# The use of essential drugs

Third report of the WHO Expert Committee

World Health Organization Technical Report Series 770



World Health Organization, Geneva 1988

#### ISBN 92 4 120770 1

#### © World Health Organization 1988

Publications of the World Health Organization enjoy copyright protection in accordance with the provisions of Protocol 2 of the Universal Copyright Convention. For rights of reproduction or translation of WHO publications, in part or *in toto*, application should be made to the Office of Publications, World Health Organization, Geneva, Switzerland. The World Health Organization welcomes such applications.

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the Secretariat of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

ISSN 0512-3054

PRINTED IN SWITZERLAND

38/7621 - Schüler SA - 15 000

# CONTENTS

		Page
1.	Introduction	7
2.	Guidelines for establishing a national programme for essential drugs	10
3.	Criteria for the selection of essential drugs	11
4.	Guidelines for the selection of pharmaceutical dosage forms	12
5.	Applications of the essential-drugs concept	13
6.	Essential drugs and primary health care	
7.	Quality assurance	14
8.	Drug utilization surveys	15
9.	Research and development	16
0.	Drug information and education activities  10.1 National responsibilities  10.2 The role of WHO	17
1.	Updating of lists of essential drugs	27
2.	Model list of essential drugs	28
3.	Changes made in revising the model list	50
4.	Glossary of terms used in the report	57
5.	Alphabetical list of essential drugs	59
<b>Ack</b>	cnowledgements	63

#### WHO EXPERT COMMITTEE ON THE USE OF ESSENTIAL DRUGS

Geneva, 30 November-4 December 1987

#### Members

Professor A.W. El Borolossy, Senior Adviser, Alquds Open University, Amman, Jordan (Chairman)

Professor U. Krylov, Director, State Research Institute for Standardization and Control of Drugs, Ministry of Health of the USSR, Moscow, USSR

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

Professor M.D. Rawlins, Department of Pharmacological Sciences, University of Newcastle upon Tyne, Newcastle upon Tyne, England

Professor R.J. Royer, Centre de Pharmacovigilance, Centre hospitalier régional et universitaire de Nancy, Nancy, France

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

Professor S. Shapiro, Director, Slone Drug Epidemiology Unit, Boston

University School of Medicine, Brookline, MA, USA

Dr Kin Shein, Head, Medical Division, Burma Pharmaceutical Industry, Rangoon, Burma

Professor U.K. Sheth, Houston, Texas, USA

Professor A.C. Zanini, Department of Pharmacology, Institute of Biomedical Sciences, University of São Paulo, Ribeirao Preto, São Paulo, Brazil (Vice-Chairman)

#### Representatives of other organizations

United Nations Children's Fund

Mr V. Reggi, Project Officer for Essential Drugs, UNICEF, New York, NY, USA

United Nations Industrial Development Organization

Dr. J. Pogány, Chief, Chemical Industries Unit, Sectoral Studies Branch, UNIDO, Vienna, Austria

International Pharmaceutical Federation

Professor F.W.H.M. Merkus, Centre for Bio-Pharmaceutical Sciences, Leyden University, Leyden, Netherlands

Dr P. Emafo, Director, Pharmaceutical Services, Federal Ministry of Health, Lagos, Nigeria

International Federation of Pharmaceutical Manufacturers Associations

Dr R. Arnold, Executive Vice-President, IFPMA, Geneva, Switzerland Ms M. Cone, Vice-President for Scientific Affairs, IFPMA, Geneva, Switzerland International Union for Pharmacology

Professor P.K.M. Lunde, Department of Pharmacotherapeutics, University of Oslo, Oslo, Norway

World Federation of Proprietary Medicines Manufacturers

Dr K. Reese, Director-General, WFPMM, Bonn, Federal Republic of Germany

#### Secretariat

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

grand August 1984

## THE USE OF ESSENTIAL DRUGS

### Third report of the WHO Expert Committee

The WHO Expert Committee on the Use of Essential Drugs met in Geneva from 30 November to 4 December 1987. The meeting was opened on behalf of the Director-General by Dr J. Cohen, Adviser on Health Policy, who emphasized that the concept of essential drugs is fundamental both to WHO's revised drug strategy<sup>1</sup> as endorsed by the World Health Assembly in resolution WHA39.27 in 1986<sup>2</sup> and to the development of comprehensive national drug policies. Regular updating of WHO's Model List of Essential Drugs is, indeed, essential in maintaining the momentum of the revised drug strategy and also as a basic element of the validated information required by the majority 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 parts of the previous report<sup>3</sup> that require no modification or merely bringing up to date. The increasing acceptance of the essential-drugs concept and the action that has been taken at the national and international levels to apply it in practice are reflected in the present report, together with the modifications that have been made to the Model List of Essential Drugs. This fifth list will be found in section 12 of the report, and the explanation of the changes in section 13.

#### 1. INTRODUCTION

In a report<sup>4</sup> 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

<sup>&</sup>lt;sup>1</sup> WHO document WHA39/1986/REC/1, Annex 5, pp. 93-101.

<sup>&</sup>lt;sup>2</sup> Handbook of resolutions and decisions of the World Health Assembly and Executive Board, Volume III, 1985–1986. 1st ed., Geneva, World Health Organization, 1987, p. 22.

<sup>&</sup>lt;sup>3</sup> WHO Technical Report Series, No. 722, 1985.

<sup>&</sup>lt;sup>4</sup> WHO Official Records, No. 226, 1975, Annex 13, pp. 96-110.

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. 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 WHA28.66,1 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.<sup>2</sup> This was subsequently revised and updated in three further reports.<sup>3, 4, 5</sup>

In undertaking a further review of the list, the present 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 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:

8









<sup>&</sup>lt;sup>1</sup> Handbook of resolutions and decisions of the World Health Assembly and Executive Board, Volume II, 1973–1984. Geneva, World Health Organization, 1985, p. 129

<sup>&</sup>lt;sup>2</sup> WHO Technical Report Series, No. 615, 1977.

<sup>&</sup>lt;sup>3</sup> WHO Technical Report Series, No. 641, 1979.

<sup>&</sup>lt;sup>4</sup> WHO Technical Report Series, No. 685, 1983.

<sup>&</sup>lt;sup>5</sup> WHO Technical Report Series, No. 722, 1985.