

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

The selection of essential drugs

Report of a
WHO Expert Committee

World Health Organization
Technical Report Series
615



World Health Organization Geneva 1977

ISBN 92 4 120615 2

© World Health Organization 1977

Publications of the World Health Organization enjoy copyright protection in accordance with the provisions of Protocol 2 of the Universal Copyright Convention. For rights of reproduction or translation of WHO publications, in part or *in toto*, application should be made to the Office of Publications, World Health Organization, Geneva, Switzerland. The World Health Organization welcomes such applications.

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.

PRINTED IN SWITZERLAND

CONTENTS

	Page
1. Introduction	7
2. General considerations	9
2.1 Statement of the problem	9
2.2 General principles for establishing a list of essential drugs	10
3. Guidelines for establishing a list of essential drugs	11
4. A more limited list of essential drugs for primary health care	13
5. Examples of the application of the guidelines by the Expert Committee	14
6. Drug information and education activities	15
7. Drug utilization surveys	17
8. Research and development	18
8.1 Pharmaceutical	18
8.2 Clinical	18
8.3 Educational	19
8.4 Regulatory	19
9. Model list of essential drugs	20
10. Recommendations for the development of the WHO programme on essential drugs	33
11. Glossary of terms used in the report	34
12. Bibliography	35

WHO EXPERT COMMITTEE ON THE SELECTION
OF ESSENTIAL DRUGS

Geneva, 17-21 October 1977

*Members : **

- Professor D. L. Azarnoff, KUMC Distinguished Professor of Medicine and Pharmacology, The University of Kansas Medical Center, College of Health Sciences and Hospital, Kansas City, KS, USA (*Chairman*)
- Dr E. G. Beausoleil, Director of Medical Services, Ministry of Health, Accra, Ghana
- Dr I. Darmansjah, Head, Department of Pharmacology, University of Indonesia, Jakarta, Indonesia (*Vice-Chairman*)
- Professor S. Garattini, Director, Mario Negri Institute, Milan, Italy
- Professor P. Lechat, Director, Institute of Pharmacology, Faculty of Medicine of the University, Paris, France
- Dr N. D. W. Lionel, Associate Professor of Pharmacology, Department of Pharmacology, University of Sri Lanka, Colombo, Sri Lanka (*Rapporteur*)
- Mr Yeap Boon Chye, Director of Pharmaceutical Services, Ministry of Health, Kuala Lumpur, Malaysia (*Rapporteur*)
- Professor A. C. Zanini, President, Consultative Committee, Central de Medicamentos, and Director of the Central Laboratory, Hospital das Clinicas of the Faculty of Medicine, University of São Paulo, São Paulo, Brazil

Representatives of other organizations

United Nations Children's Fund:

- Dr H. Probst, Procurement Officer, Supply Division, European Office of UNICEF, Palais des Nations, Geneva
- Mr J. Richman, Deputy Director, Supply Division, UNICEF, New York

Secretariat

- Dr I. T. Borda, Associate Professor of Medicine, University of Western Ontario, and Head of Gastroenterology Division, St. Joseph's Hospital, London, Ontario, Canada (*Temporary Adviser*)
- Dr V. Fattorusso, Director, Division of Prophylactic, Diagnostic and Therapeutic Substances, WHO, Geneva, Switzerland
- Miss M. Helling, Scientist, Drug Policies and Management, WHO, Geneva, Switzerland
- Dr P. K. M. Lunde, Associate Professor in Clinical Pharmacology, University of Oslo, and Head, Division of Clinical Pharmacology and Toxicology, Central Laboratory, Ulleval Hospital, Oslo, Norway (*Temporary Adviser*)

* Unable to attend : Dr E. A. Babajan, Head, Department for the Introduction of New Medicaments and Medical Techniques, Ministry of Health of the USSR, Moscow, USSR.

Dr H. Nakajima, Chief, Drug Policies and Management, WHO, Geneva, Switzerland (*Secretary*)

Dr G. Tognoni, Head, Clinical Pharmacology Laboratory and Regional Centre for Drug Information, Mario Negri Institute, Milan, Italy (*Temporary Adviser*)

Dr G. A. Ulianova, Deputy Chairman, Pharmacological Committee, Ministry of Health of the USSR, Moscow, USSR (*Temporary Adviser*)

THE SELECTION OF ESSENTIAL DRUGS

Report of a WHO Expert Committee

A WHO Expert Committee on the Selection of Essential Drugs met in Geneva from 17 to 21 October 1977. The meeting was opened on behalf of the Director-General by Dr Ch'en Wen-chieh, Assistant Director-General.

1. INTRODUCTION

In a report ¹ 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 of the most necessary drugs to those 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 health services of each country, and that 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, 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.

In October 1976, an informal consultation was convened in Geneva to advise the Director-General on the selection of essential drugs corresponding to health needs, keeping in mind the situation of developing countries where the main objective was to extend the primary health care coverage of the population. The report of this consultation ² was circulated for comments to the WHO Regional Offices, health adminis-

¹ WHO Official Records, No. 226, 1975, Annex 13, pp. 96-110.

² Unpublished WHO document DPM/76.1.

trators, experts and nongovernmental organizations in official relations with WHO. The comments received were analysed and made available to assist the Expert Committee in its deliberations. In addition, the following guidelines were proposed to the Expert Committee :

1. The extent to which countries implement schemes or establish lists of essential drugs is a national policy decision of each country.

2. As far as health services in developing countries are concerned, the organized procurement and use of essential drugs have many advantages in terms of economy and effectiveness. However, the concept of "essential drug lists" must accommodate a variety of local situations if the lists are ever to meet the real health needs of the majority of the population.

3. There are convincing justifications for WHO to propose "model" or "guiding" lists of essential drugs as a contribution to solving the problems of those Member States whose health needs far exceed their resources and which may find it difficult to initiate such an endeavour on their own.

4. Such "guiding" or "model" lists should be understood as a tentative identification of a "common core" of basic needs which has universal relevance and applicability. The further local needs move away from the core, the more the health authorities or specific sectors of the health services will have to adjust the lists. Therefore, any list proposed by WHO should set out to indicate priorities in drug needs, with the full understanding that exclusion does not imply rejection. A list of essential drugs does not imply that no other drugs are useful, but simply that in a given situation these drugs are the most needed for the health care of the majority of the population and, therefore, should be available at all times in adequate amounts and in the proper dosage forms.

5. The selection of essential drugs is a continuing process, taking into account changing priorities for public health action and epidemiological conditions, as well as progress in pharmacological and pharmaceutical knowledge. It should be accompanied by a concomitant effort in education, training and information of health personnel in the proper use of the drugs.

6. Finally, the WHO programme on essential drugs should furnish a focus for organized and systematic investigation of this approach.

Thus it will identify plans of action and research at the national and international level to meet unsatisfied basic health needs of populations which, at present, are denied access to the most essential prophylactic and therapeutic substances.

2. GENERAL CONSIDERATIONS

2.1 Statement of the problem

While drugs *alone* are not sufficient to provide adequate health care, they do play an important role in protecting, maintaining and restoring the health of people. In recent years, there has been a tremendous increase in the number of pharmaceutical products marketed ; however, there has not been a proportionate improvement in health.

Many pharmaceutical products are marketed with little concern for the differing health needs and priorities of individual countries. Promotional activities of the manufacturers have created a demand greater than the actual needs. Since up to 40% of the total health care budget in developing countries may be spent on drugs, the result has been an increase in the cost of health care or a reduction in funds available for other health services. The cost has affected even the affluent nations and their governments are increasingly worried by the rising expenditure on pharmaceutical products. In the developing countries, the problem is magnified by limited economic resources, shortage of trained health personnel, and lack of organized drug policies. In the least developed countries, where communicable diseases and lack of elementary health care are the major medical concerns, large segments of the population are in urgent need of essential drugs.

It is clear that for the optimal use of limited financial resources the available drugs must be restricted to those proven to be therapeutically effective, to have acceptable safety and to satisfy the health needs of the population. The selected drugs are here called "essential" drugs, indicating that they are of the utmost importance, and are basic, indispensable and necessary for the health needs of the population.¹

Drugs included in such a list would differ from country to country depending on many conditions, such as the pattern of prevalent diseases, the type of health personnel available, financial resources, and genetic, demographic and environmental factors.

¹ The definitions used by the Expert Committee for other terms found in this report are listed in section 11.

Because of the great differences between countries, the preparation of a drug list of uniform, general applicability and acceptability 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 notion that the number of necessary drugs is relatively small is supported by experience. Several developing countries that have adopted limited drug lists report good acceptance, as well as favourable medical and economic results. Lists and formularies with a limited number of drugs are also successfully used in many developed countries.

A limited list may not provide for the needs of every person but certainly should meet those of the vast majority. Whether or not drugs or pharmaceutical products outside the list are available in the private sector should be a local decision.

Limited drug lists have several advantages :

- (1) Reduction in the number of pharmaceutical products to be purchased, stored, analysed, and distributed ;
- (2) Improvement in the quality of drug utilization, management, information, and monitoring ;
- (3) Stimulation of local pharmaceutical industries ;
- (4) Assistance to the least developed countries in urgent need of high-priority drug programmes to solve their primary health care problems.

An effective programme of drug selection coupled with appropriate information and education may help to improve attitudes regarding the role of drugs in health and disease.

2.2 General principles for establishing a list of essential drugs

The following principles were considered by the Expert Committee to be a foundation on which to establish a list of essential drugs :

- (1) Adoption of a list of essential drugs is part of a national health policy. This implies that priority is given to achieving the widest possible coverage of the population with drugs of proven efficacy and safety, in order to meet the needs for prevention and treatment of the most prevalent diseases.

(2) Only those drugs for which adequate scientific data are available from controlled studies should be selected.

(3) Each selected pharmaceutical product must meet adequate standards of quality, including when necessary bioavailability.

(4) Concise, accurate and comprehensive drug information drawn from unbiased sources should accompany each list of essential drugs.

3. GUIDELINES FOR ESTABLISHING A LIST OF ESSENTIAL DRUGS

Criteria for the selection of essential drugs are intended to ensure that the process of selection will be unbiased and based on the best available scientific information, yet allow for a degree of variation to take into account local needs and requirements. The following guidelines are recommended :

(1) Each country should appoint a committee to establish a list of essential drugs. The committee should include individuals competent in the fields of clinical medicine, pharmacology and pharmacy, as well as peripheral health workers. Where individuals with adequate training are not available within the country, assistance from WHO could be sought.

(2) Drug selection should be based on the results of benefit and safety evaluations obtained in controlled clinical trials and/or epidemiological studies. Guidelines for such trials have been set forth in the report of a WHO Scientific Group.¹

(3) The international nonproprietary (generic) names for drugs or pharmaceutical substances should be used whenever available.² A cross-index of nonproprietary and proprietary names should initially be provided to the prescribers.

(4) Regulations and facilities should be available to ensure that the quality of selected pharmaceutical products meets adequate quality

¹ WHO Technical Report Series, No. 563, 1975.

² See *International nonproprietary names (INN) for pharmaceutical substances: Cumulative list No. 5*, Geneva, World Health Organization, 1977. Further lists of proposed and recommended INN are issued periodically as supplements to the *WHO Chronicle*; the latest lists of proposed INN (List 38) and of recommended INN (List 17) appeared as supplements to *WHO Chronicle*, 1977, Vol. 31, No. 9 and No. 10 respectively.

control standards, including stability and, when necessary, bioavailability. Where national resources are not available for this type of control, the suppliers should provide documentation of the product's compliance with the requested specifications.

(5) Cost represents a major selection criterion. In cost comparisons between drugs, the cost of the total treatment, and not only the unit cost, must be considered. In addition, the cost of nonpharmaceutical therapeutic modalities should be taken into account.

(6) Local health authorities should decide the level of expertise required to prescribe single drugs or a group of drugs in a therapeutic category. Consideration should also be given to the competence of the personnel to make a correct diagnosis. In some instances, while individuals with advanced training are necessary to prescribe initial therapy, individuals with less training could be responsible for maintenance therapy.

(7) The influence of local diseases or conditions on pharmacokinetic and pharmacodynamic parameters should be considered in making the selections : e.g., malnutrition, liver disease.

(8) When several drugs are available for the same indication, select the drug, pharmaceutical product and dosage form that provide the highest benefit/risk ratio.

(9) When two or more drugs are therapeutically equivalent, preference should be given to :

- (i) the drug which has been most thoroughly investigated ;
- (ii) the drug with the most favourable pharmacokinetic properties, e.g., to improve compliance, to minimize risk in various pathophysiological states ;
- (iii) drugs for which local, reliable manufacturing facilities for pharmaceutical products exist ;
- (iv) drugs, pharmaceutical products and dosage forms with favourable stability, or for which storage facilities exist.

(10) Fixed-ratio combinations are only acceptable if the following criteria are met :

- (i) clinical documentation justifies the concomitant use of more than one drug ;
- (ii) the therapeutic effect is greater than the sum of the effect of each ;
- (iii) the cost of the combination product is less than the sum of the individual products ;
- (iv) compliance is improved ;
- (v) sufficient drug ratios are provided to allow dosage adjustments satisfactory for the majority of the population.

(11) The list should be reviewed at least once a year and whenever necessary. New drugs should be introduced only if they offer distinct advantages over drugs previously selected. If new information becomes available on drugs already in the list which clearly shows that they no longer have a favourable benefit/risk ratio, they should be deleted and replaced by a safer drug. It should be remembered that for the treatment of certain conditions, nonpharmacological forms of therapy, or no therapy at all, may be preferable.

4. A MORE LIMITED LIST OF ESSENTIAL DRUGS FOR PRIMARY HEALTH CARE

In a number of countries, large segments of the population do not have ready access to health facilities, which tend to be oriented predominantly towards hospitals and urban areas. In an attempt to strengthen the health care system and achieve maximum population coverage with low-cost but effective and efficient health services, attention is being focused increasingly on the development of primary health care. This approach involves the use of health workers with minimum formal training to perform limited tasks at the community level.

Consequently, there is a need to identify the widest range of drugs that can be safely and adequately handled by this type of health worker. This implies the development of guidelines for further limited selection for primary health care from the list of essential drugs. Since there is a wide variation between countries in the quality and capabilities of primary health care workers, in drug policies and in disease prevalence, it was deemed impossible to prepare such a sublist at present, desirable as it would be. Therefore, the selection of drugs for this list should be made at the local level with whatever guidance WHO can provide.

5. EXAMPLES OF THE APPLICATION OF THE GUIDELINES BY THE EXPERT COMMITTEE

In the process of selecting drugs to be included in its model list of essential drugs, the Committee considered those lists already available from several countries. In addition, it reviewed and considered the hundreds of comments received in response to the report of the 1976 consultation referred to in section 1.

In deciding on the list of essential drugs, the Expert Committee had in many cases to exercise its judgement. Some examples are cited below.

1. Certain drugs capable of causing severe adverse effects, such as chloramphenicol, were included whereas others, such as phenylbutazone, were excluded. The consensus was that the benefit of chloramphenicol, when properly used, outweighed its risks whereas the same was not true for phenylbutazone, since other drugs were available with a better benefit/risk ratio. Clioquinol and noramidopyrine were excluded for similar reasons. The Expert Committee felt that life-saving drugs should not be denied to the population merely because they have a potential for misuse.

2. Very effective new drugs were considered for inclusion but not admitted because safety data on long-term use are lacking. Cimetidine, a new anti-ulcer drug, is an example.

3. The presence of a drug in a specific therapeutic category does not imply that the use of that drug alone is the only or even the proper therapy for that disorder. The prime example is the selection of codeine in the management of diarrhoeal states. The symptomatic relief provided by this drug is unquestionable. However, if improperly used in chronic inflammatory bowel disease or severe enteric infections, codeine may lead to toxic megacolon in the former case and prolongation of the duration of the disease in the latter. Symptomatic treatment should not replace accurate diagnosis and specific therapy whenever possible.

4. The Expert Committee was well aware of many drugs for the relief of nonspecific symptoms. In many instances, however, its deliberations were inhibited by the lack of diagnostic precision in such complaints and of scientific documentation of the efficacy and safety of the local remedies and medicinal plants used for these disorders.

5. Drugs belonging to a few widely used therapeutic classes have not been included in the list, e.g., topical ear, nose and throat preparations and oral antidiabetic drugs. When the guidelines adopted for

selection were applied, in the case of topical ear, nose and throat preparations, there was inadequate evidence of their value to support their inclusion. In the case of oral antidiabetic drugs, consideration of the benefit/risk ratio could not justify their inclusion.

6. DRUG INFORMATION AND EDUCATION ACTIVITIES

Information about drugs and pharmaceutical products is a prerequisite at all health care levels to ensure proper utilization and promote rational prescribing. These levels include: regulatory authorities; doctors; pharmacists; nurses and other paramedical personnel; and the consumer. The types of information required can be classified as: chemical and pharmaceutical; pharmacological; clinical; and economic.

The extent to which each type of information is required at different levels will vary. For example, regulatory authorities should have all existing data about a drug. In developing countries, however, such information is often not available. In addition, adequate manpower and expertise to evaluate the information are often lacking.

Accurate and objective information must be supplied for each drug in the essential list in a manner that is understandable to each level of prescriber. For each indication, diagnostic criteria should be provided whenever appropriate. The use of any drug without adequate knowledge may be dangerous. The inclusion of adequate and concise information with each product should allow the prescriber to obtain optimal effects while minimizing harmful effects. Since self-medication by the public is increasing, it is imperative that the information be available in a form which is understandable by individual users.

Education of health care professionals about drugs should begin early in their training and be continued not only throughout their formal training period, but throughout their entire professional life. Information should be gathered, analysed, collated and distributed by the committee which selects drugs for the essential list. In addition to that included with each product, information could be disseminated through such means as continuing education by regional training seminars, articles in medical journals, and newsletters. For the consumer, pamphlets, the mass media and posters can be used. To minimize bias, it will probably be necessary for these educational efforts to be supported by the government.

It is important that those with the greater training upgrade the knowledge of those with lesser training. For example, pharmacists

should continually inform consumers about the rational use of products as they are being dispensed.

Education about drugs must be directed towards the prescribers as well as the consumers. Both prescriber and consumer must be persuaded that, when therapeutically equivalent, the cheaper generic products are as effective as the more expensive proprietary name products. Education of the consumer is particularly important at the primary health care level where a significant proportion of drug usage will be by self-medication. Education of consumers should relieve their exaggerated fears of adverse effects of drugs as well as prevent unjustified expectations.

Model drug information sheet

Various types of information are needed by prescribers and consumers to obtain optimal utilization of drugs. The following is a sample which should be adjusted to the needs and abilities of the prescriber.

1. International nonproprietary name (INN) of each active substance
2. Pharmacological : brief description of pharmacological effects and mechanism of action ; relevant pharmacokinetic data
3. Clinical information :
 - 3.1 Indications : whenever appropriate, simple diagnostic criteria should be provided
 - 3.2 Contraindications
 - 3.3 Precautions (reference to pregnancy, lactation, etc.)
 - 3.4 Warnings
 - 3.5 Adverse effects (quantitate by category, if possible)
 - 3.6 Drug interactions (include only if clinically relevant ; be certain to include drugs used for self-medication)
 - 3.7 Dosage regimen :
 - 3.7.1 Average and range for adults and children
 - 3.7.2 Dosing interval
 - 3.7.3 Average duration of treatment
 - 3.7.4 Special situations, e.g., renal, hepatic, cardiac or nutritional insufficiencies which require either upward or downward dosage adjustments
 - 3.8 Overdosage :
 - 3.8.1 Brief clinical description of symptoms
 - 3.8.2 Non-drug treatment and supportive therapy
 - 3.8.3 Specific antidotes

4. Pharmaceutical information :
 - 4.1 Excipients
 - 4.2 Dosage forms available
 - 4.3 Strength of dosage forms
 - 4.4 Storage conditions and shelf life (expiration date)
 - 4.5 Package sizes
 - 4.6 Description of the product and package
 - 4.7 Legal category (narcotic, prescription or nonprescription)
 - 4.8 Name and address of manufacturer(s) and importer(s)

7. DRUG UTILIZATION SURVEYS

It has become increasingly evident that drugs are frequently not used to their full potential, nor according to generally accepted criteria. Little is known about the clinical consequences of the major differences that exist in prescribing patterns between countries and between regions within individual countries. The problem is complicated in general, in that drug utilization is not followed up systematically and comprehensively after the drugs have been marketed. Drug utilization data are required for selection committees to function optimally.

Drug utilization can and should be studied at various levels, depending on the purpose and the facilities available. Generally, the value of such studies may be considerably enhanced if they are made comparable by applying uniform methods (common drug classification system and units of measurement) in investigations in different regions and countries. The common methods should provide data on all relevant drugs in the particular therapeutic class, given in either cost or quantity parameters, and taking differences in therapeutic practice into consideration. The methods could be designed to quantitate the drug inventory only, or to evaluate drug utilization.

The objective of a drug utilization survey is to quantitate the present state, developmental trends and time course profiles of drug usage. This type of data can then be used : (1) to measure the effects of informational and regulatory measures, price policy, etc. ; (2) to define areas for further investigation on the absolute and relative efficacy and safety of drug therapy ; (3) to aid in the determination of benefit/risk and cost/effectiveness ; and (4) when properly interpreted, to indicate the overuse, underuse, or misuse of single drugs or therapeutic classes.

8. RESEARCH AND DEVELOPMENT

If the establishment of a list of essential drugs is to succeed in improving health and reducing drug costs in developing countries, utilization of the list should be either preceded by or developed together with supply and distribution systems and procurement procedures. To hasten self-reliance, research and development should be undertaken in the following areas.

8.1 Pharmaceutical

(1) Develop local or regional quality control facilities in order to ensure the quality of drugs on a continuing basis.

(2) Establish procurement procedures to take advantage of the benefits of purchasing in large quantities.

(3) Develop research capabilities to study dosage forms, particularly for vaccines and other heat-sensitive drugs.

(4) Develop facilities for processing simple dosage forms as a first step towards later manufacturing of raw materials. This will enable countries to optimize drug expenditure by reducing the cost of drugs and to be less dependent on imports of dosage forms.

(5) Develop an efficient country-wide distribution system with suitable trained personnel. This is to ensure that drugs of adequate quality are available at all times in sufficient quantity at appropriate places.

(6) Develop packaging of essential drugs to improve patient compliance and product stability.

8.2 Clinical

Develop the capabilities and expertise to carry out therapeutic trials in order to assess :

(1) the relative efficacy and safety of new as compared to essential drugs ;

(2) the benefits and safety of traditional medicines, including medicinal plants ;

(3) the effects of genetic and environmental differences among populations on pharmacokinetic, pharmacodynamic and therapeutic parameters.

8.3 Educational

- (1) Develop simple, concise labels for each dosage form ;
- (2) Develop appropriate public education and information programmes in diagnosis and self-medication for those conditions in which early recognition of symptoms and prompt self-medication are life-saving ;
- (3) Develop programmes for the training of personnel for pharmaceutical activities in such fields as quality control, formulation of policies, development of pharmaceutical information systems, procurement, production, storage and distribution procedures.

8.4 Regulatory

- (1) Develop controls of pharmaceutical product advertising in both the lay and scientific press.
-

9. MODEL LIST OF ESSENTIAL DRUGS ^a

Complementary ^b

Anaesthetics

General anaesthetics

ether, anaesthetic (2)
halothane (2)
nitrous oxide (2)
thiopental sodium (2)

Local anaesthetics

bupivacaine (2, 9)
lidocaine

Analgesics, antipyretics, nonsteroidal anti-inflammatory drugs and antigout drugs

acetylsalicylic acid	colchicine (7)
allopurinol (6)	
ibuprofen (1)	
indometacin	
paracetamol	

^a Numbers in parentheses following the drug names indicate :

- (1) Listed as an example of this therapeutic category : choose cheapest effective drug product acceptable ;
- (2) Specific expertise, diagnostic precision or special equipment required for proper use ;
- (3) Greater potency ;
- (4) Dosage adjustment necessary for renal insufficiency ;
- (5) To improve compliance ;
- (6) Best pharmacokinetic parameters for purpose ;
- (7) Adverse effects diminish benefit/risk ratio ;
- (8) Limited indications or narrow spectrum of activity ;
- (9) For epidural anaesthesia ;
- (10) For disease or organisms resistant to the proposed drug(s).

^b Drugs under this heading are not essential. They are added as examples of drugs that provide (a) alternatives when infectious organisms develop resistance to essential drugs, (b) treatment in rare disorders, and (c) special pharmacokinetic properties, etc. ; they should be available as funds permit.

Analgesics, narcotics and narcotic antagonists

morphine
naloxone

pethidine (1)

Antiallergics*Antihistamines*

chlorphenamine (1)

Antidotes, chelating agents, etc.

atropine
calcium disodium edetate (2)
charcoal, activated
dimercaprol (2)
pralidoxime

Antiepileptics

diazepam injection
ethosuximide
phenobarbital
phenytoin

carbamazepine (10)

Antiinfective drugs ^a*Anthelmintic drugs*

mebendazole
niclosamide
piperazine
tiabendazole

bephenium (8)
tetrachloroethylene

^a In its decisions about drugs listed in certain therapeutic classes—anthelmintics, antifilarials, antileprotics, antimalarials, antitrypanosomals, and antischistosomes—the Expert Committee referred to the corresponding WHO publications (see section 12: Bibliography). No evaluation has been made of the newer drugs at present being used in research programmes coordinated by WHO.

Antibacterial drugs

ampicillin (1)
benzathine benzylpenicillin (5)
benzylpenicillin

chloramphenicol (7)
cloxacillin (penicillinase-resistant, 1)
erythromycin
gentamicin (4)
phenoxymethylpenicillin
salazosulfapyridine
sulfadimidine (1)
sulfamethoxazole + trimethoprim
tetracycline (1, 4)

Antifilarial drugs

diethylcarbamazine
suramin

Antileprotic drugs

dapsone

Antiprotozoal drugs

Amoebicides

metronidazole

Antimalarials

chloroquine
primaquine
pyrimethamine
quinine

Antischistosomes

metrifonate
niridazole
oxamniquine

Complementary

amikacin (1, 4, 10)
doxycycline (6, 5)
procaine benzyl-
penicillin (7)
sulfadiazine (7, 8)

clofazimine (10)
rifampicin (10)

diloxanide
emetine (7)
paromomycin

amodiaquine (10)
sulfadoxine (10)

stibocaptate (10)

Antitrypanosomals

melarsoprol (5)
nifurtimox
pentamidine (5)
suramin

Leishmaniacides

pentamidine
sodium stibogluconate

Antituberculosis drugs

ethambutol
isoniazid
rifampicin
streptomycin

thioacetazone

Systemic antifungal drugs

amphotericin B
griseofulvin (8)

flucytosine (1, 8)

Antimigraine drugs

ergotamine

Antineoplastic drugs

busulfan (2)
chlormethine (1, 2)
cyclophosphamide (2)
doxorubicin (2)
fluorouracil (2)
methotrexate (2)
vincristine (2)

Antiparkinsonism drugs

levodopa

levodopa + peripheral
decarboxylase
inhibitor (6, 5)

trihexyphenidyl (1)

Blood and haematopoietic system drugs*Antianaemia drugs*

cyanocobalamin (2)

ferrous salt (1)

folic acid (2)

Anticoagulants and antagonists

heparin (2)

phytomenadione

protamine sulfate (2)

warfarin (1, 2, 6)

Plasma substitute

dextran 40

iron dextran
injection (5)**Cardiovascular drugs***Antianginal drugs*

glyceryl trinitrate

isosorbide dinitrate (1)

propranolol (1)

Antiarrhythmic drugs

lidocaine

procainamide

propranolol (1)

quinidine

Antihypertensive drugs

diazoxide injection (1)

guanethidine

hydralazine

hydrochlorothiazide (1)

propranolol (1)

Cardiac glycosides

digoxin (4)

Drugs used in shock

dopamine (2)

methyldopa (7)
phentolamine (1, 2, 8)
reserpine (7)

digitoxin

isoprenaline injection

Dermatological preparations*Topical**Antiinfective*

iodine (1)
neomycin + bacitracin

Antiinflammatory drugs

betamethasone (1, 3)
hydrocortisone

Astringents

aluminium acetate

Fungicides

miconazole (1)
nystatin

Keratoplastic agents

benzoic acid + salicylic acid podophyllin (7, 8)
coal tar

Scabicides and pediculicides

gamma benzene hexachloride benzyl benzoate

Diagnostic agents

edrophonium (2, 8)
tuberculin, purified protein
derivative (PPD)

Radiocontrast media

adipiodone meglumine (1)
barium sulfate (1)
iopanoic acid (1)
meglumine amidotrizoate (1)
sodium amidotrizoate (1)

Diuretics

furosemide
 hydrochlorothiazide (1)
 mannitol
 spironolactone

chlortalidone (6)
 triamterene (1)

Gastrointestinal drugs*Antacids*

aluminium hydroxide and/or magnesium hydroxide

Antiemetics

promethazine (1)

Antihaemorrhoidals

local anaesthetic, astringent, and antiinflammatory drug (1)

Antispasmodics

atropine (1)

Cathartics

senna (1)

*Diarrhoea**Antidiarrhoeal*

codeine

Replacement solution

oral rehydration salts (for glucose-salt solution for oral use)

For 1 litre of water :

sodium chloride (table salt)	3.5 g	Na ⁺	90
sodium bicarbonate (baking soda)	2.5 g	HCO ₃ ⁻	30
potassium chloride	1.5 g	K ⁺	20
glucose (dextrose)	20.0 g	glucose	111

Hormones*Adrenal hormones and synthetic substitutes*

dexamethasone (long-acting) (1)
 hydrocortisone
 prednisolone

fludrocortisone

Androgens

testosterone ester injection (2)

Estrogens

ethinylestradiol (1)

Insulins

compound insulin zinc suspension
 (lente) (1)
 insulin injection

Oral contraceptives

norethisterone + ethinylestradiol (1)

Progestogens

norethisterone (1)

Thyroid hormones and antagonists

levothyroxine
 potassium iodide
 propylthiouracil (1)

Immunologicals*Sera and immunoglobulins*

anti-D immunoglobulin
 antirabies hyperimmune serum
 diphtheria antitoxin
 immunoglobulin, normal human (2)
 snake antivenom
 tetanus antitoxin

Vaccines

BCG vaccine
diphtheria–tetanus vaccine
diphtheria–pertussis–tetanus vaccine
measles vaccine
poliovirus vaccine
rabies vaccine
smallpox vaccine
tetanus vaccine
typhoid vaccine

**Muscle relaxants (peripherally acting)
and antagonists**

neostigmine
suxamethonium (2)
tubocurarine (1,2)

pyridostigmine (2, 8)

Ophthalmological preparations

Topical

Antiinfective

silver nitrate
sulfacetamide
tetracycline (1)

Antiinflammatory

hydrocortisone (2, 7)

Local anaesthetics

tetracaine (1)

Miotics

pilocarpine

Mydriatics

homatropine (1)

Systemic

acetazolamide

Vitamins and minerals

ascorbic acid
calcium gluconate (2)
ergocalciferol
hexavitamin : retinol, ergocalciferol,
ascorbic acid, thiamine, riboflavin
and nicotinamide
pyridoxine
retinol

**ALPHABETICAL LIST OF ESSENTIAL AND
COMPLEMENTARY DRUGS ***

acetazolamide	cloxacillin (penicillinase-resistant)
acetylsalicylic acid	coal tar
adipiodone meglumine	codeine
allopurinol	colchicine *
aluminium acetate	compound insulin zinc suspension (lente)
aluminium hydroxide and/or magnesium hydroxide	cyanocobalamin
amikacin *	cyclophosphamide
aminophylline	
amitriptyline	dapsone
amodiaquine *	dexamethasone (long-acting)
amphotericin B	dextran 40
ampicillin	diazepam
anti-D immunoglobulin	diazepam injection
antihæmorrhoidal preparation : local	diazoxide injection
anaesthetic, astringent and	diethylcarbamazine
antiinflammatory drug	digitoxin *
antirabies hyperimmune serum	digoxin
ascorbic acid	diloxanide *
atropine	dimercaprol
	diphtheria antitoxin
bacitracin + neomycin	diphtheria-tetanus vaccine
barium sulfate	diphtheria-pertussis-tetanus vaccine
BCG vaccine	dopamine
benzathine benzylpenicillin	doxorubicin
benzoic + salicylic acid	doxycycline *
benzyl benzoate *	
benzylpenicillin	edrophonium
bephenium *	emetine *
betamethasone	ephedrine *
bupivacaine	epinephrine
busulfan	ergocalciferol
	ergotamine
calcium disodium edetate	ergometrine
calcium gluconate	erythromycin
carbamazepine *	ethambutol
charcoal, activated	ether, anaesthetic
chloramphenicol	ethinylestradiol
chlormethine	ethinylestradiol + norethisterone
chloroquine	ethosuximide
chlorphenamine	
chlorpromazine	ferrous salt
chlortalidone *	flucytosine *
clofazimine *	fludrocortisone *

* = complementary drug.

fluorouracil
 fluphenazine decanoate
 folic acid
 furosemide

 gamma benzene hexachloride
 gentamicin
 glucose (5% and 50%)
 glyceryl trinitrate
 griseofulvin
 guanethidine

 haloperidol
 halothane
 heparin
 hexavitamin : retinol, ergocalciferol,
 ascorbic acid, thiamine, riboflavin
 and nicotinamide
 homatropine
 hydralazine
 hydrochlorothiazide
 hydrocortisone

 ibuprofen
 immunoglobulin, human normal
 indometacin
 insulin injection
 intraperitoneal dialysis solution
 (1.5% glucose)
 iodine
 iopanoic acid
 iron dextran injection *
 isoniazid
 isoprenaline injection *
 isosorbide dinitrate

 levodopa
 levodopa + peripheral decarboxylase
 inhibitor *
 levothyroxine
 lidocaine
 lithium carbonate

 mannitol
 measles vaccine
 mebendazole
 meglumine amidotrizoate

melarsoprol
 methotrexate
 methyldopa *
 metrifonate
 metronidazole
 miconazole
 morphine

 naloxone
 neomycin + bacitracin
 neostigmine
 niclosamide
 nifurtimox
 niridazole
 nitrous oxide
 norethisterone
 norethisterone + ethinylestradiol
 nystatin

 oral rehydration salts (for glucose-salt
 solution for oral use)
 oxamniquine
 oxytocin

 paracetamol
 paromomycin *
 pentamidine
 pethidine *
 phenobarbital
 phenoxymethylpenicillin
 phentolamine *
 phenytoin
 phytomenadione
 pilocarpine
 piperazine
 podophyllin *
 poliovirus vaccine
 potassium chloride injection (15%)
 and oral solution
 potassium iodide
 pralidoxime
 prednisolone
 primaquine
 procainamide
 procaine benzylpenicillin *
 promethazine
 propranolol
 propylthiouracil

* = complementary drug.

protamine sulfate	sulfacetamide
pyridostigmine *	sulfadiazine *
pyridoxine	sulfadimidine
pyrimethamine	sulfadoxine *
	sulfamethoxazole + trimethoprim
quinine	suramin
quinidine	suxamethonium
rabies vaccine	testosterone ester injection
reserpine *	tetanus antitoxin
retinol	tetanus vaccine
rifampicin	tetracaine
	tetrachlorethylene *
salazosulfapyridine	tetracycline
salbutamol	thioacetazone *
senna	thiopental sodium
silver nitrate	tiabendazole
smallpox vaccine	triamterene *
snake antivenom	trihexyphenidyl
sodium amidotrizoate	trimethoprim + sulfamethoxazole
sodium bicarbonate	tuberculin, purified protein derivative
sodium chloride injection	tubocurarine
sodium lactate compound injection	typhoid vaccine
sodium stibogluconate	
spironolactone	vincristine
streptomycin	
stibocaptate *	warfarin
	water for injection

* = complementary drug.

10. RECOMMENDATIONS FOR THE DEVELOPMENT OF THE WHO PROGRAMME ON ESSENTIAL DRUGS

(1) The Expert Committee is convinced that health care can be considerably improved, in terms of both effectiveness and economy, through the selection of essential drugs; it therefore urges that this report be widely disseminated to Member States. WHO should cooperate, upon request, with countries desirous of establishing lists of essential drugs for health services, national committees for the selection of essential drugs, and quality assurance systems, as described in this report.

(2) WHO should undertake a periodic updating of the model list contained in this report, develop and disseminate adequate information

on each drug listed, and coordinate the transfer of information on the practical experience gained by the use of the list.

(3) WHO should promote, at regional and country levels, education and training activities in the proper use of essential drugs. Such activities—e.g., seminars or workshops—should be designed for specific categories of health personnel, from the health workers at the most peripheral level to the physicians at the central level, for hospital drug committees, and for the consumer.

(4) Support should be provided for collaborative clinical and epidemiological research on the use of essential drugs under different conditions in various countries in order to acquire new knowledge on their benefit/risk ratio and cost/effectiveness, particularly at primary health care level.

(5) For those countries whose needs for essential drugs exceed their financial and/or technical resources, WHO should consider the feasibility of an action programme of international cooperation aimed at extending the accessibility of these drugs to the largest possible segments of the population.

11. GLOSSARY OF TERMS USED IN THE REPORT

In its deliberations, the Expert Committee used the following definitions :

<i>Benefit/risk ratio</i>	The ratio of benefit to risk in the use of a drug ; a means of expressing a judgement concerning the role of the drug in the practice of medicine, based on efficacy and safety data along with consideration of misuse potential, severity and prognosis of the disease, etc. The concept may be applied to a single drug or in comparisons between two or more drugs used for the same indication.
<i>Bioavailability</i>	The rate and extent of absorption of a drug from a dosage form as determined by its concentration/ time curve in the systemic circulation or by its excretion in urine.
<i>Compliance</i>	Faithful adherence by the patient to the prescriber's instructions.

<i>Dosage form</i>	The form of the completed pharmaceutical product, e.g., tablet, capsule, elixir, suppository.
<i>Drug</i>	Any substance in a pharmaceutical product that is used to modify or explore physiological systems or pathological states for the benefit of the recipient.
<i>Drug formulation</i>	The composition of a dosage form, including the characteristics of its raw materials and the operations required to process it.
<i>Drug utilization</i>	The marketing, distribution, prescription and use of drugs in a society, with special emphasis on the resulting medical, social and economic consequences.
<i>Efficacy</i>	The ability of a drug to produce the purported effect as determined by scientific methods.
<i>Pharmaceutical product</i>	A dosage form containing one or more drugs along with other substances included during the manufacturing process.
<i>Therapeutic equivalence</i>	Pharmaceutical products which, when administered to the same individuals in the same regimen, will provide essentially the same efficacy and/or toxicity.

12. BIBLIOGRAPHY

WHO Technical Report Series

1. WHO Technical Report Series, No. 446, 1970 (*Clinical pharmacology. Scope, organization, training* : report of a WHO Study Group)
2. WHO Technical Report Series, No. 515, 1973 (*Schistosomiasis control* : report of a WHO Expert Committee)
3. WHO Technical Report Series, No. 524, 1973 (*Pharmacogenetics* : report of a WHO Scientific Group)
4. WHO Technical Report Series, No. 529, 1973 (*Chemotherapy of malaria and resistance to antimalarials* : report of a WHO Scientific Group)
5. WHO Technical Report Series, No. 536, 1974 (*Bioavailability of drugs : pharmacokinetic aspects* : report of a WHO Scientific Group)
6. WHO Technical Report Series, No. 542, 1974 (Third report of the WHO Expert Committee on Filariasis)

7. WHO Technical Report Series, No. 549, 1974 (Sixteenth report of the WHO Expert Committee on Malaria)
8. WHO Technical Report Series, No. 563, 1975 (*Guidelines for evaluation of drugs for use in man* : report of a WHO Scientific Group)
9. WHO Technical Report Series, No. 567, 1975 (Twenty-fifth report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations)
10. WHO Technical Report Series, No. 580, 1975 (*Control of nutritional anaemia with special reference to iron deficiency* : report of an IAEA/USAID/WHO Joint Meeting)
11. WHO Technical Report Series, No. 581, 1975 (Twentieth report of the WHO Expert Committee on Nonproprietary Names for Pharmaceutical Substances)
12. WHO Technical Report Series, No. 594, 1976 (Twenty-seventh report of the WHO Expert Committee on Biological Standardization)
13. WHO Technical Report Series, No. 605, 1977 (*Chemotherapy of solid tumours* : report of a WHO Expert Committee)
14. WHO Technical Report Series, No. 607, 1977 (Fifth report of the WHO Expert Committee on Leprosy)
15. WHO Technical Report Series, No. 610, 1977 (Twenty-eighth report of the WHO Expert Committee on Biological Standardization)

Other references

16. Davis, A. *Drug treatment in intestinal helminthiasis*, Geneva, World Health Organization, 1973
17. National drug policies. *WHO Chronicle*, 29 : 337-349 (1975)
18. Report of the Working Group on Rational Drug Therapy: Efficacy, Safety, Economy. Alexandria, WHO Regional Office for the Eastern Mediterranean, 1975 (document EM/PHARM/66)
19. Report of the Planning Group for Studies on Drug Utilization. Alexandria, WHO Regional Office for the Eastern Mediterranean, 1976 (document EM/PHARM/73)
20. World Health Organization. *Treatment and prevention of dehydration in diarrhoeal diseases. A guide for use at the primary level*, Geneva, 1976