

SELECTED ANNOTATED BIBLIOGRAPHY ON ESSENTIAL DRUGS



December 1990



WORLD HEALTH ORGANIZATION



WORLD HEALTH ORGANIZATION
ORGANISATION MONDIALE DE LA SANTE

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2.

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Regional Office for the Western Pacific
P.O. Box 2932
1099 Manila
Philippines

The literature on the rational use of drugs has become more complex since the early 1970s. Within the last decade, interest has increased in developing a conceptual framework for the rational use of drugs. Governments, international and non-governmental organizations, universities and individuals have been actively involved in the many different aspects, including the formulation of the concept of essential drugs and the development of mechanisms to increase the availability of appropriate drugs at different levels of health care. National policies and programmes have been developed which determine the type and quantity of drugs needed, their rational use and the means to procure and distribute them effectively, taking into account local economic, social and political environments.

This second edition of the annotated bibliography builds on the publication issued in May 1988 and contains 173 additional references. It provides an entry point to the literature on these diverse activities. It directs the reader to key reports, articles and books related to essential drugs. The bibliography is not exhaustive. Some publications were excluded because of space and time constraints, and because of their limited circulation and accessibility. In addition, most of the material is from English language sources only.

The publications are organized in alphabetical order by author/corporate author and each is placed, according to its main focus, into one of thirteen sections: assurance of quality; audiovisuals; drug information; economics and finance; health aspects; human resources and training; monitoring and evaluation; periodicals; pharmaceutical industry; policy and regulation; selection; supply; use. Keywords highlight specific subject areas and countries that are covered in each publication. A list of keywords pertaining to each section follows this introduction. The material is indexed by author, corporate author, subject area and country.

Most of the WHO publications should be available in national libraries. In case of difficulty it is suggested that the libraries of the WHO Regional Offices (see page 2) be approached for assistance.

WHO depository and reference libraries in each country (addresses available from WHO Headquarters) hold copies of all WHO publications. WHO publications may also be purchased from the WHO sales agents (listed overleaf) or the Distribution and Sales Office in WHO Headquarters. Please note that WHO documents are not for sale and may only be requested from the headquarters programme or regional office indicated in each bibliographic reference.

Users' comments on the bibliography, as well as suggestions for inclusion or deletion of material, are most welcome. These should be sent to:

WHO Action Programme on Essential Drugs and Vaccines
World Health Organization
1211 Geneva 27
Switzerland

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AUSTRIA: Gerold & Co., Graben 31, 1011 Vienna 1

BAHRAIN: United Schools International, Arab Region Office, P.O. Box 726, Bahrain

BANGLADESH: The WHO Representative, G.P.O. Box 250, Dhaka 5

BELGIUM: *For books:* Office International de Librairie s.a., avenue Marnix 30, 1050 Brussels. *For periodicals and subscriptions:* Office International des Périodiques, avenue Louise 485, 1050 Brussels

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CANADA: Canadian Public Health Association, 1565 Carling Avenue, Suite 400, Ottawa, Ont. K1Z 8R1

CHILE: Miguel Concha Caldera, Alferez Real 1464-Providencia, Casilla 1018, Correo 22, Santiago

CHINA: China National Publications Import & Export Corporation, P.O. Box 88, Beijing

DENMARK: Munksgaard Book and Subscription Service, P.O. Box 2148, 1016 Copenhagen K. Tel +45 33 128570. Telefax +45 33 129387

FIJI: The WHO Representative, P.O. Box 113, Suva

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GREECE: G.C. Eleftheroudakis S.A., Librairie internationale, rue Nikis 4, 105-63 Athens

HUNGARY: Kultura, P.O.B. 149, Budapest 62

ICELAND: Bókabúó Máls & Menningar, Box 392, IS-101 Reykjavik

INDIA: WHO Regional Office for South-East Asia, World Health House, Indraprastha Estate, Mahatma Gandhi Road, New Delhi 110002

IRAN (ISLAMIC REPUBLIC OF): Iran University Press, 85 Park Avenue, P.O. Box 54/551, Teheran

IRELAND: TDC Publishers, 12 North Frederick Street, Dublin 1

ISRAEL: Yozmot Ltd, P.O. Box 56055, Tel Aviv 61560

ITALY: Edizioni Minerva Medica, Corso Bramante 83-85, 10126 Turin; Via Lamarmora 3, 20100 Milan; Via Spallanzani 9, 00161 Rome

JAPAN: Maruzen Co. Ltd., P.O. Box 5050, Tokyo International, 100-31

JORDAN: Jordan Book Centre Co. Ltd., University Street, P.O. Box 301 (Al-Jubeiha), Amman

KENYA: Text Book Centre Ltd, P.O. Box 47540, Nairobi

KUWAIT: The Kuwait Bookshops Co. Ltd., Thunayan Al-Ghanem Bldg, P.O. Box 2942, Kuwait

LAO PEOPLE'S DEMOCRATIC REPUBLIC: The WHO Representative, P.O. Box 343, Vientiane

LUXEMBOURG: Librairie du Centre, 49 bd Royal, Luxembourg

MALAYSIA: Parry's Book Center Sdn. Bhd., 60 Jalan Negara, P.O. Box 10960, 50730 Kuala Lumpur Tel: 03-4087235, Fax: 03-4079180, Telex: Parry's MA

MEXICO: Librería Interacademica S.A., Av. Sonora 206, 06100-Mexico, D.F.

MOROCCO: Editions La Porte, 281 avenue Mohammed V, Rabat

NETHERLANDS: INOR - Publikaties, P.O. Box 14, 7240 BA Lochem

NEW ZEALAND: Medical Books (New Zealand), Ltd, 8 Park Avenue, P.O. Box 8565, Symonds Street, Auckland 3

NORWAY: *For subscriptions:* Narvesen Info Center, Postboks 6125 Etterstad, N-0602 Oslo 6. *For books:* Narvesen Info Center and major bookshops

PAKISTAN: Mirza Book Agency, 65 Shahrah-E-Quaid-E-Azam, P.O. Box 729, Lahore 3

PAPUA NEW GUINEA: The WHO Representative, P.O. Box 5896, Boroko, N.C.D.

PHILIPPINES: International Book Center, 5th Floor, Filipinas Life Building, Ayala Avenue, Makati, Metro Manila. National Book Store Inc., 701 Rizal Avenue, P.O. Box 1934, Manila

PORTUGAL: Livraria Rodrigues, 186 Rua da Ouro, Lisbon 2

REPUBLIC OF KOREA: The WHO Representative, Central P.O. Box 540, Seoul

SAUDI ARABIA: World of Knowledge for Publishing and Distribution, P.O. Box 576, Jeddah

SINGAPORE: The WHO Representative, 144 Moulmein Road, Singapore 1130; Newton P.O. Box 31, Singapore 9122. Select Books, 03-15 Tanglin Shopping Center, 19 Tanglin Road, Singapore 1024

SPAIN: Comercial Atheneum S.A., Consejo de Ciento 130-136, 08015 Barcelona; General Moscardó 29, Madrid 20. Librería Díaz de Santos, Calle Maldonado 6, P.O. Box 6050, 28006 Madrid; Balmes 417 y 419, 08022 Barcelona

SWEDEN: *For books:* Aktiebolaget C.E. Fritzes Kungl. Hovbokhandel, Regeringsgatan 12, 103 27 Stockholm. *For periodicals:* Wennergren-Williams AB, Box 30004, 104 25 Stockholm

SWITZERLAND: Medizinischer Verlag Hans Huber, Länggassstrasse 76, 3012 Bern 9

UNITED KINGDOM: HMSO Books, Publications Centre, 51 Nine Elms Lane, London SW8 5DR (*mail and telephone orders only*) Telephone orders: 071 873 9090. Fax orders: 071 873 2000. General enquiries: 071 873 0011. Telex: 297138. Fax(gp3): 01 873 8463. HMSO Bookshops at: 49 High Holborn, London WC1V 6HB Tel: 071 873 0011 (*counter service only*). 258 Broad Street, Birmingham B1 2HE Tel: 021 643 3740. Southey House, Wine Street, Bristol BS1 2BQ Tel: 0272 264306. 9/21 Princess Street, Manchester M60 8AS Tel: 061 834 7201. 80 Chichester Street, Belfast BT1 4JY Tel: 0232 2308451. 71 Lothian Road, Edinburgh EH3 9AZ Tel: 031 228 4181. Publications may also be ordered through HMSO's accredited agents (*see yellow pages*) or from any good bookshop.

UNITED STATES OF AMERICA: *Books (not subscriptions):* WHO Publications Center USA, 49 Sheridan Ave., Albany, NY 12210. *Subscriptions:* WHO, Distribution and Sales, 1211 Geneva 27, Switzerland. *Publications also available from the United Nations Bookshop, NY, NY 10017 (retail only)*

USSR: *Russian editions within the USSR:* Komsomolskij prospekt 18, Medicinskaja Kniga, Moscow; *Russian editions outside the USSR:* Kuzneckij most 18, Mezhdunarodnaja Kniga, Moscow G-200

VENEZUELA: Librería Médica Paris, Apartado 60.681, Caracas 106

YUGOSLAVIA: Jugoslovenska Knjiga, Terazije 27/II, 11000 Belgrade

ZIMBABWE: Textbook Sales (PVT) Ltd, 1 Norwich Union Centre, Mutare

List of abbreviations

5.

Organizations

ACHAN	Asian Community Health Action Network
AHRTAG	Appropriate Health Resources and Technologies Action Group
APHA	American Public Health Association
CADE	Coalition Against Dangerous Exports
CAP	Consumers' Association of Penang
CHAI	Catholic Hospital Association of India
CIOMS	Council for International Organization of Medical Sciences
CMC	Christian Medical Commission
EUR.PAR.	European Parliament
FDA	Food and Drug Administration
HAI	Health Action International
HTD	Health Technology Directions
IFPMA	International Federation of Pharmaceutical Manufacturers' Association
IOCU	International Organization of Consumer Unions
IRM	Institute for Research and Information on Multinationals
JIPMAR	Jawaharlal Institute of Postgraduate Medical Education and Research
NCIH	National Council for International Health
NISTADS	National Institute of Science, Technology and Development Studies
OHE	Office of Health Economics
PAHO	Pan American Health Organization
PMA	Pharmaceutical Manufacturers' Association
THIS	Tower Hamlets International Solidarity
UNAPDI	United Nations Asian and Pacific Development Institute
UNCTAD	United Nations Centre on Trade and Development
UNCTC	United Nations Centre on Transnational Corporations
UNICEF	United Nations Children's Fund
UNIDO	United Nations Industrial Development Organization
VHAI	Voluntary Health Association of India
WHO	World Health Organization

Countries

C. America	Central America
F.R. Germany	Federal Republic of Germany
N. America	North America
R. Korea	Republic of Korea
S. America	South America
UK	United Kingdom
USA	United States of America

Languages

Ara	Arabic
Chin	Chinese
Eng	English
Far	Farsi
Fre	French
Ger	German
Por	Portuguese
Rus	Russian
Spa	Spanish

Other

Conf.	Conference
GMP	Good Manufacturing Practices
nd	Not dated
ns	Not specified

Assurance of Quality

GMP
Quality control
Reference standards
Stability
WHO certification

Drug Information

Labelling information
Patient information
Prescriber information

Economics and Finance

Cost analysis
Financial needs
Financing
Price monitoring

Health Aspects

Primary health care

Human Resources and Training

Manpower needs
Training methodologies
Training programmes

Monitoring and Evaluation

Evaluation

Pharmaceutical Industry

Marketing
Research and Development
Retailers
Trade

Policy and Regulation

Drug evaluation and surveillance
Legislation
National drug policy
Registration
Regulations

Selection

Clinical pharmacology
Drug selection committees
Essential drugs list
Generics
Hospital formularies
Hospital drug committees
National formularies
Quantification
Selection

Supply

Computers
Distribution
Inventories
Kits
Local production
Procurement
Storage
Supply
Supply management

Use

Antibiotics
Compliance
Consumer Beliefs
Consumer organizations
Consumption
Drug use research
Monitoring of use
Prescribing pattern
Self medication
Therapeutic guidelines
Traditional medicine
Use

- 1 Council for International Organizations of Medical Sciences. Safety requirements for the first use of new drugs and diagnostic agents in man. Geneva : CIOMS, 1983. 61p.

KEYWORDS: Quality control, reference standards, clinical pharmacology

LANGUAGE: Eng

ADDRESS : CIOMS, c/o Distribution and Sales, WHO, 1211 Geneva 27. Switzerland.

ABSTRACT: A series of recommendations for assuring the safety of new drugs and diagnostic agents. Emphasis is placed on the safety issues that should be considered in early clinical trials of drugs. Safety requirements are given for the preclinical stages of drug testing and for subsequent evaluation to the point where potential therapeutic activity is demonstrated.

- 2 World Health Organization. Accelerated stability studies of widely used pharmaceutical substances under simulated tropical conditions. Geneva : WHO, 1986. 119p. [WHO/PHARM/86.529]. Unpublished

KEYWORDS: Stability, clinical pharmacology, reference standards

LANGUAGE: Eng

ADDRESS : Pharmaceuticals, WHO, 1211 Geneva 27. Switzerland.

ABSTRACT: This document provides a systematic survey of the stability of many widely used pharmaceutical substances. It includes an index of degradable substances and of substances resistant to degradation. It also includes stability experiments on degradable substances - simplified tests to detect or exclude gross degradation.

- 3 World Health Organization. The international pharmacopoeia : general methods of analysis. Vol. 1. Geneva : WHO, 1979. 223p.

KEYWORDS: Quality control, reference standards

LANGUAGE: Eng Fre Spa

ADDRESS : Distribution and Sales, WHO, 1211 Geneva 27. Switzerland.

ABSTRACT: Describes methods and procedures of importance in the quality control of pharmaceutical substances and dosage forms. The 42 different methods presented have been extensively revised to make use of new analytical tools. Procedures also consider various technical and economic constraints found in the third world.

- 4 World Health Organization. The international pharmacopoeia : quality specifications. Vol. 2. Geneva : WHO, 1981. 342p.

KEYWORDS: Quality control, reference standards, essential drugs list

LANGUAGE: Eng Fre Spa

ADDRESS : Distribution and Sales, WHO, 1211 Geneva 27. Switzerland.

ABSTRACT: Contains quality specifications for 126 individual pharmaceutical substances included in WHO's Model List of Essential Drugs. The specifications have proved especially useful as references for national authorities attempting to assure the quality of pharmaceuticals used in their health systems, particularly in developing countries.

- 5 World Health Organization. Specifications for pharmaceutical preparations : twenty-seventh report of the WHO Expert Committee. Geneva : WHO, 1980. 54p. [Technical Report Series; no.645]

KEYWORDS: Quality control, reference standards

LANGUAGE: Eng Fre Spa

ADDRESS : Distribution and Sales, WHO, 1211 Geneva 27. Switzerland.

ABSTRACT: Presents the various elements necessary for quality assurance in pharmaceutical supply systems. Includes recommendations on tests used for the quality control of solid oral dosage forms, such as tablets and capsules.

- 6 World Health Organization. Specifications for pharmaceutical substances : twenty-eighth report of the WHO Expert Committee. Geneva : WHO, 1982. 33p. [Technical Report Series; no.681]

KEYWORDS: Quality control, reference standards

LANGUAGE: Eng Fre Spa

ADDRESS : Distribution and Sales, WHO, 1211 Geneva 27. Switzerland.

ABSTRACT: Provides guidelines for the development of quality control facilities, including information on : the establishment, maintenance, and distribution of chemical reference substances; and techniques used in developing basic tests for quality control. Also includes a discussion of the functions and characteristics of the International Pharmacopoeia.

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- 7 World Health Organization. Specifications for pharmaceutical preparations : twenty-ninth report of the WHO Expert Committee. Geneva : WHO, 1984. 54p. [Technical Report Series; no.704]

KEYWORDS: Quality control, WHO certification, training programmes

LANGUAGE: Eng Fre Spa

ADDRESS : Distribution and Sales, WHO, 1211 Geneva 27. Switzerland.

ABSTRACT: Presents advice and recommendations for improving the quality control of drugs. The report provides information on : WHO certification schemes; design, staffing, and equipment for a first-stage laboratory for drug surveillance; functions, premises, staffing, equipment, and instruments for a medium-sized drug control laboratory; and training programmes in drug analysis.

- 8 World Health Organization. Specifications for pharmaceutical preparations : thirtieth report of the WHO Expert Committee. Geneva : WHO, 1987. 52p. [Technical Report Series; no.748]

KEYWORDS: Quality control, training programmes

LANGUAGE: Eng Fre Spa

ADDRESS : Distribution and Sales, WHO, 1211 Geneva 27. Switzerland.

ABSTRACT: Discusses the use of infrared reference spectra versus chemical reference substances. Provides guidance on : good laboratory practices in government drug control laboratories; and training programmes in drug analysis.

- 9 World Health Organization. Basic tests for pharmaceutical substances. Geneva : WHO, 1986. 210p.

KEYWORDS: Quality control, reference standards

LANGUAGE: Eng Fre Spa

ADDRESS : Distribution and Sales, WHO, 1211 Geneva 27. Switzerland.

ABSTRACT: Presents simplified tests for verifying the identity of pharmaceutical substances and detecting gross degradation. The 321 substances covered represent the majority of drug substances contained in the WHO Model List of Essential Drugs as well as a number of other widely used drug substances.

- 10 World Health Organization. Specifications for pharmaceutical preparations : thirty-first report of the WHO Expert Committee. Geneva : WHO, 1990. 79p. [Technical Report Series; no. 790]

KEYWORDS: GMP, quality control, reference standards, WHO certification

LANGUAGE: Eng Fre Spa

ADDRESS : Distribution and Sales, WHO, 1211 Geneva 27. Switzerland.

ABSTRACT: Considers questions concerning the quality assurance of pharmaceuticals and specifications for drug substances and dosage forms. Technical issues discussed include drug stability and sampling procedures, the problems created by counterfeit and substandard preparations, and corresponding need for appropriate preventive measures in both importing and exporting countries. Other topics include the further development of the International Pharmacopoeia, the establishment of international chemical reference substances, and developments in the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce. Annexed to the report is a document outlining guiding principles for small national drug regulatory authorities.

- 11 World Health Organization. The international pharmacopoeia : quality specifications. Vol. 3. Geneva : WHO, 1988. 407p.

KEYWORDS: Quality control, GMP

LANGUAGE: Eng Fre Spa

ADDRESS : Distribution and Sales, WHO, 1211 Geneva 27. Switzerland.

ABSTRACT: Presents quality specifications for 157 widely used pharmaceutical substances. Since the International Pharmacopoeia aims primarily at meeting the needs of developing countries, the monographs are based on sound, simplified and classical chemical methods appropriate for use in small and medium-sized laboratories. Each monograph gives clear and concise information on nomenclature, formulas, chemical names, description, solubility data, storage conditions, category, identity tests, purity requirements and assays. The volume also includes a list of reagents, test solutions and volumetric solutions, followed by expanded information on some general methods and amendments to the previous volumes.

- 12 Anonymous. GMP "should apply to all". The Pharmaceutical Journal 1987 Apr ; 434-435

KEYWORDS: GMP, quality control

LANGUAGE: Eng

ADDRESS :

ABSTRACT: A report of the Commonwealth Pharmaceutical Association conference emphasising the need for good manufacturing practices [GMP] and quality assurance in both developing and developed countries. Apart from having an authority responsible for quality control and GMP, each country should establish a quality control facility appropriate to its needs. For imported medicines, a simple test to check whether a product contains the right active ingredient and in roughly the right amount needs to be developed.

- 13 Anonymous. GMP and quality control in developing countries. The Pharmaceutical Journal 1987 Apr ; 436-438

KEYWORDS: National drug policy, GMP, quality control

LANGUAGE: Eng

ADDRESS :

ABSTRACT: Prevailing problems in relation to quality assurance and good manufacturing practice [GMP] in developing countries were considered at the Commonwealth Pharmaceutical Association conference, and the general feeling was that there should be a national commitment to ensure that quality essential pharmaceutical products are available to the population. The article gives the guidelines for quality assurance and GMP proposed at the conference.

- 14 Binka J Y, Wieniawski W. Quality control : think small. World Health 1985 Dec ; 10-13

KEYWORDS: WHO certification, stability, GMP, registration, legislation, regulations

LANGUAGE: Ara Eng Fre Ger Rus Spa Por Far

ADDRESS : World Health, WHO, 1211 Geneva 27. Switzerland.

ABSTRACT: Developing countries purchasing drugs on international tender may well be supplied with poor-quality drugs, especially if they have limited quality control facilities. A comprehensive quality control surveillance can eliminate most of these problems. Even a small quality control laboratory can prevent potentially serious accidents by detecting poor quality, mislabelling or deterioration of drug products.

- 15 Grimm W. Storage conditions for stability testing. Long term testing and stress tests (Part 2). Drugs Made in Germany 1986 ; 29 [1] : 39-47

KEYWORDS: Storage, stability, quality control

LANGUAGE: Eng

ADDRESS :

ABSTRACT: Provides storage conditions for four climatic zones, temperate, subtropical, hot and dry and hot and humid, using average values for temperature and partial pressure of water vapour.

- 16 Johnson C A, Mechkovski A. A bestseller for WHO? World Health 1985 Dec ; 14-15

KEYWORDS: GMP

LANGUAGE: Ara Eng Far Fre Ger Por Rus Spa

ADDRESS : World Health, WHO, 1211 Geneva 27. Switzerland

ABSTRACT: In producing the third edition of the International Pharmacopoeia, WHO has aimed to support the concept of the modest quality control laboratory. This edition provides for a full analysis of all the drugs on WHO's Model List; 70 per cent of these tests can be performed in the simplest of the recommended laboratories.

- 17 Khan R. WHO Certification Scheme : visit to countries. In: International conference of drug regulatory authorities [3rd : 1984 : Stockholm]. Information : proceedings. Uppsala, Sweden : National Board of Health and Welfare, 1984. p.9-11

KEYWORDS: WHO certification, GMP, legislation, regulations, registration

LANGUAGE: Eng

ADDRESS : National Board of Health and Welfare, Department of Drugs, P.O. Box 607, S-751 Uppsala. Sweden.

ABSTRACT: A visit to 13 developing countries showed that the WHO certificate was generally not in use in any country. A number of countries did not appear to recognize the full extent of its benefits. Argues that the Scheme is not to take the place of the national licensing and registration systems, but is one step to ensure quality control of pharmaceutical products.