This report contains the collective views of an international group of experts and does not necessarily represent the decisions or the stated policy of the World Health Organization

WHO Technical Report Series 882

THE USE OF ESSENTIAL DRUGS

Eighth report of the WHO Expert Committee

(including the revised Model List of Essential Drugs)



World Health Organization Geneva 1998 WHO Library Cataloguing in Publication Data

WHO Expert Committee on the Use of Essential Drugs (1997 · Geneva, Switzerland) The use of essential drugs : eighth report of the WHO expert committee (including the revised Model list of essential drugs)

(WHO technical report series ; 882)

1.Essential drugs - standards 2.Drug resistance, Microbial 3.National health programs - organization and administration 4.Guidelines I.Title II.Series

ISBN 92 4 120882 1 (NLM Classification: QV 55) ISSN 0512-3054

The World Health Organization welcomes requests for permission to reproduce or translate its publications, in part or in full Applications and enquiries should be addressed to the Office of Publications, World Health Organization, Geneva, Switzerland, which will be glad to provide the latest information on any changes made to the text, plans for new editions, and reprints and translations already available.

© World Health Organization 1998

Publications of the World Health Organization enjoy copyright protection in accordance with the provisions of Protocol 2 of the Universal Copyright Convention All rights reserved.

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.

Typeset in Hong Kong Printed in Spain 98/12077 --- Best-set/Fotojae --- 9500

Contents

Ţ

	1.	Introduction	1
	2.	Guidelines for establishing a national programme for essential drugs	2
	З.	Criteria for the selection of essential drugs	4
	4.	Guidelines for the selection of pharmaceutical dosage forms	5
	5.	Quality assurance 5.1 WHO's Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce	6 6
		5.2 Bioavailability5.3 The international pharmacopoeia	7 7
		5.4 Counterfeit drugs	8
	6.	Reserve anti-infective agents and monitoring of resistance 6.1 Need for surveillance of resistance	9 9
		6.2 Reserve antimicrobials	10
	7.	Applications of the essential drugs concept	13
	8.	Essential drugs and primary health care	14
		8.1 Existing systems of medicine	14
		8.2 The national health infrastructure	14
		8.3 The pattern of endemic disease	15
		8.4 Supplies	15
		8.5 Medicinal drug promotion	15
	9.	Drug donations	15
	10.	Post-registration drug studies	15
	11.	Research and development	18
I.		11.1 Pharmaceutical aspects	18
		11.2 Clinical and epidemiological aspects	18
		11.3 Educational aspects	19
	12.	Nomenclature	19
	13.	Drug information and educational activities	20
	14.	Selection and updating of lists of essential drugs	23
	15.	Model List of Essential Drugs (tenth list)	24
	16.	Considerations and changes made in revising the model list	57
	17.	Glossary of terms used in the report	67

iii

18. Alphabetical list of essential drugs	69
Acknowledgement	73
References	73
Annex 1 Application form for inclusion in the Model List of Essential Drugs	77

iv

WHO Expert Committee on the Use of Essential Drugs

Geneva, 1-5 December 1997

Members

- Professor P.M. de Buschiazzo, Department of Pharmacology, School of Medicine, University of La Plata, La Plata, Argentina (*Vice-Chairman*)
- Professor H. Fraser, Professor of Medicine and Clinical Pharmacology, Faculty of Medical Sciences, Queen Elizabeth Hospital, University of the West Indies, Bridgetown, Barbados (*Rapporteur*)
- Dr A. Haeri, Dean, School of Medicine, Shaheed Beheshti University of Medical Sciences, Eveen, Teheran, Islamic Republic of Iran
- Professor M. Hassar, Director, Department of Pharmacology, Faculty of Medicine and Pharmacy, University of Rabat, Rabat, Morocco
- Professor F. Juma, Department of Clinical Pharmacology and Medicine, College of Health Science, University of Nairobi, Nairobi, Kenya
- Dr G.P. Kilonzo, Senior Lecturer, Department of Psychiatry, Muhimbili Medical Centre, Dar-es-Salaam, United Republic of Tanzania
- Professor L. Rago, Director-General, State Agency of Medicines, Tartu, Estonia (Chairman)

Representatives of other organizations*

International Federation of Pharmaceutical Manufacturers Associations (IFPMA) Miss M. Cone, IFPMA, Geneva, Switzerland

International League of Dermatological Societies (ILDS)

Professor J.-H. Saurat, Dermatology Clinic, Cantonal Hospital, University of Geneva, Geneva, Switzerland

International Pharmaceutical Federation (FIP)

- Professor F.W.H.M. Merkus, Center for Bio-Pharmaceutical Sciences, Gorlaeus Laboratories, Leiden, Netherlands
- International Society of Chemotherapy (ISC)
- Professor J.D. Williams, Department of Medical Microbiology, The London Hospital Medical College, London, England
- International Union of Pharmacology (IUPHAR)
- Professor J.-P. Giroud, Department of Pharmacology, Faculty of Medicine, René-Descartes University, Academy of Paris, Paris, France
- United Nations Children's Fund (UNICEF)
- Ms H.B. Pedersen, Senior Technical Officer, Technical Services Centre, Supply Division, UNICEF Plads, Copenhagen, Denmark

World Self-Medication Industry (WSMI) Dr J.A. Reinstein, Director-General, WSMI, London, England

ν

^{*} Unable to attend: Commonwealth Pharmaceutical Association (CPA); International Society of Infectious Disease (ISID); United Nations Industrial Development Organization (UNIDO).

Secretariat

vi

- Dr M.R. Couper, Medical Officer, Division of Drug Management and Policies, WHO, Geneva, Switzerland (*Secretary*)
- Dr J. Idänpään-Heikkilä, Director, Division of Drug Management and Policies, WHO, Geneva, Switzerland
- Professor W. Gardjito, Department of Surgery, Dr Soetomo Hospital, Surabaya, Indonesia (*Temporary Adviser*)
- Dr T. Tsukada, Professor, Health Centre (Hoken Centre), Chuo University, Tokyo, Japan (*Temporary Adviser*)

1. Introduction

The WHO Expert Committee on the Use of Essential Drugs met in Geneva from 1 to 5 December 1997. The meeting was opened on behalf of the Director-General by Mr D. Aitken, Assistant Director-General, 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 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. Mr Aitken also emphasized the importance of the emergence of resistance to antimicrobials that, in many cases, is dangerously eroding their effectiveness. This is leading to a situation whereby it will be increasingly difficult to combat serious infections.

The Committee decided to prepare its report as a self-contained document and to incorporate into it those parts of the previous report (3) that required no modification or merely bringing up to date. The tenth Model List of Essential Drugs 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 and rational use 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.

1

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 eight further reports (3, 7-13).

In undertaking a further review of the list at its present meeting, the Expert Committee was 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 reviewed the evolution of the Model List of Essential Drugs during the past 20 years and confirmed the definition of essential drugs as 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. Model lists have proved to be invaluable in reducing costs and meeting the health needs of populations through more rational use of drugs and wider access to drugs of acceptable quality. The Committee considered model lists as informational and educational tools for health professionals and consumers. Since concern about health care costs is now a priority even in developed countries, model lists are of greater importance than ever for the development of treatment guidelines, national formularies, information for patients and the general public, and other measures to improve drug use. The Committee emphasized that model lists should be seen in the context of comprehensive national drug formularies which address not only drug use but also strategies for drug procurement and supply, drug financing, drug donations, research priorities for drug use and drugs needed for specific diseases.

2. Guidelines for establishing a national programme for essential drugs

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

预览已结束,完整报告链接和二维码如下:



https://www.yunbaogao.cn/report/index/report?reportId=5 30557