WHO CRITERIA FOR THE SELECTION OF ESSENTIAL DRUGS

UN Instrument

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a. Adoption of a list of essential drugs is part of a national health policy. This implies that priority is given to achieving the widest possible coverage of the population with drugs of proven efficiency and safety, in order to meet the needs for prevention and treatment of the most prevalent disease.

b. Only those drugs for which adequate scientific data are available from controlled studies should be selected.

c. Each selected pharmaceutical product must meet adequate standards of quality, including when necessary, bioavailability.

d. Concise, accurate and comprehensive drug information drawn from unbiased sources should accompany each list of essential drugs.

Criteria for the selection of essential drugs are intended to ensure that the process of selection will be unbiased and based on the best available scientific information, yet allow for a degree of variation to take into account local needs and requirements. The following guidelines are recommended:

i. Each country should appoint a committee to establish a list of essential drugs. The Committee should include individuals competent in the fields of clinical medicine, pharmacology and pharmacy, as well as peripheral health workers. Where individuals with adequate training are not available within the country, assistance from WHO could be sought.

ii. Drug selection should be based on the results of benefit and safety evaluations obtained in controlled clinical trials and/or epidemiological studies.

iii. The international non-proprietary (generic) names for drugs or pharmaceutical substances should be used whenever available. A cross-index of non-proprietary names should initially be provided to the prescribers.

iv. Regulations and facilities should be available to ensure that the quality of selected pharmaceutical products meet adequate quality control standards, including stability and, when necessary bioavailability. Where national resources are not available for this type of control, the supplies should provide documentation of the product's compliance with the required specifications.

v. Cost represents a major selection criterion. In cost comparisons between drugs, the cost of the total treatment, and not only the unit cost, must be considered. In addition, the cost of non-pharmaceutical therapeutic modalities should be taken into account.

vi. Local health authorities should decide the level of expertise required to prescribe single drugs or a group of drugs in a therapeutic category. Consideration should also be given to the competence of the personnel to make a correct diagnosis. In some instances, while individuals with advanced training are necessary to prescribe initial therapy, individuals with less training could be responsible for maintenance therapy.

vii. The influence of local diseases or condition on pharmackinetic and pharmacodynamic parameters should be considered in making the selection e.g. malnutrition, liver disease.

viii. When several drugs are available for the same indication, select the drug, pharmaceutical product and dosage form that provide the highest benefit/risk ratio.

ix. When two or more drugs are therapeutically equivalent, preference should be given to:

1. the drug which has been most thoroughly investigated.
2. the drug with the most favourable pharmacokinetic properties, e.g. to improve compliance, to minimize risk in various pathophysiological states;
3. drug for which local, reliable manufacturing facilities for pharmaceutical products exist;
4. drugs, pharmaceutical products and dosage forms with favourable stability, or for which storage facilities exist.

x. Fixed ratio combinations are only acceptable if the following criteria are met:
   1. clinical documenttaion justifies the concomitant use of more than one drug;
   2. the therapeutic effect is greater than the sum of the effect of each;
   3. the cost of the combination product is less than the sum of the individual products;
   4. compliance is improved;
   5. sufficient drug ratios are provided to allow dosage adjustment satisfactory for the majority of the population.

xi. The list should be reviewed at least once a year and whenever necessary. New drugs should be introduced only if they offer distinct advantages over drugs previously selected. If new information becomes available on drugs already in the list that clearly shows that they no longer have a favourable benefit/risk ratio, they should be deleted and replaced by a safer drug. It should be remembered that for the treatment of certain conditions, non-pharmacological forms of therapy or no therapy at all, may be preferable.