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The use of essential drugs

Second report of the WHO
Expert Committee

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WHO EXPERT COMMITTEE ON THE USE OF ESSENTIAL DRUGS

Geneva, 3-7 December 1984

Members

- Professor J.M. Alexandre, Department of Pharmacology, Hôpital Broussais, Paris, France
- Dr I. Bayer, Director-General, National Institute of Pharmacy, Budapest, Hungary
- Dr W.G.B. Casselman, Health Sciences Center, University of Western Ontario, London, Ontario, Canada (*Rapporteur*)
- Dr J.R. Crout, Vice-President, Medical and Scientific Affairs, Pharmaceutical Division, Boehringer-Mannheim Inc., Rockville, MD, USA
- Professor A.W. El Borolossy, Vice-President for Medical Affairs, Faculty of Medicine, University of Jordan, Amman, Jordan (*Chairman*)
- Dr S.S. Gothoskar, Drugs Controller, Directorate General of Health Services, New Delhi, India (*Vice-Chairman*)
- Dr Li Jia-Tai, Director, Institute of Clinical Pharmacology and Director of the Department of Antibiotics, First Teaching Hospital, Beijing Medical College, Beijing, China
- Professor C. Marzagao, Director, Cardiology Unit, University Eduardo Mondlane, Hospital Central do Maputo, Maputo, Mozambique
- Professor A. Pinto-Corrado, Professor of Pharmacology, School of Medicine, University of São Paulo, Ribeirao Preto SP, Brazil

Representatives of other organizations

United Nations Industrial Development Organization

- Dr Z. Csizer, Industrial Development Officer, Pharmaceutical Industries Unit, Chemical Industries Branch, UNIDO, Vienna, Austria

International Federation of Pharmaceutical Manufacturers Associations

- Dr R. Arnold, Executive Vice-President, International Federation of Pharmaceutical Manufacturers Associations, Geneva, Switzerland

International Pharmaceutical Federation

- Professor F.W.H.M. Merkus, International Pharmaceutical Federation, Department of Biopharmaceutics, Faculty of Medicine and Pharmacy, University of Amsterdam, Amsterdam, Netherlands

World Federation of Proprietary Medicine Manufacturers

- Dr K. Reese, Director-General, World Federation of Proprietary Medicine Manufacturers, Bonn, Federal Republic of Germany

Secretariat

- Dr J.F. Dunne, Chief, Pharmaceuticals, WHO, Geneva, Switzerland (*Secretary*)

THE USE OF ESSENTIAL DRUGS

Report of a WHO Expert Committee

The WHO Expert Committee on the Use of Essential Drugs met in Geneva from 3–7 December 1984. The meeting was opened on behalf of the Director-General by Dr Lu Rushan, Assistant Director-General.

1. INTRODUCTION

In a report¹ 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 those 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 health services of each country, and that 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, 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

¹ WHO Official Records, No. 226, 1975, Annex 13, pp. 96–110.

the Selection of Essential Drugs.¹ This was subsequently revised and updated in two further reports.^{2, 3}

In undertaking a further review of the list, the present Expert Committee has throughout been guided 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 and acceptability 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 those Member States whose health needs far exceed their resources and which 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. 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. Therefore, 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

¹ WHO Technical Report Series, No. 615, 1977.

² WHO Technical Report Series, No. 641, 1979.

³ WHO Technical Report Series, No. 685, 1983.

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, taking 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 in education, training and information of health personnel in the proper use of the drugs.

(6) Finally, the WHO programme on essential drugs should furnish a focus 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 become widely recognized as useful. 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, in an advanced stage of implementation.

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

(1) The establishment of a list of essential drugs, based on the recommendations of a local 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 substances¹ should be used whenever available, and

¹ See *International nonproprietary names (INN) for pharmaceutical substances: cumulative list no. 6*. Geneva, World Health Organization, 1982. Further lists of proposed and recommended INN are issued periodically as supplements to the *WHO Chronicle*.

prescribers should be provided with a cross-index of nonproprietary and proprietary names.

(3) Concise, accurate, and comprehensive drug information should be prepared to accompany the list of essential drugs.

(4) Quality, including 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) Local 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.

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

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