

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

895

THE USE OF ESSENTIAL DRUGS

Ninth report of the
WHO Expert Committee
(including the revised Model List of Essential Drugs)



World Health Organization

Geneva 2000

WHO Library Cataloguing-in-Publication Data

WHO Expert Committee on the Use of Essential Drugs (1999 : Geneva, Switzerland)

The use of essential drugs : ninth report of the WHO Expert Committee
(including the revised Model list of essential drugs)

(WHO technical report series ; 895)

1.Essential drugs — standards 2.Drug utilization 3.Guidelines I.Title II.Series

ISBN 92 4 120895 3

(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 2000

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 Singapore**

2000/13134 — Best-set/SNP — 6500

Contents

1. Introduction	1
2. The concept of essential drugs	1
3. The WHO Model List of Essential Drugs	2
4. Criteria for the selection of essential drugs	4
5. Guidelines for the selection of pharmaceutical dosage forms	6
6. Quality assurance	6
7. Pharmacovigilance	7
8. Drug utilization studies	7
9. Reserve anti-infective agents	8
10. Drug information and educational activities	10
11. Future developments	11
12. Model List of Essential Drugs (eleventh list)	13
13. Considerations and changes made in revising the model list	46
14. Glossary of terms used in the report	50
15. Alphabetical list of essential drugs	53
References	57

WHO Expert Committee on the Use of Essential Drugs

Geneva, 15–19 December 1999

Members*

Professor M. Hassar, Director, Department of Pharmacology, Faculty of Medicine and Pharmacy, University of Rabat, Rabat, Morocco (*Chairman*)

Professor P. Muscovicz de Buschiazzo, Department of Pharmacology, School of Medicine, University of La Plata, La Plata, Argentina

Dr D. Ofori-Adjei, Director, Noguchi Memorial Institute for Medical Research, University of Ghana, Accra, Ghana

Professor J.C. Petrie, Clinical Pharmacology Unit, Department of Medicine and Therapeutics, University of Aberdeen, Aberdeen, Scotland

Professor L. Rõgo, Director-General, State Agency of Medicines, Tartu, Estonia

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

Professor M. Thomas, Former Head, Clinical Pharmacology and ADR Monitoring Centre, Christian Medical College and Hospital, Vellore, India

Representatives of other organizations†

International Cystic Fibrosis (Mucoviscidosis) Association (ICFMA)

Dr G. Davidson, ICFMA, Geneva, Switzerland

Ms L. Heidet, ICFMA, Geneva, Switzerland

International Federation of Pharmaceutical Manufacturers Associations (IFPMA)

Dr O. Morin Carpentier, IFPMA, Geneva, Switzerland

International Pharmaceutical Federation (FIP)

Professor F.W.H.M. Merkus, Leiden–Amsterdam Centre for Drug Research, Leiden University, Leiden, Netherlands

International League of Dermatological Societies (ILDS)

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

International Society of Chemotherapy (ISC)

Professor T. Bergan, Institute of Medical Microbiology, National Hospital, Oslo, Norway

* Each Member of the Committee signed a statement that he or she agreed not to participate in the review of any matter under consideration in which there was a real or perceived conflict of interest. There were no real or perceived conflicts of interest disclosed.

† Unable to attend: Commonwealth Pharmaceutical Association (CPA); International Generic Pharmaceutical Alliance (IGPA); International Organization of Consumers Unions (IOCU); International Society of Infectious Disease (ISID); International Union of Pharmacology (IUPHAR); United Nations Industrial Development Organization (UNIDO).

Médecins sans Frontières (MSF)

Ms C. Perez, MSF, Paris, France

Dr J. Rigal, MSF, Paris, France

United Nations Children's Fund (UNICEF)

Ms H.B. Pedersen, Technical Services Centre, Supply Division, UNICEF Plads, Copenhagen, Denmark

WHO Collaborating Centre for Drug Statistics Methodology

Ms M. Ronning, WHO Collaborating Centre for Drug Statistics Methodology, Veitvet, Oslo, Norway

WHO Collaborating Centre for International Drug Monitoring

Dr R. Edwards, WHO Collaborating Centre for International Drug Monitoring, Uppsala, Sweden

World Self-Medication Industry (WSMI)

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

Secretariat*

Dr M.R. Couper, Medical Officer, Quality Assurance and Safety: Medicines, Department of Essential Drugs and Medicines Policy, WHO, Geneva, Switzerland (*Secretary*)

Dr Li Dakui, Senior Pharmacist, Peking Union Medical College Hospital, Beijing, China (*Temporary Adviser*)

Dr T. Fukui, Department of General Medicine and Clinical Epidemiology, Kyoto University Hospital, Kyoto, Japan (*Temporary Adviser*)

Dr S. Hill, Faculty of Medicine and Health Sciences, University of Newcastle, Waratah, NSW, Australia (*Temporary Adviser*)

Dr H.V. Hogerzeil, Coordinator, Policy, Access and Rational Use, Department of Essential Drugs and Medicines Policy, WHO, Geneva, Switzerland

Mrs J. Masiga, Mission for Essential Drugs and Supplies, Nairobi, Kenya (*Temporary Adviser*)

Dr B. van de Wal, Department of Internal Medicine, Faculty of Medicine, University of Stellenbosch, Tygerberg, Cape Province, South Africa (*Temporary Adviser*)

Mr P. Wiffen, Coordinating Editor, *Pain, Palliative and Supportive Care*, Cochrane Collaborative Review Group, Pain Relief Unit, Churchill Hospital, Oxford, England (*Temporary Adviser*)

* Each Temporary Adviser of the Committee signed a statement that he or she agreed not to participate in the review of any matter under consideration in which there was a real or perceived conflict of interest. There were no real or perceived conflicts of interest disclosed.

1. Introduction

The WHO Expert Committee on the Use of Essential Drugs met in Geneva from 15 to 19 December 1999. The meeting was opened on behalf of the Director-General by Dr M. Scholtz, Executive Director of Health Technology and Pharmaceuticals, who emphasized that the concept of essential drugs was fundamental to the development of national drug policies. Regular updating of WHO's Model List of Essential Drugs sustained the momentum of WHO's revised drug strategy (1), as endorsed by the World Health Assembly in resolution WHA 39.27 in 1986 (2), 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. Dr Scholtz also emphasized the increasing interest in and need for evidence-based decisions in the selection of essential drugs.

The Committee decided to prepare its report as a self-contained document. The eleventh Model List of Essential Drugs will be found in section 12 of the report, and explanations of the changes in section 13.

2. The concept 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, and at a price that individuals and the community can afford. This concept is intended to be flexible and adaptable to many different situations; exactly which drugs are regarded as essential remains a national responsibility.

Model lists have proved to be invaluable in improving the quality of health care and reducing costs (3, 4). Better quality of care is achieved when the list of essential drugs is linked to evidence-based treatment guidelines (5), especially when the supply system guarantees the availability of the selected drugs. Treatment guidelines can also focus training and serve as a standard for supervision and medical audit; prescribers become more familiar with the drugs and can better recognize adverse drug reactions. Lower costs are achieved through selecting cost-effective treatment. A limited range of drugs in the supply system may lead to economies of scale and competition between manufacturers, further reducing the costs.

Market approval of a pharmaceutical product is usually granted on the basis of efficacy, safety and quality and rarely on the basis of a comparison with other products already on the market, or cost. However, in some developing and most developed countries the majority of drug costs are covered by public funds or through health insurance schemes. Most public drug procurement and insurance schemes have mechanisms to limit procurement or reimbursement of drug costs. An evaluation process is therefore necessary, based on a comparison between various drug products and on cost/benefit considerations. The advantage of a new treatment over the existing one is then compared to its extra cost. Such information has proved very helpful in taking informed decisions about the selection of essential drugs. The model list is intended to help with this evaluation.

3. The WHO Model List of Essential Drugs

In a report to the Twenty-eighth World Health Assembly in 1975 (6), the Director-General pointed out that the selection of 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. By resolution WHA28.66 (7) the Assembly requested the Director-General to advise Member States on the selection and procurement, at reasonable costs, of essential drugs 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 in 1977 (8). This has subsequently been revised and updated in nine further reports (9–17). The concept of essential drugs was quickly taken up by Member States: by the end

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_30500

