which shares a common language) to review the organization of the pharmaceutical sector and study its applicability in Afghanistan.

2. National drug policy

The national drug policy (NDP) expresses the political commitment of the government and brings together key interested parties. It is developed through a process of consultation with all partners in the pharmaceutical sector and is a formal political statement of the government, which guides the action of all parties in the development of the pharmaceutical sector with a coordinated approach. To date, Afghanistan has not developed its own national drug policy.

Recommendation 4: Develop the national drug policy for Afghanistan

The development of the NDP will require:

- the creation of a national steering committee for the development, implementation, and monitoring of the NDP;
- nomination of a national focal point for essential drugs in MOPH;
- a baseline survey on selected indicators and an in-depth analysis of the pharmaceutical sector;
- drafting of a preliminary version of the NDP;
- discussing the draft NDP in a national workshop involving all interested parties;
- adoption of the NDP by the government;
- developing a plan of operation to implement the NDP: defining the priorities, roles, and responsibilities of the stakeholders; and the timing and financial implications of the planned activities, as well as setting up a mechanism for monitoring the progress of the various components.

It is suggested here that in the first stage only a baseline survey with selected indicators be carried out—before the NDP is drafted. An in-depth analysis of the pharmaceutical sector can be conducted in a second stage, 6–12 months after the first survey, before developing the pharmaceutical master plan. Both activities

\footnote{Including the current “Donation Medical Store”}
Findings and recommendations

should be carried out in close collaboration with other partners. This analysis can also be used to evaluate progress against the first survey.

The implementation of the NDP requires an essential drugs programme in MOPH, which can collaborate closely with its various departments, including the Department of Pharmacy, the Department of International Affairs, the Department of Planning, etc.

Properly trained and skilled physicians, pharmacists, pharmacy assistants, nurses, and other paramedical personnel will be instrumental to the success of the essential drugs programme. It is important to define the staffing requirements and roles of various health care professionals in ensuring the appropriate prescribing, management (including stock management and stock replenishment), dispensing, and use of pharmaceuticals. Introduction of the concept of essential drugs in the various university curricula, as well as in-service training, has to be developed accordingly.

**Recommendation 5: Review and update pharmaceutical legislation**

After the adoption of the NDP, the existing legislation for pharmaceutical products and practices will need to be reviewed in line with the overall objectives of the NDP.

3. Access

**Main findings**

*Selection:*  
The four agencies surveyed reported that they respect the WHO or MSF list of essential drugs.

*Prices:*  
Most of the NGOs given drugs free of charge. One agency sells drugs at 40% below market price, according to a fixed pricing structure.

*Supply system:*  
- Sources of procurement: Europe (mainly), Pakistan, Iran, and (exceptionally) the local market;
- Difficulties in procedures for customs clearance: quality control procedures and testing (in particular, the procedure for obtaining exemption from fees for the NGOs);
- Difficulties in distribution procedures: access, climate, land mines, and security;
- Central supply unit: this idea was welcomed. It could facilitate the work of NGOs—mainly the middle-sized and small NGOs, which currently do not have a proper independent supply structure. The expectations for such a central supply unit are assured quality, continuous availability, no more

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3 For the main findings of the survey carried out for ICRC (June-July 2000), see Annex 7.
problems with customs. Pharmaciens Sans Frontières (PSF) was mentioned as the best possible partner in setting up such a system.

Specific requests:
- All agencies expressed the urgent need for a health structures mapping system to allow MOPH to organize a good “partitioning” of the NGOs in the country.
- A meeting between MOPH and the NGOs, facilitated by WHO (as lead agency), has been requested for sharing knowledge and strengthening collaboration.
- WHO is requested to help the NGOs by discussing with MOPH the huge amount of administrative paperwork requested by the authorities.

Conclusion:
There is a great need, and opportunity, to facilitate, strengthen, and coordinate the understanding and working relations with and between the NGOs. It is important to support both MOPH and the NGOs because, in terms of actual service delivery, these two entities have to work closely together (and not in opposition) in order to expand the delivery of health care in the country. The NGOs welcome meetings, especially practical working groups on specific topics, organized by WHO.

Coordinating drug donations

It is expected that Afghanistan will rely on donations of medicines for a number of years to come, and it is important that an appropriate policy for donations be implemented to ensure that donated medicines are of good quality and address the needs of the country.

MOPH should be supported in establishing relevant mechanisms to ensure efficient coordination among the international agencies supplying essential medicines and to enhance access to information on needs and on the medical supplies provided. The inputs of the various relief/development agencies will be taken into consideration from the outset to avoid duplication. Prior to bringing medicines into the country, all agencies will need to clear their donations with MOPH and respect the guidelines for national drug donations and the essential drugs list. Capacity building of MOPH technical staff should be an integral component of this intervention.

Recommendation 6:  Adopt guidelines for drug donations and ensure interagency coordination

It is very important to provide support to the national authorities to ensure that donations of medicines comply with national guidelines for drug donations (based on WHO model guidelines) and that they address the priority needs for the country. Donor guidelines should be adopted and promoted, and mechanisms for interagency coordination and information sharing should be set up to ensure an efficient supply of medicines.

Procurement and distribution channels

MOPH currently operates with two different and independent distribution channels, one for procured items, which is managed by API, and a second one for
donated items, which is managed by the Department of Curative Medicine. Neither of them respects good drug supply management practices.

**API warehousing**

API premises offer a large storage capacity in several buildings, but currently only two storage rooms are functioning. Temperature, security, and protection from rain and dust are satisfactory. Some limited renovation would be required to improve ventilation and access. Lights and shelves are also required before the stores can be used properly.

All (54) available items (including drugs and medical supplies) are mixed on the shelves. There are no stock cards. No batch number, manufacturer, or expiration date are recorded to allow tracing of consignments. There is no real stock policy; what is received tends to be dispatched immediately without any allocation or replenishment policy. There is a list of available items but these are not categorized. The accounting section follows published general regulations for all ministries. Imported goods originate predominantly from local manufacturers in Pakistan.

**MOPH warehousing**

This warehouse stocks donations exclusively. There is no proper shelving or stock control system. No stock cards are kept with the items. Stocks are issued according to requests from health facilities against the signature of the Minister or the Director of Curative Services. There is no system to control the figures provided to the Directorate of Curative Services by the health facilities concerning their activities and requirements. New WHO emergency health kits (NEHK) were found in the store. Non-medical items (hospital tents, blankets, etc.) are kept in containers because two of the three stores were burned after being hit by rockets.

**Dispensing in health facilities and semi-private pharmacies**

The government used to run approximately 100 “API pharmacies” spread throughout the country. This number has (due to the staff reductions) been reduced tremendously, for instance in Kabul, only 14 such pharmacies are currently active. Drugs produced or supplied by API to the API pharmacies are sold at the purchase price. Drugs not available from API are procured on the market from private wholesalers and sold with a 10%-20% mark-up, which is supposed to cover staff salaries. The API pharmacies are now being essentially run as a mixed public-private business.

In-patients receive drugs available at the hospital pharmacy free of charge. All other (most) items, including medical supplies, have to be bought from the private sector.

**Recommendation 7: Create a new central medical store**

The sooner MOPH puts an effective drug procurement and distribution system in place, the sooner it will be in a position to develop its own health service provision and channel the expected donations from external partners.

To achieve this, the following components need to be put in place:
- a computerized system for drug procurement, storage, and distribution;
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- refurbishment of the entire infrastructure, including appropriate warehousing at central and provincial levels;
- development of an appropriate distribution system with proper transportation (vehicles, subcontracting, etc.) and information systems;
- training in drug supply management for health professionals at all levels of the distribution chain.

Substantial funds will be required to develop a comprehensive distribution system covering all the districts in the country. The unique geography of Afghanistan and the poor status of the infrastructure make the distribution system more difficult and costly than it would be in other countries.

Recommendation 8: Combine the two MOPH warehouses into a single one

The current arrangement with two separate warehouses is not cost effective and does not facilitate the coordination of drugs distributed from the central level. Until a new central medical store is operational in Afghanistan, all items procured under MOPH, including donations, should be managed in the same warehouse. Because the storage conditions at the API warehouses are more appropriate, it is recommended that they be used on a temporary basis until part of the API production facilities can be converted into a new warehouse.

Selection of essential drugs

The existing national essential drugs list (NEDL) was developed in 1995. It is a good document in which medicines are divided by six different levels of care. It was developed just before the last regime came into power and has neither been widely distributed nor used as a base for procurement or donations.

Recommendation 9: Use the 1995 NEDL for all procurement and donations

It is recommended that, until the 1995 NEDL is updated, the existing one be used to guide all procurement and donations.

Recommendation 10: Update the National Essential Drugs List

The NEDL needs to be updated, based on changes in health priorities, disease patterns, pricing, and new drugs available on the market. A national drug and therapeutic committee (NDTC) needs to be established to review and update the list and to develop treatment guidelines, training materials, and a national formulary (see Annex 5: Terms of Reference of Drug and Therapeutic Committee). The NDTC should incorporate a wide range of health professionals, including different medical specialities, medical doctors, paramedical professionals, and pharmacists working at different levels of the health-care system, academia, etc. Existing guidelines developed by WHO and other partners should be considered during the development of specific local guidelines.
Quantification

A responsive system needs to be put in place to quantify/forecast essential drug requirements based on (a) prevalence of the most important/common diseases and (b) the health care seeking behaviour of the population.

As the service delivery improves (in terms of both quality and geographical distribution), a larger proportion of the population can be expected to seek services. Consumption of essential drugs will increase accordingly. In addition, with the return of internally displaced people and refugees to their original homes, the geographical distribution of the population and disease patterns will change. An adequate drug supply system will have to track these changes and amend forecasts of drug requirements accordingly.

Recommendation 11: Estimate national drug requirements

National drug requirement will need to be estimated as soon as possible. It can be based on the current or the revised national essential drugs list, whichever will be available when quantification will be made. This exercise should be linked with a health facilities mapping exercise for the country.

4. Quality

API Manufacturing plant

The API manufacturing plant is located 20 minutes away from the centre of the town, on vast premises (pavilion style over two floors). The building has suffered relatively minor damage (mainly broken windows, which makes the site dusty and cold during the winter). It contains numerous machines, including machines that were commissioned but never used because of the war. Essential parts of most equipment have been stolen (i.e. engines). Other parts of the infrastructure, including electrical wiring have also been stolen or destroyed.

API manufacturing was started in 1975 with financial and technical support from the French Government and the Institut Pasteur for the production of vaccines. Subsequent investments were made by the Government of Afghanistan to develop the country’s capacity for pharmaceutical production. Technical expertise was hired directly by the government (mainly from India). WHO provided assistance to API through the years with raw materials and equipment, including a generator.

The factory used to be very active, running two shifts and having more than 300 employees on staff. The products covered a diverse range, from shampoos and toothpaste to oral rehydration salt (ORS), syrups, IV solutions, and vaccines. The factory was able to produce products in blister packs, as suppositories, and in ampoules and vials. The current staff of 20 includes one engineer and 11 pharmacists, none of whom have received GMP training.

The quality control area has no equipment, no reagents, etc. Remaining equipment and reagents have been transferred to the MOPH Quality Control Laboratory (see below).
Raw materials are imported—mainly from India but also from China, Russia, and Western European countries. The most recent importation took place last year. The remaining stocks are sufficient for two to three months of production. However, it was reported that large quantities of raw material for producing ORS (which was supported by UNICEF up to 1992) are still in stock.

The financial position of API has been eroded over the last several years because of the strong devaluation of the Afghani, which has not been matched by price corrections and timely payments.

Although a real inspection of the site was not carried out, it can be concluded that, because of the current structural problems, the lack of trained staff, and the absence of a quality assurance unit, API is not in a position to produce pharmaceuticals according to WHO GMP standards.

Recommendation 12: Conduct an in-depth technical and economic assessment of the API manufacturing plant

There is a need for in-depth technical assessment of the API manufacturing plant, as well as an economic analysis of their production vs. importation. The mission assumes that current premises are too extensive, that substantial refurbishing is required, and that most equipment cannot be repaired.

Any production should start with a limited range of products after the overall physical and organizational manufacturing environment has been improved. ORS might be a suitable starting point as its production is technically not too challenging, raw materials (which would need to be tested) are already in stock, and renewed support from UNICEF could be sought.

It is recommended that the new API manufacturing plant be run as an autonomous government body linked to MOPH to enable it to take appropriate professional and economic action, such as management of its human and financial resources (see Organigram 3).

National Quality Control Laboratory

The NQCL comprises three rooms in MOPH premises. It contains basic equipment (UV spectrophotometer, dissolution machine, pH meter, two microscopes, and a scale) provided by WHO. It carries out physico-chemical tests only, and the available reagents cover only 65% of the tests requested. For many tests, there are no reference standards available.

Sampling is done at customs and all tests are costed. NGOs are officially not charged, contrary to the situation of the private sector.4

On average, 100 tests are done per month, on a first-come, first-served basis. For any priority testing, authorization is required from the Minister or her representative.

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4 NGOs have to pay for the tests, after which they can apply to MOPH for a letter of exemption in order to be refunded. This procedure takes time and has created problems for NGOs.
The NQCL has three staff members, all of them pharmacists. In addition, three other pharmacists (trainees) support the laboratory on a temporary basis. None of the staff has received specific quality control-related training since graduation.

**Recommendation 13: Arrange for external quality control for testing medicines**

MOPH is currently not in a position to adequately control the quality of drugs entering the market. As a result, many substandard medicines are found in both the public and private sectors. Until the country re-establishes a well-functioning national regulatory authority with a national quality control laboratory, provision should be made within MOPH for external testing of medicines. Specific requirements for quality assurance should be made for donations. NGOs known to be suppliers of quality drugs (through assessment of their documentation and previous tests) should be exempted from routinely submitting samples.

**Recommendation 14: Strengthen NQCL capacity**

The development of the NQCL's local capacity will require substantial technical and financial investments, with:

- training and coaching by a consultant;
- procurement of basic equipment (high performance liquid chromatography, water bath, magnetic stirrer, etc.), reagents, books, shelves, and cabinets;
- moving the NQCL to new premises (the API manufacturing plant)

5. Rational Use

The mission did not have time to directly assess the use of medicines by health professional and patients. The information reported below is based on discussions with the people met.

Irrational use of drugs is a common problem in Afghanistan, with a high proportion of prescription of antimicrobials and injections. Additionally, there is a strong preference, by both professionals and consumers, for expensive brand-name products. The generics in the country are perceived to be of low quality (less effective, more side-effects, etc.), often leading to the prescribing of twice the dosage or simultaneous prescription of therapeutically similar products. Consumers can't always afford to buy a complete treatment, leading to additional concerns in terms of direct health outcomes as well as development of drug resistance.

It was reported that the national formulary was developed in 1996, but no copies were seen.

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5 Long-term technical support is required, either through the continued presence of a technical advisor or through regular visits with technical backstopping between missions.
Recommendation 15: Training health professionals in rational use of medicines

Basic (pre-service and in-service) training on rational drug use should be provided to health personnel working at the PHC level. These staff often have only a basic formal education. The training should therefore focus on (clinical) diagnosis and appropriate treatment of a limited range of priority diseases, proper referral mechanisms, and appropriate dispensing practices.

More elaborate training will be required to bring the practices of all health professionals, including nurses, midwives, and medical doctors, in line with new developments, including the implementation of the NDP, the NEDL, and standard treatment guidelines, etc. It will be particularly important to rebuild the confidence of both professionals and consumers in the quality of the drugs available (initially via the public sector through an effective drug supply system, later also in the private sector through the development of regulatory services).

To conduct this training, additional documents/manuals need to be prepared and coordinated by the NDTC, including a training manual on prescribing and on standard treatment guidelines. Existing material from various NGOs/UN agencies should form the basis of agreed upon national guidelines, in order to ensure shared ownership by all partners.

6. Traditional medicine

In Kabul, Unani medicine (traditional medicine used in Afghanistan, which literally means Greek medicine) can be found in little stands in the local market. These stands are usually managed by Afghan Sikhs, whose knowledge is passed from father to son. It was reported that their services are sought when allopathic medical treatment has failed. The products they use include both spices and herbal medicines, which come from Afghanistan, India, or Pakistan. It was also reported that outside the cities, the majority of the population relies on traditional medicine as its first, and often only, source of health care.
Conclusions

The overall pharmaceutical situation in Afghanistan has deteriorated dramatically over the last 20 years. The health infrastructure has been greatly damaged; access to essential drugs is extremely limited and their procurement relies heavily on donations from the international community. Proper systems and controls to ensure the quality of medicines produced in or entering the country are not in place, and MOPH personnel have not been exposed to new scientific developments and specialized training in their respective fields.

Major technical and financial assistance will be required to develop pharmaceutical systems offering an appropriate level of services, critically needed by the population. Pharmaceutical services need to be reorganized, new policies developed and advocated, infrastructure refurbished, facilities properly equipped, and staff trained. Building up an efficient pharmaceutical sector will take years and will require long-term commitment from any partner engaging in the country.

The level of dedication, commitment, and professionalism demonstrated by Afghan counterparts gives the team confidence that, if given suitable and sufficient support, the foundation to reconstruct the pharmaceutical sector is in place. Such an endeavour needs to be initiated very rapidly to take the best advantage of current opportunities and unique momentum. WHO is committed to working closely with the Government of Afghanistan in providing technical assistance, engaging in fund-raising activities, and supporting MOPH in coordinating the efforts of other United Nations agencies and NGOs involved in the development of a sustainable pharmaceutical sector.
**Recommendations for immediate action**

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<th>General</th>
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<td>Nominate an essential drugs focal point in WHO Office in Kabul</td>
<td>WHO</td>
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<td>Send documents to WHO Office in Kabul</td>
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<td>The 2 warehouses (API and MOPH) should be combined as soon as possible</td>
<td>MOPH</td>
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<tr>
<td>Draft funding proposal(s), taking into consideration the outcome of the Tokyo meeting, and discuss with potential donors</td>
<td>WHO</td>
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<th>Guidelines for drug donations</th>
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<td>Send 50 copies of the “Guidelines for drug donations” to MOPH and arrange translation in national language</td>
<td>WHO</td>
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<tr>
<td>Review the guidelines with WHO and make adjustments if necessary</td>
<td>MOPH</td>
</tr>
<tr>
<td>Organize meeting to discuss the implications of the guidelines with partners (UN agencies, NGOs, etc.) and rules and coordination mechanisms</td>
<td>MOPH</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>National essential drugs list (NEDL)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Appoint the National Drug and Therapeutic Committee (Annex 5)</td>
<td>MOPH</td>
</tr>
<tr>
<td>Review the 1995 NEDL and update (based on the priority diseases and existing treatment protocols) by level of health care facility</td>
<td>NDTDC</td>
</tr>
<tr>
<td>Organize workshops to brief national experts on the essential drugs concept and determine the process, establish working groups, etc.</td>
<td>NDTDC/WHO</td>
</tr>
<tr>
<td>Officially launch the NEDL and disseminate widely</td>
<td>MOPH</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Training of key staff</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Study visit of Director of API to MOHME and DRA Iran</td>
<td>WHO</td>
</tr>
<tr>
<td>Study visit of NQCL staff member to NQCL Iran</td>
<td>WHO</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NDP process**</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Appoint committee to develop the NDP (Annex 6)</td>
<td>MOPH</td>
</tr>
<tr>
<td>Brief national experts on essential drugs concept (see workshop for NEDL above)</td>
<td>WHO</td>
</tr>
<tr>
<td>Conduct baseline survey on selected indicators and in-depth situation analysis</td>
<td>MOPH/WHO</td>
</tr>
<tr>
<td>Subsequent steps will include drafting, review, and adoption</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quality control</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Arrange for collaboration between NQCL of Afghanistan with counterparts in the region (e.g. Iran). In addition to training (see above), this could involve sending samples for (confirmation) testing.</td>
<td>WHO</td>
</tr>
</tbody>
</table>

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**Footnotes:**

5 From funds already available under JPRM, EDM/HQ, and possibly EHA (DFID).

7 The process recommended by WHO includes the following three steps:
   - Identify of the priority diseases in the country.
   - Determine the standard treatment (which will form the basis of standard treatment guidelines).
   - Draft a national essential drugs list.

6 Development of the NDP will take considerable time and the process should not be accelerated without consultation with and involving all partners. However, the process should be initiated as soon as possible.
Annex 1: Recommendations to the Ministry of Public Health, Afghanistan, for strengthening the pharmaceutical sector

1. Introduction

Essential Drugs are a vital component of the health care delivery system. Interruptions and a non-continuous supply of essential drugs, substandard quality, and inappropriate use of medicines all contribute to reduced use, and even distrust, of the health services by the general population. As a result, health outcomes will be affected negatively. A national essential drugs programme, based on a comprehensive national drug policy promoting the three main objectives of (a) improved access, (b) ensured quality, and (c) rational use by health care professionals and the general public has proven to be a cost-effective way of strengthening health services in general and the pharmaceutical sector in particular.

The authorities in Afghanistan currently face two sets of challenges. Health services, including the availability of essential drugs, need to be strengthened as soon as possible but there are only very limited resources available. The international community will increasingly be involved in supporting the health sector. This positive response will be most effective and will lead to the development of sustainable systems if properly managed and coordinated by MOPH from the outset.

The following activities are recommended for immediate action (initiated as soon as possible) to intermediate action (initiated within six months) by MOPH as a basis for setting up a comprehensive national essential drugs programme that will secure the long-term development and sustainability of the pharmaceutical sector in Afghanistan. WHO, through its country office, is committed to offering the national authorities extensive assistance in introducing a national essential drugs programme in Afghanistan.

2. National drug policy (NDP)

The national drug policy, developed through a process of consultation with all partners in the pharmaceutical sector, is a formal political statement of the Government, which guides the coordinated action of all parties in the development of the pharmaceutical sector.

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5 This document was presented to Her Excellency The Minister of Public Health Afghanistan prior to her departure to the International Conference on Reconstruction Assistance to Afghanistan, 20-21 January 2002.
Immediate

Donor coordination
The inputs of the various relief/development agencies should be coordinated from the outset to avoid duplication of action and unnecessary tension between the various partners.

Development of structure of pharmaceutical services
MOPH is responsible for seeing that a range of pharmaceutical services is delivered in the country. Some functions, including policy development, legislation, and overall supervision of pharmaceutical services, fall under the Pharmacy Department of MOPH. Other functions, such as drug supply and drug regulation and control, could be the responsibility of autonomous bodies affiliated to MOPH.

It is important to build on the experience and effective systems in place in neighbouring countries such as Iran and Pakistan. It is therefore suggested that the Director of the Pharmaceutical Institute visit Iran to review the organization of the pharmaceutical sector there and to study its applicability in Afghanistan. This could be covered from existing funds already available in WHO.

Intermediate

National drug policy (NDP)
The development of an NDP expresses the political commitment of the government and brings together key interested parties. NDP development will require:

• the formation of a national steering committee for the development, implementation, and monitoring of the NDP;
• nomination of a national focal point for essential drugs;
• in-depth analysis of the pharmaceutical sector;
• drafting of a preliminary version of the NDP;
• discussion of the draft NDP in a national workshop for all interested parties;
• adoption of the NDP by the Government of Afghanistan;
• development of a plan of operation to implement the NDP, defining the priorities, the roles and responsibilities of the stakeholders, the timing, and the financial implications of the planned activities as well as setting up a mechanism for monitoring the progress of the various components.

The implementation of the NDP requires an essential drugs programme in MOPH, which will collaborate closely with its various departments, including the Department of Pharmacy, the Department of International Affairs, the Department of Planning, etc.

Human resources development plan
Properly trained and skilled physicians, pharmacists, pharmacy assistants, nurses, and other paramedical personnel will be instrumental to the success of the essential drugs programme. The roles and staffing requirements of various health care professionals in ensuring the appropriate prescribing, management, dispensing, and use of pharmaceuticals have to be defined. Basic and in-service training has to be developed accordingly.
3. Access

Immediate

Donor guidelines
It is very important for the national authorities to take control of the selection and distribution of essential drugs by all parties involved in procurement and/or service delivery. Development and adoption of donor guidelines (based on the WHO model guidelines) are proposed as a framework for MOPH to assist the donors in making appropriate drug donations.

In addition, MOPH should immediately develop an effective system under which it will have an overview of all medicines entering the country as part of current international support. Under such a system, prior to bringing in medicines, all agencies will need to clear their donation with MOPH and respect the national essential drugs list.

Selection
The existing (1995) national essential drugs list (NEDL), organized by level of care, is a good document that needs to be updated based on changes in health priorities, disease patterns, pricing, and new drugs available on the market. It is recommended that an NDTC be nominated to review and update the list and develop treatment guidelines, training materials, and the national formulary. The NDTC should incorporate a wide range of health professionals, including different medical specialities, medical doctors and pharmacists working at different levels of the health care system, academia, etc. Expenses related to this activity can be covered by funds already available in WHO.

It is recommended that, until the 1995 NEDL is updated, the existing one be used to guide all procurement and donations.

Quantification
A responsive system needs to be put in place to quantify/forecast requirements for essential drugs based on (a) prevalence of the most important/common diseases and (b) the behaviour of the population in seeking health-care.\textsuperscript{10}

Drug distribution system
The sooner MOPH puts an effective drug procurement and distribution system in place, the sooner it will be in a position to develop its own health service provision and channel the expected efforts from various external partners.

To achieve this, the following components need to be put in place:
• setting up a computerized system for drug procurement, storage, and distribution;
• refurbishing the infrastructure, including appropriate warehousing at central and provincial levels;

\textsuperscript{10} As the service delivery improves (in terms of both quality and geographical distribution), a larger proportion of the population can be expected to seek services. Consumption of essential drugs will increase accordingly.
• developing an appropriate distribution system with proper transportation (vehicles, subcontracting, etc.) and information systems;
• training on drug supply management.

4. Quality

Immediate

Quality control
MOPH is currently not in a position to adequately control the quality of drugs entering the market; as a result, many substandard medicines are found in both the public and private sectors. Until the country re-establishes a well-functioning national regulatory authority with a national quality control laboratory, provision should be made within MOPH for external testing of medicines. This should apply equally to drug donations.

Intermediate

Legislation/regulation
A basic drug regulatory authority should be (re)established as soon as possible. It should provide at least the following services:
• drug registration (which could be limited to the NEDL);
• inspection of drug supply services (imports, distribution, and retail pharmacies);
• drug quality control (basic chemical tests).

The existing legislation for pharmaceutical products and practice needs to be reviewed in line with the overall objectives of the NDP.

5. Rational drug use

Immediate

Training
Basic (pre-service and in-service) training on rational drug use should be provided to health personnel working at the primary health care (PHC) level, who will often have only a basic formal education. The training should therefore focus on (clinical) diagnosis and appropriate treatment of a limited range of priority diseases, proper referral mechanisms, and appropriate dispensing practices.

More elaborate training will be required to bring the practices of all health professionals, including nurses and medical doctors, in line with new developments, including the implementation of the NDP, the NEDL, and standard treatment guidelines, etc.

To conduct this training, several documents/manuals need to be prepared, including a training manual on prescribing and standard treatment guidelines.

Project Submission Title: Essential Drugs – Supply and Technical Support
Your Agency’s Project Number:
Appealing Agency/Agencies: WHO
Implementing partners: MOPH, NGOs, UNICEF, UNFPA

Project Overview

Sector: (Select by X in the box)

<table>
<thead>
<tr>
<th>Food Aid</th>
<th>Education</th>
<th>Infrastructure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mine Action</td>
<td>Human Rights</td>
<td>Refugees and Returnee Assistance (multisectoral)</td>
</tr>
<tr>
<td>Health</td>
<td>X</td>
<td>Food Security</td>
</tr>
<tr>
<td>Health</td>
<td></td>
<td>Security</td>
</tr>
<tr>
<td>Water and Sanitation</td>
<td>Community Empowerment</td>
<td>Coordination and Support Services</td>
</tr>
<tr>
<td>Shelter and Non-food Items</td>
<td>Income Generation</td>
<td></td>
</tr>
</tbody>
</table>

Identify the subsectors the project will address: (Select by X in the box)

<table>
<thead>
<tr>
<th>Agriculture</th>
<th>Mine Awareness</th>
<th>Community Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capacity Building</td>
<td>X</td>
<td>Mine Survey</td>
</tr>
<tr>
<td>Drug Control</td>
<td>Mine Clearance</td>
<td>Security of Assistance Personnel</td>
</tr>
<tr>
<td>Environment</td>
<td>Nutrition</td>
<td>Sanitation</td>
</tr>
<tr>
<td>Disability</td>
<td>Safe Motherhood</td>
<td>Potable Water</td>
</tr>
<tr>
<td>Gender</td>
<td>Sexual Violence–Prevention &amp; Management</td>
<td>Support Services/Administration</td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>Reproductive Health</td>
<td>X Other (Specify below):</td>
</tr>
<tr>
<td>Human Rights/Protection</td>
<td>Mental Health</td>
<td>X</td>
</tr>
<tr>
<td>Land Resource Management</td>
<td>Psycho-Social Support</td>
<td></td>
</tr>
<tr>
<td>Infrastructure Rehabilitation (Irrigation channels/roads etc)</td>
<td>Governance/Social Change</td>
<td></td>
</tr>
<tr>
<td>Information Management</td>
<td>Peace Building/Promotion</td>
<td></td>
</tr>
<tr>
<td>Logistics</td>
<td>X Preparedness and Contingency Planning</td>
<td></td>
</tr>
</tbody>
</table>
Identify which of the 5 Strategic Goals the project is geared to address: (Select by X in the box)

<table>
<thead>
<tr>
<th>Alleviation of Human Suffering</th>
<th>X</th>
<th>Human Rights</th>
<th>Basic Social Services</th>
<th>X</th>
<th>Sustainable Livelihood</th>
<th>Refugee Assistance and Refugee Return</th>
</tr>
</thead>
</table>

Objectives:

1. To ensure an uninterrupted availability of quality life-saving drugs and medical supplies for primary health care services
2. To improve utilization of primary health care services by increasing perceived credibility of the system to provide health care

Activities:

1. Establish National Drug and Therapeutic Committee for prioritization and updating of National Essential Drugs List and policy development
2. Initial and regular quantification of requirements based on trends in utilization
3. Development of system for drug quality assurance and regulation
4. Coordination of drugs donated through health sector partners
5. Development and implementation of a computerized system for drug procurement, storage, and distribution
6. Refurbishment of the required infrastructure, including stores, depots, cold rooms, integrated with existing health care programs including EPI, PHC
7. Development, publishing, and dissemination of training materials and guidelines
8. Training on Drug Supply Management, Rational Use
9. Implementation of appropriate delivery system kits for basic services, intended for referral level

Link with Medical Science Education for curriculum development and training of pharmacists
Link with Technical Advisory Unit for Pharmacy Policy Advisor to Central MOPH for oversight

Outputs:

1. Updated National Essential Drugs List by level of care
2. List of quantities of drugs required, updated quarterly based on trends in utilization, national level
3. Nationally recognized guidelines for quality assurance
4. Drugs regularly tested for conformity with quality standards
5. Infrastructure refurbished and meeting requirements for drug storage
6. Training materials and guidelines disseminated
7. 400 health workers (about 50% of all health facilities) trained on Rational Drug Use
8. 100% of Regional and Provincial Pharmacy Officers (Health Management Teams) trained in Drug Supply Management and Supervision
9. At least 80% availability of key essential drugs in supported health care facilities
Indicators:

1. Increasing trend of utilization of health care services
2. Number of health workers trained on Rational Drug Use
3. % of Regional and Provincial Pharmacy Officers (Health Management Teams) trained in Drug Supply Management and Supervision
4. % availability of key essential drugs in supported health care facilities
5. % of drugs tested and found conforming to quality standards

Impact:

1. Increased utilization of essential primary health care services
2. Reduced morbidity and mortality

Place: (Select by X in the box)

<table>
<thead>
<tr>
<th>Afghanistan (Specify the province and district below)</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pakistan</td>
<td></td>
</tr>
<tr>
<td>Iran</td>
<td></td>
</tr>
</tbody>
</table>

Provinces:

(All) National Program

Districts:

CITIES:

Project Duration:

Start Date (month & year)
1 February 2002

End Date (month & year)
31 December 2002
Pharmaceutical Situation in Afghanistan

Budget for Period 1 October 2001–31 December 2002

Budget Lines:

<table>
<thead>
<tr>
<th>Item #</th>
<th>Description</th>
<th>Amount in US$</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Prioritization and updating of national Essential Drugs List</td>
<td>10 000</td>
</tr>
<tr>
<td></td>
<td>Initial and regular quantification of requirements based on trends in utilization—technical support</td>
<td>30 000</td>
</tr>
<tr>
<td></td>
<td>Development and implementation of system for drug quality assurance and regulation—sending samples, training, basic lab</td>
<td>300 000</td>
</tr>
<tr>
<td></td>
<td>Coordination of drugs donated through health sector partners</td>
<td>10 000</td>
</tr>
<tr>
<td></td>
<td>Development and implementation of a computerized system for drug procurement, storage, and distribution</td>
<td>300 000</td>
</tr>
<tr>
<td></td>
<td>Refurbishment of the required infrastructure, including stores, depots, cold rooms, integrated with existing health care programs including EPI, PHC – 1 central, 6 regional warehouses</td>
<td>800 000</td>
</tr>
<tr>
<td></td>
<td>Development, publishing, and dissemination of training materials and guidelines</td>
<td>40 000</td>
</tr>
<tr>
<td></td>
<td>Training on Drug Supply Management, Rational Use</td>
<td>60 000</td>
</tr>
<tr>
<td></td>
<td>Procurement of essential drugs and supplies</td>
<td>20 000 000</td>
</tr>
<tr>
<td></td>
<td>Implementation of appropriate delivery system—kits for basic services, indent for referral level</td>
<td>3 500 000</td>
</tr>
<tr>
<td></td>
<td>TOTAL</td>
<td>25 050 000</td>
</tr>
</tbody>
</table>

Funds Made Available since 1 October 2001:

<table>
<thead>
<tr>
<th>Item #</th>
<th>Description</th>
<th>Donor</th>
<th>Date Funds Available</th>
<th>Amount in US$</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Donation</td>
<td>WHO–HQ</td>
<td>1 February 2002</td>
<td>20 000</td>
</tr>
<tr>
<td></td>
<td>Regular Budget</td>
<td>WHO–RO</td>
<td>1 January 2002</td>
<td>40 500</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td></td>
<td></td>
<td>60 500</td>
</tr>
</tbody>
</table>

Funds Requested for the period: $ 24 989 500

Other details

Total Number of Beneficiaries (individuals):

10 000 000
Type of Beneficiaries:

<table>
<thead>
<tr>
<th></th>
<th>IDPs</th>
<th>Refugees</th>
<th>Vulnerable Populations in situ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Families</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female Households</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elderly</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disabled</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Implementing Capacity:

WHO is present in seven regions with over 250 local and international staff to deliver assistance to each province. The organization plays a key role in coordinating national and regional health supporting agencies, NGOs, and the regional Ministry of Public Health. National strategies are decided in such forums.

Feasibility Study/Needs Assessment:

<table>
<thead>
<tr>
<th>Title</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essential Drug Programme in Afghanistan</td>
<td>Round Table Public Health Workshop, 23–24 August 2000</td>
</tr>
</tbody>
</table>

Sustainability:

National Capacity Building and ownership

Constraints:

Security, absorption capacity, recovery of transportation and communication sectors

Monitoring and Evaluation:

Drug Management System will automatically provide transparent feedback, which will be further monitored by the trained Regional and Provincial Pharmacy Officers. Pre-test and post-test
Pharmaceutical Situation in Afghanistan
Annex 3: Programme of mission

14.01.02 Arrival Peter Graaff in Islamabad
Joint meeting with Drs Jama and Elo with DFID (M Kapilla)
Meeting with Dr Elo, Dr Moumin and Dr Rana on WHO priorities for action under Joint Appeal
Interview of Dr Buthaina (Pharmacist)
Development of ATIMS project submission for essential drugs

15.01.02 Arrival Guitele Baghdadi and Christine Chomilier in Islamabad
Transfer of Peter Graaff and Guitele Baghdadi to Kabul
Meeting with WR to initiate the programme for Kabul period
Interview with Dr Buthaina
Meeting with Dr Bile WR Pakistan to request EDL and Q/C procedures in Pakistan
Meeting with Dr Jama

16.01.02 Meeting with head of International Affairs Department, MOPH
Meeting with CIDA
Meeting with Director Avicenna Pharmaceutical Institute and Planning Director
Drafting of recommendations for Her Excellency Dr Suhaila Seddiq, Minister of Public Health

17.01.02 Meeting with Avicenna Pharmaceutical Institute team
Debriefing with Her Excellency Dr Suhaila Seddiq, Minister of Public Health
Visit of public and private pharmacies
Arrival of Christine Chomilier in Kabul
Security briefing

18.01.02 Debriefing and report writing

19.01.02 Meeting with Avicenna Pharmaceutical Institute team
Visit to API warehouse
Visit to API manufacturing plant
Visit to MOPH warehouse
Visit to National Quality Control Laboratory

20.01.02 Transfer of Peter Graaff and Guitele Baghdadi to Islamabad
Report writing
Meeting with Dr Qudarat (Pharmacist)
Meeting with NGOs: Aide Medicale Internationale Kabul (AMI)
Meeting with NGOs: Médecins Sans Frontières France Kabul (MSF)

21.01.02 Meeting with WHO Office Pakistan, Dr Kaka
Meeting with Drug Regulatory Authority team, Pakistan
Meeting with Humanitarian Coordinator Office
Report writing
Meeting in Ali Abad Hospital (Kabul)
Meeting with UNICEF (Kabul)
Meeting with ICRC (Kabul)
Meeting with IFRC (Kabul)
Pharmaceutical Situation in Afghanistan

22.01.02  Report writing
          Meeting with WHO Office Pakistan
          Meeting with Humanitarian Coordinator Office
          Meeting with UNHCR Kabul
          Debriefing with Dr Moumin in Kabul
          Transfer of Christine Chomilier to Islamabad

23.01.02  Report writing
          Preparation for up-coming press briefing in Geneva
          Meeting with Humanitarian Coordinator Office
          Debriefing WR Afghanistan
          Departure of Peter Graaff and Guitelle Baghdadi to Cairo and
          Geneva

24.01.02  Meeting in UNJLC with David Kaatrud, Yvan Flores, Dr Elo

25.01.02  Departure of Christine Chomilier to Geneva
Annex 4: People met

Islamabad

WHO
Dr Jama
Dr Elo
Dr Momin
Dr Rana Graber
Dr Andre Griebspoor
Dr Yvan Flores
Dr Qudarat
Mr Murtaza
Dr Buthaina (Pharmacist volunteer)

Other
Dr Kapilla (DFID)
David Kaattrud (Head of UNJLC)

Kabul

WHO
Dr Said Yousef
Dr Momin
Dr Bashir Noormal (WHO National Training Coordinator)

Government
Her Excellency Dr Suhaila Seddiq, Minister of Public Health
Director International Affairs, MOPH
Ph Karimullah (Director Avicenna Pharmaceutical Institute)
Ph Ahmad Jan (Planning Director, Avicenna Pharmaceutical Institute)
Ph Hamed (Member drug quality control, Pharmaceutical Institute)
Ph Saleh Ahmed (focal point appointed by API)

Other
Dr Olivier Brasseur (UNFPA)
Hong-Won Yu (CIDA)
Paul Adam (Logistics Supply Coordinator AMI)
Georges Dutreix (Head of Mission MSF)
Ali Alad Hospital Team Kabul
M. Baba (Acting Country Representative UNICEF)
Mark Steinbeck (Head and Relief Co-ordinator ICRC)
Mrs Jean Geladi (Health Co-ordinator IFCR)
Dr Nabi (Deputy Health Co-ordinator IFRC)
Filippo Grandi (Head of Mission Afghanistan UNHCR)
Annex 5: Terms of reference of drug and therapeutic committee

a) Why are drug and therapeutic committees (DTCs) needed?

Essential drugs are one of the most cost-effective ways of saving lives and improving health and constitute 20%-40% of health budgets in many developing countries. Increasing drug costs and lack of resources often result in an inability of public health systems to procure sufficient drugs to meet patient demand. Despite this, drugs are often managed and used inefficiently and irrationally; this may be due to many factors: e.g. inadequate training of health staff, lack of continuing education and supervision, and lack of updated reliable unbiased drug information. Particular areas of inefficiency and drug use problems include:

- poor drug selection without consideration for relative efficacy, cost effectiveness and local availability;
- inefficient procurement practices, resulting in non-availability, inadequate drug quality, or overly expensive drugs;
- prescribing not in accordance with standard treatment protocols;
- poor dispensing practices, resulting in medication errors and lack of patient knowledge concerning dosage schedules;
- patient non-adherence to dosage schedules and treatment advice.

Inefficient drug use affects the safety and quality of therapeutic care. According to WHO:

Rational drug use requires that the patients receive drugs appropriate to their clinical needs in doses that meet their individual requirements (right dose, right intervals and right duration). These drugs must be of acceptable quality, and available and affordable, at the lowest cost to patients and the community.

When drug use is not in accordance with this definition, it is often associated with undesirable health and/or economic outcomes, such as unnecessary hospital admissions. Other consequences are increasing resistance of bacterial pathogens to antibiotics, adverse drug reactions, and preventable side-effects and interactions from drugs.

Some inefficiencies result from lack of an effective forum that brings together pharmacists, clinicians and administrators to balance the demand for quality care with financial constraints. Tension may exist between prescribers and financial managers concerning which drugs should be available for what problems.

11 Chapter one of WHO manual, Drug and therapeutics committees: A practical guide, 4th draft, 31.12.01.
DTCs are a forum to bring together all stakeholders involved in drug use; they may exist at any level within the health care system—at district level (overseeing primary health care facilities), in hospitals, or at the national level. Hospital DTCs have been shown in developed countries to be very effective in safeguarding and promoting efficient and rational use of drugs (Weekes and Brookes 1996, Crawford and Santell 1994) through, for example, the:

- establishment of documented rules and policies for all aspects of drug management including the selection of formulary list drugs and agreement of treatment protocols;
- conducting continuing education, audit and feedback, drug utilization review, and monitoring of adverse drug reactions and medication errors.

b) The Goals and Objectives of the DTC

The goal of a DTC is to ensure that patients are provided with the best possible cost-effective and quality of care through determining what drugs will be available, at what cost, and how they will be used.

In order to achieve this goal a DTC will have the following objectives:

1. to develop and implement an efficient and cost-effective formulary system which includes consistent standard treatment protocols, a formulary list, and a formulary manual;
2. to ensure that only efficacious, safe, cost-effective, and good quality drugs are used;
3. to ensure best possible drug safety through monitoring, evaluating, and thereby preventing, as far as possible, adverse drug reactions and medication errors;
4. to develop and implement interventions to improve drug use by prescribers, dispensers, and patients; this will require the investigation and monitoring of drug use.

c) Functions of the DTC

There are many possible functions of a DTC, and the committee must decide which ones to undertake, the performance of which may be dependent upon local capacities and structure. Furthermore, certain functions will require liaison with other committees or teams, e.g. the infection control committee, procurement team. The most important functions are summarized below.

Advisory Committee to Medical Staff, Administration and Pharmacy

The DTC is a valuable resource that can provide advice to medical staff, nurses, administration, pharmacy, and other departments and groups within the hospital. The DTC can advise on all issues, policies, and guidelines concerning drug selection, use, and distribution. Usually a DTC will provide advice and an executive body, usually the pharmacy, will implement it.
Development of Drug Policies

The DTC is the most appropriate body to develop drug policies within the hospital, since the committee members will have the most experience and training in drug therapy and distribution. Policies and procedures are the primary activity within a DTC since they provide the foundation for other recommendations that may later arise from the DTC. Drug policies may vary according to different hospitals and countries, but all hospitals should have specific policies concerning:

1. criteria for including drugs on the formulary list (essential drug list);
2. standard treatment guidelines and treatment algorithms, which should be the basis of formulary selection;
3. periodic use of drugs not on the formulary list, e.g. restricting their use to specified prescribers on a named-patient basis only, or only allowing 10% of the hospital drug budget to be spent on them;
4. drugs, such as third-generation antibiotics, that are restricted to certain practitioners, departments, or patients; structured order forms may be used to implement this policy;
5. drugs that are under investigation for safety or efficacy;
6. generic substitution and therapeutic interchange;
7. drug representatives and promotional literature.

Evaluating and Selecting Drugs for the Formulary List

Perhaps the most important function of a DTC is the evaluation and selection of drugs for the hospital essential drug list or formulary. Drugs should be selected on the basis of any standard treatment protocols that have been developed or adapted for use in the hospital. The evaluation of drugs requires significant expertise and time commitment and a rigorous transparent approach. Documented evidence for the efficacy, safety, quality, and cost of all drugs under consideration for inclusion in the formulary list must be examined. Periodic review is necessary because of changing costs and indications, new information on safety, and the emergence of new drugs. The documents reviewed will depend upon the expertise of the committee and may include reputable textbooks, published treatment guidelines and formularies, newsletters, and primary drug literature.

Developing Standard Treatment Guidelines (STGs)

Standard treatment guidelines or protocols are a proven way to promote rational use of drugs provided they are (1) developed in a participatory way involving end-users, (2) easy to read and up to date, and (3) introduced with an official launch, training, and wide dissemination (Grimshaw and Russell 1993). Furthermore, STGs provide a benchmark of satisfactory treatment in the monitoring and auditing of drug use. A DTC should either develop STGs from scratch or adapt STGs from elsewhere for use in the hospital. Development from scratch will result in greater local ownership and acceptance but is difficult and will consume time and resources. Adaptation or adoption of STGs from elsewhere is much easier and quicker, but will result in less local ownership and acceptance.
Assessing Drug Use to Identify Problems

There are a number of problems in how drugs are used that may be corrected by appropriate changes within the formulary list or by other interventions. It is important for the DTC to identify these problems and make appropriate recommendations. Appropriate methods to identify drug use problems include:
1. aggregate drug data review, including ABC and VEN analysis and the use of defined daily dose methodology;
2. monitoring indicators of drug use, including adherence to standard treatment guidelines;
3. drug utilization review (DUR) or drug use evaluation (DUE);
4. monitoring adverse drug reactions and medication errors;
5. antimicrobial resistance surveillance.

Conducting Effective Interventions to Improve Drug Use

There is no point in a DTC collecting information on drug use problems if nothing is done to correct the problems. The DTC is the main body within a hospital responsible for providing drug information to health staff and also for conducting interventions to promote more rational drug use. Monitoring and supervision, auditing and feedback, educational programmes, in-service training, use of standard treatment guidelines, provision of unbiased drug information, prescribing restrictions and automatic stop orders are some important interventions.

Managing Adverse Drug Reactions

Adverse drug reactions are increasing in incidence and are serious in terms of patient harm and unnecessary economic costs. Adverse drug reactions are thought to cause 3%-4% of all hospital admissions in the USA. It has been estimated that the incidence of adverse drug reactions in the USA in 1994 was 6.7% (2.2 million events) with 106,000 fatalities (Lazarou et al. 1998). Adverse drug reactions may be due to the unknown effects of new (or older) drugs or due to poor drug quality. DTCs are responsible to the public to ensure that patients are treated as safely as possible. Monitoring and minimizing adverse drug reactions is an essential part of this function (see section 5.3).

Managing Medication Errors

Medication errors occur in all health care settings, no matter how good the health care staff are with regard to the prescribing, dispensing, and administration of drugs. Even if there is no error on the part of health care staff, patients may take drugs incorrectly. Causes are numerous and include lack of knowledge, tiredness of staff, careless work attitudes, poor procedures, lack of policies, unfamiliar dosage forms and human error. DTCs can reduce such errors by monitoring, analysing, reporting errors and implementing corrective action when error frequency exceeds acceptable levels.

Information on Dissemination and Transparency

The DTC must disseminate information regarding its activities, decisions, and recommendations to the staff who must do the implementation. While this may seem obvious, it is often forgotten. Omission of adequate information dissemina-
tion leads to loss of credibility. It is also very important that the committee operate in such a way as to ensure transparency in all its decisions and to avoid conflict of interest. In particular, members should have no relationships with pharmaceutical companies. The only acceptable contact with pharmaceutical companies concerns the flow of information about their drug products in a way that is as unbiased as possible.
Pharmaceutical Situation in Afghanistan
Annex 6: Terms of reference of the mission

- Review the current pharmaceutical situation amongst different parts of the population and the activities carried out by various actors in the field of essential drugs.
- Collaborate with the national authorities in determining the short-term and medium-term requirements in terms of policy, access, quality, and rational use of essential drugs.
- Collaborate with the national authorities in developing an outline for a plan of action for the rehabilitation of the pharmaceutical services with a specific focus on the rehabilitation of the drug supply system, including donor coordination.
- Provide technical assistance as appropriate.
- Initiate/strengthen partnerships with international and national partners involved in drug supply and/or implementation of essential drugs programmes.
- Prepare a follow-up mission aimed at an in-depth analysis and evaluation of the pharmaceutical sector in Afghanistan.
Pharmaceutical Situation in Afghanistan
Annex 7: Main findings of survey carried out for ICRC (June–July 2000)

Selection
• 75% of surveyed agencies report to respect 1 of 3 different lists of essential drugs (WHO Model list 1999, NEDL 1995, ACBAR EDL 1997).

Financing
• 20 agencies represent 80% of the global health budget (ref. ACBAR data 1989).
• Total drug expenses are far below the minimum requirements.

<table>
<thead>
<tr>
<th>Sector</th>
<th>US$ per year</th>
<th>US$ per person</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHC</td>
<td>1 300 000</td>
<td>0.06</td>
</tr>
<tr>
<td>Hospital</td>
<td>2 760 000</td>
<td>0.14</td>
</tr>
<tr>
<td>Others</td>
<td>1 020 000</td>
<td>0.05</td>
</tr>
<tr>
<td>Total</td>
<td>5 080 000</td>
<td>0.25</td>
</tr>
</tbody>
</table>

Prices
• Paying mechanisms differ from one agency to another. Some offer drugs free of charge, others charge 40%–80% of the drug price, while others charge a consultation fee or a fixed amount per prescription.

Supply system
• Sources of drugs include Pakistan, Afghanistan, Iran, and Europe.
• 50% of surveyed agencies report difficulties with customs clearance procedures.
• 50% of surveyed agencies report that transport in remote areas is very difficult.
• 40% of surveyed agencies report problems related to the quality of medicines.