

THE SELECTION AND USE OF ESSENTIAL MEDICINES

Report of the WHO Expert Committee,
October 2007
(including the Model List of
Essential Medicines for Children)



**World Health
Organization**

The World Health Organization was established in 1948 as a specialized agency of the United Nations serving as the directing and coordinating authority for international health matters and public health. One of WHO's constitutional functions is to provide objective and reliable information and advice in the field of human health, a responsibility that it fulfils in part through its extensive programme of publications. The Organization seeks through its publications to support national health strategies and address the most pressing public health concerns of populations around the world. To respond to the needs of Member States at all levels of development, WHO publishes practical manuals, handbooks and training material for specific categories of health workers; internationally applicable guidelines and standards; reviews and analyses of health policies, programmes and research; and state-of-the-art consensus reports that offer technical advice and recommendations for decision-makers. These books are closely tied to the Organization's priority activities, encompassing disease prevention and control, the development of equitable health systems based on primary health care, and health promotion for individuals and communities. Progress towards better health for all also demands the global dissemination and exchange of information that draws on the knowledge and experience of all WHO's Member countries and the collaboration of world leaders in public health and the biomedical sciences. To ensure the widest possible availability of authoritative information and guidance on health matters, WHO secures the broad international distribution of its publications and encourages their translation and adaptation. By helping to promote and protect health and prevent and control disease throughout the world, WHO's books contribute to achieving the Organization's principal objective – the attainment by all people of the highest possible level of health.

The *WHO Technical Report Series* makes available the findings of various international groups of experts that provide WHO with the latest scientific and technical advice on a broad range of medical and public health subjects. Members of such expert groups serve without remuneration in their personal capacities rather than as representatives of governments or other bodies; their views do not necessarily reflect the decisions or the stated policy of WHO. An annual subscription to this series, comprising about six such reports, costs CHF 168.00/US\$ 151.00 (CHF 128.40/US\$ 115.00 in developing countries). For further information, please contact: WHO Press, World Health Organization, 20 avenue Appia, 1211 Geneva 27, Switzerland (tel. +41 22 791 3264; fax: +41 22 791 4857; e-mail: bookorders@who.int; order on line: <http://www.who.int/bookorders>).

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

950

THE SELECTION AND USE OF ESSENTIAL MEDICINES

Report of the WHO Expert Committee, October 2007
(including the Model List of Essential Medicines for Children)



**World Health
Organization**

WHO Library Cataloguing-in-Publication Data

The selection and use of essential medicines : report of the WHO Expert Committee,
October 2007 (including the model list of essential medicines for children).

(WHO technical report series ; no. 950)

1. Essential drugs — administration and dosage. 2. Drug information services. 3. Drug
utilization. 4. Child. I. World Health Organization. II. Series.

ISBN 978 92 4 120950 2
ISSN 0512-3054

(NLM classification: QV 55)

© World Health Organization 2008

All rights reserved. Publications of the World Health Organization can be obtained from WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland (tel.: +41 22 791 3264; fax: +41 22 791 4857; e-mail: bookorders@who.int). Requests for permission to reproduce or translate WHO publications — whether for sale or for noncommercial distribution — should be addressed to WHO Press, at the above address (fax: +41 22 791 4806; e-mail: permissions@who.int).

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 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. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

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.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

This publication contains the collective views of an international group of experts and does not necessarily represent the decisions or the policies of the World Health Organization.

**Typeset in Switzerland
Printed in Switzerland**

Contents

WHO Expert Committee on the Selection and Use of Essential Medicines	vii
Declaration of interests	ix
1. Introduction	1
2. Open session	2
Presentation of Subcommittee Report	3
Report on Informal Consultation on Research Priorities for Children's Medicines	5
Other matters	5
Participant statements	6
3. Review of the report of the Subcommittee (including the provisional Model List of Essential Medicines for Children)	7
3.1 General issues	7
3.2 Review of matters referred to the Subcommittee	10
3.3 Review of recommended additions to the list for children	11
3.3.1 Subcutaneous immunoglobulin	11
3.4 Review of responses from applicants to recommendations made by the Subcommittee	11
3.4.1 Artemether injection	11
3.4.2 Artesunate + amodiaquine	13
3.4.3 Artemether + lumefantrine	16
3.4.4 Artesunate + mefloquine	18
3.4.5 Racecadotril	20
3.5 Review of other applications	21
3.6 Review of other comments on the provisional list	21
4. Update on related activities	24
4.1 Report on preliminary work on neonates	24
4.2 Report on research priorities	25
Conclusion	26
References	26
Annex 1	
Report of an Informal Consultation on Research Priorities for Children's Medicines, 2007	27
Annex 2	
First Meeting of the Subcommittee of the Expert Committee on the Selection and Use of Essential Medicines	35
1. Introduction	37

2. Open session	39
3. Policy items	41
3.1 Criteria for the selection of essential medicines for children	41
3.2 Criteria for selection of fixed-dose combination products	44
3.3 Paediatric age categories	45
3.4 Preferred dosage forms	45
3.5 Position paper on off-label use	46
3.6 Review of adherence	47
3.7 Review of regulatory activities	47
4. The WHO Model List of Essential Medicines for Children — by Section	47
Section 1. Anaesthetics	47
Section 2. Analgesics, antipyretics, non-steroidal anti-inflammatory medicines (NSAIDs), medicines used to treat gout and disease modifying agents in rheumatoid disorders (DMARDs)	48
Section 3. Antiallergics and medicines used in anaphylaxis	50
Section 4. Antidotes and other substances used in poisonings	51
Section 5. Anticonvulsants/antiepileptics	52
Section 6. Anti-infective medicines	53
Section 6.1 <i>Anthelmintics</i>	53
Section 6.2 <i>Antibacterials</i>	54
6.2.1 Beta Lactam medicines	54
6.2.2 Other antibacterials	56
6.2.3 Antileprosy medicines	61
6.2.4 Antituberculosis medicines	61
Section 6.3 <i>Antifungal medicines</i>	62
Section 6.4 <i>Antiviral medicines</i>	64
6.4.1 Antiherpes medicines	64
6.4.2 Antiretrovirals	64
New application: Abacavir (scored tablet 300 mg):	
Section 6.4.2.1	66
New application: Lamivudine (scored tablet 150 mg)	66
Fixed-dose combinations	67
New application: Triple fixed-dose combinations	68
6.4.3 Other antivirals	69
Section 6.5 <i>Antiprotozoal medicines</i>	69
6.5.1 Antiamoebic and anti giardiasis medicines	70
6.5.2 Antileishmaniasis medicines	70
6.5.3 Antimalarial medicines	71
6.5.3.1 For curative treatment	71
6.5.3.2 For prophylaxis	72
New application: Artemether injection	72
New application: Artemether + lumefantrine fixed-dose combination	73
New application: Artesunate (rectal capsules)	75

New application: Artesunate + amodiaquine fixed-dose combination	77
New application: Artesunate + mefloquine fixed-dose combination	79
6.5.4 Medicines for pneumocystis and toxoplasmosis	81
6.5.5 Antitrypanosomal medicines	82
6.5.5.1 African trypanosomiasis	82
6.5.5.2 American trypanosomiasis	82
Section 7. Antimigraine medicines	83
Section 8. Antineoplastic, immunosuppressives and medicines used in palliative care	84
Section 10. Medicines affecting the blood	85
Section 11. Blood products and plasma substitutes	86
Section 11.1 Plasma substitutes	86
Section 11.2 Plasma fractions for specific use (Complementary List)	87
Section 12. Cardiovascular medicines	88
Section 13. Dermatological medicines (topical)	89
Section 13.1 Antifungal medicines	90
Section 13.2 Anti-infective medicines	90
Section 13.3 Anti-inflammatory and antipruritic medicines	90
Section 13.4 Astringent medicines	90
Section 13.5 Medicines affecting skin differentiation and proliferation	91
Section 13.6 Scabicides and pediculicides	91
Section 14. Diagnostic agents	91
Section 15. Disinfectants and antiseptics	92
Section 16. Diuretics	92
Section 17. Gastrointestinal medicines	93
Section 17.1 Antacids and other antiulcer medicines	93
Section 17.2 Antiemetic medicines	93
Section 17.3 Anti-inflammatory medicines	94
Section 17.4 Laxatives	94
Section 17.5 Medicines used in diarrhoea	94
New application: Racecadotril	95
Section 18. Hormones, other endocrine medicines and contraceptives	96
Section 19. Immunologicals	98
Section 20. Muscle relaxants (peripherally-acting) and cholinesterase inhibitors	98
Section 21. Ophthalmological preparations	99
Section 23. Peritoneal dialysis solution	100
Section 24. Psychotherapeutic medicines	100
Section 24.1 Medicines used in psychotic disorders	101
Section 24.2 Medicines used in mood disorders	101
24.2.1 Medicines used in depressive disorders	101
24.2.2 Medicines used in bipolar disorders	102

Section 24.3	<i>Medicines used in generalized anxiety and sleep disorders</i>	102
Section 24.4	<i>Medicines used for obsessive compulsive disorders and panic attacks</i>	102
Section 25.	Medicines acting on the respiratory tract	102
Section 26.	Solutions correcting water, electrolyte and acid-base disturbances	103
Section 27.	Vitamins and minerals	104
5.	Summary of recommendations	105
	Needs identified	105
	Gaps identified	106
	Priorities for reviews	107
	References	107
	Appendix 1	
	Declaration of interests of Subcommittee Members	110
	Appendix 2	
	WHO Model List of Essential Medicines for Children	112
	Appendix 3	
	The Anatomical Therapeutic Chemical (ATC) classification system	142
	Appendix 4	
	Alphabetical list of essential medicines for children (with ATC classification code numbers)	158
	Appendix 5	
	Summary of reviews requested during the Subcommittee meeting	167
	Appendix 6	
	List of individuals and institutions sending in comments to the Subcommittee	173

预览已结束，完整报告链接

<https://www.yunbaogao.cn/report/index/report>