NATIONAL DRUG FORMULARY AND ESSENTIAL DRUGS LIST ACT

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ARRANGEMENT OF SECTIONS

SECTION

An Act to prescribe a National Drug Formulary and Essential Drugs List and to prohibit importation into and manufacture in Nigeria of any drug not in the List.

[1989 No. 43.]

[13*th December,* 1989]

[Commencement.]

1. National Drug Formulary and Essential Drugs List

There is hereby prescribed for the Federal Republic of Nigeria a National Drug For- mulary and Essential Drugs List as specified in the First Schedule to this Act (hereinafter referred to as "the List").

[First Schedule.]

2. Prohibition on importation, etc., of drugs not in the List

No person shall import into, advertise, display for sale, sell or manufacture in Nigeria any drug which is not contained in the List.

3. Importation, etc., of drugs not in the List

(1) Notwithstanding the provisions of section I of this Act, where the Minister is sat- isfied that it is necessary to import or manufacture any drug not in the List on the following grounds that-

(a) the drug is a cure for-

(i) any uncommon disease; or

(ii) a disease requiring highly specialised skill for diagnosis and treatment; or

(b) there is intolerance or lack of response to the common drugs listed;

(c) a drug of greater activity than the one in the List was not included in the List due to insufficient experience with it under local conditions,

he may, on the recommendation of the appropriate body, permit the importation or manu- facture of such drug and the inclusion of such drug in the List.

4. Establishment of Review Committee and membership

(1) For the purposes of the implementation of the List, there is hereby established the National Drug Formulary and Essential Drug List Review Committee (hereinafter re- ferred to as "the Review Committee").

(2) The Review Committee shall consist of the following members to be appointed by the Minister, that is-

(a) two clinical pharmacologists, one of who shall be the chairman;

(b) the Director of Food and Drugs Administration and Control in the Federal Ministry of Health;

(c) the Director of Hospital Services and Training in the Federal Ministry of Health;

(d) the Director of Primary Health Care Programme in the Federal Ministry of Health;

(e) four heads of pharmacy departments appointed from State Ministries of Health so however that not more than one shall be appointed from anyone particular State on zonal rotation;

(f) one representative of the Pharmaceutical Society of Nigeria;

(g) one representative of the Nigerian Medical Association;

(h) one representative of the Pharmaceutical Manufacturers Association of Nigeria; and

(i) two medical practitioners appointed by the Minister.

5. Functions of the Review Committee

The Review Committee shall, from time to time, review the List and advise the Min- ister on any addition to or deletion from the List, as may be necessary.

6. Tenure of office of members of the Review Committee

(1) The tenure of office of members of the Review Committee, other than those ap- pointed from the Federal Ministry of Health, shall be three years.

(2) A member of the Review Committee shall be eligible for reappointment for a further period of three years.

7. Pharmaceutical companies, etc.

A pharmaceutical company or firm or any other body (corporate or unincorporate) may make representation to the Review Committee on any drug or formulation not in the List which it considers to be necessary for essential health care and it shall be expedient for the Review Committee to consider such representation.

8. Offences and penalties

(1) Any person who contravenes the provisions of section 2 of this Act shall be guilty of an offence and liable, on conviction, to a fine of NlOO,OOO or to imprisonment for a term not exceeding fi ve years.

(2) Where an offence under this Act is committed by a body corporate, every director or person in authority in that body corporate shall be held liable.

9. Monitoring of the List

There shall be established in the Department of Food and Drugs Administration and Control in the Ministry, a Secretariat, which shall be responsible for the monitoring and implementation of the List.

10. Removal of drug from the List

Notwithstanding the provisions of section 5 of this Act, the Minister may remove any drug from the List where it has been established to his satisfaction that the drug in ques- tion is no longer safe for use.

11. Information for guidance of medical practitioners, etc.

The Drug Formulary contained in the Second Schedule to this Act shall serve as in- formation guidance to medical practitioners, pharmacists and other users of the informa- tion specified therein.

[Second Schedule.]

12. Interpretation

In this Act, unless the context otherwise requires-

"appropriate body" means the National Drug Formulary and Essential Drug List Review Committee established by section 4 of this Act;

"essential drugs" means drugs that satisfy the health care needs of the majority of the population;

"Minister" means the Minister charged with responsibility for health matters and

"Ministry" shall be construed accordingly.

13. Short title

This Act may be cited as the National Drug Formulary and Essential Drugs List Act.

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FIRST SCHEDULE

[Section 1.]

General information for use of the Formulary

A. ARRANGEMENT OF INFORMATION

This National Drug Formulary and Essential Drugs List is divided into two parts. Part I is the Essential Drugs List and Part IT, is the Drug Formulary.

Part I, the Essential Drugs List, is divided into two sections: The first section or main section contains the general List of essential drugs, numbering 204 different drug entities. The second section contains a small List of 31 drugs for the primary health care level.

Part II is divided into four chapters. Chapter 3, the Classified Notes on Drugs and Prepara- tions, is divided into nineteen sections according to main pharmacological divisions or to main drug treatment areas. Chapter 4, the Formulary section, is an extension of Chapter 3, contain- ing the different dosage form presentations, strengths and the compositions of drug prepara- tions described in Chapter 3. It also covers the formulations of extemporaneous preparations which are in common use and can be readily prepared in pharmacies.

An index of names of drugs and preparations is included for quick reference in the book.

B. CLASSIFIED NOTES ON DRUGS

1. The formulary provides drug information for the drugs selected in the only Essential Drugs List. However, other drugs in common use but not included in the Essential Drugs List are mentioned.

2. The pharmaco-therapeutic notes included under the main pharmacological divisions, therapeutic and sub-therapeutic groups, are intended to provide a quick reference guide to doctors, pharmacists, nurses, etc., on the use of the various groups of drugs in the Essential Drugs List. These short notes are not meant to replace the consultation of appropriate text- books, etc., for more broad-based information.

3. The notes are followed by the selected drugs and their relevant drug information (dosage forms, pharmacological properties, uses, adverse effects, dosage, etc.). Again, these prescrib- ing and dispensing information are considered to be very important, concise, and by no means inclusive of all possible information relating to the indications, adverse and side effects, etc., of many drugs.

C. DRUG TITLES

Drug titles are given in their pharmacopoeial or non-proprietary (generic) names in both the Formulary and the Essential Drugs List, except in the case of Diagnostic Agents (Chapter 3, section 19) where, for practical purposes, the proprietary names of certain products have also been included. Details of the drug dosage formulations and common extemporaneous preparations are given in Chapter 4, the Formulary section.

Introduction

THE SELECTION OF ESSENTIAL DRUGS

Definition

"Essential drugs" have been defined by The World Health Organisation (WHO) as those drugs that satisfy the health care needs of the majority of the population. They should there- fore be available at all times in adequate amounts and in the appropriate dosage forms at all levels of the health care delivery system of the country. Their selection is based on the most common local diseases. The concept of essential drugs was approved by the World Health Assembly in 1975, and in 1977 the World Health Organisation produced its first model list of essential drugs. Since then more than eighty countries, practically all in the Third World, have adopted lists of essential drugs based on the WHO model list.

As emphasised by the World Health Organisation an essential drugs list only indicates priorities in drug needs. Tt does not mean that no other drugs are useful and exclusion does not necessarily imply rejection.

The need for an Essential Drugs List

In recent years there has been a big increase in the number of drugs marketed, but this increase has not been matched by a proportional improvement in health. If anything, the indis- criminate use of multiple drugs in treatment has led to a big increase in the frequency of drug- induced diseases.

The present situation is that drugs are procured with little regard to the needs and priori- ties of health care in the country. Availability of drugs in the health care system is largely a response to the sales promotional activities of manufacturers and distributors. Such pressures lead to a proliferation of available drugs which bear little relation to the actual needs of the

population. The result is the present situation in which the basic drug needs of a large percent- age of the population cannot be satisfactorily met by the available drugs. There is therefore need for a change to a system in which, as far as the public sector of the health care system is concerned, priority is given to drugs proven to be therapeutically effective, to be reasonably safe and to satisfy the health needs of the population. These are the so called "essential" drugs.

Having accepted the *Alma Ata* declaration of health for all by the year 2000, making health care accessible to the entire population has become a major concern of the government, and the primary health care programme is designed to make the attainment of the goal of health for all possible.

One of the essential elements of primary health care is the provision of essential drugs. Drugs occupy a unique position in health care. They make health care credible because they can cure diseases, relieve symptoms and alleviate suffering. The psychological satisfaction produced by drugs creates a favourable environment on which the preventive and education elements of health care can be built with consequent further improvement in health. It is obvi- ous, therefore, that the present situation in which regular availability of the most needed drugs cannot be ensured is not conducive to the attainment of the goal of health for all. On the other hand, the successful application of the essential drugs concept will go a long way towards improving the availability of the most needed drugs in Nigerian health care delivery system.

Criteria for selection

In selecting this list of essential drugs the Federal Ministry of Health was guided by the following principles-

1. The drugs in an essential drugs list should satisfy the health care needs of the great major- ity of the people at all levels of health care delivery.

2. They should be drugs for which there is sufficient evidence of efficacy and safety from controlled clinical studies and from experience in general use.

3. The preferred dosage forms are those which have a reasonable shelf-life and are able to withstand adverse environmental conditions unavoidable in the distribution chain. For exam- ple,

tablets and capsules are probably more stable under our prevailing ambient temperatures than mixtures, syrups and elixirs. Except in infants, where specific paediatric formulations are indispensable, convenient paediatric doses can be achieved from the use of a wide range of dosage strengths of tablets (e.g. aspirin tablets, 75 mg., 100 mg., 300 mg., 500 mg., 600 mg.) or of scored tablets.

4. They should be drugs for which quality certification can be readily obtained from local institutions, or from the country of origin or through the auspices of the World Health Organisation.

5. They should be drugs that can either be manufactured locally using locally produced or imported raw materials or that can be imported in bulk, cheaply.

6. The drugs have been selected, as much as possible, in their generic names.

7. Where there is a large number of drugs in a particular therapeutic group (e.g. antihypertensives), preference is given to the drugs for which there is local experience with regard to efficacy and safety.

8. When one drug has been named in a particular chemical group containing a variety of structural analogues (e.g. thiazide diuretics), other members of the group can be substituted for the named drug. Factors which may determine the choice of product in this instance in- clude comparative cost, frequency of administration, ease of procurement and availability of desired dosage forms.

9. Selection of one member of a pharmacodynamic group (e.g, beta-adrenoceptor blockers, direct vasodilators, non-steroidal anti-inflammatory drugs) does not preclude the use of other drugs in the same group, provided they satisfy the requirements for safety and efficacy.

10. Single component drug formations are, as a rule, preferred to fixed-dosage drug combinations since individualisation of dosage in therapy is often difficult or impossible with the

latter. However, in some instances, a fixed-dosage drug combination meets the requirements of a given clinical situation and has clearly-defined advantages in efficacy, safety and comp- liance, over separately administered single drugs. Such fixed-dosage combinations have been included in the List.

11. Drugs and preparations with unproven or doubtful therapeutic effect, even when

hallowed by long usage, have not been selected. For this reason remedies like throat lozenges, expectorants, tonics, gripe water and enzyme mixtures are not in the List.

12. Drugs with known serious side effects but with acceptable risk/benefit ratio because of the severity of the conditions for which they are used, have been included in the expectation that

their procurement, storage, distribution and use would be subject to the usual medico- legal and ethical constraints associated with such drugs.

Deficiencies of an Essential Drugs List

Although, if carefully selected, an Essential Drugs List should satisfy the needs of the vast majority of the population, it is clear that it will not provide the needs of every person. Situations which the Essential Drugs List may not cover include-

1. Uncommon diseases, especially where the drug treatment is still subject to frequent changes.

2. Diseases requmng highly specialised skills and facilities for diagnosis and treatment. These, as a rule, will be encountered only in tertiary health care institutions.

3. Instances where less popular drugs may need to be used due either to lack of response or intolerance to the commoner drugs listed. Patients in this kind of situation often need to be evaluated in tertiary health care centres.

4. Drugs of probably greater activity than the ones selected but for which experience in the field and particularly under local conditions is not sufficiently convincing to be listed. The high cost of a drug still under patent may make its selection untenable even when there is lo- cal evidence of its comparability with, or even advantage over, selected ones.

Expected advantages of an Essential Drugs List

Experience from other countries which have operated an essential drugs policy over the past few years has demonstrated a number of advantages-

1. There will be a reduction in the number of drugs deployed in the health care system. This will make easier the administrative processes involved in procurement, storage and distribu- tion.

2. With the limited number of drugs and the use of generic rather than proprietary names, it would be easy to provide concise, accurate and comprehensive information in the form of a national formulary on all the drugs in the Essential Drugs List.

3. It should be a lot easier for prescribers to familiarise themselves with the pharmacological properties of the prescribed drugs, thus improving the quality of drug treatment.

4. Drug utilisation in the various sectors of the health care system can easily be monitored. True quantitive requirements can therefore be determined. Knowledge of this should stimulate local pharmaceutical industries in the production of needed drugs in the right amounts.

5. It should be easier for the Federal Ministry of Health to formulate strategies for the evaluation of the quality of drugs and for the inspection of factories for compliance with the guidelines for good manufacturing practices.

6. It should be relatively easy for local committees, especially in the tertiary health care institutions, to meet the needs of the various specialities and unusual clinical situations not covered by the National Drug Formulary and Essential Drugs List.

Finally, this Essential Drugs List contains 205 different drugs including a few fixed combination products. Drugs which are useful in more than one therapeutic area have recurred in the list, but counted only once. The drugs are shown with the pharmaceutical dosage forms and strengths in which they should be available. An index of the drugs is included for easy reference.

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