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Model List of Essential Drugs
(Seventh List)

Fifth report of the
WHO Expert Committee

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WHO Expert Committee on the Use of Essential Drugs

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Members

Professor I. Darmansjah, Professor of Pharmacology, University of Indonesia, Jakarta, Indonesia

Professor M. M. Duran, Department of Dermatology, Javeriana University, Bogotá, Colombia

Professor A. W. El-Borolossy, Emeritus Professor of Pharmacology, Cairo, Egypt (*Vice-Chairman*)

Dr A. Kucers, Director of Medical Services, Fairfield Hospital, Victoria, Australia

Professor V. K. Lepakhin, Head, Department of Pharmacology, University of People's Friendship, Moscow, USSR

Professor Li Jia-Tai, Director, Institute of Clinical Pharmacology, Beijing Medical University, Beijing, China

Professor M. M. Reidenberg, Head, Division of Clinical Pharmacology, Cornell Medical Center, New York Hospital, New York, NY, USA (*Rapporteur*)

Professor L. A. Salako, Professor of Clinical Pharmacology, Department of Pharmacology and Therapeutics, University of Ibadan, Ibadan, Nigeria (*Chairman*)

Representatives of other organizations

Commonwealth Pharmaceutical Association

Mr M. M. Sesay, Assistant Project Officer, Government Central Medical Stores, Freetown, Sierra Leone

International Federation of Pharmaceutical Manufacturers Associations (IFPMA)

Ms M. Cone, Vice-President for Scientific Affairs, IFPMA, Geneva, Switzerland

International Pharmaceutical Federation

Professor F. W. H. M. Merkus, Professor of Biopharmaceutics, Centre for Biopharmaceutical Sciences, Leiden University, Leiden, Netherlands

United Nations Children's Fund (UNICEF)

Dr P. Carlevaro, Essential Drugs Adviser, UNICEF, New York, NY, USA

World Federation of Proprietary Medicines Manufacturers (WFPMM)

Dr J. A. Reinstein, Director-General, WFPMM, London, England

Secretariat

Dr M. R. Couper, Medical Officer, Division of Drug Management and Policies, WHO, Geneva, Switzerland (*Secretary*)

Dr J. F. Dunne, Director, Division of Drug Management and Policies, WHO, Geneva, Switzerland

1. Introduction

The WHO Expert Committee on the Use of Essential Drugs met in Geneva from 18 to 22 November 1991. The meeting was opened on behalf of the Director-General by Dr J. F. Dunne, Director of the Division of Drug Management and Policies, who emphasized that the concept of essential drugs was fundamental both to WHO's revised drug strategy (*1*), as endorsed by the World Health Assembly in resolution WHA39.27 in 1986 (*2*), and to the development of comprehensive national drug policies. Regular updating of WHO's Model List of Essential Drugs sustained the momentum of the revised drug strategy and was a basic element of the validated information required by most of WHO's Member States for optimal rationalization of drug procurement and supply.

The Expert Committee decided to prepare its report as a self-contained document and to incorporate into it those parts of the previous report (*3*) that require no modification or merely bringing up to date. The seventh list will be found in section 15 of this report, and explanations of the changes in section 16.

In a report (*4*) to the Twenty-eighth World Health Assembly in 1975, the Director-General reviewed the main drug problems facing the developing countries and outlined possible new drug policies. The Director-General also referred to the experience gained in some countries where schemes of basic or essential drugs had been implemented. Such schemes were intended to extend the accessibility of the most necessary drugs to populations whose basic health needs could not be met by the existing supply system. The Director-General pointed out that the selection of these essential drugs would depend on the health needs and on the structure and development of the health services of each country. Lists of essential drugs should be drawn up locally, and periodically updated, with the advice of experts in public health, medicine, pharmacology, pharmacy and drug management. He also considered that adequate information on the properties, indications and use of the drugs listed should be provided. By resolution WHA28.66 (*5*), the Health Assembly requested the Director-General to implement the proposals contained in his report and, in particular, to advise Member States on the selection and procurement, at reasonable cost, of essential drugs of established quality corresponding to their national health needs.

Following wide consultation, an initial Model List of Essential Drugs was included in the first report of the Expert Committee on the Selection of Essential Drugs (*6*). This has subsequently been revised and updated in five further reports (*3*, *7-10*).

In undertaking a further review of the list at its present meeting, the Expert Committee has been guided throughout by the following statement contained in the previous reports:

Because of the great differences between countries, the preparation of a drug list of uniform, general applicability is not feasible or possible. Therefore, each country has the direct responsibility of evaluating and adopting a list of essential drugs, according to its own policy in the field of health.

The list of essential drugs based on the guidelines put forward in this report is a model which can furnish a basis for countries to identify their own priorities and to make their own selection.

The Committee also draws attention to the following guidelines set out in the initial report:

1. The extent to which countries implement schemes or establish lists of essential drugs is a national policy decision of each country.
2. As far as health services in developing countries are concerned, the organized procurement and use of essential drugs have many advantages in terms of economy and effectiveness. However, the concept of "essential drug lists" must accommodate a variety of local situations if the lists are ever to meet the real health needs of the majority of the population.
3. There are convincing justifications for WHO to propose "model" or "guiding" lists of essential drugs as a contribution to solving the problems of Member States whose health needs far exceed their resources and who may find it difficult to initiate such an endeavour on their own.
4. Such "guiding" or "model" lists should be understood as a tentative identification of a "common core" of basic needs which has universal relevance and applicability. In certain situations, there is a need to make available additional drugs essential for rare diseases. The further local needs move away from the core, the more the health authorities or specific sectors of the health services will have to adjust the lists. However, any list proposed by WHO should set out to indicate priorities in drug needs, with the full understanding that exclusion does not imply rejection. A list of essential drugs does not imply that no other drugs are useful, but simply that in a given situation these drugs are the most needed for the health care of the majority of the population and, therefore, should be available at all times in adequate amounts and in the proper dosage forms.
5. The selection of essential drugs is a continuing process, which should take into account changing priorities for public health action and epidemiological conditions, as well as progress in pharmacological and pharmaceutical knowledge. It should be accompanied by a concomitant effort to supply information and give education and training to health personnel in the proper use of the drugs.
6. Finally, the WHO Action Programme on Essential Drugs should be a focal point for organized and systematic investigation of this approach.

Thus it will identify plans of action and research at the national and international level to meet unsatisfied basic health needs of populations which, at present, are denied access to the most essential prophylactic and therapeutic substances.

2. Guidelines for establishing a national programme for essential drugs

Since the first report on the selection of essential drugs was published in 1977, the concept of essential drugs has been widely applied. It has provided a rational basis not only for drug procurement at national level but also for establishing drug requirements at various levels within the health care system. In fact, many developing countries have already selected essential drugs according to their needs and the related programmes are, in some cases, at an advanced stage of implementation.

In order to ensure that an essential drugs programme is adequately instituted at national level, several steps are recommended:

1. The establishment of a list of essential drugs, based on the recommendations of a committee, is the starting-point of the programme. The committee should include individuals competent in the fields of medicine, pharmacology and pharmacy, as well as peripheral health workers. Where individuals with adequate training are not available within the country, cooperation from WHO could be sought.
2. The international nonproprietary (generic) names for drugs or pharmaceutical substances (*11*) should be used whenever available, and prescribers should be provided with a cross-index of non-proprietary and proprietary names.
3. Concise, accurate and comprehensive drug information should be prepared to accompany the list of essential drugs.
4. Quality, including drug content, stability and bioavailability, should be assured through testing or regulation, as discussed in section 5. Where national resources are not available for this type of control, the suppliers should provide documentation of the product's compliance with the required specifications.
5. Competent health authorities should decide the level of expertise required to prescribe individual drugs or a group of drugs in a therapeutic category. Consideration should be given, in particular, 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.
6. The success of the entire essential drugs programme is dependent upon the efficient administration of supply, storage and distribution at every

point from the manufacturer to the end-user. Government intervention may be necessary to ensure the availability of some drugs in the formulations listed, and special arrangements may need to be instituted for the storage and distribution of drugs that have a short shelf-life or require refrigeration.

7. Efficient management of stocks is necessary to eliminate waste and to ensure continuity of supplies. Procurement policy should be based upon detailed records of turnover. In some instances, drug utilization studies may contribute to a better understanding of true requirements.
8. Research, both clinical and pharmaceutical, is sometimes required to settle the choice of a particular drug product under local conditions. Facilities for such research must be provided.
9. A national drug regulatory authority should be established along the lines recommended in the guiding principles for small national drug regulatory authorities presented in Annex 1. The authority should interact with other interested bodies, including organizations responsible for drug procurement in the public and private sectors and the committee referred to in item 1.

3. Criteria for the selection of essential drugs

Essential drugs are those that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage forms.

The choice of such drugs depends on many factors, such as the pattern of prevalent diseases; the treatment facilities; the training and experience of the available personnel; the financial resources; and genetic, demographic and environmental factors.

Only those drugs should be selected for which sound and adequate data on efficacy and safety are available from clinical studies and for which evidence of performance in general use in a variety of medical settings has been obtained.