THE CONCEPT OF ESSENTIAL MEDICINES

Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford. The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations. Careful selection of a limited range of essential medicines results in a higher quality of care, better management of medicines (including improved quality of prescribed medicines) and more cost-effective use of health resources.

The list of essential medicines relate closely to guidelines for clinical health care practice, which are used for the training and supervision of health professionals. Lists of essential medicines also guide the procurement and supply of medicines in the public sector, schemes that reimburse medicine costs, medicine donations, and local medicine production.

The Essential Medicines List aims to identify cost-effective medicines for priority conditions, together with the reasons for their inclusion, linked to evidence-based clinical guidelines and with special emphasis on public health aspects and considerations of value of money.

The core list presents a list of minimum medicine needs for a basic health care system, listing the most efficacious, safe and cost-effective medicines for priority conditions. Priority conditions are selected on the basis of current and estimated future public health relevance, and potential for safe and cost-effective treatment.

The complementary list presents essential medicines for priority diseases, for which specialized diagnostic or monitoring facilities, and/or specialist medical care, and/or specialist training are needed. In case of doubt medicines may also be listed as complementary on the basis of consistent higher costs or less attractive cost-effectiveness in a variety of settings.

Procedure for Revision
This list is a dynamic list and revised every two years. The procedures for updating the List are in line with the WHO recommended process for developing clinical practice guidelines. Key components are a systematic approach to collecting and reviewing evidence and a transparent development process with several rounds of review.

Selection Criteria
The choice of essential medicines depends on several factors, including the public health relevance and sound and adequate data on the efficacy, safety and comparative cost-effectiveness of available treatments. Stability in various conditions, the need for special diagnostic or treatment facilities and pharmacokinetic properties are also considered if appropriate. When adequate scientific evidence is not available on current treatment of a priority disease, the Expert Committee may either defer the issue until more evidence becomes available, or choose to make recommendations based on expert opinion and experience.
Most essential medicines should be formulated as single compounds. Fixed-ratio combination products are selected only when the combination has a proven advantage in therapeutic effect, safety or compliance over single compounds administered separately.

In cost comparisons between medicines, the cost of the total treatment, and not only the unit cost of the medicine, is considered. Cost and cost-effectiveness comparisons may be made among alternative treatments within the same therapeutic group, but generally not be made across therapeutic categories (for example, between treatment of tuberculosis and treatment of malaria). The absolute cost of the treatment will not constitute a reason to exclude a medicine from the List that other wise meets the stated selected criteria. The patent status of a medicine is not considered in selecting medicines for the List.

Other factors which are also considered factors such as local demography and pattern of disease, treatment facilities, training and experience of the available personnel, local availability of individual pharmaceutical products, financial resources, and environmental factors.

Quality of products
Priority is given to ensuring that available medicines have been made according to good manufacturing practices and are of assured quality. Factors that are to be considered are:

- Knowledge of, and confidence in the origin of the product;
- The pharmaceutical stability of the product, particularly in the environment that it will be used;
- Where relevant, bioavailability and bioequivalence information

It is recommended that medicines be purchased from known manufacturers, their duly accredited agents or recognized international agencies known to apply high standards in selecting their suppliers.

Promoting rational use
The selection of essential medicines is only one step to improve the quality of health care. It should be followed by the appropriate use of the selected medicines. Each individual should receive the right medicine, in an adequate dose for an adequate duration, with appropriate information, planning of treatment follow up, and at an affordable cost. In each country and setting, this is influenced by a number of factors, such as regulatory decisions, procurement, information, training, and the context where medicines are prescribed or recommended.

Training education and the provision of medicines information
For the safe, effective and prudent use of essential medicines, relevant, reliable and independent medicines information should be available. Health care professionals should receive education about the use of medicines not only during their training but also throughout their careers. More highly trained individuals should be encouraged to assume a responsibility to educate those with less training. Health care providers and those responsible for dispensing medicines should take every opportunity to inform consumers about the rational use of these products, including those for self-medication, at the time they are dispensed.
Governments, universities and professional associations have a major responsibility to collaborate on improving undergraduate, postgraduate and continuing education in clinical pharmacology, therapeutics and medicines information issues. Problem-based pharmacotherapy teaching has been shown to be an effective strategy in this area.

Appropriate medicines information that is well presented ensures that medicines are used properly and decreases inappropriate medicine use. Ministries of health must take the responsibility for arranging for the provision of such information. Independent medicine information activities should be properly funded and if necessary financed through health care budgets. Electronic, readily accessible sources of medicines information are becoming available in many settings and can be the basis of reliable medicines information systems.

**Standard clinical guidelines**

Standard clinical guidelines are an effective tool for assisting health professionals to choose the most appropriate medicine for a given condition. These should be developed and updated on a regular basis. It is not sufficient to develop standard clinical guidelines without an education and training program to encourage their use.

**Drugs and Therapeutic Committees**

Drugs and Therapeutic Committees should play an important role in helping to develop and implement an effective essential medicines program. These committees should be encouraged to select products for local use from a national essential medicines list, to measure and monitor the use of medicines in their own environments and undertake interventions to improve medicines use. There is good evidence that involving Drugs and Therapeutic Committees and prescribers in guideline development can contribute to improving prescribing behaviour.

**Measuring and monitoring use**

Drugs utilization studies are those dealing with the development, regulation, marketing, distribution, prescription, dispensing, and use of medicines in a society, with special emphasis on the resulting medical, social and economic consequences. These studies can examine any level of therapeutic chain, from medicines development to their actual use by people. They can provide consumption indicators in a given country, area of institution. Consumption can be quantified as economic expenditure (either in absolute terms or as percentage of total health budget), as number of units, or as defined daily doses. They can aim at describing the consumption of all medicines, or of particular groups of medicines or therapeutic areas. Drug utilization studies can be medicine-oriented (on the use of a particular medicine or group of medicines), or problem-oriented (on the treatment of a particular condition or disease).

The efficacy of a medicine is most reliably defined on the basis of randomized clinical trials, which, if well conducted, provide the most reliable estimates of the treatment effect of a new medicine. Clinical trials cannot be conducted in all possible populations or settings and their results should therefore be carefully translated into routine clinical practice. Drug utilization studies aim at providing evidence on the use and the effects of medicines in routine conditions, and they thus can provide additional evidence of the evaluation of effectiveness.
Such studies are important tools for identifying those factors or elements of the therapeutic chain in need of improvement or change. The results should be taken into consideration when taking regulatory action, selecting medicines, information, training, and teaching. Institutional and local drug and therapeutic committees should set up drug utilization studies and other methods for the surveillance of the use of medicines and of its effects.