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The use of essential drugs

Second report of the WHO
Expert Committee

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Geneva, 3-7 December 1984

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THE USE OF ESSENTIAL DRUGS

Report of a WHO Expert Committee

The WHO Expert Committee on the Use of Essential Drugs met in Geneva from 3–7 December 1984. The meeting was opened on behalf of the Director-General by Dr Lu Rushan, Assistant Director-General.

1. INTRODUCTION

In a report¹ 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.

Following wide consultation, an initial model list of essential drugs was included in the first report of the Expert Committee on

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

the Selection of Essential Drugs.¹ This was subsequently revised and updated in two further reports.^{2, 3}

In undertaking a further review of the list, the present Expert Committee has throughout been guided 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 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 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 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

¹ WHO Technical Report Series, No. 615, 1977.

² WHO Technical Report Series, No. 641, 1979.

³ WHO Technical Report Series, No. 685, 1983.

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. 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 recognized as useful. 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, in 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

¹ See *International nonproprietary names (INN) for pharmaceutical substances: cumulative list no. 6*. Geneva, World Health Organization, 1982. Further lists of proposed and recommended INN are issued periodically as supplements to the *WHO Chronicle*.

prescribers should be provided with a cross-index of nonproprietary and proprietary names.

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

(4) Quality, including stability and bioavailability, should be assured through testing or regulation, as discussed in section 5. 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 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 adequate 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. 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.

In the great majority of cases 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 provides 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 the cost factor 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, exemplified by acetylsalicylic acid and paracetamol, a range of dosage strengths is provided from which suitable 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 indicated by special circumstances. In most instances, dosage is specified in terms of a selected salt or ester but, in other instances—for example, chloroquine—it is calculated, in accordance with common practice, in terms of the active moiety.

5. QUALITY ASSURANCE

Quality assurance of drugs, as embodied in good manufacturing practice and subsequent monitoring of quality through to utilization, is a critical element in any essential drugs programme. All aspects of these procedures have been dealt with *in extenso* in the twenty-sixth,¹ twenty-seventh,² and twenty-eighth³ reports of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (see also section 13.2.7).

WHO has set up a "Certification scheme on the quality of pharmaceutical products moving in international commerce" in accordance with resolution WHA28.65,⁴ which provides valuable safeguards in relation to imported products, particularly for countries lacking adequate laboratory facilities for drug analyses (see section 13.2.6).

Bioavailability is a specific problem that is of particular importance for products of low solubility or a narrow therapeutic index. In addition, unsatisfactory formulation can result in therapeutic failure due to lack of absorption. This has been discussed in the report of a WHO Scientific Group on the Bioavailability of Drugs⁵ and consideration should now be given to its revision.

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 Official Records, No. 226, p. 35 and Annex 12, p. 88. Republished as a supplement to the *WHO Chronicle*, Vol. 31, No. 12, 1977.

⁵ WHO Technical Report Series, No. 536, 1974.

6. DRUG UTILIZATION SURVEYS

It has become evident that drugs are frequently not used to their full potential or according to generally accepted criteria. Little is known about the clinical consequences of the major differences that exist in prescribing patterns between countries or between regions within individual countries. Drug utilization data are rarely obtained systematically and comprehensively after a drug has been marketed. This information is needed, however, if drug selection committees are to function optimally.

Depending on their purpose and on the facilities available, drug utilization studies can be carried out at various levels. The value of such studies is enhanced by employing 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 both to cost and quantities prescribed, and taking differences in therapeutic practice into consideration. Studies can be designed to either quantify the drug inventory only, or evaluate drug utilization.

The basic objective of drug utilization surveys is to quantify present usage and possible future demands. Data can also 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 individual drugs or therapeutic classes of drugs.

7. 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, use of the list should be either preceded by, or developed together with, adequate supply and distribution systems and procurement procedures. To hasten 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 the quality of drugs on a continuing basis.
- (2) Development of procurement procedures to take advantage of the benefits of purchasing large quantities of drugs.
- (3) Development of research facilities to study dosage forms, particularly for vaccines and other heat-sensitive drugs.
- (4) Development of facilities for processing simple dosage forms, in preparation for later decisions concerning the possibility of local manufacture of raw materials.
- (5) Development of an efficient country-wide distribution system with suitable trained personnel.
- (6) Development of packaging of essential drugs to improve product stability and patient compliance.

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

8. SPECIALIZED APPLICATIONS OF THE ESSENTIAL-DRUGS CONCEPT

Although the concept of essential drugs is directed primarily to the needs of developing countries, it has value in other contexts. The provision of drugs on ships provides an obvious example. It is particularly noteworthy that the model list used to prepare a list of standard drugs and clinic equipment for 10 000 persons for 3 months was developed jointly by WHO and the Office of the United Nations High Commissioner for Refugees as part of an emergency health kit.¹ This kit is also being adopted by other organizations involved in meeting emergency health care needs.

9. UPDATING OF LISTS OF ESSENTIAL DRUGS

Experience with the original and revisions to the model list, and with regional and national lists of essential drugs, has confirmed the need for regular review and updating. Revision is rendered necessary not only by 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 wider choice of new medicaments, but that are still used widely and successfully elsewhere.

The present Expert Committee introduced changes only where definite advantages were considered to accrue. However, several important modifications have been made, and these are listed in section 11. The Expert Committee noted that, as far as is possible, individual sections of the list should be reviewed by subsequent committees on the basis of specialist advice and documentation.

¹ WHO emergency health kit. *Standard drugs and clinic equipment for 10 000 persons for 3 months*. Geneva, World Health Organization, 1984, 43 pp.

10. MODEL LIST OF ESSENTIAL DRUGS

(Fourth Revision)

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* and that various drugs could serve as alternatives. It is imperative that this be 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 such as diphenoxylate or loperamide or, when indicated for cough relief, noscapine or 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 following the drug names indicate:

- (1) Drugs subject to international control under (a) the Single Convention on Narcotic Drugs (1961), and (b) the Convention on Psychotropic Substances (1971);
- (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 following 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 The numbers preceding the drug groups and subgroups in the model list (e.g. 11; 17.6.2) were allocated in accordance with English alphabetical order; they have no formal significance.

Main list	Complementary list	Route of administration, dosage forms, and strengths ^a
1. Anaesthetics		
1.1 General anaesthetics and oxygen		
ether, anaesthetic (2)		inhalation
diazepam (1b, 2)		injection, 5 mg/ml in 2-ml ampoule
halothane (2)		inhalation
ketamine (2)		injection, 50 mg/ml in 10-ml vial
nitrous oxide (2)		inhalation
oxygen		inhalation (medicinal gas)
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
<input type="checkbox"/> lidocaine		injection, 1%, 2% (hydrochloride) in vial injection, 1%, 2% + epinephrine 1:100 000 in vial topical forms, 2–4% (hydrochloride)

2. Analgesics, Antipyretics, Nonsteroidal Antiinflammatory 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
<input type="checkbox"/> ibuprofen		tablet, 200 mg
indometacin		capsule or tablet, 25 mg
paracetamol		tablet, 100–500 mg suppository, 100 mg
colchicine (b, c) (7)		tablet, 0.5 mg
<input type="checkbox"/> probenecid (b, c)		tablet, 500 mg

2.2 Opioid analgesics

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 in 5 ml tablet, 10 mg
<input type="checkbox"/> pethidine (A) (1a, 4)		injection, 50 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".

Main list	Complementary list	Route of administration, dosage forms, and strengths ^a
3. Antiallergics		
<input type="checkbox"/> chlorphenamine		tablet, 4 mg (maleate) injection, 10 mg in 1-ml ampoule
<input type="checkbox"/> dexamethasone		tablet, 0.5 mg, 4 mg injection, 4 mg (sodium phosphate) in 1-ml ampoule
epinephrine		injection, 1 mg (as hydrochloride) in 1-ml ampoule
<input type="checkbox"/> prednisolone		tablet, 5 mg

4. Antidotes and Other Substances Used in Poisonings

4.1 General

charcoal, activated		powder
ipecacuanha		syrup, containing 0.14% ipecacuanha alkaloids calculated as emetine
<input type="checkbox"/> magnesium sulfate		powder, 10–30 g

4.2 Specific

atropine		injection, 1 mg (sulfate) in 1-ml ampoule
deferoxamine		injection, 500 mg (mesilate) in vial
dimercaprol (2)		injection in oil, 50 mg/ml in 2-ml ampoule
naloxone		injection, 0.4 mg (hydrochloride) in 1-ml ampoule
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
methylthioninium chloride ^b		injection, 10 mg/ml in 10-ml ampoule
penicillamine (2)		capsule or tablet, 250 mg

5. Antiepileptics

<input type="checkbox"/> diazepam (1b)		injection, 5 mg/ml in 2-ml ampoule
ethosuximide		capsule or tablet, 250 mg
phenobarbital (1b)		tablet, 50 mg, 100 mg syrup, 15 mg/5 ml
phenytoin		capsule or tablet, 25 mg, 100 mg (sodium salt) injection, 50 mg (sodium salt)/ml in 5-ml 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".

^bSynonym: methylene blue.

Main list	Complementary list	Route of administration, dosage forms, and strengths ^a
5. Antiepileptics (continued)		
	carbamazepine (b, c)	tablet, 200 mg
	valproic acid (b, c) (2, 4, 7)	tablet, 200 mg (sodium salt)

6. Antiinfective Drugs

6.1 Anthelmintic drugs

<input type="checkbox"/> mebendazole		tablet, 100 mg
niclosamide		tablet, 500 mg
piperazine		tablet, 500 mg (citrate or adipate) elixir or syrup (as citrate) equivalent to 500 mg hydrate/5 ml
praziquantel		tablet, 600 mg
pyrantel		chewable tablet, 250 mg (as embonate) oral suspension, 50 mg (as embonate)/ml
tiabendazole		chewable tablet, 500 mg

6.2 Antiamoebic drugs

chloroquine		tablet, 200 mg (as phosphate or sulfate)
<input type="checkbox"/> diloxanide		tablet, 500 mg (furoate)
<input type="checkbox"/> metronidazole		tablet, 200–500 mg
	dehydroemetine (s) (7)	injection, 60 mg (hydrochloride) in 1-ml ampoule

6.3 Antibacterial drugs

6.3.1 Penicillins

<input type="checkbox"/> ampicillin (4)		capsule or tablet, 250 mg, 500 mg (anhydrous) powder for oral suspension, 125 mg (anhydrous)/5 ml powder for injection, 500 mg (as sodium salt) in vial
benzathine benzylpenicillin (5)		injection, 1.44 g benzylpenicillin (=2.4 million IU)/5 ml in vial
benzylpenicillin		powder for injection, 0.6 g (= 1 million IU), 3.0 g (= 5 million IU) (as sodium or potassium salt) in vial
<input type="checkbox"/> cloxacillin		capsule, 500 mg (as sodium salt) powder for injection, 500 mg (as sodium salt) 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".

Main list	Complementary list	Route of administration, dosage forms, and strengths ^a
6. Antiinfective Drugs (continued)		
6.3 Antibacterial drugs (continued)		
6.3.1 <i>Penicillins</i> (continued)		
phenoxymethylpenicillin		tablet, 250 mg (as potassium salt) powder for oral suspension, 250 mg (as potassium salt)/5 ml
procaine benzylpenicillin		powder for injection, 1 g (=1 million IU), 3 g (=3 million IU)
6.3.2 <i>Other antibacterial drugs</i>		
<input type="checkbox"/> chloramphenicol (7)		capsule, 250 mg powder for injection, 1 g (as sodium succinate) in vial oral suspension, 150 mg in 5 ml (as palmitate salt)
erythromycin		capsule or tablet, 250 mg (as stearate or ethyl succinate) oral suspension, 125 mg (as stearate or ethyl succinate)/5 ml powder for injection, 500 mg (as lactobionate) in vial
<input type="checkbox"/> gentamicin (4)		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 suppository, 500 mg; 1 g
salazosulfapyridine (2)		tablet, 500 mg
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
<input type="checkbox"/> tetracycline		capsule or tablet, 250 mg (hydrochloride)
doxycycline (B) (5, 6)		capsule or tablet, 100 mg (as hydrochloride) injection, 100 mg (as hydrochloride)/5 ml in ampoule
nitrofurantoin (A, B) (4, 7)		tablet, 100 mg
6.3.3 <i>Antileprosy drugs</i>		
clofazimine		capsule, 50 mg, 100 mg
dapsone		tablet, 50 mg, 100 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>
6. Antiinfective Drugs (continued)		
6.3 Antibacterial drugs (continued)		
6.3.3 <i>Antileprosy drugs</i> (continued)		
rifampicin		capsule or tablet, 150 mg, 300 mg
	ethionamide (b)	tablet, 125 mg, 250 mg
	protionamide (b)	tablet, 125 mg
6.3.4 <i>Antituberculosis drugs</i>		
ethambutol		tablet, 100–500 mg (hydrochloride) ^b
isoniazid		tablet, 100 mg–300 mg
pyrazinamide		tablet, 500 mg
rifampicin		capsule or tablet, 150 mg, 300 mg
streptomycin (4)		powder for injection, 1 g (as sulfate)/in vial
thioacetazone + isoniazid		tablet 50 mg + 100 mg, 150 mg + 300 mg
6.4 Antifilarial drugs		
diethylcarbamazine		tablet, 50 mg (citrate)
suramin sodium		powder for injection, 1 g in vial
6.5 Antifungal drugs		
amphotericin B (4)		powder for injection, 50 mg in vial
griseofulvin		tablet or capsule, 125 mg, 250 mg
nystatin		tablet, 500 000 IU
		pessary, 100 000 IU
	flucytosine (b) (4, 8)	capsule, 250 mg
		infusion, 2.5 g in 250 ml
6.6 Antileishmaniasis drugs		
pentamidine (5)		powder for injection, 200 mg (isetionate or mesilate) in vial
□sodium stibogluconate		injection, 33%, equivalent to 10% antimony, in 30-ml vial
6.7 Antimalarial drugs		
□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 phosphate)
quinine		tablet, 300 mg (as bisulfate or sulfate)
		injection, 300 mg (as dihydrochloride)/ml in 2-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".

^bTwo strengths are required for individual dosage adjustment.

Main list	Complementary list	Route of administration, dosage forms, and strengths ^a
6. Antiinfective Drugs (continued)		
6.7 Antimalarial drugs (continued)		
	amodiaquine (b)	suspension, 150 mg (as hydrochloride)/5 ml tablet, 200 mg (as dihydrochloride dihydrate)
	sulfadoxine + pyrimethamine (b)	tablet, 500 mg + 25 mg
6.8 Antischistosomal drugs		
	metrifonate	tablet, 100 mg
	oxamniquine	capsule, 250 mg syrup, 250 mg/5 ml
	praziquantel	tablet, 600 mg
6.9 Antitrypanosomal drugs		
	melarsoprol (5)	injection, 3.6% solution
	pentamidine (5)	powder for injection, 200 mg (isetionate or mesilate) in vial
	suramin sodium	powder for injection, 1 g in vial
	<input type="checkbox"/> nifurtimox (c) (2, 8)	tablet, 30 mg, 120 mg, 250 mg

7. Antimigraine Drugs

ergotamine (7)	tablet, 2 mg (as tartrate)
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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
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8.2 Cytotoxic drugs

bleomycin (2)	powder for injection, 15 mg (as sulfate) in vial
calcium folinate (2) ^b	tablet, 15 mg
cisplatin (2)	injection, 3 mg/ml in 10-ml ampoule 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
dactinomycin (2)	powder for injection, 0.5 mg in vial
<input type="checkbox"/> doxorubicin (2)	powder for injection, 10 mg, 50 mg (hydrochloride) 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".

^bDrug for "rescue therapy" with methotrexate.

Main list	Complementary list	Route of administration, dosage forms, and strengths ^a
8. Antineoplastic and Immunosuppressive Drugs (continued)		
8.2 Cytotoxic drugs (continued)		
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) injection, 50 mg (as sodium salt) in vial
procarbazine		capsule, 50 mg (as hydrochloride)
vinblastine (2)		powder for injection, 10 mg in vial
vincristine (2)		powder for injection, 1 mg, 5 mg (sulfate) in vial
8.3 Hormones and antihormones		
<input type="checkbox"/> dexamethasone		tablet, 0.5 mg, 4 mg injection, 4 mg (sodium phosphate) in 1-ml ampoule
<input type="checkbox"/> prednisolone		tablet, 5 mg injection, 20 mg, 25 mg (as sodium phosphate or succinate) in vial
tamoxifen		tablet, 10 mg, 20 mg

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
	levodopa (A)	tablet or capsule, 250 mg

10. Blood, Drugs affecting the

10.1 Antianaemia drugs

ferrous salt		tablet, equivalent to 60 mg iron oral solution, equivalent to 15 mg iron (as sulfate) in 0.6 ml
ferrous salt + folic acid ^b		tablet, 60 mg + 200 µg
folic acid (2)		tablet, 1 mg injection, 1 mg (as sodium salt) in 1-ml ampoule
<input type="checkbox"/> hydroxocobalamin (2)		injection, 1 mg in 1-ml ampoule
	<input type="checkbox"/> iron dextran (B) (5)	injection, equivalent to 50 mg iron/ml in 2-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.

Main list	Complementary list	Route of administration, dosage forms, and strengths ^a
10. Blood, Drugs affecting the (continued)		
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, 5 mg (sodium salt)

11. Blood Products and Blood Substitutes

11.1 Plasma substitute

<input type="checkbox"/> dextran 70		injectable solution, 6%
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11.2 Plasma fractions for specific uses

albumin, human (2, 8)		injectable solution, 25% (dried)	All plasma fractions should comply with the WHO Requirements for the Collection, Processing and Quality Control of Human Blood and Blood Products ^b
factor VIII concentrate (c) (2, 8)		(dried)	
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) 0.5 mg
<input type="checkbox"/> isosorbide dinitrate		tablet, (sublingual) 5 mg
<input type="checkbox"/> propranolol		tablet, 10 mg, 40 mg (hydrochloride) injection, 1 mg (hydrochloride) in 1-ml ampoule
<input type="checkbox"/> verapamil		tablet, 40 mg, 80 mg (hydrochloride) injection, 2.5 mg/ml (hydrochloride) in 2-ml ampoule

12.2 Antidysrhythmic drugs

isoprenaline		tablet, 10 mg, 15 mg (hydrochloride or sulfate)
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

^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".

^bTwenty-seventh Report of the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 626, 1978, Annex 1).

Main list	Complementary list	Route of administration, dosage forms, and strengths ^a
12. Cardiovascular Drugs (continued)		
12.2 Antidysrhythmic drugs (continued)		
<input type="checkbox"/> quinidine	<input type="checkbox"/> procainamide (a)	tablet, 200 mg (sulfate) tablet, 250 mg, 500 mg (hydrochloride) injection, 100 mg (hydrochloride)/ml in 10-ml ampoule
12.3 Antihypertensive drugs		
<input type="checkbox"/> hydralazine		tablet, 50 mg (hydrochloride)
<input type="checkbox"/> hydrochlorothiazide		tablet, 50 mg
<input type="checkbox"/> propranolol		tablet, 40 mg, 80 mg (hydrochloride)
<input type="checkbox"/> sodium nitroprusside (2, 8)		powder for preparing infusion, 50 g in ampoule
<input type="checkbox"/> reserpine		tablet, 0.1 mg, 0.25 mg injection, 1 mg in 1-ml ampoule
	methyldopa (A, B) (7)	tablet, 250 mg
12.4 Cardiac glycosides		
digoxin (4)		tablet, 0.0625 mg, 0.25 mg oral solution, 0.05 mg/ml injection, 0.25 mg/ml in 2-ml ampoule
	digitoxin (b) (6)	tablet, 0.05 mg, 0.1 mg oral solution, 1 mg/ml injection, 0.2 mg in 1-ml ampoule
12.5 Drugs used in shock or anaphylaxis		
dopamine		injection, 40 mg (hydrochloride)/ml in 5-ml vial
epinephrine		injection, 1 mg (as hydrochloride) in 1-ml ampoule
13. Dermatological Drugs		
13.1 Antifungal drugs		
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
13.2 Antiinfective drugs		
gentian violet ^b		aqueous or alcoholic solution, 1%
<input type="checkbox"/> neomycin + <input type="checkbox"/> bacitracin		ointment, 5 mg neomycin sulfate + 500 IU bacitracin zinc/g

^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".

^bAlso known as crystal violet (International Nonproprietary Name: methylrosanilinium chloride).

Main list	Complementary list	Route of administration, dosage forms, and strengths ^a
13. Dermatological Drugs (continued)		
13.3 Antiinflammatory 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 acetate		solution, 13% for dilution
13.5 Keratoplastic and keratolytic agents		
coal tar		solution, topical 20%
podophylline		solution, 10–25%
salicylic acid		solution, topical 5%
13.6 Scabicides and pediculicides		
benzyl benzoate		lotion, 25%
lindane ^b		cream or lotion, 1%

14. Diagnostic Agents

14.1 Ophthalmic drugs

fluorescein eye drops, 1% (sodium salt)

14.2 Radiocontrast media

<input type="checkbox"/> meglumine amidotrizoate		injection, 60% in 20-ml ampoule
<input type="checkbox"/> sodium amidotrizoate		injection, 50% in 20-ml ampoule
barium sulfate		powder
<input type="checkbox"/> iopanoic acid		tablet, 500 mg
<input type="checkbox"/> propylidone		injection, 600 g/l in 20-ml ampoule
	<input type="checkbox"/> iohexol (c)	injection, 300 mg in 5- or 10-ml ampoule
	<input type="checkbox"/> iotroxate (c)	solution, 8 g (as iodine) in 100 to 250 ml

15. Disinfectants

<input type="checkbox"/> chlorhexidine		solution, 5% (digluconate) for dilution
<input type="checkbox"/> iodine		solution, 2.5%
	gentian violet ^c (A)	topical solution, 1%

^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".

^bPreviously identified as gamma benzene hexachloride.

^cAlso known as crystal violet (International Nonproprietary Name: methylosanilinium chloride).

<i>Main list</i>	<i>Complementary list</i>	<i>Route of administration, dosage forms, and strengths*</i>
16. Diuretics		
<input type="checkbox"/> amiloride		tablet, 5 mg (hydrochloride)
<input type="checkbox"/> furosemide		tablet, 40 mg injection, 10 mg/ml in 2-ml ampoule
<input type="checkbox"/> hydrochlorothiazide		tablet, 50 mg
mannitol		injectable solution, 10%, 20%
spironolactone		tablet, 25 mg
	chlortalidone (B) (6)	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
	calcium carbonate (A, B)	tablet, 600 mg

17.2 Antiemetic drugs

<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
metoclopramide		tablet, 10 mg (as hydrochloride) injection, 5 mg/ml in 2-ml ampoule

17.3 Antihaemorrhoidal drugs

<input type="checkbox"/> local anaesthetic, astringent and antiinflammatory drug		ointment or suppository
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17.4 Antispasmodic drugs

<input type="checkbox"/> atropine		tablet, 1 mg (sulfate) injection, 1 mg (sulfate) in 1-ml ampoule
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17.5 Cathartic drugs

<input type="checkbox"/> senna		tablet, 7.5 mg (sennosides) (or traditional dosage forms)
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17.6 Diarrhoea, Drugs used in

17.6.1 Antidiarrhoeal (symptomatic) drugs

<input type="checkbox"/> codeine (1a)		tablet, 30 mg (phosphate)
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*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
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17. Gastrointestinal Drugs (continued)

17.6 Diarrhoea, Drugs used in (continued)

17.6.2 Replacement solution

oral rehydration salts (for glucose-salt solution)	g/litre
sodium chloride	3.5
trisodium citrate dihydrate ^b	2.9
potassium chloride	1.5
glucose	20.0

18. Hormones

18.1 Adrenal hormones and synthetic substitutes

<input type="checkbox"/> dexamethasone		tablet, 0.5 mg, 4 mg injection, 4 mg (sodium phosphate) in 1-ml ampoule
hydrocortisone		powder for injection, 10 mg (as sodium succinate) in vial
<input type="checkbox"/> prednisolone		tablet, 5 mg
	fludrocortisone (c)	tablet, 0.1 mg (acetate)

18.2 Androgens

testosterone (2)		injection, 200 mg (enantate) in 1-ml ampoule injection, 25 mg (propionate) in 1-ml ampoule
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18.3 Contraceptives

<input type="checkbox"/> ethinylestradiol + <input type="checkbox"/> levonorgestrel		tablet, 0.03 mg + 0.15 mg, 0.05 mg + 0.25 mg
<input type="checkbox"/> ethinylestradiol + <input type="checkbox"/> norethisterone		tablet, 0.05 mg + 1.0 mg
	depot medroxy-progesterone acetate (s) (7, 8)	injection, 150 mg in 3-ml vials
	<input type="checkbox"/> norethisterone (s)	tablet, 0.35 mg
	norethisterone enantate (s) (7, 8)	injection, 200 mg in vial

18.4 Estrogens

<input type="checkbox"/> ethinylestradiol		tablet, 0.05 mg
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^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".

^bMay be replaced by sodium bicarbonate (sodium hydrogen carbonate), 2.5 g/litre, when citrate salt is not available.

<i>Main list</i>	<i>Complementary list</i>	<i>Route of administration, dosage forms, and strengths^a</i>
18. Hormones <i>(continued)</i>		
18.5 Insulins and other antidiabetic agents		
insulin injection (soluble)		injection, 40 IU/ml in 10-ml vial, 80 IU/ml in 10-ml vial
intermediate acting insulin		injection, 40 IU/ml in 10-ml vial, 80 IU/ml in 10-ml vial (as compound insulin zinc suspension or isophane insulin)
glibenclamide		tablet, 5 mg
18.6 Ovulation inducers		
	<input type="checkbox"/> clomifene (c) (2, 8)	tablet, 50 mg (citrate)
18.7 Progestogens		
norethisterone		tablet, 5 mg
18.8 Thyroid hormones and antithyroid drugs		
levothyroxine		tablet, 0.05 mg, 0.1 mg (sodium salt)
potassium iodide		tablet, 60 mg
<input type="checkbox"/> propylthiouracil		tablet, 50 mg

19. Immunologicals

19.1 Diagnostic agents

tuberculin, purified protein derivative (PPD)	injection
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19.2 Sera and immunoglobulins

anti-D immunoglobulin (human)	injection, 0.25 mg/ml	All plasma fractions should comply with the WHO Requirements for the Collection, Processing, and Quality Control of Human Blood and Blood Products ^b
antirabies hyperimmune serum	injection, 1000 IU in 5-ml ampoule	
antivenom sera	injection	
antiscorpion sera	injection	
diphtheria antitoxin	injection, 10 000 IU, 20 000 IU, in vial	
immunoglobulin, human normal (2)	injection	
tetanus antitoxin	injection, 50 000 IU, in vial	
tetanus antitoxin (human)	injection, 500 IU 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".

^bWHO Technical Report Series, No. 626, 1978, Annex 1.

Main list	Complementary list	Route of administration, dosage forms, and strengths*
19. Immunologicals (continued)		
19.3 Vaccines		
19.3.1 For universal immunization		
BCG vaccine (dried)		injection
diphtheria-pertussis-tetanus vaccine		injection
diphtheria-tetanus vaccine		injection
measles vaccine		injection
poliomyelitis vaccine (inactivated)		injection
poliomyelitis vaccine (live attenuated)	oral solution	All vaccines should comply with the WHO Requirements for Biological Substances ^b
tetanus vaccine	injection	
19.3.2 For specific groups of individuals		
influenza vaccine		injection
meningococcal vaccine		injection
rabies vaccine		injection
typhoid vaccine		injection
yellow fever vaccine		injection

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, 0.5 mg (metilsulfate) in 1-ml ampoule
suxamethonium (2)		injection, 50 mg (chloride)/ml in 2-ml ampoule
	pyridostigmine (a) (2, 8)	tablet, 60 mg (bromide) injection, 1 mg (bromide) in 1-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".

^bDried BCG Vaccine (Revised 1978) (WHO Technical Report Series, No. 638, 1979); Diphtheria Toxoid, Pertussis Vaccine, Tetanus Toxoid, and Combined Vaccines (Revised 1978) (WHO Technical Report Series, No. 638, 1979), Addendum 1983 (WHO Technical Report Series, No. 700, 1984, and Addendum 1984 (WHO Technical Report Series, No. 725, 1985); Measles Vaccine (Live) and Measles Vaccine (Inactivated) (WHO Technical Report Series, No. 329, 1966); Poliomyelitis Vaccine (Oral) (Revised 1982) (WHO Technical Report Series, No. 687, 1983); Poliomyelitis Vaccine (Inactivated) (Revised 1981) (WHO Technical Report Series, No. 673, 1982); Influenza Vaccine (Inactivated) (Revised 1978) (WHO Technical Report Series, No. 638, 1979); Meningococcal Polysaccharide Vaccine (WHO Technical Report Series, No. 658, 1981), Addendum 1980, incorporating Addendum 1976 (WHO Technical 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).

<i>Main list</i>	<i>Complementary list</i>	<i>Route of administration, dosage forms, and strengths^a</i>
21. Ophthalmological Preparations		
21.1 Antimicrobial agents		
silver nitrate		solution (eye drops), 1%
sulfacetamide		eye ointment, 10% (sodium salt) solution (eye drops), 10% (sodium salt)
<input type="checkbox"/> tetracycline		eye ointment, 1% (hydrochloride)
21.2 Antiinflammatory agents		
<input type="checkbox"/> hydrocortisone (2, 7)		eye ointment, 1% (acetate)
21.3 Local anaesthetics		
<input type="checkbox"/> tetracaine		solution (eye drops), 0.5% (hydrochloride)
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		
<input type="checkbox"/> homatropine		solution (eye drops), 2% (hydrobromide)
	epinephrine (A, B)	solution (eye drops), 2% (as hydrochloride)
22. Oxytocics		
<input type="checkbox"/> ergometrine		tablet, 0.2 mg (maleate) injection, 0.2 mg (maleate) in 1-ml ampoule
oxytocin		injection, 10 IU in 1-ml ampoule
23. Peritoneal Dialysis Solution		
intraperitoneal dialysis solution (of appropriate composition)		parenteral solution
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

^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".

Main list	Complementary list	Route of administration, dosage forms, and strengths ^a
24. Psychotherapeutic Drugs (continued)		
<input type="checkbox"/> diazepam (1b)		tablet, 5 mg
<input type="checkbox"/> fluphenazine (5)		injection, 25 mg (decanoate or enantate) in 1-ml ampoule
<input type="checkbox"/> haloperidol		tablet, 2 mg injection, 5 mg in 1-ml ampoule
imipramine		tablet, 10 mg, 25 mg (hydrochloride)
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
epinephrine		injection, 1 mg (as hydrochloride) in 1-ml ampoule
<input type="checkbox"/> salbutamol		tablet, 4 mg (sulfate) oral inhalation (aerosol), 0.1 mg (sulfate) per dose syrup, 2 mg (sulfate)/5 ml injection, 50 µg/ml in 5-ml ampoule
	beclometasone (b)	oral inhalation (aerosol), 0.05 mg (dipropionate) per dose
	cromoglicic acid (b)	oral inhalation (cartridge), 20 mg (sodium salt) per dose
ephedrine		tablet, 30 mg (as hydrochloride) elixir, 15 mg (as hydrochloride)/5 ml injection, 50 mg (sulfate) in 1-ml ampoule

25.2 Antitussives

<input type="checkbox"/> codeine (1a)		tablet, 10 mg (phosphate)
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26. Solutions Correcting Water, Electrolyte, and Acid-Base Disturbances

26.1 Oral

oral rehydration salts (for glucose-salt solution)		For composition see 17.6.2 Replacement solution
potassium chloride		oral solution

26.2 Parenteral

<input type="checkbox"/> compound solution of sodium lactate		injectable solution
glucose		injectable solution, 5% isotonic, 50% hypertonic

^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>
26. Solutions Correcting Water, Electrolyte, and Acid-Base Disturbances (continued)		
26.2 Parenteral (continued)		
glucose with sodium chloride		injectable solution, 4% glucose, 0.18% sodium chloride (Na ⁺ 30 mmol, Cl ⁻ 30 mmol/l)
potassium chloride		injectable solution
sodium bicarbonate		injectable solution, 1.4% isotonic (Na ⁺ 167 mmol/l, HCO ₃ ⁻ 167 mmol/l);
		8.4% solution in 10-ml ampoule
sodium chloride		injectable solution, 0.9% isotonic (Na ⁺ 154 mmol/l, Cl ⁻ 154 mmol/l)
26.3 Miscellaneous		
water for injection		in 2-ml, 5-ml, 10-ml ampoules
27. Vitamins and Minerals		
ascorbic acid		tablet, 50 mg
<input type="checkbox"/> ergocalciferol		capsule or tablet, 1.25 mg (50 000 IU) oral solution, 0.25 mg/ml (10 000 IU)
<input type="checkbox"/> nicotinamide		tablet, 50 mg
pyridoxine		tablet, 25 mg (hydrochloride)
retinol		capsule or tablet, 7.5 mg (25 000 IU) 60 mg (200 000 IU) ^b oral solution, 15 mg/ml (50 000 IU)
riboflavin		tablet, 5 mg
sodium fluoride (8)		tablet, 0.5 mg (as fluoride)
thiamine		tablet, 50 mg (hydrochloride)
	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".

^bFor use in the treatment and prophylaxis of xerophthalmia.

10.1 ALPHABETICAL LIST OF ESSENTIAL DRUGS

(Fourth Revision)

<i>Drug</i>	<i>Page</i>	<i>Drug</i>	<i>Page</i>
A		C	
acetazolamide	29	☐calamine lotion	24
acetylsalicylic acid	15	calcium carbonate	25
albumin, human	22	calcium folinate	20
allopurinol	15	calcium gluconate	31
aluminium acetate	24	carbamazepine	17
aluminium hydroxide	25	☐carbidopa + levodopa	21
☐amiloride	25	charcoal, activated	16
☐aminophylline	30	☐chloramphenicol	18
☐amitriptyline	29	☐chlorhexidine	24
amodiaquine	20	☐chloroquine	17, 19
amphotericin B	19	☐chlorphenamine	16
☐ampicillin	17	☐chlorpromazine	29
anti-D immunoglobulin (human)	27	chlortalidone	25
antihaemophilic fraction (see factor VIII concentrate)	22	☐cimetidine	25
antihaemorrhoidal preparation: local anaesthetic, astringent and antiinflammatory drug	25	cisplatin	20
antirabies hyperimmune serum	27	clofazimine	18
antiscorpion sera	27	clomifene	27
antivenom sera	27	☐cloxacillin	17
ascorbic acid	31	coal tar	24
☐atropine	16, 25	☐codeine	15, 25, 30
☐azathioprine	20	colchicine	15
		cromoglicic acid	30
		cyclophosphamide	20
		cytarabine	20
B		D	
☐bacitracin + ☐neomycin	23	dactinomycin	20
barium sulfate	24	dapsone	18
BCG vaccine (dried)	28	deferoxamine	16
beclometasone	30	dehydroemetine	17
benzathine benzylpenicillin	17	depot medroxyprogesterone acetate	26
benzoic acid + salicylic acid	23	☐dexamethasone	16, 21, 26
benzyl benzoate	24	☐dextran 70	22
benzylpenicillin	17	☐diazepam	15, 16, 30
☐betamethasone	24	diethylcarbamazine	19
☐biperiden	21	digitoxin	23
bleomycin	20	digoxin	23
☐bupivacaine	15	diloxanide	17
		dimercaprol	16

<i>Drug</i>	<i>Page</i>	<i>Drug</i>	<i>Page</i>
D (continued)		G	
diphtheria antitoxin	27	□gallamine	28
diphtheria-pertussis-tetanus vaccine	28	□gentian violet ¹	23, 24
diphtheria-tetanus vaccine	28	□gentamicin	18
dopamine	23	□glibenclamide	27
□doxorubicin	20	glucose	26, 30
doxycycline	18	glucose with sodium chloride	31
E		glyceryl trinitrate	22
ephedrine	30	griseofulvin	19
epinephrine	16, 23, 29, 30	H	
□ergocalciferol	31	□haloperidol	30
□ergometrine	29	halothane	15
ergotamine	20	heparin	22
erythromycin	18	□homatropine	29
ethambutol	19	□hydralazine	23
ether, anaesthetic	15	□hydrochlorothiazide	23, 25
□ethinylestradiol	26	□hydrocortisone	24, 26, 29
□ethinylestradiol + □levonorgestrel	26	□hydroxocobalamin	21
□ethinylestradiol + □norethisterone	26	I	
ethionamide	19	□ibuprofen	15
ethosuximide	16	imipramine	30
etoposide	21	immunoglobulin, human normal	27
F		indometacin	15
factor VIII concentrate	22	influenza vaccine	28
factor IX complex (coagulation factors II, VII, IX, X) concentrate	22	insulin injection, solution	27
ferrous salt	21	insulin, intermediate acting	27
ferrous salt + folic acid	21	intraperitoneal dialysis solution	29
flucytosine	19	□iodine	24
fludrocortisone	26	□iohexal	24
fluorescein	24	iotroxate	24
fluorouracil	21	□iopanoic acid	24
□fluphenazine	30	□ipecacuanha	16
folic acid	21	□iron dextran	21
folic acid + □ferrous salt	21	isoniazid	19
□furosemide	25	isoniazid + thioacetazone	19
		isoprenaline	22
		□isosorbide dinitrate	22

¹ Also known as crystal violet (International Nonproprietary Name: methylosanilinium chloride).

<i>Drug</i>	<i>Page</i>	<i>Drug</i>	<i>Page</i>
K		N (continued)	
ketamine	15	norethisterone + □ethinylestradiol	26
L		nystatin	19, 23
levodopa	21	O	
levodopa + □carbidopa	21	oral rehydration salts (for glucose salt solution)	26, 30
□levonorgestrel + □ethinylestradiol	26	oxamniquine	20
levothyroxine	27	oxygen	15
□lidocaine	15, 22	oxytocin	29
lindane	24	P	
lithium carbonate	30	paracetamol	15
M		penicillamine	16
magnesium hydroxide	25	pentamidine	19, 20
magnesium sulfate	16	□pethidine	15
mannitol	25	phenobarbital	16
measles vaccine	28	phenoxymethylpenicillin	18
□mebendazole	17	phenytoin	16
meglumine amidotrizoate	24	phytomenadione	22
melarsoprol	20	pilocarpine	29
meningococcal vaccine	28	piperazine	17
mercaptapurine	21	podophylline	24
methotrexate	21	poliomyelitis vaccine	28
methylidopa	23	potassium chloride, oral solution	26, 30
methylthioninium chloride	16	potassium chloride, parenteral	31
metoclopramide	25	potassium iodide	27
metrifonate	20	praziquantel	17, 20
□metronidazole	17, 18	□prednisolone	16, 21, 26
□miconazole	23	primaquine	19
□morphine	15	probenecid	15
N		□procainamide	23
naloxone	16	procaine benzylpenicillin	18
□neomycin + □bacitracin	23	procarbazine	21
□neostigmine	28	□promethazine	25
□nicotinamide	31	□propranolol	22, 23
niclosamide	17	propylidone	24
□nifurtimox	20	□propylthiouracil	27
nitrofurantoin	18	protamine sulfate	22
nitrous oxide	15	protionamide	19
□norethisterone	26, 27	pyrantel	17
norethisterone enantate	26	pyrazinamide	19

<i>Drug</i>	<i>Page</i>	<i>Drug</i>	<i>Page</i>
P (continued)		S (continued)	
pyridostigmine	28	□sulfadimidine	18
pyridoxine	31	sulfadoxine + pyrimethamine	20
pyrimethamine + sulfadoxine	20	□sulfamethoxazole + trimethoprim	18
		suramin sodium	19, 20
		suxamethonium	28
Q		T	
□quinidine	23	tamoxifen	21
quinine	19	testosterone	26
		tetanus antitoxin	27
		tetanus antitoxin, human	27
		tetanus vaccine	28
R		□tetracaine	29
rabies vaccine	28	□tetracycline	18, 29
□reserpine	23	thiamine	31
retinol	31	thioacetazone + isoniazid	19
riboflavin	31	thiopental	15
rifampicin	19	tiabendazole	17
		□timolol	29
S		trimethoprim + □sulfa-	
salazosulapyridine	18	methoxazole	18
□salbutamol	30	trisodium citrate dihydrate	26
salicylic acid	24	tuberculin, purified protein	
salicylic acid + benzoic acid	23	derivative (PPD)	27
□senna	25	typhoid vaccine	28
silver nitrate	29		
sodium amidotrizoate	24	V	
sodium bicarbonate	31	valproic acid	17
sodium calcium edetate	16	□verapamil	22
sodium chloride	26	vinblastine	21
sodium chloride with glucose	31	vincristine	21
sodium fluoride	31		
□sodium lactate, compound		W	
solution	30	□warfarin	22
sodium nitrite	16	water for injection	31
□sodium nitroprusside	23		
□sodium stibogluconate	19	Y	
sodium thiosulfate	16	yellow fever vaccine	28
spectinomycin	18		
spironolactone	25		
streptomycin	19		
sulfacetamide	29		

11. CHANGES MADE IN REVISING THE MODEL LIST

Amendments to the individual entries in the model list are detailed below. The meanings of the typographical symbols used and of the numbers in parentheses following the drug names are not all the same as in the previous list (see Explanatory Notes in section 10). To avoid confusion, users are therefore urged to refer only to the present list (Fourth revision) and to cite the number of the report in which it is published (WHO Technical Report Series No. 722).

Group 1.1. General anaesthetics and oxygen: Diazepam is now listed additionally in this group as well as in groups 5 and 24. Ketamine is added as an intravenous anaesthetic.

Group 2.1. Non-opioids: Probenecid is qualified with a square symbol.

Group 2.2. Opioid analgesics: Codeine is now listed additionally in this group as well as in groups 17.6.1 and 25.2. Morphine is qualified with a square symbol and an oral formulation is introduced. Naloxone is deleted from this group but is retained in group 4.2.

Group 3. Antiallergics: □Dexamethasone and □prednisolone are listed additionally in this group (and in group 8.3) as well as in group 18.1. Cromoglicic acid is deleted from the complementary list but is retained in group 25.1.

Group 4.1. Antidotes and Other Substances Used in Poisonings.
General: Magnesium sulfate replaces sodium sulfate as an osmotic purgative.

Group 4.2. Antidotes and Other Substances Used in Poisonings.
Specific: Protamine sulfate is deleted but is retained in group 10.2. Methylthioninium chloride and penicillamine are transferred to the main list.

Group 5. Antiepileptics: Diazepam is qualified with a square symbol.

Group 6.1. Anthelmintic drugs: Praziquantel is now listed additionally in this group as well as in group 6.8.

Group 6.2. Antiamoebic drugs: Diloxanide is qualified with a square symbol.

- Group 6.3.2. Other antibacterial drugs:* An oral suspension is added to the listed formulations of chloramphenicol. Amikacin is deleted.
- Group 6.3.3. Antileprosy drugs:* A 50-mg capsule of clofazimine is added.
- Group 6.6. Antileishmaniasis drugs:* Sodium stibogluconate is qualified with a square symbol.
- Group 6.7. Antimalarial drugs:* A tablet formulation of amodiaquine is added to the complementary list.
- Group 8. Antineoplastic and Immunosuppressive Drugs:* This section is now organized under three subheadings: 8.1 *Immunosuppressive drugs*; 8.2 *Cytotoxic drugs*; 8.3 *Hormones and antihormones*.
- Group 8.1. Immunosuppressive drugs:* Azathioprine is qualified with a square symbol.
- Group 8.2. Cytotoxic drugs:* Busulfan and chlorambucil are deleted. Cisplatin, dactinomycin, etoposide, mercaptopurine, and vinblastine are added to the main list.
- Group 8.3. Hormones and antihormones:* Dexamethasone and prednisolone are listed additionally in this group (and in group 3) as well as in group 18.1. Tamoxifen is added to the main list.
- Group 10.1. Antianaemia drugs:* The combination of ferrous salt + folic acid is transferred to the main list and a footnote is added indicating that it is intended as a nutritional supplement for use during pregnancy.
- Group 11.1. Plasma substitute:* Dextran 70 is qualified with a square symbol.
- Group 11.2. Plasma fractions for specific uses:* Antihemophilic fraction in the complementary list is redesignated as factor VIII concentrate.
- Group 12.2. Antidysrhythmic drugs:* Procainamide is transferred to the complementary list and is qualified by the letter (B). Quinidine is transferred to the main list.
- Group 12.3. Antihypertensive drugs:* Reserpine is transferred to the main list.

- Group 13.2. Antiinfective drugs:* Gentian violet is added to the main list.
- Group 13.5. Keratoplastic and keratolytic agents:* Podophylline is added to the main list.
- Group 14. Diagnostic agents:* Edrophonium is deleted. Tuberculin, purified protein derivative is transferred to group 19.1.
- Group 14.2. Radiocontrast media:* □ Adipiodone meglumine is deleted. Propylidone is added to the main list. Iohexol and iotroxate are added to the complementary list and are qualified by the letter (C).
- Group 17.1. Antacids and other antiulcer drugs:* Cimetidine is qualified with a square symbol.
- Group 17.2. Antiemetic drugs:* Metoclopramide is transferred to the main list and an injectable formulation is added.
- Group 17.6.2. Replacement solution:* Trisodium citrate dihydrate is now preferred to sodium bicarbonate as an ingredient in oral rehydration salts.
- Group 18.3. Contraceptives:* Injectable preparations of depot medroxyprogesterone acetate and norethisterone enantate are added to the complementary list and are qualified by the letter (B).
- Group 18.5. Insulins and other antidiabetic agents:* An intermediate acting insulin (as compound insulin zinc suspension or isophane insulin) replaces compound insulin zinc suspension in the main list.
- Group 19. Immunologicals:* A new subgroup 19.1, *Diagnostic agents*, is added to accommodate tuberculin purified protein derivative, which is transferred from group 14.
- Group 19.2. Sera and immunoglobulins:* Antiscorpion sera and tetanus antitoxin (human) are added to the main list.
- Group 19.3.1. Vaccines for universal immunization:* An inactivated injectable formulation of poliomyelitis vaccine is added to the main list.

Group 21.2. Ophthalmological preparations. Antiinflammatory agents: Hydrocortisone is qualified with a square symbol.

Group 21.4. Miotics and antiglaucoma drugs: The designation of this group is changed from *miotics* to *miotics and antiglaucoma drugs*. Pilocarpine is qualified with a square symbol. Timolol is added to the main list.

Group 24. Psychotherapeutic drugs: Imipramine is added to the main list, both as a tablet and an injectable formulation.

Group 25.1. Antiasthmatic drugs: A 100-mg tablet of aminophylline is added to the main list. An injectable formulation of salbutamol is added to the main list. Ephedrine is transferred from the complementary list to the main list.

Group 26.2. Solutions Correcting Water, Electrolyte, and Acid-Base Disturbances. Parenteral: An 8.4% solution of sodium bicarbonate is added to the main list.

12. ESSENTIAL DRUGS AND PRIMARY HEALTH CARE

12.1 Criteria for the selection of drugs for primary health care

The Expert Committee on the Selection of Essential Drugs in its first report recommended the compilation of a separate list of drugs appropriate for use in primary health care. After broad consultation, and having regard to situations in which a traditional healer or community health worker rather than a qualified doctor is the patients' first point of reference, the present Expert Committee has selected 23 substances from the main list that might be considered for this purpose. They are listed in section 12.2. It cannot be emphasized too strongly that, in practice, this selection must be determined nationally since the training and responsibilities of these workers vary within wide limits. The following factors, however, will inevitably influence the content of the list.

(1) *Existing systems of medicine.* The establishment of primary health care services should not result in abrupt disruption of prevailing cultural patterns in rural communities, but the work of traditional healers should be adapted and supplemented in such a way 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 manned health post to be one or more days' travelling time 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.

12.2 A model list of drugs for primary health care

acetylsalicylic acid
activated charcoal
an antacid
an antihemorrhoidal drug
atropine (antispasmodic)
benzoic acid + salicylic acid
benzyl benzoate
calamine lotion
chlorhexidine solution
chloroquine
chlorphenamine
ephedrine (asthma)
ergometrine (postpartum haemorrhage)
gentian violet¹

¹ Also known as crystal violet (International Nonproprietary Name: methylrosanilinium chloride).

iodine
ipecacuanha
iron/folic acid (nutritional supplement during pregnancy)
lindane
mebendazole
oral rehydration salts
paracetamol
piperazine
tetracycline eye ointment

The selected drugs, which should be available in the dosage forms specified in the main list, can be used effectively and safely by responsible individuals with little formal medical knowledge. The list is adapted to the needs of a malarious area (free from chloroquine resistance) where helminthic infections are also endemic, and the instructions for using the drugs can be based upon the recognition of a few basic clinical signs and symptoms.

Highly trained workers might use a wider range of drugs appropriate to their diagnostic skills with acceptable safety. However, where there is no scarcity of medical manpower, the provision of comprehensive emergency and domiciliary services involves the use of many potent drugs. Decisions regarding the availability of specific drugs to community health workers can be taken only when all relevant locally operative factors have been taken into account.

In ideal circumstances antibiotics, for instance, should be used only by individuals with advanced diagnostic skills and with access to appropriate microbiological facilities. However, the need for these drugs is as great in isolated rural communities as elsewhere, and health administrators have a prime responsibility to ensure that, as far as possible, basic medical services are brought within the reach of the whole population.

13. DRUG INFORMATION AND EDUCATION ACTIVITIES

13.1 National responsibilities

Provision of information about drugs and pharmaceutical products is a prerequisite at all health care levels to ensure their proper utilization and promote rational prescribing. These levels

include: regulatory authorities; physicians; pharmacists; nurses and other health 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 varies. For example, regulatory authorities should be provided with existing technical data about a particular drug. In developing countries, however, such information is often not available, and 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, but the inclusion of sufficient and concise information with each product should allow the prescriber to achieve optimum effects while minimizing harmful effects. Since self-medication by the public is increasing, it is imperative that the information be available in a form that is understandable by individual users.

Health care professionals should receive education about drugs at an early stage of their training and this process should be continued not only throughout their formal training period, but throughout their entire professional life. For this purpose information should be gathered, analysed, collated, and distributed by the committee that selects essential drugs for the list. In addition to that included with each product, such information could be disseminated through regional training seminars, articles in medical journals, and newsletters. For the consumer, information could be provided through pamphlets, the mass media, and posters. To minimize bias, it will probably be necessary for these educational programmes to be supported by governments. It is important that the more highly trained individuals educate those who are less trained. For example, pharmacists should continually inform consumers about the rational use of products at the time they are dispensed.

Both prescriber and consumer must be persuaded that, when therapeutically equivalent, cheaper generic products are as effective as more expensive proprietary products. Consumer education is particularly important at the primary health care level, where a significant proportion of drug usage is by self-medication.

Drug information sheets

Various types of information are needed by prescribers and consumers to ensure the safe and effective use of drugs. The following list is a sample that should be adjusted to meet the needs and abilities 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).

13.2 The role of WHO

The promulgation of the Model List of Essential Drugs is only one aspect of the support that WHO offers to the implementation of effective national drug policies. National health authorities should be aware of—and, where appropriate, contribute to—the various complementary services that WHO provides to facilitate the work of national drug regulators.

13.2.1 *Information sheets on essential drugs*

The Expert Committee takes note of, and commends, the model information sheets on essential drugs that have been prepared within the Secretariat and urges that the series be maintained in a complete and regularly updated form. It acknowledges, however, that because of the widely differing circumstances under which drugs are used, this information must be adapted to local needs if it is to be used at national level. It thus endorses the Secretariat's current policy of supplying this information to national health authorities on the clear understanding that it constitutes source material for countries wishing to develop drug formularies or compendia.

The Expert Committee suggests that WHO should explore further the possible utility of developing a model drug formulary incorporating therapeutic information consonant with that already promulgated by the Organization.

13.2.2 *Exchange of information on regulatory decisions*

Over a period of many years the World Health Assembly has adopted a series of resolutions to promote the development of efficient channels of communication between national authorities concerning the safety and efficacy of drugs moving in international commerce. The basic fields of activity were identified in resolution WHA15.41 adopted in 1962, which, inter alia, requests the Director-General to study means of:

- securing regular exchange of information on the safety and efficacy of pharmaceutical preparations; and, in particular,
- securing prompt transmission to national health authorities of new information on serious side-effects of pharmaceutical preparations.

In order to promote more effective use of the established channels of communication, and to ensure that they are adequately responsive to the needs of all Member States, the Director-General invited all national health authorities in 1980 to nominate a senior official responsible for providing technical advice on the safety and efficacy of drugs to whom such information could be directed. These officials would also arrange for WHO to be kept informed of any decisions taken nationally that were of wider relevance and concern.

The Expert Committee notes that, so far, 107 countries have responded to this request. The creation of a network of officials with assigned responsibilities has greatly increased the flow of information, which is now collated by WHO and distributed to national authorities on a monthly basis.

13.2.3 *Drug Information bulletins*

Without supporting background information, regulatory decisions taken in one country are open to misinterpretation elsewhere.

The Expert Committee commends the Secretariat's initiative in producing the quarterly WHO Drug Information bulletin in an attempt to respond to this need, and notes with interest that many national health authorities have requested permission to translate its contents into their national languages. However, the Committee recognizes the logistic barriers that WHO faces in making this information widely available. It emphasizes the need for national health authorities to ensure that such information be transmitted to those individuals and institutions to whom it has direct relevance.

13.2.4 *The International Conference of Drug Regulatory Authorities*

The International Conference of Drug Regulatory Authorities, jointly sponsored by WHO and the United States Food and Drug Administration, was first held in Annapolis, Maryland, USA, in 1980. Subsequent conferences have been convened on a biennial basis. The second was held in Rome in 1982 and the third in Stockholm in 1984. An indication of its success is provided by the support it attracts: the most recent was attended by representatives from 57 countries, the majority of these being developing countries.

The Expert Committee considers that this conference provides a valuable means of intercommunication between national drug regulatory authorities. It strongly recommends that it continues to be held under the auspices of WHO.

13.2.5 *International Nonproprietary Names (INN)*

The need to identify each pharmaceutical substance by a unique, globally accepted generic name is of critical importance in facilitating communication as well as in the labelling and advertising of medicinal products in international commerce.

This is the objective of the WHO programme on the selection of international nonproprietary names which, since 1950, has published the names of roughly 5000 new products. Its role is to coordinate and harmonize the activities of existing national drug nomenclature commissions, which have come to accept a common set of conventions for devising generic names. Officially assigned generic names now rarely differ from the INN, and some countries have disestablished their national commissions and automatically accept all recommended INN.

The procedure for selecting INN allows manufacturers to contest those names that are either identical or similar to their licensed trademarks. In contrast, trademark applications are disallowed, in accordance with present procedure, only when they are identical to an INN. A case for increased protection of INN is now apparent as a result of competitive promotion of products no longer protected by patents. Rather than marketing these products under the generic name, many companies apply for a trademark derived from an INN. This practice endangers the principle that INN are public property; it can frustrate the rational selection of further INN for related substances, and it will ultimately compromise the safety of patients by promoting confusion in drug nomenclature.

The Committee requests manufacturers not to apply for trademarks that are derived from INN and encourages national drug regulatory authorities to disallow the use of such trademarks.

While INN are widely used in reference books and publications they are not always identified as such, or even accorded preference, particularly in the case of older substances that may have several different generic names. Editors are urged to give preferential use to INN in reference works, journals, and data banks and to allow the

use of a code name for a new substance (pending the assignment of an INN) rather than an unofficial name.

13.2.6 *Certification scheme on the quality of pharmaceutical products moving in international commerce*

Drugs intended for export are not always subjected to the same control procedures as those produced for the home market. In this case, developing countries lacking adequate laboratory facilities for drug analysis are at a particular disadvantage. To redress this unsatisfactory situation, WHO has sought to extend and unify schemes already operated by the health authorities of some exporting countries under which certificates are issued on request to foreign importers in respect of drugs subjected to statutory control.

Definitive proposals relating to a certification scheme on the quality of pharmaceutical products moving in international commerce were adopted by WHO in 1975 (resolution WHA28.65).¹ Since then, 108 countries have agreed to participate through designated national authorities.

The scheme provides an administrative mechanism whereby importing countries can:

(1) obtain assurance that a given product has been authorized for sale in the exporting country, and, if not, obtain information on the reasons why authorization has been withheld in the country of export;

(2) obtain assurance that the manufacturing plant in which the product is produced (a) is subject to inspections at suitable intervals, and (b) conforms to the requirements for good practices in the manufacture and quality control of drugs, as recommended by WHO;

(3) exchange information on the implementation of inspections and controls exercised by the authorities in the exporting country. In the case of serious quality defects, requests for enquiries may also be made.

Certificates relating to specific products from identified manufacturers are issued by the competent authority of the *exporting country, but only upon the request of the importing authority or other interested party.*

Certificates may be requested whenever a product is imported. They are of particular value if the manufacturer is unknown to the

¹ WHO Official Records No. 226, 1975, p. 88 *et seq.*

importing authority and if a drug is being imported for the first time. For products that were imported before the WHO scheme came into operation, the authorities of the importing country may consider requesting certificates when renewing the import licences, updating the registration files, or issuing new tenders.

The Expert Committee endorses a recommendation adopted by the 3rd International Conference of Drug Regulatory Authorities, Stockholm, 1984, which states that:

“The information provided under the Scheme, as it now exists, is inadequate for the initial registration of a new product, particularly insofar as it does not include data on safety and efficacy officially approved in the country of origin. WHO is requested to explore the feasibility of extending the Scheme, if necessary by formal amendment, to secure the provision of this additional information”.¹

13.2.7 *Quality control of drugs*

The development of the WHO Model List of Essential Drugs has provided a natural focus for the International Pharmacopoeia. It has also enhanced its potential value to developing countries.

According to the recommendations formulated at the 28th and 29th meetings of the WHO Expert Committee on Specifications for Pharmaceutical Preparations, essential drugs have been accorded priority in the third edition of the *International pharmacopoeia*. All quality specifications are supported by classical methods of testing and analysis, and a plan for a small quality control laboratory has been provided in which the majority of these tests can be performed.²

Having regard to the importance of assuring the quality of essential drugs, the Expert Committee commends the institution of such a laboratory and the adoption of the *International pharmacopoeia* by those countries currently lacking means to confirm independently the quality of the supplies they procure.

¹ *Proceedings of the 3rd International Conference of Drug Regulatory Authorities, Stockholm, 10–15 June, 1984*. Stockholm, Swedish National Board of Health and Welfare, 1984.

² WHO Technical Report Series, No. 704, 1984.

14. 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 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>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: — the variation of drug concentrations in tissues with time, — absorption, distribution, metabolism, and excretion of drugs and metabolites.
<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.

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