



**Transitional Islamic Government of Afghanistan
Ministry of Health**

National Medicine Policy

2003

THE NATIONAL MEDICINES POLICY OF THE ISLAMIC TRANSITIONAL ADMINISTRATION OF AFGHANISTAN

In the framework of the general policy of the Ministry of Public Health to serve the goals of health, economic welfare and national development, a national medicines policy is to be instituted. This present document defines that policy.

Explanation: A policy document of this type does not constitute a law or lay down firm rules. Its principal purpose is to explain what the goals of national policy will be in this field, goals which have been widely discussed and accepted. It will also provide, by way of example, some of the ways in which a government can hope to achieve those goals, and some of the institutions, which will be involved. All further details will be provided in the Law on Medicines, which is intended to bring the policy into effect, and in the various regulations, which will be developed under that Law.

A policy document such as this is largely concerned with long-term objectives, which often change little over time. However in a country such as Afghanistan, which is likely to develop rapidly, further elaboration of the policy will surely be called for after some five years and if necessary it can be revised earlier.

I – DEFINITION AND GOALS

- 1.** There shall be a National Medicines Policy for Afghanistan, which has been adopted by the Ministry of Public Health of the Islamic Transitional Administration.
- 2.** The essential purposes of this Policy shall be to ensure:
 - That all medicines available in the country, whether of domestic or foreign origin, are effective, safe and of good quality, and are fairly priced.

- That medicines are used in a proper manner, appropriate to the needs of the patient
- That all reasonably necessary medicines are accessible to patients at all times and in all parts of the country
- That a patient needing a medicine shall not be deprived of it because of any unreasonable financial barrier

3. The Policy shall be founded on the basis of the best existing practice in the country, while benefiting from experience elsewhere in the region and in the world at large.

4. The Government, acting primarily through the Ministry of Public Health and its partners, will ensure the coordinated introduction and implementation of the Medicines Policy.

5. Alongside official initiatives to implement and advance the policy, the Government will promote the active involvement of all the parties involved, including the health professions, trade and industry and the general public.

II – SUPPLY AND CONTROL OF MEDICINES

In keeping with overall Government policy, the task of manufacturing, importing and distributing medicines will be accorded primarily to the competitive private sector. The State, for its part, will assume responsibility for the maintenance of standards through a process of licensing and inspection.

In order to ensure continuity in the supply of cost-effective medicines to public sector hospitals the State may in the phase of transition, and thereafter exceptionally or in emergency situations, make special arrangements for the public importation or manufacture of medicines or vaccines.

Explanation: The special provisions for the State to procure and supply certain products for the public sector are essentially intended to operate during the period of national recovery and development and may also operate temporarily in health emergencies to supplement the role of the private sector where the latter fails or is unable to meet certain needs of the population.

III - EFFICACY, SAFETY AND QUALITY OF MEDICINES

The task of ensuring that medicines are as efficacious and safe as possible, and that the necessary standards of quality are attained, will devolve primarily upon a National Medicines Agency, charged with the evaluation and licensing of individual medicines and medicinal products, and with the Inspectorate of Medicines.

Explanation: As in other countries, any firm or agency wishing to manufacture or import a medicine in Afghanistan will have to apply to the National Medicines Agency for permission to do so, and will be required to supply evidence both that the product can be reliably and safely used for its intended purpose and that the labelling and packaging materials provide adequate information to the prescriber and user. If a licence is granted and the medicine is marketed, the Inspectorate will then ensure that the standards set in the licence are maintained.

Efficacy, safety and quality are not absolute standards; no medicine, for example, can be expected to work in every case, and all medicines involve some risks. In deciding precisely what standards will be applied, the Agency will be able to rely on the wide experience in regulation which has been built up throughout the world, and the harmonization of practice which has been reached by agreement between agencies.

Special provision will be made to ensure the continued use of traditional medicines, where appropriate.

IV - THE PROPER AND APPROPRIATE USE OF MEDICINES

Prescribers, pharmacists and patients all bear responsibility for ensuring that medicines are used in a manner which is consistent with current knowledge and opinion, and which is appropriate to the individual's needs.

Explanation: In any country, medicines are often prescribed for patients who do not need them, or used for the wrong indication, in excessive amounts or in the wrong way. Even when a medicine has been properly prescribed, it may be wrongly dispensed in the pharmacy, or incorrectly used by the patient. All these practices present a risk to health and they result in waste of scarce resources. The parties concerned need to have access to current information and advice if medicines are to be used to the

best effect and safely.

V - ADVERTISING AND PROMOTION OF MEDICINES

The private sector will be free to advertise and promote its medicines to the health professions and (in the case of a certain limited range of medicines) to the public. The Government will set standards to which such promotion should adhere, and the Inspectorate of Medicines will be charged with ensuring that these standards are maintained.

VI - INFORMATION ON MEDICINES

There shall be a Medicines Information Centre, ensuring the provision of reliable and impartial information on medicines to the health professions and the public. Its activities shall include the compilation and updating of the Afghanistan National Formulary, the publication of a Bulletin on Medicines, the maintenance of a register of adverse effects of medicines, and the provision of information on request to health professionals and others.

Explanation: Although, as noted in Section V, much information on individual medicines is likely to be made available by their manufacturers and importers, experience in many countries has shown the need for an impartial national information centre to provide data and advice on good treatment. A health professional will for example sometimes need advice on making a choice between two or more alternative medicines, and updated knowledge on the effects and risks of medicines is all the time becoming available in the world literature. A Medicines Information Centre, working together with similar centres in other countries, will bring together this information and make it available where it is needed. One of its main activities will be to develop the Afghanistan National Formulary into a handbook providing essential information on all products on the market. Between editions of the Formulary, a Bulletin on Medicines will provide updates on new medicines and means of treatment. The Information Centre will also study the unwanted effects of new and old medicines, which are not always the same in every country. Information will also be sent to libraries where it can be consulted by the public. As the use of computers becomes more widespread it will be possible to provide reliable information and advice on medicines promptly through the Internet to all who need it.

VII - ACCESSIBILITY OF MEDICINES

The public and the private sectors should play complementary roles in ensuring that medicines are promptly and readily accessible throughout the country.

Explanation: Experience from many countries shows that a competitive private sector provides the best guarantee that medicines are very widely distributed and consistently available. The State will make efforts to promote competition and provide incentives to the sector. Direct involvement of the state in procurement and supply of medicines will be limited in principle to those situations where the market fails such as the emergencies cited in Section II above or the provision of medicines to certain remote areas.

VIII – LOWERING OF FINANCIAL BARRIERS

Illness inevitably involves suffering, inconvenience and expense; in ensuring that the burden of illness is so far as possible fairly shared, the community must apportion its resources so as to ensure that individuals are not so unfairly burdened with the costs of medicine that they are unable to undergo adequate treatment.

Explanation: The financial resources of the State to provide for health care are limited, and it is important to use them efficiently and where they are most needed. To this end the State will promote measures to ensure that the prices of medicines are reasonable and that wastage is kept to a minimum. Insurance against medicine costs will be further developed and special provisions will be progressively introduced for the weakest members of the community or those with exceptional needs (the chronically ill) to receive medicines at little or no cost.

IX – POLICY DEVELOPMENT: INVOLVEMENT OF THE HEALTH PROFESSIONS AND COMMUNITY

Members of the medical, pharmaceutical, dental, veterinary and nursing professions and other health workers, as well as representatives of the public will be encouraged to contribute actively to the implementation and continuing development of the Medicines Policy. To this end, an Advisory Council on Medicines Policy will be established to advise the Minister of Public Health; its

constitution and task will be defined in regulation.

Explanation: A Medicines Policy cannot be static: as science develops and the economy grows, new challenges will arise and new opportunities will present themselves. To ensure progress, the contribution of those working with medicines throughout the country is vital, especially in ensuring that the quality of treatment is maintained and improved. Experience in many countries has shown that a health profession can successfully promote the basic and continuing education of its members, establish recognized standards of practice (for example in standard treatment guidelines) and ensure that these standards are maintained. Representatives of patients and the public can identify current problems and suggest solutions.

X - SELECTION OF MEDICINES

With many thousands of medicines existing in the world, and a scarcity of resources to finance them, it will often be necessary to set priorities. To this end the National Medicines Agency charged with advising the Minister of Health on those medicines which are most necessary or acceptable in particular situations. The selections must be impartial and must be updated from time to time. In particular it will be necessary to maintain:

- a. A National list of Essential Medicines, vital to basic health care, which must be prioritized as regards regulatory approval and supply to health services.
- b. A List of Free Sale Medicines, i.e. medicines that can be bought and used by any member of the public without prescription to relieve mild symptoms.
- c. Medicines which because of their particular risks or specialized mode of use must be subject to special restrictions on their availability.

Explanation: Such selective lists are not intended to deprive patients of necessary treatment, but to ensure that the most suitable treatment is available in the most appropriate way, and that the available funds are put to the best use. In some situations exceptions will need to be made - for example where a patient with a rare disease needs a medicine, which is not on sale in Afghanistan - and (as in the past) suitable arrangements will be made to render this possible.

The National List of Essential Medicines was first issued in February 2003.