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The use of essential drugs

Fourth report of the WHO
Expert Committee

World Health Organization
Technical Report Series
796



World Health Organization, Geneva 1990

WHO Library Cataloguing in Publication Data

WHO Expert Committee on the Use of Essential Drugs

The use of essential drugs: fourth report of the WHO Expert Committee.

(World Health Organization technical report series; 796)

I. Essential drugs I. Title II. Series

ISBN 92 4 120796 5
ISSN 0512-3054

(NLM Classification: QV 55)

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PRINTED IN SWITZERLAND

90/8500 - Schüler SA - 14 000

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Geneva, 27-30 November 1989

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THE USE OF ESSENTIAL DRUGS

Fourth report of the WHO Expert Committee

The WHO Expert Committee on the Use of Essential Drugs met in Geneva from 27 to 30 November 1989. The meeting was opened on behalf of the Director-General by Dr Hu Ching-Li, Assistant Director-General, who emphasized that the concept of essential drugs is fundamental both to WHO's revised drug strategy,¹ as endorsed by the World Health Assembly in resolution WHA39.27 in 1986,² and to the development of comprehensive national drug policies. Regular updating of WHO's Model List of Essential Drugs sustains the momentum of the revised drug strategy and is a basic element of the validated information required by most of WHO's Member States for optimal rationalization of drug procurement and supply.

The Expert Committee decided to prepare its report as a self-contained document and to incorporate into it parts of the previous report³ that require no modification or merely bringing up to date. The sixth list will be found in section 13 of this report, and explanations of the changes in section 14.

1. INTRODUCTION

In a report⁴ 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 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

¹ WHO document WHA39/1986/REC/1, Annex 5, pp. 93-101.

² *Handbook of resolutions and decisions of the World Health Assembly and Executive Board, Volume III, 1985-1989*, 2nd ed. Geneva, World Health Organization, 1990, p. 50.

³ WHO Technical Report Series, No. 770, 1988.

⁴ WHO Official Records, No. 226, 1975, Annex 13, pp. 96-110.

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. He also considered that adequate information on the properties, indications, and use of the drugs listed should be provided. By resolution WHA28.66,¹ 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.

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.² This was subsequently revised and updated in four further reports.³⁻⁶

In undertaking a further review of the list, the present Expert Committee has been guided throughout by the following statement contained in the previous reports:

Because of the great differences between countries, the preparation of a drug list of uniform, general applicability 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 Committee also draws attention to the following guidelines set out in the initial report:

(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

¹ *Handbook of resolutions and decisions of the World Health Assembly and Executive Board, Volume II, 1973-1984*. Geneva, World Health Organization, 1985, p. 129.

² WHO Technical Report Series, No. 615, 1977.

³ WHO Technical Report Series, No. 641, 1979.

⁴ WHO Technical Report Series, No. 685, 1983.

⁵ WHO Technical Report Series, No. 722, 1985.

⁶ WHO Technical Report Series, No. 770, 1988.

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 Member States whose health needs far exceed their resources and who 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. In certain situations, there is a need to make available additional drugs essential for rare diseases. 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. However, 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, which should take 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 to supply information and give education and training to health personnel in the proper use of the drugs.

(6) Finally, the WHO Action Programme on Essential Drugs should be a focal point 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. GUIDELINES FOR ESTABLISHING A NATIONAL PROGRAMME FOR ESSENTIAL DRUGS

Since the first report on the selection of essential drugs was published in 1977, the concept of essential drugs has become widely applied. It has provided a rational basis not only for drug procurement at national level but also for establishing drug requirements at various levels within the health care system. In fact, many developing countries have already selected essential drugs according to their needs and the related programmes are, in some cases, at an advanced stage of implementation.

In order to ensure that an essential drugs programme is adequately instituted at national level, several steps are advised:

(1) The establishment of a list of essential drugs, based on the recommendations of a local committee, is the starting-point of the programme. The committee should include individuals competent in the fields of medicine, pharmacology, and pharmacy, as well as peripheral health workers. Where individuals with adequate training are not available within the country, cooperation from WHO could be sought.

(2) The international nonproprietary (generic) names for drugs or pharmaceutical substances¹ should be used whenever available, and prescribers should be provided with a cross-index of non-proprietary and proprietary names.

(3) Concise, accurate, and comprehensive drug information should be prepared to accompany the list of essential drugs.

(4) Quality, including drug content, stability, and bioavailability, should be assured through testing or regulation, as discussed in section 8. Where national resources are not available for this type of control, the suppliers should provide documentation of the product's compliance with the required specifications.

(5) Local health authorities should decide the level of expertise required to prescribe individual drugs or a group of drugs in a therapeutic category. Consideration should be given, in particular, to the competence of the personnel to make a correct diagnosis. In some instances, while individuals with advanced training are

¹ See *International nonproprietary names (INN) for pharmaceutical substances: cumulative list no. 7*. Geneva, World Health Organization, 1988. Further lists of proposed and recommended INN are published periodically in *WHO drug information*.

necessary to prescribe initial therapy, individuals with less training could be responsible for maintenance therapy.

(6) The success of the entire essential drugs programme is dependent upon the efficient administration of supply, storage, and distribution at every point from the manufacturer to the end user. Government intervention may be necessary to ensure the availability of some drugs in the formulations listed, and special arrangements may need to be instituted for the storage and distribution of drugs that have a short shelf-life or require refrigeration.

(7) Efficient management of stocks is necessary to eliminate waste and to ensure continuity of supplies. Procurement policy should be based upon detailed records of turnover. In some instances, drug utilization studies may contribute to a better understanding of true requirements.

(8) Research, both clinical and pharmaceutical, is sometimes required to settle the choice of a particular drug product under local conditions.

3. CRITERIA FOR THE SELECTION 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.

The choice of such drugs depends on many factors, such as the pattern of prevalent diseases; the treatment facilities; the training and experience of the available personnel; the financial resources; and genetic, demographic, and environmental factors.

Only those drugs should be selected for which sound and adequate data on efficacy and safety are available from clinical studies and for which evidence of performance in general use in a variety of medical settings has been obtained.

Each selected drug must be available in a form in which adequate quality, including bioavailability, can be assured; its stability under the anticipated conditions of storage and use must be established.

Where two or more drugs appear to be approximately similar in the above respects, the choice between them should be made on the basis of a careful evaluation of their relative efficacy, safety, quality, price, and availability. In cost comparisons between drugs, the cost of the total treatment, and not only the unit cost of the drug, must

be considered. Cost is a major consideration in the choice of some drugs for the list. In some cases the choice may also be influenced by other factors, such as comparative pharmacokinetic properties, or by local considerations such as the availability of facilities for manufacture or storage.

Most essential drugs should be formulated as single compounds. Fixed-ratio combination products are acceptable only when the dosage of each ingredient meets the requirements of a defined population group and when the combination has a proven advantage over single compounds administered separately in therapeutic effect, safety, or compliance.

4. GUIDELINES FOR THE SELECTION OF PHARMACEUTICAL DOSAGE FORMS

The purpose of selecting dosage forms and strengths for the drugs in the model list is to provide guidance to countries wishing to standardize or minimize the number of preparations in their own drug lists. As a general rule, pharmaceutical forms are selected on the basis of their general utility and their wide availability internationally. In many instances, a choice of preparations is provided, particularly in relation to solid dosage forms. Tablets are usually less expensive than capsules but, while cost should be taken into account, the selection should also be based on a consideration of pharmacokinetics, bioavailability, stability under ambient climatic conditions, availability of excipients, and established local preference.

In a few instances where there is no uniformity of tablet strength, for example acetylsalicylic acid and paracetamol, a dosage range is provided from within which suitable tablet strengths should be selected on the basis of local availability and need. When precise dosage is not mandatory, the use of scored tablets is recommended as a simple method of making dosage more flexible if so required and, in some instances, to provide a convenient paediatric dose. Specific paediatric dosages and formulations are included in the list only when dictated by special circumstances. In many instances, dosage is specified in terms of a selected salt or ester, but in others

—for example chloroquine—it is calculated, in accordance with common practice, in terms of the active moiety.

5. RESERVE ANTIMICROBIALS AND MONITORING RESISTANCE

The increasing prevalence of strains of common pathogenic bacteria resistant to widely available, relatively cheap antimicrobials included in the model list is dangerously eroding their effectiveness. The need for more systematic and coordinated international approaches to laboratory monitoring of antimicrobial sensitivity is important and urgent. It has already been emphasized that reference laboratories are needed in developing as well as in developed countries in order to monitor the resistance of important bacterial pathogens.^{1, 2} Knowledge of prevailing sensitivity patterns is vital to the proper selection and use of antimicrobials and to the development of appropriate prescribing policies. Without these data the health of seriously ill patients could be jeopardized.

It is becoming increasingly common for important pathogens to emerge in a country or locality that are shown, on sensitivity testing, to have developed resistance to all normally appropriate essential drugs. In these circumstances a reserve antimicrobial is needed. A reserve antimicrobial may be useful in a wide range of infections, but in order to reduce the risk of development of resistance and because of its relatively high cost, it would be inappropriate to recommend its unrestricted use.

The concept of reserve antimicrobials is only of practical relevance when information is available on the prevailing sensitivities of important bacterial pathogens. Within this context the third-generation cephalosporins, the quinolones, and vancomycin are most important.

There are many third-generation cephalosporins. Some are suitable for the treatment of bacterial meningitis or severe pneumonia, particularly in children, where there is evidence that some strains of *Haemophilus influenzae* type b are resistant to chloramphenicol.

¹ *Surveillance of antimicrobial resistance. Report of a WHO Consultation.* Geneva, World Health Organization, 1982 (unpublished document BVI/PHA/ANT/82.2). Available on request from Pharmaceuticals, World Health Organization, Geneva, Switzerland.

² WHO Scientific Working Group. Antimicrobial resistance. *Bulletin of the World Health Organization*, **61**: 383–394 (1983).

Some will also cure gonorrhoea and chancroid. However, they should be used for gonorrhoea only where strains resistant to penicillin and spectinomycin are prevalent, and for chancroid only where there is a high prevalence of *Haemophilus ducreyi* strains resistant to tetracyclines and trimethoprim/sulfamethoxazole.

Ciprofloxacin is an example of a widely used member of the quinolone family of antimicrobial agents, but the comparative costs of alternative broad-spectrum products will be an important determinant of selection. Certain other quinolones are of value as reserve agents, particularly in the following circumstances:

- (a) For typhoid fever and other systemic salmonella infections where there are strains of *Salmonella* resistant to chloramphenicol, amoxicillin, and trimethoprim/sulfamethoxazole.
- (b) For severe shigellosis with *Shigella* spp strains that are resistant to the above three antimicrobials and to tetracyclines.
- (c) For gonorrhoea and chancroid, as alternatives to cephalosporins, when oral administration is appropriate.
- (d) For hospital-acquired infections due to Gram-negative bacilli, including *Escherichia coli*, *Klebsiella* spp, and *Pseudomonas aeruginosa*, that are resistant to essential drugs such as amoxicillin, tetracyclines, piperacillin, chloramphenicol, and gentamicin.

Meticillin-resistant *Staphylococcus aureus* strains are resistant to all beta-lactam antimicrobials and usually also to unrelated drugs such as erythromycin, clindamycin, chloramphenicol, the tetracyclines, and the aminoglycosides. The only effective reserve drug for infections due to these multiresistant organisms is vancomycin, which is expensive and must be given intravenously.

6. APPLICATIONS OF THE ESSENTIAL-DRUGS CONCEPT

The concept of essential drugs has been endorsed unanimously by the World Health Assembly. It is intended to be flexible and adaptable to many different situations; exactly which drugs are regarded as essential remains a national responsibility.

The concept of essential drugs has been disseminated and promoted extensively at the country level by WHO's Action

Programme on Essential Drugs as well as by bilateral agencies. The wide applicability of the concept is now evident from experience gained in many countries. Most national lists of essential drugs are stratified to reflect requirements at different levels within the health care infrastructure. Typically, a very short list has been compiled for community health workers while the most comprehensive lists have been reserved for large urban and regional hospitals. Many countries have also successfully applied the concept to teaching hospitals and facilities providing specialized care. The concept has also been applied in the dissemination of drug information.

The model list has been adopted by many international and bilateral agencies which now include drug supply and the rationalization of drug use in their health care programmes. Adoption of the list has resulted in greater international co-ordination in health care development, and it is also being used to evaluate whether drug donations are appropriate in a given situation.

A shorter, adapted list has proved to be of particular value in emergency situations. It is contained in an emergency health kit,¹ designed to cover the basic needs of a population of 10 000 for a period of about 3 months, which has been developed and updated by WHO, the Office of the United Nations High Commissioner for Refugees, UNICEF, *Médecins sans frontières*, the League of Red Cross and Red Crescent Societies, the Christian Medical Commission, and several other nongovernmental organizations. Many non-profit suppliers maintain a stock of most of the drugs on the list, which allows a rapid response to demand.

7. ESSENTIAL DRUGS AND PRIMARY HEALTH CARE

It cannot be emphasized too strongly that, in practice, the selection of drugs for primary health care must be determined nationally since the training and responsibilities of the personnel charged to administer this care vary considerably. Highly trained workers are able to use a wide range of drugs appropriate to their

¹ *The new emergency health kit. Lists of drugs and medical supplies for a population of 10 000 persons for approximately 3 months.* Geneva, World Health Organization, 1990 (unpublished WHO document DAP/90.1). Available on request from Action Programme on Essential Drugs, World Health Organization, Geneva, Switzerland.

diagnostic skills with acceptable safety, and decisions about the availability of specific drugs can be made only when all relevant local factors have been taken into account. The following considerations will inevitably influence the compilation of such drug lists.

(1) *Existing systems of medicine.* The establishment of primary health care services in developing countries should not result in abrupt disruption of prevailing cultural patterns in rural communities. The work of traditional healers, for example, should be adapted and supplemented so as to ensure that innovation is successfully integrated into existing systems of care.

(2) *The national health infrastructure.* The type of primary health care service that a country requires is dependent upon the proximity and nature of the first referral facilities. It is still not unusual in some countries for the nearest permanently staffed health post to be a day's travelling time or more from isolated villages in its catchment area.

(3) *Training and supplies.* The numbers of trained personnel, the facilities placed at their disposal, and the supplies entrusted to them determine both the scope and the limitations of the primary health care system. Workers with one or more years' vocational training can obviously accomplish more than personnel reliant upon an intensive course of practical instruction lasting only a few weeks. But, whatever the circumstances, little can be accomplished unless continuity of essential supplies and information is assured.

(4) *The pattern of endemic disease.* The prevalence of major endemic infections and parasitic diseases may vary from region to region within a country in conformity with climatic, geographical, topographical, social, economic, and occupational factors. Careful planning and, in some cases, epidemiological surveys are required to ensure that the most effective drugs are provided, and to obtain full benefit from limited resources.

8. QUALITY ASSURANCE

Quality assurance of drugs, as embodied in good manufacturing practice and subsequent monitoring of quality through to utilization, is a crucial element in any essential drugs programme. All aspects of these procedures have been dealt with *in extenso* in the twenty-sixth to thirty-first reports of the WHO

Expert Committee on Specifications for Pharmaceutical Preparations.¹⁻⁶

Priority should be given to ensuring that the available drugs have been made according to Good Manufacturing Practices⁷ and are of generally recognized quality. This requires knowledge of and confidence in the origin of the product. The risks of procuring drugs from anonymous sources cannot be overstressed. It is recommended that drugs are purchased directly from known manufacturers, their duly accredited agents, or recognized international agencies known to apply high standards in selecting their suppliers.

Developing countries with inadequate laboratory facilities for drug analysis may be unable to carry out the process of quality assurance. In this connection, the Committee would emphasize the importance of WHO's Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.⁶ This has been available since 1975 as a means of exchanging information between regulatory authorities in importing and exporting countries. Its purposes are:

1. To provide assurance that a given product has been authorized to be placed on the market in the exporting country, and, if not, to explain why authorization has been withheld.

2. To provide assurance that the plant in which the product is manufactured is subject to inspections at suitable intervals and conforms to the requirements for good practices in the manufacture and quality control of drugs, as recommended by WHO.

3. To provide for exchange of information on the implementation of inspections and controls by the authorities in the exporting country. In the case of serious quality defects inquiries may also be made.

¹ WHO Technical Report Series, No. 614, 1977.

² WHO Technical Report Series, No. 645, 1980.

³ WHO Technical Report Series, No. 681, 1982.

⁴ WHO Technical Report Series, No. 704, 1984.

⁵ WHO Technical Report Series, No. 748, 1987.

⁶ WHO Technical Report Series, No. 790, 1990.

⁷ *Certification scheme on the quality of pharmaceutical products moving in international commerce and text of good manufacturing practices (GMP)*. Geneva, World Health Organization, 1987 (unpublished document PHARM/82.4 Rev. 3). Available on request from Pharmaceuticals, World Health Organization, Geneva, Switzerland.

In 1988 the scope of the certification scheme was extended, in accordance with World Health Assembly resolution WHA41.18,¹ to provide for a more comprehensive exchange of information between governments. Drug substances as well as finished dosage forms were included within the scheme and provision was made for the exchange of officially approved, product-specific prescribing information on the safety and efficacy of finished products.

The Committee wishes to encourage national authorities to issue certificates in precise conformity with the format proposed by WHO in order to ensure that clear details are given about a product's place of manufacture or assembly, and whether or not WHO's standards of good manufacturing practice have been applied. Countries that have not already done so are urged to extend the system of licensing to manufacturers of pharmaceutical products destined exclusively for export. The licensing system should ensure that these manufacturers are subject to inspection, that they comply with internationally recognized requirements for good manufacturing practices, and that every reasonable precaution is taken to ensure that the quality of their products meets pharmacopoeial specifications.

Poor bioavailability is a particular problem for products of low solubility or narrow therapeutic index. It can result in inadequate drug absorption and thus treatment failure just as readily as products deficient in active ingredients. The bioavailability of essential drugs should continue to receive consideration since it is a key factor in quality assurance.

The Committee appreciates that the development of the Model List of Essential Drugs has provided a natural focus for the third edition of *The International Pharmacopoeia*,² thus enhancing its potential value to developing countries. Essential drugs are accorded priority and all quality specifications are supported by classical methods of testing and analysis. A plan for a small quality control laboratory in which most of these tests can be performed has been available since 1984.³ Since quality assurance of essential drugs is so important, the Committee recommends the setting up of such laboratories to national governments and the adoption of

¹ WHO Technical Report Series, No. 790, 1990, Annex 5.

² *The International Pharmacopoeia*, third edition. Geneva, World Health Organization, Vol. 1, 1979; Vol. 2, 1981; Vol. 3, 1988.

³ WHO Technical Report Series, No. 704, 1984.

The International Pharmacopoeia by those countries currently lacking the means to confirm independently the quality of the supplies they procure. In this context, attention is also drawn to the WHO publication *Basic tests for pharmaceutical substances*,¹ which enables the identity of drug substances to be verified and gross degradation to be excluded when laboratory facilities for full pharmacopoeial analyses are not available.

The Committee emphasizes the need to extend the coverage of *The International Pharmacopoeia* to include not only essential drug substances, but also the dosage forms specified in the Model List of Essential Drugs, together with additional information on bioavailability, stability, and recommended packaging and storage conditions.

9. DRUG SURVEYS

Little is known about the clinical consequences of different prescribing patterns between countries or between regions within a country. There are few systematic and comprehensive data on the utilization of drugs after they have been marketed, but it is recognized that they are frequently not used to their full potential or in accordance with generally accepted criteria. Furthermore, many drugs can produce serious adverse effects. It is important, whenever feasible, to quantify these risks in order to identify the safest available products and to remove from the market those that are unacceptably dangerous. Such information is essential if drug selection committees are to function optimally.

Depending on their purpose and the facilities available, drug surveys can be carried out at various levels. Their value is enhanced by using standard procedures (common drug classification systems and units of measurement) in different regions and countries. These procedures should be used to provide data on all relevant drugs in a particular therapeutic class, paying attention to both cost and quantities prescribed, and taking differences in therapeutic practice into consideration.

The basic objective of drug surveys is to quantify present usage and possible future demands. Studies can be designed to quantify the drug inventory only or to evaluate drug utilization. Data can also be

¹ *Basic tests for pharmaceutical substances*. Geneva, World Health Organization, 1986.

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 individual drugs or therapeutic classes of drugs.

Highly evolved national drug regulatory authorities are increasing their investment in post-marketing surveillance. This is expensive and calls for sustained international collaboration. For many years the WHO Collaborating Centre on International Drug Monitoring has collated the reports of the national monitoring schemes of some thirty industrialized countries and, more recently, WHO has collaborated with the Council for International Organizations of Medical Sciences to promote epidemiologically based methods of monitoring.

The ability of most developing countries to carry out such studies is limited by cost. Nevertheless, when concern arises over the safety of a drug used exclusively for a tropical disease, the need for post-marketing surveillance is as great as in any other situation. Such surveillance may require the establishment of special reporting facilities and, exceptionally, small follow-up studies of persons exposed to specific drugs may be necessary.

10. RESEARCH AND DEVELOPMENT

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

Pharmaceutical aspects

- (1) Development of local or regional quality control facilities in order to ensure that drug quality is maintained.
- (2) Development of procurement procedures to take advantage of the benefits of purchasing large quantities of drugs.
- (3) Development of facilities for processing and packaging simple dosage forms, and ensuring the quality of the product.

(4) Development of an efficient countrywide distribution system with suitably trained personnel.

Clinical aspects

Development of facilities and expertise to carry out therapeutic trials in order to assess:

- the relative efficacy and safety of new candidate compounds for inclusion in an essential drugs list;
- the benefits and safety of traditional medicines, including medicinal plants; and
- the effects of genetic and environmental differences among populations on pharmacokinetic, pharmacodynamic, and therapeutic parameters.

Educational aspects

- (1) Development of simple, concise labels for each dosage form.
- (2) Development of training programmes in policy formulation, quality control, development of pharmaceutical information systems, procurement, production, storage, and distribution procedures.
- (3) Development of appropriate public education and information programmes in diagnosis and self-medication for conditions for which early recognition of symptoms and prompt self-medication are crucial.

11. DRUG INFORMATION AND EDUCATION

For the safe, effective, and prudent use of essential drugs, relevant and reliable drug information should be available. In order to provide this, a series of publications entitled *WHO Model Prescribing Information* is being prepared. Of the first two titles, *Drugs used in anaesthesia*¹ has already been published and *Drugs used in parasitic diseases*² will appear shortly. Further titles are in

¹ *WHO model prescribing information: drugs used in anaesthesia*. Geneva, World Health Organization, 1989.

² *WHO model prescribing information: drugs used in parasitic diseases*. Geneva, World Health Organization, 1990.

preparation. The Committee supports with great enthusiasm the provision of model prescribing information and urges that it receives high priority within WHO.

Health care professionals should receive education about the use of drugs not only during their preliminary training but throughout their entire professional careers. The more highly trained individuals should assume a responsibility to educate those with less training. In particular, pharmacists should accept every opportunity to inform consumers about the rational use of products at the time they are dispensed.

Drug information sheets

The following is an example of a format for supplying information to facilitate the safe and effective use of drugs to prescribers and consumers. The content should be adjusted to the needs, knowledge, and responsibilities of the prescriber.

- (1) International Nonproprietary Name (INN) of each active substance.
- (2) Pharmacological data: a brief description of pharmacological effects and mechanism of action.
- (3) Clinical information:
 - (a) Indications: whenever appropriate, simple diagnostic criteria should be provided.
 - (b) Dosage regimen and relevant pharmacokinetic data:
 - average and range for adults and children;
 - dosing interval;
 - average duration of treatment;
 - special situations, e. g., renal, hepatic, cardiac, or nutritional insufficiencies that require either increased or reduced dosage.
 - (c) Contraindications.
 - (d) Precautions and warnings (reference to pregnancy, lactation, etc.).
 - (e) Adverse effects (quantify by category, if possible).
 - (f) Drug interactions (include only if clinically relevant; drugs used for self-medication should be included).
 - (g) Overdosage:
 - brief clinical description of symptoms;
 - non-drug treatment and supportive therapy;
 - specific antidotes.

- (4) Pharmaceutical information:
- (a) Dosage forms.
 - (b) Strength of dosage form.
 - (c) Excipients.
 - (d) Storage conditions and shelf-life (expiry date).
 - (e) Pack sizes.
 - (f) Description of the product and package.
 - (g) Legal category (narcotic or other controlled drug, prescription or nonprescription).
 - (h) Name and address of manufacturer(s) and importer(s).

12. UPDATING OF LISTS OF ESSENTIAL DRUGS

An essential drug list must be flexible enough to accommodate, as necessary, new drugs, new information on established drugs, and changes in the status of internationally controlled substances. Experience with the original model list and the subsequent revisions, as well as with regional and national lists of essential drugs, has confirmed the need for regular review and updating. Revision is necessary not only because of advances in drug therapy but also in order to meet the needs of practice in the light of experience. Frequent and extensive changes are clearly undesirable since they result in disruption of channels of procurement and distribution and may have implications for the training of health personnel. For this reason a number of drugs have been retained on the model list that have been largely superseded in countries where there is a more extensive range of new medicaments, but that are still used widely and successfully elsewhere.

13. MODEL LIST OF ESSENTIAL DRUGS

(Sixth List)

Explanatory Notes¹

Many drugs included in the list are preceded by a square symbol (□) to indicate that they represent an *example of a therapeutic group*

¹ The drug sections and subsections in the model list appear in English alphabetical order and have no formal significance.

and that various drugs could serve as alternatives. It is imperative that this is understood when drugs are selected at national level, since choice is then influenced by the comparative cost and availability of equivalent products. Examples of acceptable substitutions include:

- Codeine: other drugs for the symptomatic treatment of diarrhoea in adults, such as loperamide or, when indicated for cough relief, dextromethorphan.
- Hydrochlorothiazide: any other thiazide-type diuretic currently in broad clinical use.
- Hydralazine: any other peripheral vasodilator having an antihypertensive effect.
- Senna: any mild stimulant laxative (either synthetic or of plant origin).
- Sulfadimidine: any other short-acting, systemically active sulfonamide unlikely to cause crystalluria.

Numbers in parentheses after the drug names indicate:

- (1) Drugs subject to international control under (a) the Single Convention on Narcotic Drugs, 1961,¹ (b) the Convention on Psychotropic Substances, 1971,² or (c) the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.³
- (2) Specific expertise, diagnostic precision, or special equipment required for proper use.
- (3) Greater potency or efficacy.
- (4) In renal insufficiency, contraindicated or dosage adjustments necessary.
- (5) To improve compliance.
- (6) Special pharmacokinetic properties for purpose.
- (7) Adverse effects diminish benefit/risk ratio.
- (8) Limited indications or narrow spectrum of activity.
- (9) For epidural anaesthesia.

Letters in parentheses after the drug names indicate the reasons for the inclusion of *complementary drugs*:

- (A) When drugs in the main list cannot be made available.
- (B) When drugs in the main list are known to be ineffective or inappropriate for a given individual.
- (C) For use in rare disorders or in exceptional circumstances.

¹ *Single convention on narcotic drugs, 1961*. New York, United Nations, 1977.

² *Convention on psychotropic substances, 1971*. New York, United Nations, 1977.

³ *Convention against illicit traffic in narcotic drugs and psychotropic substances, 1988*. New York, United Nations, 1988.

<i>Main list</i>	<i>Complementary list</i>	<i>Route of administration, dosage forms, and strengths*</i>
1. Anaesthetics		
1.1 General anaesthetics and oxygen		
diazepam (1b, 2)		injection, 5 mg/ml in 2-ml ampoule
ether, anaesthetic (2)		inhalation
halothane (2)		inhalation
ketamine (2)		injection, 50 mg (as hydrochloride)/ml in 10-ml vial
nitrous oxide (2)		inhalation
oxygen		inhalation (medicinal gas)
<input type="checkbox"/> thiopental (2)		powder for injection, 0.5 g, 1.0 g (sodium salt) in ampoule
1.2 Local anaesthetics		
<input type="checkbox"/> bupivacaine (2, 9)		injection, 0.25%, 0.5% (hydrochloride) in vial injection for spinal anaesthesia, 0.5% (hydrochloride) in 4-ml ampoule to be mixed with 7.5% glucose solution
<input type="checkbox"/> lidocaine		injection, 1%, 2% (hydrochloride) in vial injection, 1%, 2% + epinephrine 1:200 000 in vial injection for spinal anaesthesia, 5% (hydrochloride) in 2-ml ampoule to be mixed with 7.5% glucose solution topical forms, 2–4% (hydrochloride) dental cartridge, 2% (hydrochloride) + epinephrine 1:80 000
1.3 Preoperative medication		
atropine		injection, 1 mg (sulfate) in 1-ml ampoule
chloral hydrate		syrup, 200 mg/5 ml
<input type="checkbox"/> diazepam (1b)		injection, 5 mg/ml in 2-ml ampoule
<input type="checkbox"/> morphine (1a)		injection, 10 mg (sulfate or hydrochloride) in 1-ml ampoule
<input type="checkbox"/> promethazine		elixir or syrup, 5 mg (hydrochloride)/5 ml
2. Analgesics, Antipyretics, Nonsteroidal Anti-inflammatory Drugs, and Drugs Used to Treat Gout		
2.1 Non-opioids		
acetylsalicylic acid		tablet, 100–500 mg suppository, 50–150 mg
allopurinol (4)		tablet, 100 mg
colchicine (7)		tablet, 500 µg
<input type="checkbox"/> ibuprofen		tablet, 200 mg

*When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

2. Analgesics, Antipyretics, Nonsteroidal Anti-inflammatory Drugs, and Drugs Used to Treat Gout (continued)

2.1 Non-opioids (continued)

<input type="checkbox"/> indometacin	capsule or tablet, 25 mg
paracetamol	tablet, 100–500 mg suppository, 100 mg syrup, 125 mg/5 ml

2.2 Opioid analgesics

<input type="checkbox"/> codeine (1a)	tablet, 30 mg (phosphate)
<input type="checkbox"/> morphine (1a)	injection, 10 mg (sulfate or hydrochloride) in 1-ml ampoule oral solution, 10 mg/5ml tablet, 10 mg (sulfate)
<input type="checkbox"/> pethidine (A) (1a, 4)	injection, 50 mg (hydrochloride) in 1-ml ampoule tablet, 50 mg, 100 mg (hydrochloride)

3. Antiallergics and Drugs Used in Anaphylaxis

<input type="checkbox"/> chlorphenamine	tablet, 4 mg (hydrogen maleate) injection, 10 mg (hydrogen maleate) in 1-ml ampoule
<input type="checkbox"/> dexamethasone	tablet, 500 µg, 4 mg injection, 4 mg (as sodium phosphate) in 1-ml ampoule
epinephrine	injection, 1 mg (as hydrochloride) in 1-ml ampoule
hydrocortisone	powder for injection, 100 mg (as sodium succinate) in vial
<input type="checkbox"/> prednisolone	tablet, 5 mg

4. Antidotes and Other Substances Used in Poisonings

4.1 General

<input type="checkbox"/> charcoal, activated	powder
ipecacuanha	syrup, containing 0.14% ipecacuanha alkaloids calculated as emetine

4.2 Specific

atropine	injection, 1 mg (sulfate) in 1-ml ampoule
deferoxamine	powder for injection, 500 mg (mesilate) in vial

*When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

<i>Main list</i>	<i>Complementary list</i>	<i>Route of administration, dosage forms, and strengths*</i>
4. Antidotes and Other Substances Used in Poisonings (continued)		
4.2 Specific (continued)		
dimercaprol (2)		injection in oil, 50 mg/ml in 2-ml ampoule
<input type="checkbox"/> methionine		tablet, 250 mg (racemate)
methylthioninium chloride (methylene blue)		injection, 10 mg/ml in 10-ml ampoule
naloxone		injection, 400 µg (hydrochloride) in 1-ml ampoule
penicillamine (2)		capsule or tablet, 250 mg
potassium ferric hexacyanoferrate(II)·2H ₂ O (Prussian blue)		powder for oral administration
sodium calcium edetate (2)		injection, 200 mg/ml in 5-ml ampoule
sodium nitrite		injection, 30 mg/ml in 10-ml ampoule
sodium thiosulfate		injection, 250 mg/ml in 50-ml ampoule

5. Antiepileptics

carbamazepine		scored tablet, 100 mg, 200 mg
<input type="checkbox"/> diazepam (1b)		injection, 5 mg/ml in 2-ml ampoule (intravenous or rectal)
ethosuximide		capsule or tablet, 250 mg
		syrup, 250 mg/5 ml
phenobarbital (1b)		tablet, 15–100 mg
		elixir, 15 mg/5 ml
phenytoin		capsule or tablet, 25 mg, 100 mg (sodium salt)
		injection, 50 mg (sodium salt)/ml in 5-ml vial
valproic acid (7)		enteric coated tablet, 200 mg, 500 mg (sodium salt)

6. Anti-infective Drugs

6.1 Anthelmintic drugs

6.1.1 Intestinal anthelmintics

levamisole (8)		tablet, 50 mg, 150 mg (as hydrochloride)
<input type="checkbox"/> mebendazole		chewable tablet, 100 mg
niclosamide		chewable tablet, 500 mg
piperazine		tablet, 500 mg hydrate (as adipate or citrate)
		elixir or syrup (as citrate) equivalent to 500 mg hydrate/5 ml
praziquantel		tablet, 150 mg, 600 mg

*When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

6. Anti-infective Drugs (continued)

6.1 Anthelmintic drugs (continued)

6.1.1 Intestinal anthelmintics (continued)

pyrantel		chewable tablet, 250 mg (as embonate) oral suspension, 50 mg (as embonate)/ml
tiabendazole		chewable tablet, 500 mg lotion, 500 mg/5 ml

6.1.2 Specific anthelmintics

albendazole ^b		chewable tablet, 200 mg
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6.1.3 Antifilarials

diethylcarbamazine		tablet, 50 mg (dihydrogen citrate)
ivermectin		scored tablet, 6 mg
suramin sodium (2, 7)		powder for injection, 1 g in vial

6.1.4 Antischistosomes

metrifonate		tablet, 100 mg
oxamniquine		capsule, 250 mg
praziquantel		syrup, 250 mg/5 ml tablet, 600 mg

6.2 Antibacterials

6.2.1 Penicillins

<input type="checkbox"/> amoxicillin (4)		capsule or tablet, 250 mg, 500 mg (anhydrous) powder for oral suspension, 125 mg (anhydrous)/5 ml
ampicillin (4)		powder for injection, 500 mg (as sodium salt) in vial
benzathine benzylpenicillin (5)		powder for injection, 1.44 g benzylpenicillin (= 2.4 million IU) in 5-ml vial
benzylpenicillin		powder for injection, 600 mg (= 1 million IU), 3 g (= 5 million IU) (as sodium or potassium salt) in vial
<input type="checkbox"/> cloxacillin		capsule, 500 mg (as sodium salt) powder for oral solution, 125 mg (as sodium salt)/5 ml powder for injection, 500 mg (as sodium salt) in vial
phenoxymethylpenicillin		tablet, 250 mg (as potassium salt) powder for oral suspension, 250 mg (as potassium salt)/5 ml
<input type="checkbox"/> piperacillin		powder for injection, 1 g, 2 g (as sodium salt) in vial

*When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

^bFor the treatment of echinococcosis and cysticercosis.

<i>Main list</i>	<i>Complementary list</i>	<i>Route of administration, dosage forms, and strengths*</i>
6. Anti-infective Drugs (continued)		
6.2 Antibacterials (continued)		
6.2.1 Penicillins (continued)		
procaine benzylpenicillin		powder for injection, 1 g (= 1 million IU), 3 g (= 3 million IU)
6.2.2 Other antibacterial drugs		
<input type="checkbox"/> chloramphenicol (7)		capsule, 250 mg oral suspension, 150 mg (as palmitate salt)/5 ml powder for injection, 1 g (as sodium succinate) in vial
<input type="checkbox"/> erythromycin		tablet or capsule, 250 mg (as stearate or ethyl succinate) powder for oral suspension, 125 mg (as stearate or ethyl succinate) powder for injection, 500 mg (as lactobionate) in vial
<input type="checkbox"/> gentamicin (2,4,7)		injection, 10 mg, 40 mg (as sulfate)/ml in 2-ml vial
<input type="checkbox"/> metronidazole		tablet, 200–500 mg injection, 500 mg in 100-ml vial suppository, 500 mg, 1 g oral suspension, 200 mg (as benzoate)/5 ml
spectinomycin (8)		powder for injection, 2 g (as hydrochloride) in vial
<input type="checkbox"/> sulfadimidine (4)		tablet, 500 mg oral suspension, 500 mg/5 ml injection, 1 g (sodium salt) in 3-ml ampoule
<input type="checkbox"/> sulfamethoxazole + trimethoprim (4)		tablet, 100 mg + 20 mg, 400 mg + 80 mg oral suspension, 200 mg + 40 mg/5 ml
<input type="checkbox"/> tetracycline		capsule or tablet, 250 mg (hydrochloride)
	doxycycline (B) (5,6)	capsule or tablet, 100 mg (as hyclate) powder for injection, 100 mg (as hyclate) in ampoule
	nitrofurantoin (B) (4,7)	tablet, 100 mg
	trimethoprim (B)	tablet, 100 mg, 200 mg
6.2.3 Antileprosy drugs		
clofazimine		capsule, 50 mg, 100 mg
dapsone		tablet, 50 mg, 100 mg
rifampicin		capsule or tablet, 150 mg, 300 mg

*When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

Main list	Complementary list	Route of administration, dosage forms, and strengths*
6. Anti-infective Drugs (continued)		
6.2 Antibacterials (continued)		
6.2.4 Antituberculosis drugs		
ethambutol (4)		tablet, 100–400 mg (hydrochloride)
isoniazid		tablet, 100–300 mg
pyrazinamide		tablet, 500 mg
rifampicin		capsule or tablet, 150 mg, 300 mg
rifampicin + isoniazid		tablet, 150 mg + 100 mg, 300 mg + 150 mg
streptomycin (4)		powder for injection, 1 g (as sulfate) in vial
thioacetazone + isoniazid		tablet, 50 mg + 100 mg, 150 mg + 300 mg
6.3 Antifungal drugs		
amphotericin B (4)		powder for injection, 50 mg in vial
griseofulvin		capsule or tablet, 125 mg, 250 mg
<input type="checkbox"/> ketoconazole (2)		tablet, 200 mg oral suspension, 100 mg/5 ml
nystatin		tablet, 500 000 IU pessary, 100 000 IU
	flucytosine (B) (4,8)	capsule, 250 mg infusion, 2.5 g in 250 ml
6.4 Antiprotozoal drugs		
6.4.1 Antiamoebic and anti giardiasis drugs		
<input type="checkbox"/> diloxanide		tablet, 500 mg (furoate)
<input type="checkbox"/> metronidazole		tablet, 200–500 mg injection, 500 mg in 100-ml vial oral suspension, 200 mg (as benzoate)/5 ml
	chloroquine (B)	tablet, 150 mg (as phosphate or sulfate)
6.4.2 Antileishmaniasis drugs		
<input type="checkbox"/> meglumine antimoniate		injection, 30%, equivalent to approx. 8.5% antimony, in 5-ml ampoule
pentamidine (5)		powder for injection, 200 mg (as isetionate) in vial
6.4.3 Antimalarial drugs		
6.4.3(a) For curative treatment		
<input type="checkbox"/> chloroquine		tablet, 150 mg (as phosphate or sulfate) syrup, 50 mg (as phosphate or sulfate)/5 ml
primaquine		tablet, 7.5 mg, 15 mg (as diphosphate)

*When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

<i>Main list</i>	<i>Complementary list</i>	<i>Route of administration, dosage forms, and strengths^a</i>
6. Anti-infective Drugs (continued)		
6.4 Antiprotozoal drugs (continued)		
6.4.3 Antimalarial drugs (continued)		
6.4.3(a) For curative treatment (continued)		
<input type="checkbox"/> quinine		tablet, 300 mg (as bisulfate or sulfate) injection, 300 mg (as dihydrochloride)/ml in 2-ml ampoule
	mefloquine (B)	tablet, 250 mg (as hydrochloride)
	<input type="checkbox"/> sulfadoxine + pyrimethamine (B)	tablet, 500 mg + 25 mg
	<input type="checkbox"/> tetracycline (B)	capsule or tablet, 250 mg (hydrochloride)
6.4.3(b) For prophylaxis		
chloroquine		tablet, 150 mg (as phosphate or sulfate) syrup, 50 mg (as phosphate or sulfate)/5 ml
proguanil		tablet, 100 mg (hydrochloride)
6.4.4 Antitrypanosomal drugs		
6.4.4(a) African trypanosomiasis		
melarsoprol (5)		injection, 3.6% solution
pentamidine (5)		powder for injection, 200 mg (as isetionate) in vial
suramin sodium		powder for injection, 1 g in vial
6.4.4(b) American trypanosomiasis		
benznidazole (7)		tablet, 100 mg
nifurtimox (2,8)		tablet, 30 mg, 120 mg, 250 mg
6.5 Insect repellents		
diethyltoluamide ^b		topical solution, 50%, 75%

7. Antimigraine Drugs

7.1 For treatment of acute attack

acetylsalicylic acid	tablet, 300–500 mg
ergotamine (7)	tablet, 2 mg (tartrate)
paracetamol	tablet, 300–500 mg

7.2 Prophylaxis

<input type="checkbox"/> propranolol	tablet, 10 mg, 20 mg (hydrochloride)
--------------------------------------	--------------------------------------

^aWhen the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

^bGeneric name for *N,N*-diethyl-*m*-toluamide (deet).

8. Antineoplastic and Immunosuppressive Drugs

8.1 Immunosuppressive drugs

- | | |
|---|---|
| <input type="checkbox"/> azathioprine (2) | tablet, 50 mg
powder for injection, 100 mg
(as sodium salt) in vial |
|---|---|

8.2 Cytotoxic drugs

- | | |
|--|--|
| bleomycin (2) | powder for injection, 15 mg
(as sulfate) in vial |
| cisplatin (2) | powder for injection, 10 mg,
50 mg in vial |
| cyclophosphamide (2) | tablet, 25 mg
powder for injection, 500 mg in vial |
| cytarabine (2) | powder for injection, 100 mg in vial |
| dacarbazine (2) | powder for injection, 100 mg in vial |
| dactinomycin (2) | powder for injection, 500 µg in vial |
| <input type="checkbox"/> doxorubicin (2) | powder for injection, 10 mg, 50 mg
(hydrochloride) in vial |
| etoposide (2) | capsule, 100 mg
injection, 20 mg/ml in 5-ml ampoule |
| fluorouracil (2) | injection, 50 mg/ml in 5-ml ampoule |
| mercaptopurine (2) | tablet, 50 mg |
| methotrexate (2) | tablet, 2.5 mg (as sodium salt)
powder for injection, 50 mg
(as sodium salt) in vial |
| procarbazine | capsule, 50 mg (as hydrochloride) |
| vinblastine (2) | powder for injection, 10 mg (sulfate)
in vial |
| vincristine (2) | powder for injection, 1 mg, 5 mg
(sulfate) in vial |
| calcium folinate (c)
(2) ^b | tablet, 15 mg
injection, 3 mg/ml in 10-ml ampoule |

8.3 Hormones and antihormones

- | | |
|---|---|
| <input type="checkbox"/> dexamethasone | tablet, 500 µg, 4 mg
injection, 4 mg (as sodium phosphate)
in 1-ml ampoule |
| <input type="checkbox"/> ethinylestradiol | tablet, 50 µg |
| <input type="checkbox"/> prednisolone | tablet, 5 mg
injection, 20 mg, 25 mg (as sodium
phosphate or sodium succinate)
in vial |
| tamoxifen | tablet, 10 mg, 20 mg (as citrate) |

9. Antiparkinsonism Drugs

- | | |
|---|--|
| <input type="checkbox"/> biperiden | tablet, 2 mg (hydrochloride)
injection, 5 mg (lactate) in 1-ml
ampoule |
| levodopa + <input type="checkbox"/> carbidopa (5,6) | tablet, 100 mg + 10 mg,
250 mg + 25 mg |

^aWhen the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

^bDrug for "rescue therapy" with methotrexate.

Main list	Complementary list	Route of administration, dosage forms, and strengths ^a
10. Blood, Drugs affecting the		
10.1 Antianaemia drugs		
ferrous salt		tablet, equivalent to 60 mg iron oral solution, equivalent to 25 mg iron (as sulfate)/ml
ferrous salt + folic acid ^b folic acid (2)		tablet, 60 mg + 250 µg tablet, 1 mg injection, 1 mg (as sodium salt) in 1-ml ampoule
hydroxocobalamin (2)	<input type="checkbox"/> iron dextran (B) (5)	injection, 1 mg in 1-ml ampoule injection, equivalent to 50 mg iron/ml in 2-ml ampoule
10.2 Anticoagulants and antagonists		
heparin		injection, 1000 IU/ml, 5000 IU/ml, 20 000 IU/ml in 1-ml ampoule
phytomenadione		injection, 10 mg/ml in 5-ml ampoule
protamine sulfate		injection, 10 mg/ml in 5-ml ampoule
<input type="checkbox"/> warfarin (2,6)		tablet, 1 mg, 2 mg, 5 mg (sodium salt)

11. Blood Products and Plasma Substitutes

11.1 Plasma substitutes

<input type="checkbox"/> dextran 70		injectable solution, 6%
<input type="checkbox"/> polygeline		injectable solution, 3.5%

11.2 Plasma fractions for specific uses^c

albumin, human (2,8)		injectable solution, 5%, 25% (dried)
	<input type="checkbox"/> factor VIII concentrate (c) (2,8)	(dried)
	<input type="checkbox"/> factor IX complex (coagulation factors II, VII, IX, X) concentrate (c) (2,8)	(dried)

12. Cardiovascular Drugs

12.1 Antianginal drugs

glyceryl trinitrate		tablet (sublingual), 500 µg
<input type="checkbox"/> isosorbide dinitrate		tablet (sublingual), 5 mg
<input type="checkbox"/> nifedipine		capsule or tablet, 10 mg
<input type="checkbox"/> propranolol		tablet, 10 mg, 40 mg (hydrochloride) injection, 1 mg (hydrochloride) in 1-ml ampoule

^aWhen the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".
^bNutritional supplement for use during pregnancy.

^cAll plasma fractions should comply with the Requirements for the Collection, Processing and Quality Control of Blood, Blood Components, and Plasma Derivatives. Thirty-ninth report of the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 786, 1989, Annex 4).

Main list	Complementary list	Route of administration, dosage forms, and strengths ^a
12. Cardiovascular Drugs (continued)		
12.2 Antidysrhythmic drugs		
lidocaine		injection, 20 mg (hydrochloride)/ml in 5-ml ampoule
<input type="checkbox"/> propranolol		tablet, 10 mg, 40 mg (hydrochloride) injection, 1 mg (hydrochloride) in 1-ml ampoule
verapamil (8)		tablet, 40 mg, 80 mg (hydrochloride) injection, 2.5 mg (hydrochloride)/ml in 2-ml ampoule
	<input type="checkbox"/> procainamide (B)	tablet, 250 mg, 500 mg (hydrochloride) injection, 100 mg (hydrochloride)/ml in 10-ml ampoule
	<input type="checkbox"/> quinidine (A)	tablet, 200 mg (sulfate)
12.3 Antihypertensive drugs		
<input type="checkbox"/> hydralazine		tablet, 25 mg, 50 mg (hydrochloride) powder for injection, 20 mg (hydrochloride) in ampoule
<input type="checkbox"/> hydrochlorothiazide		tablet, 25 mg, 50 mg
<input type="checkbox"/> nifedipine		capsule or tablet, 10 mg
<input type="checkbox"/> propranolol		tablet, 40 mg, 80 mg (hydrochloride)
	methyldopa (B) (7)	tablet, 250 mg
	<input type="checkbox"/> reserpine (A)	tablet, 100 µg, 250 µg injection, 1 mg in 1-ml ampoule
	<input type="checkbox"/> sodium nitroprusside (C) (2,8)	powder for infusion, 50 mg in ampoule
	<input type="checkbox"/> captopril (B)	scored tablet, 25 mg
12.4 Cardiac glycosides		
digoxin (4)		tablet, 62.5 µg, 250 µg oral solution, 50 µg/ml injection, 250 µg/ml in 2-ml ampoule
	digitoxin (B) (6)	tablet, 50 µg, 100 µg injection, 200 µg in 1-ml ampoule
12.5 Drugs used in vascular shock		
dopamine		injection, 40 mg (hydrochloride)/ml in 5-ml vial
12.6 Antithrombotic drugs		
acetylsalicylic acid		tablet, 100 mg

13. Dermatological Drugs

13.1 Antifungal drugs (topical)

benzoic acid + salicylic acid		ointment or cream, 6% + 3%
<input type="checkbox"/> miconazole		ointment or cream, 2% (nitrate)
nystatin		ointment or cream, 100 000 IU/g
	selenium sulfide (C)	shampoo, 2%

^aWhen the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

<i>Main list</i>	<i>Complementary list</i>	<i>Route of administration, dosage forms, and strengths*</i>
13. Dermatological Drugs (continued)		
13.2 Anti-infective drugs		
<input type="checkbox"/> methylrosanilinium chloride (gentian violet)		aqueous solution, 1% tincture, 1%
mupirocin		cream, 2%
<input type="checkbox"/> neomycin + <input type="checkbox"/> bacitracin		ointment, 5 mg neomycin sulfate + 500 IU bacitracin zinc/g
silver sulfadiazine		cream 1%, in 500-g container
13.3 Anti-inflammatory and antipruritic drugs		
<input type="checkbox"/> betamethasone (3)		ointment or cream, 0.1% (as valerate)
<input type="checkbox"/> calamine lotion		lotion
<input type="checkbox"/> hydrocortisone		ointment or cream, 1% (acetate)
13.4 Astringent drugs		
aluminium diacetate		solution, 13% for dilution
13.5 Keratoplastic and keratolytic agents		
benzoyl peroxide		lotion or cream, 5%
coal tar		solution, topical 5%
dithranol		ointment, 0.1–2%
fluorouracil		ointment, 5%
<input type="checkbox"/> podophyllum resin (7)		solution, topical 10–25%
salicylic acid		solution, topical 5%
13.6 Scabicides and pediculicides		
benzyl benzoate		lotion, 25%
lindane (7)		cream, lotion, or powder, 1%
permethrin		lotion, 1%
13.7 Sun-blocking agents		
	<i>p</i> -aminobenzoic acid, sun protection factor 15	cream, lotion, or gel
	<input type="checkbox"/> benzophenones, sun protection factor 15	cream, lotion, or gel

14. Diagnostic Agents

14.1 Ophthalmic drugs

fluorescein	eye drops, 1% (sodium salt)
<input type="checkbox"/> tropicamide	eye drops, 0.5%

14.2 Radiocontrast media

<input type="checkbox"/> amidotrizoate	injection, 140–420 mg iodine (as sodium or meglumine salts)/ml in 20-ml ampoule
barium sulfate	powder suspended in water

*When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

Main list	Complementary list	Route of administration, dosage forms, and strengths ^a
14. Diagnostic Agents (continued)		
14.2 Radiocontrast media (continued)		
<input type="checkbox"/> iopanoic acid		tablet, 500 mg
<input type="checkbox"/> propyl iodone		oily suspension, 500–600 mg/ml in 20-ml ampoule ^b
	<input type="checkbox"/> iotroxate (c)	injectable solution, 5–8 g iodine (as meglumine salt) in 100–250 ml

15. Disinfectants and Antiseptics

<input type="checkbox"/> chlorhexidine		solution, 5% (digluconate) for dilution
<input type="checkbox"/> hydrogen peroxide		solution, 1.5%
<input type="checkbox"/> iodine		solution, 2.5%

16. Diuretics

<input type="checkbox"/> amiloride (4,7,8)		tablet, 5 mg (hydrochloride)
<input type="checkbox"/> furosemide		tablet, 40 mg
		injection, 10 mg/ml in 2-ml ampoule
<input type="checkbox"/> hydrochlorothiazide		tablet, 25 mg, 50 mg
	mannitol (c)	injectable solution, 10%, 20%
	spironolactone (c)	tablet, 25 mg

17. Gastrointestinal Drugs

17.1 Antacids and other antiulcer drugs

aluminium hydroxide		tablet, 500 mg
		oral suspension, 320 mg/5 ml
<input type="checkbox"/> cimetidine		tablet, 200 mg
		injection, 200 mg in 2-ml ampoule
magnesium hydroxide		oral suspension, equivalent to 550 mg magnesium oxide/10 ml
sodium citrate		oral solution, 8.82% (0.3 mol/l)

17.2 Antiemetic drugs

metoclopramide		tablet, 10 mg (as hydrochloride)
		injection, 5 mg/ml in 2-ml ampoule
<input type="checkbox"/> promethazine		tablet, 10 mg, 25 mg (hydrochloride)
		elixir or syrup, 5 mg (hydrochloride)/5 ml
		injection, 25 mg (hydrochloride)/ml in 2-ml ampoule

17.3 Antihaemorrhoidal drugs

<input type="checkbox"/> local anaesthetic, astringent, and anti-inflammatory drug		ointment or suppository
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17.4 Anti-inflammatory drugs

hydrocortisone		suppository, 25 mg (acetate)
sulfasalazine (2)		tablet, 500 mg

^aWhen the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

^bFor administration only into the bronchial tree.

Main list	Complementary list	Route of administration, dosage forms, and strengths ^a
17. Gastrointestinal Drugs (continued)		
17.5 Antispasmodic drugs		
<input type="checkbox"/> atropine		tablet, 1 mg (sulfate) injection, 1 mg (sulfate) in 1-ml ampoule
17.6 Cathartic drugs		
<input type="checkbox"/> senna		tablet, 7.5 mg (sennosides) (or traditional dosage forms)
17.7 Diarrhoea, Drugs used in		
17.7.1 Oral rehydration		
oral rehydration salts (for glucose-electrolyte solution)		powder, 27.9 g/l
<i>Components</i>	<i>g/litre</i>	
sodium chloride	3.5	
trisodium citrate dihydrate ^b	2.9	
potassium chloride	1.5	
glucose	20.0	
17.7.2 Antidiarrhoeal (symptomatic) drugs		
<input type="checkbox"/> codeine (1a)		tablet, 30 mg (phosphate)

18. Hormones, Other Endocrine Drugs, and Contraceptives

18.1 Adrenal hormones and synthetic substitutes

<input type="checkbox"/> dexamethasone		tablet, 500 µg, 4 mg injection, 4 mg (as sodium phosphate) in 1-ml ampoule
hydrocortisone		powder for injection, 100 mg (as sodium succinate) in vial
<input type="checkbox"/> prednisolone		tablet, 1 mg, 5 mg
	fludrocortisone (c)	tablet, 100 µg (acetate)

18.2 Androgens

testosterone (c) (2)	injection, 200 mg (enantate) in 1-ml ampoule
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18.3 Contraceptives

18.3.1 Hormonal contraceptives

<input type="checkbox"/> ethinylestradiol + <input type="checkbox"/> levonorgestrel		tablet, 30 µg + 150 µg, 50 µg ÷ 250 µg
<input type="checkbox"/> ethinylestradiol + <input type="checkbox"/> norethisterone		tablet, 50 µg + 1.0 mg
	depot medroxy- progesterone acetate (b) (7,8)	injection, 150 mg/ml in 1-ml and 3-ml vials
	<input type="checkbox"/> norethisterone (b) norethisterone enantate (b) (7,8)	tablet, 350 µg powder for injection, 200 mg in vial

^aWhen the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

^bTrisodium citrate dihydrate may be replaced by sodium bicarbonate (sodium hydrogen carbonate) 2.5 g/l. However, as the stability of the latter formulation is very poor under tropical conditions, it is only recommended when manufactured for immediate use.

<i>Main list</i>	<i>Complementary list</i>	<i>Route of administration, dosage forms, and strengths*</i>
19. Immunologicals		
19.1 Diagnostic agents		
tuberculin, purified protein derivative (PPD) ^b		injection
19.2 Sera and immunoglobulins^c		
anti-D immunoglobulin (human)		injection, 250 µg in single-dose vial
antirabies hyperimmune serum		injection, 1000 IU in 5-ml ampoule
antiscorpion sera		injection
antitetanus immunoglobulin (human)		injection, 500 IU in vial
antivenom sera		injection
diphtheria antitoxin		injection, 10 000 IU, 20 000 IU in vial
immunoglobulin, human normal (2)		injection
tetanus antitoxin (equine)		injection, 50 000 IU in vial

*When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

^bAll tuberculins should comply with the Requirements for Tuberculins (Revised 1985). Thirty-sixth report of the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 745, 1987, Annex 1).

^cAll plasma fractions should comply with the Requirements for the Collection, Processing and Quality Control of Blood, Blood Components, and Plasma Derivatives (Revised 1988). Thirty-ninth report of the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 786, 1989, Annex 4).

<i>Main list</i>	<i>Complementary list</i>	<i>Route of administration, dosage forms, and strengths^a</i>
19. Immunologicals (continued)		
19.3 Vaccines^b		
<i>19.3.1 For universal immunization</i>		
BCG vaccine (dried)		injection
diphtheria-pertussis-tetanus vaccine		injection
diphtheria-tetanus vaccine		injection
measles-mumps-rubella vaccine		injection
measles vaccine		injection
poliomyelitis vaccine (inactivated)		injection
poliomyelitis vaccine (live attenuated)		oral solution
tetanus vaccine		injection
<i>19.3.2 For specific groups of individuals</i>		
hepatitis B vaccine		injection
influenza vaccine		injection
meningococcal vaccine		injection
rabies vaccine		injection
rubella vaccine		injection
typhoid vaccine		injection
yellow fever vaccine		injection

^aWhen the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

^bAll vaccines should comply with the following Requirements for Biological Substances. Dried BCG Vaccine (Revised 1985) (WHO Technical Report Series, No. 745, 1987) and Amendment 1987 (WHO Technical Report Series, No. 771, 1988); Diphtheria, Tetanus, Pertussis, and Combined Vaccines (Revised 1989) (Fortieth report of the WHO Expert Committee on Biological Standardization, WHO Technical Report Series, 1990, in press); Measles Vaccine (Live) (Revised 1987) (WHO Technical Report Series, No. 771, 1988); Mumps Vaccine (Live) (WHO Technical Report Series, No. 760, 1987); Rubella Vaccine (Live) (WHO Technical Report Series, No. 610, 1977) and Addendum 1980 (WHO Technical Report Series, No. 658, 1981); Poliomyelitis Vaccine (Oral) (Revised 1989) (Fortieth report of the WHO Expert Committee on Biological Standardization, WHO Technical Report Series, 1990, in press); Poliomyelitis Vaccine (Inactivated) (Revised 1981) (WHO Technical Report Series, No. 673, 1982) and Addendum 1985 (WHO Technical Report Series, No. 745, 1987); Hepatitis B Vaccine Prepared from Human Plasma (Revised 1987) (WHO Technical Report Series, No. 771, 1988); Influenza Vaccine (Inactivated) (Revised 1978) (WHO Technical Report Series, No. 638, 1979); Meningococcal Polysaccharide Vaccine (WHO Technical Report Series, No. 594, 1976) and Addendum 1980, incorporating Addendum 1976, (WHO Technical Report Series, No. 658, 1981); Rabies Vaccine for Human Use (Revised 1980) (WHO Technical Report Series, No. 658, 1981); Typhoid Vaccine (Live attenuated, Ty 21a Oral) (WHO Technical Report Series, No. 700, 1984); Yellow Fever Vaccine (Revised 1975) (WHO Technical Report Series, No. 594, 1976) and Addendum 1987 (WHO Technical Report Series, No. 771, 1988).

<i>Main list</i>	<i>Complementary list</i>	<i>Route of administration, dosage forms, and strengths*</i>
20. Muscle Relaxants (Peripherally Acting) and Cholinesterase Inhibitors		
<input type="checkbox"/> gallamine (2)		injection, 40 mg (triethiodide)/ml in 2-ml ampoule
<input type="checkbox"/> neostigmine		tablet, 15 mg (bromide) injection, 500 µg, 2.5 mg (metilsulfate) in 1-ml ampoule
suxamethonium (2)		injection, 50 mg (chloride)/ml in 2-ml ampoule powder for injection (chloride)
	pyridostigmine (B) (2,8)	tablet, 60 mg (bromide) injection, 1 mg (bromide) in 1-ml ampoule

21. Ophthalmological Preparations

21.1 Anti-infective agents

gentamicin		solution (eye drops), 0.3%
<input type="checkbox"/> idoxuridine		solution (eye drops), 0.1% eye ointment, 0.2%
silver nitrate		solution (eye drops), 1%
<input type="checkbox"/> tetracycline		eye ointment, 1% (hydrochloride)

21.2 Anti-inflammatory agents

prednisolone		solution (eye drops), 0.5%
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21.3 Local anaesthetics

<input type="checkbox"/> tetracaine		solution (eye drops), 0.5% (hydrochloride)
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21.4 Miotics and antiglaucoma drugs

acetazolamide		tablet, 250 mg
<input type="checkbox"/> pilocarpine		solution (eye drops), 2%, 4% (hydrochloride or nitrate)
<input type="checkbox"/> timolol		solution (eye drops), 0.25%, 0.5% (maleate)

21.5 Mydriatics

atropine		solution (eye drops), 0.1%, 0.5%, 1% (sulfate)
	epinephrine (A)	solution (eye drops), 2% (as hydrochloride)

*When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

<i>Main list</i>	<i>Complementary list</i>	<i>Route of administration, dosage forms, and strengths*</i>
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22. Oxytocics and Antioxytocics

22.1 Oxytocics

<input type="checkbox"/> ergometrine		tablet, 200 µg (hydrogen maleate) injection, 200 µg (hydrogen maleate) in 1-ml ampoule
oxytocin		injection, 10 IU in 1-ml ampoule

22.2 Antioxytocics

<input type="checkbox"/> salbutamol (2)		tablet, 4 mg (as sulfate) injection, 50 µg (as sulfate)/ml in 5-ml ampoule
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23. Peritoneal Dialysis Solution

intraperitoneal dialysis solution (of appropriate composition)	parenteral solution
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24. Psychotherapeutic Drugs

<input type="checkbox"/> amitriptyline		tablet, 25 mg (hydrochloride)
<input type="checkbox"/> chlorpromazine		tablet, 100 mg (hydrochloride) syrup, 25 mg (hydrochloride)/5 ml injection, 25 mg (hydrochloride)/ml in 2-ml ampoule
<input type="checkbox"/> diazepam (1b)		scored tablet, 2 mg, 5 mg
<input type="checkbox"/> fluphenazine (5)		injection, 25 mg (decanoate or enantate) in 1-ml ampoule
<input type="checkbox"/> haloperidol		tablet, 2 mg, 5 mg injection, 5 mg in 1-ml ampoule
lithium carbonate (2,4)		capsule or tablet, 300 mg

25. Respiratory Tract, Drugs acting on the

25.1 Antiasthmatic drugs

<input type="checkbox"/> aminophylline (2)		tablet, 100 mg, 200 mg injection, 25 mg/ml in 10-ml ampoule
beclometasone		inhalation (aerosol), 50 µg (dipropionate) per dose
epinephrine		injection, 1 mg (as hydrochloride) in 1-ml ampoule
<input type="checkbox"/> salbutamol		tablet, 2 mg, 4 mg (as sulfate) inhalation (aerosol), 100 µg (sulfate) per dose syrup, 2 mg (as sulfate)/5 ml injection, 50 µg (as sulfate)/ml in 5-ml ampoule

*When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

<i>Main list</i>	<i>Complementary list</i>	<i>Route of administration, dosage forms, and strengths^a</i>
25. Respiratory Tract, Drugs acting on the <i>(continued)</i>		
25.1 Antiasthmatic drugs <i>(continued)</i>		
	<input type="checkbox"/> cromoglicic acid (B)	inhalation (aerosol), 20 mg (sodium salt) per dose
	ephedrine (A)	tablet, 30 mg (hydrochloride) elixir, 15 mg (hydrochloride)/5 ml injection, 50 mg (sulfate) in 1-ml ampoule
25.2 Antitussives		
	<input type="checkbox"/> codeine (1a)	tablet, 10 mg (phosphate)

26. Solutions Correcting Water, Electrolyte, and Acid-Base Disturbances

26.1 Oral rehydration		
oral rehydration salts (for glucose–electrolyte solution)		for composition see 17.7.1 (p. 37)
potassium chloride		oral solution
26.2 Parenteral		
<input type="checkbox"/> compound solution of sodium lactate		injectable solution
glucose		injectable solution, 5% isotonic, 50% hypertonic
glucose with sodium chloride		injectable solution, 4% glucose, 0.18% sodium chloride (30 mmol/l sodium solution)
potassium chloride (2)		injectable solution, 1.5 mmol/ml in 20-ml ampoule
sodium bicarbonate		injectable solution, 1.4% isotonic (167 mmol/l solution) 8.4% solution in 10-ml ampoule (1 mol/l solution)
sodium chloride		injectable solution, 0.9% isotonic (154 mmol/l solution)
26.3 Miscellaneous		
water for injection		2-ml, 5-ml, 10-ml ampoules

27. Vitamins and Minerals

<input type="checkbox"/> ergocalciferol		capsule or tablet, 1.25 mg (50 000 IU) oral solution, 250 µg/ml (10 000 IU/ml)
iodine		iodized oil, 1 ml (480 mg iodine), 0.5 ml (240 mg iodine) in ampoule (oral or injectable) capsule, 200 mg

^aWhen the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

<i>Main list</i>	<i>Complementary list</i>	<i>Route of administration, dosage forms, and strengths^a</i>
27. Vitamins and Minerals <i>(continued)</i>		
<input type="checkbox"/> nicotinamide		tablet, 50 mg
pyridoxine		tablet, 25 mg (hydrochloride)
<input type="checkbox"/> retinol		sugar-coated tablet, 10 000 IU (as palmitate) (5.5 mg)
		capsule, 200 000 IU (as palmitate) (110 mg)
		oral oily solution, 100 000 IU/ml in multidose dispenser (as palmitate)
		water-miscible injection, 100 000 IU (as palmitate) (55 mg) in 2-ml ampoule
riboflavin		tablet, 5 mg
sodium fluoride (8)		tablet, 500 µg
thiamine		tablet, 50 mg (hydrochloride)
	ascorbic acid (c)	tablet, 50 mg
	calcium gluconate (c), (2.8)	injection, 100 mg/ml in 10-ml ampoule

^aWhen the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

14. CONSIDERATIONS AND CHANGES MADE IN REVISING THE MODEL LIST

Amendments to the individual entries in the list are detailed below. Where no other explanation is offered, the transfer of a drug from the complementary list to the main list signifies accrued evidence of widespread use and acceptance.

Section 1. Anaesthetics

1.2 *Local anaesthetics:* For bupivacaine, a 0.5% solution (hydrochloride) in a 4-ml ampoule to be mixed with 7.5% glucose solution is added since, in many countries, this is becoming the standard preparation for spinal anaesthesia.

Section 2. Analgesics, Antipyretics, Nonsteroidal Anti-inflammatory Drugs, and Drugs Used to Treat Gout

2.1 *Non-opioids:* Colchicine is transferred to the main list since it is widely used for acute gout. Probenecid is deleted since it is now considered obsolete in the treatment of gout.

2.2 *Opioid analgesics:* A toxic metabolite of pethidine accumulates during therapy and causes central nervous system excitation, including myoclonus and seizures. Morphine or alternatives including hydromorphone and levorphanol are preferred when they are available.

Section 3. Antiallergics and Drugs Used in Anaphylaxis

Antihistamines with ostensibly less sedative action are being developed and some are in use. It is, however, considered premature to include one of these.

Section 4. Antidotes and Other Substances Used in Poisonings

4.2 *Specific:* Potassium ferric hexacyanoferrate(II)·2H₂O (Prussian blue) is added as a specific antidote for thallium poisoning.

Section 5. Antiepileptics

For diazepam the footnote on rectal use of the solution is replaced by “(intravenous or rectal)” directly after the strength of the

injection, since there is evidence that the rectal route is as effective as the intravenous route and may be preferred even if a sterile solution is available.

Oral benzodiazepines are now in use, but it is considered premature to include one.

Section 6. Anti-infective Drugs

6.1.1 Intestinal anthelmintics: Levamisole is transferred to the main list since its value as a treatment for ascariasis is undisputed.

6.1.2 Specific anthelmintics: Albendazole is added for the specific treatment of echinococcosis and cysticercosis.

6.1.3 Antifilarials: Suramin is qualified by the numbers (2) and (7) since it must only be used in a hospital setting. Ivermectin is transferred to the main list since its value in the treatment of onchocerciasis is now confirmed.

6.2.1 Penicillins: Oral amoxicillin replaces oral ampicillin because it is better absorbed and causes fewer adverse effects. The square symbol preceding ampicillin injection is removed.

6.2.2 Other antibacterial drugs: The numbers (2) and (7) after gentamicin are added in order to discourage its indiscriminate use. Dosage must always be calculated according to the weight of the patient.

6.2.4 Antituberculosis drugs: Combination tablets of rifampicin and isoniazid are added for the treatment of tuberculosis on the grounds that these will improve compliance. It is essential that all products containing rifampicin are shown to have adequate bioavailability.

6.3 Antifungal drugs: A square symbol is added to ketoconazole to indicate that other imidazoles could serve as alternatives.

6.4.1 Antiamoebic and anti giardiasis drugs: The title of this section is altered to accommodate giardiasis. Dehydroemetine is deleted since it is cardiotoxic and there is no evidence that it is more effective than metronidazole in tissue amoebiasis.

6.4.2 Antileishmaniasis drugs: Sodium stibogluconate is deleted and a square symbol is added to meglumine antimoniate since the latter is more widely used and is considerably cheaper.

6.4.3 Antimalarial drugs: The square symbol preceding chloroquine is retained solely to accommodate hydroxychloroquine. Amodiaquine is no longer recommended either for treatment or for prophylaxis.

6.5 Insect repellents: This new subsection is added in recognition of the importance of preventing arthropod-borne disease.

Antiviral drugs

A subsection on antiviral drugs was considered because the Committee recognizes the importance of viral illnesses and the need for effective antiviral drugs. However, because of their limited efficacy, toxicity, and high cost none of those currently available is considered to qualify for inclusion. Aciclovir is, none the less, accepted as being of value in the treatment of severe herpes infections, and zidovudine is acknowledged to suppress the progression of HIV infection temporarily. Neither is considered essential, however, for the reasons given above.

Section 7. Antimigraine Drugs

This section is divided into two subsections: *7.1 For treatment of acute attack* and *7.2 Prophylaxis*, which includes propranolol.

Section 8. Antineoplastic and Immunosuppressive Drugs

8.2 Cytotoxic drugs: Dacarbazine is added for the specific treatment of malignant melanoma and Hodgkin's disease.

Section 10. Blood, Drugs affecting the

The square symbol preceding hydroxocobalamin is deleted since the use of cyanocobalamin has largely been abandoned.

Section 11. Blood Products and Plasma Substitutes

11.1 Plasma substitutes: Polygeline is added to this section since it may have advantages over dextran. However, only one of these plasma substitutes is necessary.

11.2 Plasma fractions for specific uses: Albumin 5% is added since albumin 25% is hyperosmolar. A square symbol is added both to factor VIII to accommodate cryoprecipitate and to factor IX complex to accommodate plasma and cryoprecipitate-poor plasma.

Section 12. Cardiovascular Drugs

12.3 Antihypertensive drugs: Captopril is added as an example of an angiotensin-converting enzyme (ACE) inhibitor, since these drugs are now widely used in the treatment of hypertension.

12.6 Antithrombotic drugs: This new subsection is added to accommodate recent advances in the treatment of myocardial infarction.

Section 13. Dermatological Drugs

13.1 Antifungal drugs (topical): Selenium sulfide shampoo is added for the treatment of pityriasis versicolor and seborrhoeic dermatitis.

13.2 Anti-infective drugs: A square symbol is added to methylrosanilinium chloride to accommodate other dyes, particularly brilliant green. Mupirocin is added for the specific treatment of impetigo.

13.5 Keratoplastic and keratolytic agents: Benzoyl peroxide is added for the treatment of acne. Fluorouracil is added for the treatment of plantar warts.

13.6 Scabicides and pediculicides: Permethrin is added for the treatment of parasitic infestations as a cheaper alternative to lindane.

13.7 Sun-blocking agents: This new subsection is added since ultraviolet damage to the skin from solar radiation contributes to basal cell carcinoma and other skin tumours, particularly in patients with xeroderma pigmentosum. Sun-blocking agents with a sun protection factor of 15 or higher are effective in preventing these diseases.

Section 14. Diagnostic Agents

14.2 Radiocontrast media: Propylidone oily suspension replaces the water suspension since the latter has been associated with intense bronchial spasm. Iohexol is deleted since non-ionic contrast media are more costly and offer no clear advantage over ionic media.

Section 15. Disinfectants and Antiseptics

Hydrogen peroxide is added for the removal of debris in dental practice.

Section 19. Immunologicals

19.1 Diagnostic agents: The Committee recognizes the importance of patch testing for occupationally acquired contact dermatitis, but is unable to recommend specific products for use at this time.

19.2 Sera and immunoglobulins: The term tetanus antitoxin (human) is altered to antitetanus immunoglobulin (human).

19.3.1 Vaccines for universal immunization: The triple vaccine, measles, mumps, and rubella combined vaccine (MMR), is added for early administration of rubella vaccine.

Section 20. Muscle Relaxants (Peripherally Acting) and Cholinesterase Inhibitors

Neostigmine injection 2.5 mg strength is added since this is the standard dose used in anaesthetic practice.

Section 21. Ophthalmological Preparations

21.1 Anti-infective agents: Gentamicin eye drops replace sulfacetamide ointment and eye drops because gentamicin has better antimicrobial efficacy and is more widely used.

21.2 Anti-inflammatory agents: Prednisolone eye drops replace hydrocortisone ointment since the former has a shorter duration of action and is therefore a safer preparation for general use.

21.5 Mydriatics: Atropine eye drops replace homatropine eye drops for use as a long-acting therapeutic mydriatic. Other short-acting mydriatics are available for diagnostic purposes.

Section 22. Oxytocics and Antioxytocics

22.2 Antioxytocics: Salbutamol is qualified by the number (2) to ensure that this drug is used only by those with specific expertise.

Section 25. Respiratory Tract, Drugs acting on the

25.1 *Antiasthmatic drugs*: Beclometasone aerosol is transferred to the main list because of its recognized advantage over systemic therapy in the treatment of asthma.

Section 27. Vitamins and Minerals

Iodized oil is included for the prophylaxis of goitre in areas where severe iodine deficiency is endemic and where dietary intake of iodine, including iodized salt, is inadequate.

15. GLOSSARY OF TERMS USED IN THE REPORT

In the course of its work, the Expert Committee used certain terms with the meanings given below:

<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 condition.
<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>Excipient</i>	Any component of a finished dosage form other than the claimed therapeutic ingredient or ingredients.
<i>Pharmaceutical product</i>	Synonymous with dosage form.
<i>Pharmacokinetics</i>	The study of the rate of drug action, particularly with respect to: <ul style="list-style-type: none"> —the variation of drug concentrations in tissues with time, and —the absorption, distribution, metabolism, and excretion of drugs and metabolites.
<i>Drug equivalence</i>	The similar efficacy and/or toxicity of different pharmaceutical products given to the same individual.

**16. ALPHABETICAL LIST OF ESSENTIAL DRUGS
(Sixth List)**

<i>Drug</i>	<i>Page</i>	<i>Drug</i>	<i>Page</i>
A		B (continued)	
acetazolamide	41	benzyl benzoate	35
acetylsalicylic acid	25, 31, 34	benzylpenicillin	28
albendazole	28	betamethasone	35
albumin, human	33	biperiden	32
allopurinol	25	bleomycin	32
aluminium diacetate	35	bupivacaine	25
aluminium hydroxide	36		
amidotrizoate	35	C	
amiloride	36	calamine lotion	35
<i>p</i> -aminobenzoic acid	35	calcium folinate	32
aminophylline	42	calcium gluconate	44
amitriptyline	42	captopril	34
amoxicillin	28	carbamazepine	27
amphotericin B	30	carbidopa + levodopa	32
ampicillin	28	charcoal, activated	26
anti-D immunoglobulin (human)	39	chloral hydrate	25
antihaemophilic fraction (<i>see</i> factor VIII concentrate)	33	chloramphenicol	29
antihaemorrhoidal preparation: local anaesthetic, astringent, and anti-inflammatory drug	36	chlorhexidine	36
antirabies hyperimmune serum	39	chloroquine	30, 31
antiscorpion sera	39	chlorphenamine	26
antitetanus immunoglobulin (human)	39	chlorpromazine	42
antivenom sera	39	cimetidine	36
ascorbic acid	44	cisplatin	32
atropine	25, 26, 37, 41	clofazimine	29
azathioprine	32	clomifene	38
		cloxacillin	28
		coal tar	35
		codeine	26, 37, 43
		colchicine	25
B		condoms	38
bacitracin + neomycin	35	copper-containing intrauterine device	38
barium sulfate	35	cromoglicic acid	43
BCG vaccine (dried)	40	cyclophosphamide	32
beclometasone	42	cytarabine	32
benzathine benzylpenicillin	28		
benznidazole	31	D	
benzoic acid + salicylic acid	34	dacarbazine	32
benzophenones	35	dactinomycin	32
benzoyl peroxide	35		

<i>Drug</i>	<i>Page</i>	<i>Drug</i>	<i>Page</i>
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dextran 70	33	folic acid	33
diaphragms	38	folic acid + ferrous salt	33
diazepam	25, 27, 42	furosemide	36
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diethyltoluamide	31	G	
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dopamine	34	H	
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ethinylestradiol + levonorgestrel	37	immunoglobulin, human normal	39
ethinylestradiol + norethisterone	37	indometacin	26
ethosuximide	27	influenza vaccine	40
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		insulin, intermediate-acting	38
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ferrous salt	33	iotroxate	36
ferrous salt + folic acid	33	ipecacuanha	26
flucytosine	30	iron dextran	33
fludrocortisone	37	isoniazid	30

<i>Drug</i>	<i>Page</i>	<i>Drug</i>	<i>Page</i>
I (continued)		M (continued)	
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isoniazid + thioacetazone	30	miconazole	34
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K		N	
ketamine	25	naloxone	27
ketoconazole	30	neomycin + bacitracin	35
L		neostigmine	41
levamisole	27	niclosamide	27
levodopa + carbidopa	32	nicotinamide	44
levonorgestrel + ethinylestradiol	37	nifedipine	33, 34
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lidocaine	25, 34	nitrofurantoin	29
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methylthioninium chloride (methylene blue)	27	phenytoin	27
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		piperazine	27
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<i>Drug</i>	<i>Page</i>	<i>Drug</i>	<i>Page</i>
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<i>Drug</i>	<i>Page</i>	<i>Drug</i>	<i>Page</i>
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ACKNOWLEDGEMENT

The Committee wishes to record its appreciation of the contribution made by Dr Leo Offerhaus, Ministry of Health, The Hague, Netherlands (representing the WHO Regional Office for Europe).

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