WHO Model Formulary for Children

Based on the
Second Model List of
Essential Medicines for
Children 2009

make medicines child size

2010

World Health Organization

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Report of the WHO Expert Committee
(including the WHO Model List of Essential Medicines and the 2nd WHO Model List of Essential Medicines for Children)
WHO Technical Report Series, No. 958, 2010 (in print)

Pocket book of hospital care for children.

2005 (378 pages)

The international pharmacopoeia, fourth edition.

Volume 1: general notices; monographs for pharmaceutical substances (A–O)
Volume 2: monographs for pharmaceutical substances (P–Z); monographs for dosage forms and radiopharmaceutical preparations; methods of analysis; reagents.
2006 (1500 pages), also available in CD-ROM version

Basic tests for drugs: pharmaceutical substances, medicinal plant materials and dosage forms.

1998 (94 pages)

Quality assurance of pharmaceuticals: a compendium of guidelines and related materials.

Volume 1: 1997 (244 pages)
Volume 2: Good manufacturing practices and inspection.
2nd updated edition, 2007 (in print)

WHO Expert Committee on Specifications for Pharmaceutical Preparations.

Forty-third report.
WHO Technical Report Series, No. 953, 2009 (172 pages)

International nonproprietary names (INN) for pharmaceutical substances.

Cumulative List no. 13
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e-mail: bookorders@who.int; order on line: http://www.who.int/bookorders)

Contents

Abbreviations

ACE	angiotensin-converting enzyme
AIDS	acquired immunodeficiency syndrome
ALP	alkaline phosphatase
APTT	activated partial thromboplastin time
ART	antiretroviral
ATC	anatomical therapeutic chemical
AUC	area under the curve
AV	atrioventricular
BCG	Bacillus Calmette–Guérin (vaccine)
BNFC	British National Formulary for Children
BP	British Pharmacopoeia
BSA	body surface area
CNS	central nervous system
CrCl	creatinine clearance
CSF	cerebrospinal fluid
ECG	electrocardiogram
EEG	electroencephalogram
EMLc	Essential Medicines List for Children
G6PD	glucose 6-phosphate dehydrogenase
GFR	glomerular filtration rate
GI	gastrointestinal
GORD	gastro-oesophageal reflux disease
GVHD	graft-versus-host disease
HIV	human immunodeficiency virus
Ht	height
IM	intramuscular
INR	international normalized ratio
IV	intravenous
MB	multibacillary leprosy
MDI	metered dose inhaler
MDR-TB	multidrug-resistant tuberculosis
MMR	measles, mumps, rubella
MRI	magnetic resonance imaging
MSSA	methicillin-sensitive *Staphylococcus aureus*
MTCT	mother-to-child transmission
NSAIM	non-steroidal anti-inflammatory medicine
ORS	oral rehydration solution
PB	paucibacillary leprosy
PCP	*Pneumocystis carinii (Pneumocystis jiroveci)* pneumonia
PDA	patent ductus arteriosus
PR	per rectum
PTB	pulmonary tuberculosis
PVC	polyvinyl chloride
SC	subcutaneous
SIADH	syndrome of inappropriate antidiuretic hormone secretion
spp.	species
SSRI	selective serotonin reuptake inhibitor
TB	tuberculosis
TSH	thyroid stimulating hormone
USP	United States Pharmacopeia
WHO	World Health Organization
Wt	weight

Introduction

In 2007, the World Health Assembly passed a Resolution titled 'Better Medicines for Children'. This resolution recognized the need for research and development into medicines for children, including better dosage forms, better evidence and better information about how to ensure that medicines for treating the common childhood diseases are given at the right dose for children of all ages. The World Health Organization has therefore developed a program of work on medicines for children, including the development of a Model List of Essential Medicines for children (EMLc). As an extra resource for health-care workers and national programmes that supply medicines for children, this new edition of the WHO Model Formulary has been prepared, based on the 2nd edition of the EMLc, to provide prescribers with the best information about how to use the medicines included on the List.

In developing the WHO Model Formulary for Children, the editors have based decisions on treatment regimens on the best available evidence from clinical studies in children, that have been assessed and evaluated by the WHO Expert Committee on Selection and Use of Essential Medicines. However, as has been found by all authorities in relation to medicines for children, in many cases the recommendations on dose and duration of treatment in children have to be extrapolated from studies in adults and adjusted based on our understanding of the effect of age and development on the absorption, distribution and metabolism and excretion of different medicines in children of different ages. One of the aims of this publication is therefore not only to describe what is known about treatments, but to highlight where more research is needed.

An electronic version of the WHO Formulary for Children is also available, intended as a starting point for developing institutional or national formularies. The text of the Formulary can be used by groups who wish to develop their own version, by adapting the text or by adding or deleting entries to align the formulary to their own list of essential medicines.

This edition of the WHO Model Formulary is fully compatible with the 2nd List of Essential Medicines for Children, as recommended by the WHO Expert Committee on the Selection and Use of Essential Medicines in March 2009. Comments and suggestions are welcome and should be sent to:

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Factors influencing paediatric drug therapy

Medicines in children

> It was once said that the moral test of government is how that government treats those who are in the dawn of life, the children; those who are in the twilight of life, the elderly; and those who are in the shadows of life—the sick, the needy and the handicapped.[1]

Children are among the most vulnerable individuals in any society. Nowhere is this more true than in their access to appropriate health care. As part of the treatment of children, health-care workers need access to drug dosage information. This formulary aims to provide that information universally, to assist in the management of children.

The use of medicines in infants and children presents a unique set of challenges to the prescriber. Physiological variances between children and adults, including the ontogeny of organ maturity and body composition, significantly influence the actions, effectiveness and safety of medicines. However, most pharmacokinetic and pharmacodynamic studies provide little, if any, information on drug action in infants and children, because they are usually conducted in adults.

Paediatric pharmacology developed initially from the extrapolation of therapeutic practice and experience in adults and the use of "scaled down" adult doses. This practice is clinically successful for the majority of drugs which are relatively non-toxic and have a wide margin between therapeutic and toxic doses. Drugs with a narrow therapeutic margin, such as the aminoglycoside antibiotics and digoxin, require more sophisticated knowledge and individualized dosage regimens. Doses of such agents are scaled by weight or allometrically ($wt^{3/4}$), then modified according to the results of serum drug concentration measurements, if these are available. Over the last two decades, there has been an increased recognition of the necessity to perform studies specifically in children and adolescents. Major national and international approaches, such as those of the European Union and the United States, have resulted in some new information to improve the use of medicines in children.

This formulary is the result of the establishment of the *WHO Model List of Essential Medicines for Children* (EMLc). The list can be accessed at http://www.who.int/selection_medicines/en/.

Absorption