Annex 8
National drug regulatory legislation: guiding principles for small drug regulatory authorities

Introduction

Countries in both the developed and developing world need to fit their approach to drug regulation to their resources. All countries share the responsibility of assuring the quality, safety and efficacy of medicinal products, including biologicals.

In order to ensure the quality of pharmaceutical products, the manufacture and subsequent handling of the products — including their distribution within the domestic market and their movement in international trade — must take place under defined conditions and in conformance with prescribed standards. Medicinal products cannot
be treated like most consumer commodities. Both legislative and administrative controls must reflect the special considerations to be applied to such products.

Provision of assistance to countries with limited resources has long been regarded as a vital element of the work of WHO. In the wake of the 1985 Conference on the Rational Use of Drugs held in Nairobi, WHO embarked on the development of two key documents, the *Guidelines for developing national drug policies* (1), in which legislation and regulation are identified and described as the first component of a drug policy, and the “Guiding principles for small national drug regulatory authorities”, which was published in 1990 (2) and endorsed by the World Health Assembly in 1994 (Resolution WHA47.17). Many countries have since begun to implement drug regulatory activities in accordance with these guidelines, but some still need to develop and/or update their basic drug legislation to support drug regulation. As stated in the latter (2):

Small countries which have yet to introduce comprehensive legal provisions for drug regulation can draw from a diversity of national systems in determining their own requirements. None the less, problems in establishing drug control in developing countries have too often resulted from the adaptation of provisions successful elsewhere but of a complexity that precludes their effective implementation in the country of adoption. It is of paramount importance that legislation and administrative practices are attuned to available resources and that every opportunity is taken to obtain and use information provided by regulatory authorities in other countries.

The manufacture, marketing or importation of medicinal and other health care products continues to be regulated in many countries by statutory texts that are not attuned to prevailing needs or available resources, or by independent legal provisions introduced piecemeal over a period of many years. Even where there is no specific law that relates to medicinal products, there will almost certainly be some legislative provisions that apply to health care products in general. In formulating a new law, therefore, the existing provisions must be carefully considered. There should be wide consultation with interested parties, particularly those directly concerned with manufacture, importation, distribution and supply of medicinal products.

The present guidelines, with an example of a legislative scheme for medicinal products and accompanying commentary, are intended for drug regulators, those drafting legislation and parliamentarians in countries wishing to review or elaborate legal texts to regulate
medicinal products. The first draft of these guidelines was developed after an informal consultation on drug legislation for drug regulation by small national drug regulatory authorities, held in Geneva in 1993. The text was subsequently circulated for consultation and comments to members of the responsible WHO Expert Advisory Panel, to all WHO Member States through the WHO Information Officers, and to relevant nongovernmental organizations, in particular the two nongovernmental organizations representing the pharmacy profession — the International Pharmaceutical Federation (FIP) and the Commonwealth Pharmaceutical Association (CPA). The text was revised and finalized in the light of comments received, at a further informal consultation that was convened in Geneva in 1996. It should be noted that the scheme given in section 4 is an example, and countries with different cultural and legal backgrounds might consider different approaches, although the overall content of the example would still be relevant (see Appendix 1 for a provisional legislative scheme on registration of pharmacy personnel).

These guidelines are not intended to be translated as they stand into national legislations but to be used as source documentation and to be adapted as necessary. While they should be of immediate value to many countries still in the process of establishing drug regulatory and legislative systems, other countries might also profit from such a framework. As regards the latter, it must be emphasized that authorities should always be cautious about changing systems and procedures that work effectively.

Drafting national legislation: points for consideration

These guidelines are based upon and complement the “Guiding principles for small national drug regulatory authorities” published by WHO (2). They are intended to assist governments in formulating laws and regulations to define and control the national market in medicinal products in the interest of public health. They describe an administrative framework for a regulatory system to ensure the quality, safety and efficacy of licensed (authorized) medicinal products, and to authorize withdrawal of unsafe and/or illicit medicinal products from the market.

The advice assumes that only in exceptional circumstances will a small authority become engaged in full evaluation of all toxicological, pharmacological or clinical properties of a novel medicinal product (for example, a new chemical entity) during the regulatory assessment for marketing authorization. In most instances, the decision will be
guided by the regulatory status of the product in the country of origin
on the basis of information provided through the WHO Certification
Scheme on the Quality of Pharmaceutical Products Moving in Interna-
tional Commerce (3). However, such approval may depend on a
knowledge and acceptance of the standards and competence of the
drug regulatory authority of the exporting country, by the drug regu-
laratory authority of the importing country.

Objectives

1. The objective of the drug regulatory legislation is to provide a
framework for drug regulation through the establishment of a na-
tional drug regulatory authority.

2. The primary responsibility of a drug regulatory authority is to
operate a system of administration and enforcement to ensure that all
medicinal products subject to a drug regulatory authority control
conform to acceptable standards of quality, safety and efficacy; the
promotion and marketing of medicinal products is in accordance with
product information as approved; the use of drugs is rational; and that
all personnel, premises and practices employed to manufacture, store,
distribute and sell, supply and dispense these products comply with
requirements to ensure the continued conformity of the products with
these standards, up to the time of usage/consumption.

3. The objectives of the drug regulatory authority can be effectively
accomplished only if:

(a) there is a mandatory system to license/authorize:
   (i) all medicinal products, whether locally manufactured or
       imported;
   (ii) all local manufacturers, importing and exporting agents, and
distributors; and
   (iii) all premises and facilities used locally to manufacture, store
or distribute medicinal products.
(b) all stages of manufacture and distribution of medicinal products
are supervised by appropriately qualified professional staff;
(c) the licensing/authorizing system is complemented by an efficient
system of inspection with access to quality control laboratory
facilities;
(d) the legislation is enforceable.

4. In addition to providing for licensing/authorizing, a law on medici-
nal products must define the terms of reference, powers and functions
of the drug regulatory authority, the powers of enforcement, and
include provision on the right to appeal or otherwise react to the decisions of the drug regulatory authority.

**Scope and extent of the legislation**

5. The scope of the term “medicinal product” must be defined in all encompassing terms to cover pharmaceuticals, biological products (vaccines, blood products, other biologicals) and herbal products, whether for animal or for human use, including traditional medicines sold in package form (but not products harvested by traditional medicine practitioners) and products known in many countries as “pharmafoods”, “nutriceuticals”, or “cosmeceuticals” intended for therapeutic use. The drug regulatory authority must also determine to what extent it intends to exempt related products, such as diagnostic materials, medical devices, cosmetics, health foods and food supplements from the scope of its marketing authorizations. The legislation must state whether it includes or excludes related products. In borderline cases it may be left to the regulatory authority to decide whether a substance or preparation is considered a medicinal product.

6. The legislation must apply to all institutions and individuals, within both the public and private sectors, that are engaged in or connected with any aspect of manufacture, promotion, procurement, distribution, sale, or supply of medicinal products.

**Terms of reference for the drug regulatory authority**

7. The terms of reference, functions, responsibilities, powers and composition of the drug regulatory authority must be set out in the legislation. The structure, name and style of the authority will be determined essentially by precedent. In some countries with extremely limited human resources, it may be necessary for a single individual to function in this capacity. It is particularly important to designate the advisory apparatus and to define the circumstances in which its advice must be obtained.

8. The terms of reference of the authority need to be clearly set out in the law in a way that establishes its responsibilities with respect to the following functions:

(a) to require that all medicinal products manufactured in, imported into (including donations) or exported from the country conform

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*This text uses the terms "law" and "legislation". In formulating the legal provisions, it should be noted that certain regulatory matters will be specified in the main statute (enabling or principal law, act or decree) while other matters will be addressed in subsidiary legal texts such as orders, by-laws, regulations and the like.*
to established criteria of quality, safety and efficacy, and that the personnel, premises and practices employed to manufacture, promote, procure, store, distribute and sell such products comply with defined codes of practice and other requirements;

(b) to require continued conformity of medicinal products with such standards until their delivery to the end-user;

(c) to require that medicinal products are imported, manufactured, exported, stocked, sold, distributed or otherwise dealt with by duly authorized persons;

(d) to grant or refuse, after due assessment, licences/authorizations for medicinal products, whether locally manufactured or imported, and whether destined for the national market or for export;

(e) to inspect and license/authorize all domestic manufacturing premises, importing agents, wholesalers, distributors, clinics, hospital dispensaries, retail pharmacies and other outlets where medicinal products are sold;

(f) to sample and test finished medicinal products released into the distribution chain to ensure their compliance with approved specifications;

(g) to monitor and review the implementation of the legislation; and

(h) to ensure that advertising and marketing are in accordance with product information approved by the drug regulatory authority.

**Structure of the drug regulatory authority**

9. In order to discharge its duties effectively, the drug regulatory authority must function within an administrative and legal environment that assures its independence of action and its access to effective channels of communication. Procedures should be laid down giving the mechanism by which members and staff of the authority are appointed, their terms of reference and duration of office. Legislative provisions need to be supplemented or complemented by administrative procedures designed to safeguard the independence, integrity, effectiveness and impartiality of the authority. For instance, administrative or disciplinary rules should specify that members and staff should not be involved in any activity that is liable to create a conflict of interest. To maintain the independence of the authority, responsibilities for regulation of medicinal products should be administratively and operationally separated from activities concerned with their procurement or distribution.

10. The authority must exercise its powers independently and impartially. Lawful and *bona fide* activities and decisions must
be protected by conferring relevant empowerment(s)/immunities on staff and others working for the authority. Conversely, provision must exist to enable affected parties to obtain relief or redress in accordance with national law. The legislation should contain a clause on the confidentiality of sensitive commercial data.

11. The conditions of service, remuneration and working arrangements must be such that vested interests cannot exert any undue influence over staff or others working for the authority.

**Products, personnel, facilities and practices that are subject to regulation**

12. Regulatory controls should extend to all medicinal products on the domestic market as well as those destined for export. As most developing countries rely mainly on imports to meet their drug requirements, it is important that not only the imported medicinal products themselves, but also the procedures involved in promoting, importing, storing, distributing or selling them, are regulated by law. Countries with domestic manufacturing capabilities need to ensure that regulations provide safeguards for the quality of starting materials imported or obtained locally, either through a licensing process or as part of good manufacturing practices (GMP).

**Issuance of definitive product authorization/licence and transitional provisions**

13. In countries without a comprehensive system in place for the regulation of medicinal products, legislation provisions must be formulated for:

- authorizing/licensing of all products proposed for marketing after the “appointed date” for the licensing system;
- transitional arrangements to ensure that products on the market before the appointed date can continue to be marketed, within the regulatory system;
- the subsequent review and full registration of products authorized under the transitional provisions; and
- the regulation of renewal of the product authorization/licence after lapse of the period for which the licence is being issued.

**Product licensing/issue of marketing authorizations**

14. The legislation should establish the legal framework under which applications to market medicinal products are submitted to the drug regulatory authority, and the procedure for the assessment of applications and the granting or refusal of marketing authoriza-
tions. The assessment should be based on defined criteria for safety, quality and efficacy. The legislation should place the onus on the applicant to provide information and data necessary for this assessment.

15. The legislation should provide for regulations determining the amount of licensing/authorizing and renewal fees.

Transitional arrangements

16. A procedure is proposed in the “Guiding principles for small national drug regulatory authorities” (2) in which an inventory is drawn up of all medicinal products on the market before an appointed date. These products have the status of being “provisionally authorized/licensed” until such time as full authorizations/licences are granted. Depending on the timing of the implementation and the availability of information on medicinal products in circulation, the inventory can be established by:

— including requirements under the legislation that manufacturers, importers and distributors of medicinal products who intend to continue to manufacture, promote, import, distribute and sell medicinal products after the appointed date must submit specified information on those products to the regulatory authority, before the appointed date;
— compiling the inventory on a more “informal” basis, from available information (price lists, publications, etc.) and data supplied voluntarily by companies.

In either case the information should be collected in a form suitable for entry into a computerized database such as the computerized drug registration system developed within WHO. This will enable the inventory of products to be organized and sorted for subsequent review (see Appendix 2).

Review of provisionally authorized/licensed products

17. The legislation should establish a framework for the review and assessment of provisionally authorized/licensed products, for full registration under the product authorization procedures for new products. The timetable for the review should be determined by administrative procedures, as the pace at which these assessments can be undertaken will depend on available resources. Priorities for the review of provisionally authorized/licensed products should normally be determined by therapeutic class and based on health-related priorities established within the national drug policy or national health framework/policy.
18. The legal mandate to request the submission of applications for re-registration of medicinal products marketed prior to the appointed day should be embodied in the legislation, but details of the format and content of applications are, again, best dealt with in regulatory guidelines, to allow greater flexibility.

**Authorizing/licensing of manufacturers, importers, exporters, distributors and retail outlets**

19. Organizations engaged in the manufacture, promotion, import, export, distribution, sale or supply of provisionally registered or licensed medicinal products must meet prescribed criteria or requirements regarding facilities, personnel and practices, intended to ensure the quality of the product up to the time of usage/consumption. These criteria and requirements must be specified in law. In addition to numerous resolutions of WHO’s governing bodies, several texts developed under the aegis of the Organization offer guidance on the elaboration of such criteria and requirements (see Appendix 2).

**Enforcement**

20. The administrative capacity of the drug regulatory authority must be complemented by an effective inspectorate, suitably trained and mandated to monitor compliance with the legislation. To achieve this it is necessary to liaise with other relevant law enforcement offices attached to related government agencies or authorities, and in some countries it may also be necessary to enlist the services of these law enforcement offices. In this case, the law must contain provision to confer appropriate authority on such offices to exercise statutory powers under the law governing medicinal products.

21. Provision must exist requiring manufacturers to recall unsafe, defective or inappropriately labelled medicinal products from the market and destroy them, to suspend manufacture if facilities or operations are found to be below standard, and to cease unethical promotion activities.

22. The emergence in recent years of counterfeit and other illicit products within domestic and international markets has imposed an extra dimension on the work of regulatory authorities and inspectors. It has also created a need for enhanced collaboration between regulatory authorities, licence holders, customs officials and law enforcement authorities, and for greater vigilance by all persons involved with the manufacture, distribution and sale of medicinal products. Consideration should now be given to legal provisions that facilitate timely and efficient exchange of information between the
parties concerned, both nationally and internationally, to counteract illicit trade.

**Penalties**

23. The law must provide a range of specific penalties and other measures to deter violations of provisions of the legislation. Provision for the right to appeal, or other measures to react to the decisions of the drug regulatory authority, should be included.

**Monitoring and evaluation**

24. A legislative text containing the above provisions lays the basis for an important administrative system. It is advisable, therefore, for the text to contain provision for overseeing and reviewing the operation of the system. The drug regulatory authority should thus have as one of its tasks the preparation of general and thematic reports, at periodic intervals, on the implementation of the law. These reports should, *inter alia*, underline deficiencies and weaknesses in the system and propose remedial action. Statutory provision requiring such reports to be tabled before the legislative assembly will ensure that they receive due attention.

**Defining the scope of the marketing authorization procedure for medicinal products**

This section complements the “Guiding principles for small national drug regulatory authorities” published by WHO (2).

The formulation of laws and regulations to define and control the national market in medicinal products is discussed elsewhere. In this section the scope of the application of the authorization/licensing system is discussed, with particular reference to finished medicinal products.

The prime objective of every national drug regulatory system is to ensure the safety, quality and efficacy of medicinal products. For administrative and judicial purposes a precise definition of “medicinal product” must be established in the national drugs legislation. This definition commonly reflects the usage for which the product is intended, e.g. “medicinal purpose” (see paragraph 5, p. 106).

In turn, “medicinal purpose” must be defined. Any such definition will refer to the treatment and prevention of disease, but — in order to include products such as contraceptives and anaesthetic drugs — the meaning is commonly extended in a more arbitrary sense to
include diagnosis of a disease or a physiological condition, and modification of a physiological function.

Safe and effective use of a medicinal product depends not only upon its innate biological activity, but also upon the judgement, knowledge and qualifications of the person responsible for supplying, selling, prescribing, or administering it, and on the evaluation by the national drug regulatory authority. Products must be classified subject to international conventions concerning narcotics and psychotropic substances. Furthermore, each medicinal product should be classified according to whether it is:

(a) available only on the authority of a doctor, dentist or veterinary surgeon — prescription-only medicines; or
(b) available under the supervision of a pharmacist only from a registered pharmacy — pharmacy-only medicines; or
(c) available from retail outlets other than under the supervision of a pharmacist.

The terms of reference of a national drug regulatory authority are typically directed to regulation of the distribution, sale, supply and promotion of medicinal products, not to regulating the practice of medicine. However, decisions taken by the drug regulatory authority will no doubt influence prescribing behaviour and may contribute to rational use of drugs.

The drug legislation should include exemptions from the authorization/licensing provisions, for extemporaneous dispensing and small-scale production carried out by or with the order of appropriately qualified practitioners (pharmacists, physicians, veterinarians and registered practitioners of other named systems of medicine). Safeguards covering quality assurance and limits on quantities should be included. Special provision is included in many drug acts to regulate the range of medicinal products that practitioners other than registered practitioners are legitimately allowed to use. Such provisions have been developed in many countries for herbal products and homoeopathic products in particular.

Every regulatory authority faces the difficulty of determining whether particular “borderline” products are “medicinal products” within the meaning of the drug legislation. Tonics, food supplements, medicinal soaps and shampoos and other topical preparations for which medicinal therapeutic claims are made are examples of these products. Sufficient flexibility should be preserved in drafting the legislation to enable specific classes of products to be subject to or specifically
excluded from the requirement for registration. The drug regulatory authority may be given statutory power to decide in borderline cases whether a product is medicinal or not.

**Administrative coordination**

Determining the scope of the marketing authorization will be strongly influenced by existing administrative arrangements. It is particularly important to recognize that a department of veterinary services or one dealing with traditional medicine practices may administratively oversee services without exercising regulatory control over the products used within the specific discipline. Before any decision to extend regulatory action to products relevant to these or other departments is contemplated, there is a need for interdepartmental consultation and coordination to determine any required legislative change, with a view to defining the products to be subjected to legal controls, the parameters of the proposed jurisdiction, the required regulatory powers and the associated responsibilities. The mechanics of exercising controls must be discussed and mutually agreed upon. There must be a clear demarcation of responsibilities and access to effective channels of communication. The administrative and technical competence of the ministries, departments, agencies or authorities must be respected at all times; issues of possible duplication or conflict of interest must be clarified as soon as possible.

Several legislative and administrative strategies exist to ensure closer and effective coordination between all concerned parties. Provision should be made, for instance, for prior consultation with such parties before the authority considers regulatory action. Representation of such interests on the authority itself is another possible option. The authority may even establish a sub-committee (e.g. a sub-committee on medical devices) with the mandate of assessing a particular type of product for regulatory action.

**Availability of data**

For the assessment of certain products, particularly those used in traditional medicine, often only limited data are available. When evaluating such products great care should therefore be exercised. The onus is on the applicant to provide the data required by the authority with respect to quality, safety, efficacy and registration status in other countries. Regulatory agencies may, however, require additional information about ingredients or the availability of similar medicinal products in other countries. Access to published sources of information is needed and authorities may also solicit the cooperation
of drug regulatory authorities in other countries willing to share available data, subject to existing rules of confidentiality. WHO also has an important role to play in coordinating the supply of information from its own sources and through its information officers.

The revised WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce covers medicinal products both for human use and for use in food-producing animals. Experience to date suggests that its extension to cover a group of veterinary medicines has facilitated the work of authorities. The rationale underlying the Certification Scheme is equally applicable to all health-related products. By legislation, the concept of a certificate provided for by the existing scheme can be extended to cover all or selected health products.

**Technical competence**

In view of the technical nature of the work involved in the regulation of medicinal products, the drug regulatory authority should employ appropriately qualified scientific staff. In addition the authority should be able to enlist the assistance of professionals who might have specialist knowledge about some of these products. Through contact with other authorities, guidance can be obtained on technical issues which require more detailed expertise. For the purposes of marketing authorizations the legislation may provide for the recognition of a medicinal product which possesses a marketing authorization in a named state.

In an increasingly interdependent world, schemes of mutual support and cooperation will provide the basis for establishing systems to ensure the quality, safety and efficacy of as many health-related products as possible.

**Example of a legislative scheme for regulating medicinal products**

**General considerations**

The structure of the example legislative scheme is based on certain assumptions. Most small developing countries have only a few qualified health professionals and are thus compelled to assign a variety of functions and responsibilities to every available official. This is in contrast to the situation in developed countries, and even in developing countries with adequate human resources for health, where there is always a group of officials — often operating within a hierarchical structure supported by advisers and committees — entrusted with regulatory responsibilities for different health care products or prod-
ucts with health implications such as drugs, food, devices, herbal medicines, cosmetics, pesticides, chemicals, narcotics, etc.

In the regulatory arena, it is customary to work through institutional mechanisms such as boards, committees or commissions consisting of several professionals. In countries without any regulatory system in place, members of a newly created mechanism will normally have to function almost on a day-to-day basis until most of the preliminary work is completed. With only a handful of qualified health professionals available to attend to all the functions in the ministry of health and even in the hospitals, it will be difficult for some small developing countries to ensure that such boards or committees will even have a quorum. Even if such boards or committees are created, it may well be that one or two officials will have to undertake most of the routine work.

This legislative scheme envisages the establishment of a drug regulatory authority or of a medicinal products board. The latter mechanism is particularly appropriate for those countries which are able to assign a sufficient number of personnel to serve on such a board. In this event, provision can be made for the appointment of a secretary to the board.

The scheme applies only to “medicinal products” (hereafter referred to as medicinal products or products). However, there is flexibility to extend the scheme to cover other health-related products, if so desired. It may well be that some countries wish to extend the same (or similar) control regimes to other products such as devices, herbal medicines, food and cosmetics, with a few additional provisions and regulation-making powers.

The drug regulatory authority or the board will be the authority in charge of the day-to-day implementation of the law. The legislative scheme provides for the creation of a small advisory committee to give guidance on general or specific policy and other related issues. The nature and composition of the board and the advisory committee depend essentially on the expertise that is available in the country and that can be mobilized for the purpose. For this reason, the size, composition and other details are not specified in the scheme itself, but left to be addressed in the regulations.

The control system provided for by the legislative scheme is structured around an “inventory” of the medicinal products available in the country. Regulation is not possible unless there is the information on available products (i.e. imported and/or manufactured) shortly after the law has come into operation.
The first step towards regulation of medicinal products is essentially the compilation of the inventory. Manufacturers and importers can be required, by law, to transmit to the drug regulatory authority or the board relevant information concerning the products placed on the market on or before a particular date (appointed date), as may be specified in an official publication such as the gazette. Notification will have the effect of "provisional authorization/registration" for the product. Notified products will be listed in an inventory which will be published or made available for public inspection. After the appointed date, a medicinal product for which information has not been provided and which does not have the status of being provisionally authorized/registered may not be imported or manufactured without the written permission of the drug regulatory authority or the board, thus facilitating control over the medicinal products currently on the market.

Provisionally authorized/registered medicinal products listed in the inventory will be subjected to a rapid screening process, primarily to secure the withdrawal of those products that do not meet standards of quality, safety and efficacy. The definitive assessment of provisionally authorized/registered medicinal products will be planned in accordance with established priorities.

New products (i.e. those not provisionally authorized/registered) may be imported or manufactured only with the prior written permission of the drug regulatory authority or of the board. Products which are the subject of applications after the appointed date for import or manufacture will be subjected to technical assessment before authorization/licence is granted.

While the proposed legislative scheme is primarily concerned with the control of medicinal products that are being imported or manufactured or sought to be imported or manufactured, the scheme provides for control of products for export as well.

Modern information technology, using desk-top computers, will facilitate the recording, updating and retrieval of information and entries (see Appendix 2). In the not too distant future it should be possible to access regulatory information provided by selected regulatory authorities and by relevant international organizations such as WHO.

As regulatory decisions affect the parties involved in manufacture, import, export or distribution, the legislative scheme provides for a right of appeal to the minister or to another administrative authority against any decision of the drug regulatory authority or the board.
The minister or such other authority may, upon considering the facts of the case, decide to affirm, modify, or rescind the decision of the drug regulatory authority or the board, or to refer it back to the drug regulatory authority or the board for reconsideration. The right of appeal to the minister or to another administrative authority is an administrative safeguard, as an aggrieved person will always have the right to appeal to a court of law, in accordance with the general laws of the country. As the decision of the minister or of such other authority will be subject to scrutiny, subject to applicable legal principles, the minister or the authority will be expected to exercise an unbiased perspective based on sound policy, scientific knowledge and the particular facts of the case. Courts of law are not normally concerned with technical decisions determined by those with the necessary scientific or technical experience and skills.

Critical to the success of the approach on which this legislative scheme is based is maximum use (through the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce) of regulatory information concerning individual medicinal products available through drug regulatory authorities. Regulatory information disseminated by WHO will also be of value here (see Appendix 2).

Besides regulating medicinal products, the legislative scheme may also regulate — through an authorization/licensing system — those who manufacture, import, export, store, dispense or distribute medicinal products. The scheme provides for regulations to specify who may be eligible for authorizations/licences and the procedures for applying for such authorizations/licences.

The legislative scheme contains only the minimum or basic provisions which a law must contain to provide a sound legislative basis for regulating drugs or medicinal products. In adapting this law to suit individual needs and circumstances additional provisions may have to be included. The provisions of the legislative scheme will be in addition to those already contained in other legislation dealing with health practitioners, such as medical practitioners and pharmacists. (See Appendix 1 for an example of a legislative scheme concerned with the registration of pharmacy personnel.)

Due to constitutional or administrative legal principles, the laws and regulations of some countries do not necessarily apply to the state or public sector, unless there is specific provision to the contrary. Even if they do apply, sometimes they are not as strictly followed as in the private sector or by the general public. This legislative scheme provides for the state or the public sector to be bound to the same extent
as the private sector or the general public. There is no scientific basis for exempting medicinal products procured or manufactured by or on behalf of the state or the public sector from regulatory and control regimes.

_Potential value of the scheme_

The basis on which the legislative scheme is structured is of particular value to small national drug regulatory authorities, with limited human and other resources, for a number of reasons:

- The scheme requires an inventory of medicinal products on the market to be compiled, and places the burden of providing the necessary information on importers, manufacturers and exporters. After the appointed date, a medicinal product for which the necessary documentation has not been submitted may not be imported, manufactured or exported without the written permission of the drug regulatory authority or the board, thus facilitating supervision of the movement of medicinal products on the market.
- The inventory can be compiled using a small desk-top computer with a software program tailor-made for the purpose.
- After the appointed date, the drug regulatory authority or the board can decide on the type of regulatory action to be taken for any individual medicinal product or group of medicinal products, bearing in mind the country’s national drug policy and health care needs, and the nature of the regulations covering the product in other countries that have comprehensive systems in place for the assessment and regulation of medicinal products. The scheme provides for a system of “provisional authorization/registration” for medicinal products for which information was provided on or before the appointed date, and a system of product licensing for medicinal products proposed for import, manufacture or export after the appointed date. Provisionally authorized/registered medicinal products must qualify for product licences/marketing authorizations after evaluation, or may have to be withdrawn from the market if so decided by the drug regulatory authority or the board. The process for such evaluation has to be phased in as small national drug regulatory authorities without trained personnel or adequately equipped laboratories will find it difficult to undertake the assessment and registration of drugs following the same procedures as countries where regulatory systems have evolved over many decades and which are able to rely on qualified personnel for the assessment of medicinal products.
• The scheme is flexible enough to permit provisionally authorized/registered medicinal products to remain on the market until such time as a decision is taken to prohibit or otherwise regulate them, thus preventing any sudden or artificial shortages. This approach is preferred to those which do not permit any medicinal products to be marketed unless authorized, registered or licensed since personnel constraints will not permit the speedy assessment of medicinal products. Under the scheme the market will be gradually regulated through a process of assessment leading to product registration or withdrawal of the provisionally registered status. As described in section 2.2 of the “Guiding principles for small national drug regulatory authorities” (2), entitled “Screening of provisionally registered products”, the initial screening process must be rapid to secure the withdrawal of products which, on the basis of a review of their ingredients and indications, are judged not to meet admissible standards of safety, quality and efficacy. This must be followed by the phased-in definitive assessment of all provisionally authorized/registered products according to priority. Applications for products which are to be imported, manufactured or exported for the first time after the appointed date will be assessed at the same time.

• In addition to screening individual medicinal products, or groups of medicinal products, the legislative scheme provides for regulatory action of a general nature. Through regulations or orders provision can be made for compliance with good manufacturing standards; the use of the WHO Certification Scheme on the Quality of Pharmaceuticals Moving in International Commerce; compliance with International Nonproprietary Names (INNs) for pharmaceutical substances, labelling and advertising requirements, etc.

**Model legislative text and commentary**

*The text of the commentary is set in italics.*

**Part A. Administration**

1. There shall be established a drug regulatory authority which shall comprise pharmacists, physicians and others.

*In order to discharge statutory functions and exercise statutory powers effectively, it is important that the office of the drug regulatory authority should be accorded high visibility within the official structure and be staffed by suitably qualified professionals. This includes not only the provision of attractive terms of employment and salary structures, but also access to effective and speedy channels of communication to those in authority, while safeguarding, at all times, the independence of the*
office. Under ideal circumstances, the person who functions as the officer of the drug regulatory authority [or the secretary of the board] should no longer be involved in drug procurement functions; but where this is not possible, because of staffing constraints, every precaution must be taken to ensure that the two functions of drug regulation and drug procurement are kept distinct and separate.

When appointing the officer(s) of the drug regulatory authority [or members of the board] and of the advisory committee, one issue which must be addressed is conflict of interest. It is important to ensure that regulatory responsibilities are discharged without fear or favour.

In relation to medicinal product regulation and procurement, it must be emphasized that such products should be considered a special category; appropriate administrative regulations, including tender or import procedures, must guarantee the independence of those entrusted with regulatory as well as procurement functions.

2. The functions of the drug regulatory authority shall, inter alia, be:

(a) to require all medicinal products manufactured in, imported into or exported from the country to conform to prescribed standards of quality, safety and efficacy, and that the personnel, premises and practices employed to manufacture, promote, procure, store, distribute and sell such products comply with defined codes of practice and other requirements;

(b) to require continued conformity of medicinal products to such standards until their delivery to the end-user;

(c) to require that medicinal products are imported, manufactured, exported, stocked, sold, distributed or otherwise dealt with by duly authorized persons;

(d) to grant, after due assessment, authorizations/licences for medicinal products, whether locally manufactured or imported, and whether destined for the national market or export;

(e) to cancel the authorization/registration of, or cause to be recalled from the market, medicinal products the continued use of which may be detrimental to public health;

(f) to maintain an inventory of provisionally authorized/registered medicinal products;

(g) to publish lists of provisionally authorized/registered medicinal products and of products with marketing authorizations from time to time, for public information;

(h) to ensure that dossiers for marketing authorization of medicinal products are kept up to date by the applicants and to approve alterations/changes thereto;
(i) to inspect and license/authorize all manufacturing premises, importing agents, wholesalers, distributors, hospital dispensaries, pharmacies and retail outlets;

(j) to sample, analyse and otherwise test finished medicinal products released into the distribution chain, to ensure their compliance with labelled specifications;

(k) to monitor the market for the presence of illegal/counterfeit medicinal products;

(l) to ensure that the promotion and marketing of medicinal products is in accordance with product information as approved by the drug regulatory authority;

(m) to approve the use of unregistered/unauthorized medicinal products for clinical trial purposes or for compassionate use and to regulate clinical trials on medicinal products;

(n) to disseminate information on medicinal products to the health professions in order to promote their rational use;

(o) to collect authorization/registration and application and renewal fees;

(p) to monitor and review the implementation of the legislation;

(q) to advise the minister on matters concerning control and authorization/registration of medicinal products;

(r) to amend the rules and regulations as deemed necessary to keep pace with time demand(s).

This section lists some of the more important functions of the drug regulatory authority. Additional functions can be added to this catalogue.

3. The drug regulatory authority shall appoint such other officers as may be necessary to assist it (or the board) to perform duties and to exercise powers under this Law. Such officers shall be known as "authorized officers".

For purposes of inspection, supervision and monitoring, the drug regulatory authority [or board] will need the assistance of other officers. The number and type of officers needed depend essentially on the profile of the pharmaceutical industry. However, it is important that the human resources needed to implement the Law are duly taken into consideration in the health resources planning process.

4. The minister shall, in consultation with the drug regulatory authority, appoint a medicinal products advisory committee to advise the drug regulatory authority on any general matter concerning the implementation of the technical aspects of the Law or with regard to any specific medicinal product.
It is envisaged that the committee will provide guidance on technical/scientific as well as administrative matters. As there are significant differences between countries in the availability of pharmacologists, medical practitioners and pharmacists who can be considered for appointment to a committee of this nature, the legislative scheme does not address issues such as composition, size, quorum, working procedures and other aspects. Committee members should be free from conflict of interest. These are matters to be regulated by way of regulations promulgated under the Law. The representative of the drug regulatory authority should be an ex-officio member; ideally, such an officer should serve as the secretary of the committee as well.

Part B. Provisional registration/marketing authorization and inventory of medicinal products

5.1 The drug regulatory authority shall, by order published in the gazette [variant: or through other means of notification], require manufacturers, importers and exporters of medicinal products to notify the drug regulatory authority of such particulars as are specified in the order concerning the medicinal products which such manufacturers, importers, or exporters wish to continue to manufacture, import, export or sell after such date (hereafter referred to as the appointed date) as is specified in the order.

5.2 Medicinal products for which a notification has been received by the drug regulatory authority on or before the appointed date shall be listed in the provisionally authorized/registered medicinal products inventory (hereafter referred to as the inventory), and until granted a product licence/marketing authorization or ordered by the drug regulatory authority (or board) not to be manufactured, imported, exported or sold, such products shall have the status of provisionally authorized/registered medicinal products.

5.3 After the appointed date no person shall import, manufacture, export or sell a medicinal product not listed in the inventory without the prior written permission of the drug regulatory authority unless a product authorization/licence has been granted in respect of such product under section 6 of this Law.

5.4 The inventory, the format of which may be laid down in regulations, shall be made available for inspection at such place and at such times as specified by the drug regulatory authority in an order published in the gazette or one or more newspapers as may be specified in the regulations.

5.5 The inventory shall be revised accordingly as and when provisionally authorized/registered products listed therein have been granted a
product authorization/licence under section 6.1, or the drug regulatory authority has ordered under section 6.3 that any such provisionally authorized/registered medicinal product should not be manufactured, imported, exported or sold from such date as is specified in the order.

This section provides for a system of provisional authorization/registration for medicinal products which are being manufactured, imported, exported or sold from a specific date, and which will be continued to be manufactured, imported, exported or sold even after that date (appointed date).

Medicinal products which are notified on or before the appointed date will be listed in a provisionally authorized/registered medicinal products inventory. The scheme envisages this inventory as well as a register. The latter is for medicinal products which have been granted a product licence/marketing authorization. The procedure for screening provisionally authorized/registered products, as well as new applications for other medicinal products, is contained in section 6.

For a provisionally authorized/registered medicinal product, the drug regulatory authority may decide one of two things: either to grant a product licence/marketing authorization, or to phase out or ban its manufacture, import, sale or export. In either event, the product will be deleted from the inventory. If a product licence/marketing authorization is granted, it will be entered in the register of medicinal products for which a product licence/marketing authorization has been granted (see section 9).

At some point — depending on the pace at which the screening process can proceed — the inventory will cease to exist, as all products which had the provisionally authorized/registered status would have been screened and either granted a product licence/marketing authorization or eliminated from the market.

Section 14 makes it an offence to manufacture, import, sell or export a product unless it has a marketing authorization or is deemed to be provisionally authorized/registered.

A renewal process will be established at regular intervals for those products which show satisfactory performance in the market and comply with regulations.

**Part C. Screening of products and issuance of product licences/authorizations**

6.1 In accordance with the national drug policy and the country’s health-care needs, and in relation to considerations of product
quality, safety and efficacy, the drug regulatory authority shall decide whether a provisionally authorized/registered product, or a product which is not listed in the inventory but for which an application for its manufacture, import, export or sale has been filed after the appointed date, should be granted a product licence/marketing authorization.

6.2 The drug regulatory authority may at any time call upon any manufacturer, importer or exporter to furnish such information as is required in order to enable a provisionally authorized/registered product, or a product proposed for manufacture, import or export after the appointed date, to be evaluated and assessed.

6.3 The drug regulatory authority may at any time, after scientific evaluation, determine that an authorized/registered product should not be eligible for a product authorization/licence and that such product should not be manufactured, imported, sold or exported, either with immediate effect or from such date as is specified in an order made by the drug regulatory authority.

6.4 Upon an order made under subsection 6.1 or 6.3 taking effect, the inventory shall be accordingly revised with respect to the entry for the relevant product.

This section deals with the factors to be taken into account in screening medicinal products (either those which are provisionally authorized/registered or for which a new application has been made for manufacture, import, export or sale) and the procedures to be followed in granting a product licence/marketing authorization.

7. Any manufacturer, importer or exporter who fails, without valid reason, to furnish such particulars within the stipulated time-limit, or within an extended time-limit as may have been granted by the drug regulatory authority, shall not be entitled to manufacture, import, sell or export the medicinal product from such date as is specified by the drug regulatory authority in a communication addressed to the manufacturer, importer or exporter.

This section addresses the situation where a manufacturer, importer or exporter has not submitted the particulars and data necessary for the product to be screened.

8. In determining whether a product licence/marketing authorization should be granted or not, the drug regulatory authority shall consult the medicinal products advisory committee, relevant authorities and health professionals, and may take into account regulatory information from other countries and relevant international organizations.
This section addresses the consultative process that must take place when products are being screened.

The drug regulatory authority may wish to consider how a particular medicinal product has been regulated in other countries. Product licences/marketing authorizations may be subject to various terms and conditions relating to:

- manufacture
- import
- export
- marketing
- distribution
- prescription
- use
- labelling
- packaging
- pricing
- advertising/promotion or
- conditions of sale.

The legislative scheme assumes that drug regulatory authorities in small countries should make the maximum use of regulatory information available in the public domain. Such information is available through a number of sources such as the WHO Certification Scheme on the Quality of Pharmaceuticals Moving in International Commerce (the WHO Certification Scheme); the authorities of countries with advanced drug regulatory systems; the World Health Organization; and drug-related commercial as well as non-commercial publications (e.g. national formularies; drug compendia; medical journals).

Appendix 2 describes the various publications and services that have been developed specifically to support drug regulatory authorities.

9. The drug regulatory authority shall maintain a register of medicinal products for which marketing authorizations have been issued and shall make the register, or extracts from it, available at such place and at such times as specified by the drug regulatory authority in an order published in the gazette or one or more newspapers as may be specified in the regulations.

This section provides for a register to be maintained of medicinal products for which product licences/marketing authorizations have been granted. This register will eventually replace the inventory as all provisionally authorized/registered products are screened.

10. Regulations made under this Law shall specify the terms, conditions, and validity of product licences/marketing authorizations, the
format of the register, and the particulars to be furnished to obtain a product licence/marketing authorization for provisionally approved/authorized products or for products not listed in the inventory, and other requirements, including the payment of fees, for applications for a product licence/marketing authorization.

This section provides for regulations to be made on matters relating to licences/marketing authorizations and the register. The use of modern technology such as computers facilitates the compilation, updating and printing of the inventory and the register. WHO has developed a model package for computer-assisted drug registration which can be adapted to develop such inventories or registers and even to the issuing of licences/marketing authorizations (see Appendix 2).

11.1 The drug regulatory authority may revoke or suspend the marketing authorization for importation, manufacture, sale or exportation of a medicinal product if it appears or there is reason to suspect that the conditions for the licence are no longer being fulfilled.

11.2 The drug regulatory authority may vary the provisions of the marketing authorization provided it is satisfied that such a variation does not adversely affect the safety, quality or efficacy of the medicinal product.

11.3 The order of the drug regulatory authority may specify how the order is to take effect, particularly with regard to recalling the product from the market and the procedures, if any, for notifying health professionals and the public.

11.4 An applicant (licence/marketing authorization holder) shall not deviate from the particulars submitted in the drug registration dossier unless authorized by the drug regulatory authority. A formulation or other error pertaining to a medicine shall be immediately reported to the drug regulatory authority. An adverse drug event reported to a licence/marketing authorization holder shall be conveyed to the drug regulatory authority by the licence holder within three days of the initial report.

This section empowers the regulatory authority to take prompt action to withdraw a product from the market when such a course of action is warranted by public health considerations.

12.1 Any manufacturer, importer or exporter who is aggrieved by an order made by the drug regulatory authority (see sections 11.1–11.4) may appeal to the minister/authority, in writing, within two weeks from the date of the order.
12.2 On receipt of an appeal the minister/authority may decide whether or not the drug regulatory authority should be directed to rescind, suspend, vary, modify, reconfirm or reconsider the order against which the appeal has been lodged.

This section provides for administrative relief, prior to institution of action in a court of law in accordance with the country's legal and judicial system. Provision for administrative relief in the first instance is important, as litigation is generally protracted, costly and inconvenient to all parties concerned.

**Part D. Other activities requiring authorization/licensing**

13.1 On or after such date as is specified in a notice published in the gazette or in any official publication as may be specified in the regulation, a person carrying on a business of manufacturing, importing, exporting, compounding, storing, dispensing, selling, supplying or otherwise distributing medicinal products must possess a valid authorization/licence in order to carry out that activity.

13.2 The licensing authority shall maintain a register of pharmacies. An application for registration of pharmacy premises under this section must be made in accordance with regulations issued by the minister.

13.3 The particulars to be furnished by applicants for an authorization/licence, their qualifications and suitability, and the terms, requirements and conditions under which such authorizations/licences may be granted, shall be specified by the drug regulatory authority in regulations made under the Law.

13.4 Any person aggrieved by a decision of the drug regulatory authority may appeal, within two weeks of the notification of the decision of the drug regulatory authority, to the minister/authority.

13.5 On receipt of an appeal the minister/authority may decide whether or not the drug regulatory authority should be directed to rescind, suspend, vary, modify, reconfirm or reconsider the order in respect of which the appeal has been lodged.

*Parts B and C were concerned with medicinal products, whereas Part D deals with individuals, companies, firms, hospital clinics or dispensaries, pharmacies, etc., who need a licence/authorization to engage in various activities.*

*There is a right of appeal to the minister/authority against any decision of the drug regulatory authority. Provision for administrative relief in*
the first instance is important, as litigation generally tends to be protracted, costly and inconvenient for all parties concerned.

Part E. General provisions

14. It shall be an offence under this Law for any person to manufacture, import, sell or export a product after the appointed date unless such product at the time of manufacture, import, distribution or export has the status of a provisionally authorized/registered medicinal product under section 5.2 or has received a product licence/marketing authorization under section 6.

This section deals with the situation in which a product which is neither provisionally authorized/registered nor covered by a product licence/marketing authorization is manufactured, imported, distributed, sold or exported after the appointed date.

15. After such date as is specified under section 13.1 of the Law, it shall be an offence for any person to engage in any of the activities mentioned in that section, unless this person holds a valid authorization/licence granted by the drug regulatory authority or is otherwise legally entitled to engage in any such activity.

This section deals with the situation in which a person engages in an activity mentioned in section 13 without a licence or legal right (under another law).

16.1 No person shall manufacture, import, export, compound, store, sell, promote or distribute a medicinal product:

(a) that is unfit for use in humans or in animals;
(b) that is adulterated;
(c) that contains any natural or added deleterious substance which renders it injurious to health;
(d) that has been manufactured, prepared, preserved, packaged or stored for sale under insanitary and/or unfavourable conditions; or
(e) that has been labelled, packaged or promoted in a manner that is false, misleading, deceptive or likely to create an erroneous impression regarding its source, character, value, quality, composition, potency, merit or safety.

16.2 No person shall manufacture, import, export, distribute, sell, supply or use any counterfeit starting materials.

16.3 No person shall manufacture a medicinal product using any counterfeit starting materials or without taking reasonable measures
to ensure that the starting materials used in the manufacture of such medicinal products are not counterfeit or of suspect quality.

16.4 No manufacturer, importer, exporter, distributor, pharmacist, health practitioner, health worker or other person shall manufacture, import, export, compound, prepare, promote, sell, supply, obtain, display, dispense or otherwise distribute, for a fee or by way of sample or gift, any medicinal product which is a counterfeit or known or suspected to be a counterfeit.

*This section is of a general nature aimed at ensuring that only medicinal products which meet acceptable standards are marketed.*

One potential problem area in implementing this provision is the lack of quality control facilities where products could be tested and verified in small developing countries. Through cooperative arrangements with neighbouring countries with good quality control facilities, however, it should be possible to have products tested there. Participation in the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce also provides an opportunity for quality defects to be investigated.

17. Where any standard is prescribed for any medicinal product, no person shall label, package, sell, offer for sale, distribute or promote any such medicinal product which does not conform to such standard in such a manner that makes it likely to be mistaken for the medicinal product for which the standard has been prescribed.

*The applicable standards will have to be specified in the regulations.*

18.1 The drug regulatory authority or any authorized officer shall have the power to visit and inspect any manufacturing plant, processing unit, business establishment, warehouse, office, or any premises used for or in connection with the manufacture, import, export, distribution, storage, sale, supply, dispensing or use of any medicinal product, to take samples of any medicinal product or of any substance, and to examine records or other documents relating to any medicinal product.

18.2 No person shall refuse to permit the drug regulatory authority or any authorized officer to enter and inspect or take samples or documents.

18.3 An inspector may at any reasonable time and on production of his or her certificate of authority enter any premises:

(a) for the purpose of ascertaining whether there is or has been any contravention of the legislation;
(b) generally, for the purpose of discharging his or her functions under the legislation.

18.4 An inspector may:

(a) inspect the premises, any article and any document for the purposes of the legislation;
(b) seize any substance, article or document which he or she has reasonable cause to believe to be a substance, article or document in which or by means of which an offence under the legislation is being or has been committed.

"Premises" for the purposes of this section includes any premises, ship, aircraft or vehicle. "Premises" does not include a private residence.

It will be useful to develop a plan of action, with appropriate checklists and guide, to enable authorized officers to conduct inspections.

19. Any person who contravenes or fails to comply with any provision of this Law or any regulation or any order made under this Law shall be guilty of an offence, and on conviction shall be liable to a fine between .......... and ............ or imprisonment for a term not exceeding ............ months/years, or both; in the case of a continuing offence, to a fine not exceeding ................ for every day or part of a day during which the offence has continued.

The minimum and maximum penalties (imprisonment and/or fine) must be determined in line with the penalties generally prescribed by other laws currently in force in the country.

The need for "deterrent penalties" must be carefully balanced against the risk of "overkill". Too high a penalty, particularly one entailing mandatory jail sentences, for instance, can lead to lax enforcement and will be counterproductive in the long run. On the other hand, products like medicinal products need to be manufactured and handled with great care; any deliberate or negligent departure from established standards and norms can result in otherwise avoidable mortality and morbidity. The ubiquitous problem of counterfeit drugs has reinforced the need for severe penalties for certain types of violations involving deliberate or fraudulent behaviour.

20. The provisions of this Law shall extend to all persons, in both the public and private sectors, engaged in manufacturing, importing, exporting, compounding, storing, distributing, promoting, selling or in any other way dealing with medicinal products.

In some countries express statutory provision is required in order for a law to apply to the state or to the public (government) sector. It is
important that regulatory controls apply to all medicinal products, irrespective of who is responsible for their manufacture, import or export, distribution or sale.

21. Regulations shall be made for all or any of the matters for which the Law provides for regulations to be made and, in particular, for the following purposes:

(a) Prohibiting, limiting, restricting, or imposing conditions on, either generally or in relation to: (i) a particular medicinal product; (ii) the manufacture, import, export, compounding, dispensing, administration, sale or supply of medicinal products; (iii) printed packaging material, package leaflets and data sheets/product information, promotion to health professionals, advertising to the general public and conduct of marketing practices.

(b) Withdrawing medicinal products from sale or distribution.

(c) Prescribing the standards to be followed in the manufacture, storage, sale, supply, dispensing and distribution of medicinal products.

(d) Classifying medicinal products for purposes of regulating importation, manufacture, compounding, prescribing, dispensing, selling, storage and distribution.

(e) Regulating persons entitled to import, manufacture, compound, export, store, prescribe, dispense or sell medicinal products.

(f) Prescribing the terms, conditions, procedures and time-limit for the issuance of licences/authorizations under Parts C and D of the Law and the forms, fees, particulars and records necessary for applications for licensing and grounds for suspension, cancellation or withdrawal of licences/product authorizations.

(g) Regulating the composition and terms of reference of the medicinal products advisory committee and/or board of medicinal products.

(h) Granting exemptions from the requirement of a product licence/marketing authorization for imports of medicinal products required for a named patient or to meet a public health emergency.

(i) Designating laboratories and analysts for the purposes of conducting analyses and submitting reports.

(j) Regulating the licensing/authorizing and licensing/authorization renewal fees in order to support the drug regulatory functions.

(k) Prescribing any regulation in matters pertaining to this Law.

(l) Regulating clinical trials on medicinal products.

(m) Regulating drug donations.

(n) Regulating the obligation to report on drug adverse reactions.
(o) Regulating the obligation to report on product variations such as quality or manufacturing change.

There are a number of sections which provide for regulations to be made. This catalogue is in addition to the matters referred to in those sections.

Part F. Interpretation

22. The legislation should include an interpretation of terms which may be used in a special context. In the model text given here, terms which might need interpretation include:

“Appointed date” means the date specified under section 5.1 of the Law.

“Inventory” refers to the listing of provisionally registered/authorized medicinal products under section 5.2 of the Law.

“Medicinal product” means any medicine intended for human or veterinary use, presented in its finished dosage form or as a starting material for use in such dosage form, as defined in paragraph 5, p. 106 (see also p. 111).

“Minister” means the minister responsible for matters relating to medicinal products.

“Person” includes an individual as well as a body corporate, partnership or association of persons, and establishments such as hospital pharmacies, clinics, and health centres storing or distributing medicinal products.

“Provisionally authorized/registered” is used in relation to a medicinal product which has been listed in the inventory under section 5 of the Law and which has not been screened for purposes of a product licence/marketing authorization under sections 6 and 9 of the Law.

“Register” means the register of medicinal products for which a product licence/marketing authorization has been issued in terms of sections 6 and 9 of the Law or the register of persons, i.e. the pharmacist and pharmacy assistant.

“Sell” means to sell for cash or on credit or by way of exchange, whether by wholesale or retail; “sale” shall have a corresponding meaning.

The above are some of the more important terms used in the legislative scheme which need to be defined, but other terms may also require definition. The WHO text on Good manufacturing practices for phar-
maceutical products (see Appendix 2) contains a number of definitions of terms such as “manufacture” which can be included, after adap-
tation if necessary, in the definition section.

References


Selected bibliography

See also the list of references on pages 141–142.


Consolidated list of products whose consumption and/or sale have been banned, withdrawn, severely restricted or not approved by governments. New York, United Nations, 1991.


Examples of national legislation adopted since 1988

Albania
The Drug Law, date of enactment 20 April 1994

Bulgaria
Degree No. 109 of 17 April 1995 promulgating the Law on Medicaments and Pharmacies with Regard to Human Medicine
(see also International digest of health legislation, 1996, 47(1):56–60, Bulg. 96.1)

Estonia
Medicinal Products Act of 19 December 1995

Ghana
The Pharmacy Act, dated 30 December 1994
(see also International digest of health legislation, 1996, 47(1):63, Ghana 96.2)

Latvia
Law on Pharmaceutical Activities of 27 April 1993
(see also International digest of health legislation, 1995, 46(2):220, Lat. 95.1)

Malawi
Drug Act of 1988

Myanmar
Drug Law of 30 October 1992

Republic of Korea
The Pharmaceutical Act, as amended up to 7 January 1994
(see also International digest of health legislation, 1995, 46(3):352, ROK 95.1)

Sierra Leone
Pharmacy and Drug Act of 1988
Appendix 1

Provisional legislative scheme for registration of pharmacy personnel

In order to assist countries to update existing laws or to draft new ones, this document offers a provisional legislative scheme on registration of pharmacy personnel. The text and provisions should be adapted to suit national conditions, requirements and situations.

1. No person shall practise as a pharmacist unless his or her name has been registered as a pharmacist by the licensing authority by virtue of this Law.

2. An applicant for registration as a pharmacist must:
   (a) hold a pharmaceutical qualification granted by a university or institution of equivalent standing;
   (b) have practised the pharmaceutical profession for a period of not less than two years;
   (c) be in good health and have no police record;
   (d) fluently speak and read the national language and possibly others;
   (e) pass such an examination as the minister may consider necessary.

3. Except as is provided by this Law, no person other than a person registered as a pharmacist shall:
   (a) conduct and administer a registered pharmacy;
   (b) in the course of any trade or business prepare, mix, compound or dispense any medicinal product or poison except under the supervision of a pharmacist; or
   (c) assume, take, exhibit or in any way make use of any title, emblem or description reasonably calculated to suggest that he or she is registered as a pharmacist.

For the purpose of subsection (c) of this section the use of the word “pharmacist” or “chemist” or “druggist” or any similar word or combination of words shall be deemed to suggest that the owner of the business on those premises is, or purports to be, a registered pharmacist.

4. No person shall practise as a pharmaceutical technician or as an assistant in pharmacy unless he or she has obtained registration as a pharmaceutical technician or assistant in pharmacy by the licensing authority by virtue of this Law.

5. An applicant for registration as a pharmaceutical technician or assistant in pharmacy must:
(a) hold a recognized certificate as a pharmaceutical technician or assistant in pharmacy;
(b) have practised within the pharmaceutical profession for a period of not less than two years in a pharmacy under the supervision of a pharmacist;
(c) be in good health and have no police record;
(d) fluently speak and read the national language and possibly others;
(e) pass such an examination as the minister may consider necessary.

6. The applications for registration under sections 2 and 5 of this Law must be made in accordance with the regulation issued by the minister.

7. The licensing authority shall maintain a register of pharmacists and technicians or assistants in pharmacy.

8. Pharmacists and technicians or assistants in pharmacy must perform their duties in accordance with the ethics of the pharmaceutical profession and in particular must:

(a) at all times act in the interest of the patient;
(b) uphold the honour and dignity of the pharmaceutical profession and not bring the profession into disrepute;
(c) at all times have regard to the laws and regulations applying to medicinal products and pharmaceutical practice, and maintain a high standard of professional conduct;
(d) respect the confidentiality of information acquired in the course of their professional practice;
(e) offer services to the public in premises which reflect the professional nature of pharmacy.

9. The minister shall by regulation establish a pharmaceutical practice committee ideally comprising:

(a) a pharmacist chairman appointed by the minister;
(b) three registered pharmacists;
(c) two registered technicians or assistants in pharmacy;
(d) one lay member.

10. The pharmaceutical practice committee shall:

(a) advise the minister on any matter relating to the pharmaceutical profession and the practice of pharmacy;
(b) ensure the maintenance of high standards of practice and conduct among pharmacists and technicians or assistants in pharmacy and promulgate codes of conduct;
(c) set standards of education and training, where appropriate, for pharmacists and/or technicians.
The pharmaceutical practice committee may regulate its own procedure.

11.1 The minister shall by regulation establish a disciplinary committee to inquire into the conduct of a registered pharmacist or registered technician or assistant in pharmacy whom it is alleged has been convicted of a criminal offence or is in breach of any of the provisions of section 8 of this Law.

11.2. The disciplinary committee shall ideally comprise:

(a) a chairman with a legal background, appointed by the minister;
(b) two registered pharmacists;
(c) one registered technician or assistant in pharmacy.

No member of the pharmaceutical practice committee shall be a member of the disciplinary committee.

11.3 The disciplinary committee shall, after inquiry, have power:

(a) to issue a reprimand/warning to a registered pharmacist or registered technician or assistant in pharmacy;
(b) to adjourn an inquiry with conditions;
(c) to recommend to the minister that the name of a registered pharmacist, a registered technician or assistant in pharmacy be suspended or removed from the respective register;
(d) to regulate its own procedure.

12. The minister, by regulation, may fix fees for the initial registration of pharmacists, technicians or assistants in pharmacy, and pharmacies. Annual fees may also be payable to retain the names of pharmacists, technicians or assistants in pharmacy, and pharmacies on the respective registers.

13. Any person who contravenes section 1, 3 or 4 of this Law shall be guilty of an offence and liable to a fine not exceeding [amount to be specified].
Appendix 2
Guidelines, documents and other regulatory instruments established by WHO to support drug regulatory authorities

Over the years WHO has issued many technical and administrative guidance documents that bear direct relevance to drug regulation, such as:

- Guiding principles for small national drug regulatory authorities (1)
- Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce (2)
- Guidelines on import procedures for pharmaceutical products (2)
- Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability (2)
- Provisional guidelines on the inspection of pharmaceutical manufacturers (3)
- Good manufacturing practices (GMP) for pharmaceutical products (3)
- Good manufacturing practices for biological products (4)
- Guidelines for the assessment of herbal medicines (2)
- Guidelines for assuring the quality of pharmaceutical and biological products prepared by recombinant DNA technology (3)
- Guidelines for good clinical practice (GCP) for trials on pharmaceutical products (5)
- Use and protection of recommended International Nonproprietary Names for pharmaceutical substances (6, 7, 10)
- Guidelines for stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms (2)
- Ethical criteria for medicinal drug promotion (8)
- Model List of Essential Drugs and Eighth Report of the WHO Expert Committee on the Use of Essential Drugs (9)

WHO also fosters exchange of information among drug regulatory authorities, and the following four WHO publications are particularly
helpful for worldwide regulatory information. The WHO Pharmaceuticals newsletter, published monthly, contains notifications received from WHO Member States on the regulation of human and veterinary drugs and medical devices, and also provides information on the surveillance of marketed products. The quarterly WHO drug information contains a section on “Regulatory matters” dealing with individual drugs subjected to regulatory action. Another quarterly, International digest of health legislation, reproduces important regulatory texts adopted by WHO Member States and geo-political groupings such as the EU. The Essential drugs monitor reports on current developments and new publications. The Consolidated list of products whose consumption and/or sale have been banned, withdrawn, severely restricted or not approved by governments published annually by the United Nations is another good source of information. As the introduction to the 1991 Consolidated list states: “It constitutes a tool which helps Governments to keep up-to-date with regulatory decisions taken by other Governments and assists them in considering the scope for eventual regulatory action. It enables government agencies which review applications for product registration to ascertain easily restrictive regulatory decisions made in other countries. It complements and consolidates the information produced within the United Nations system, including the World Health Organization’s quarterly bulletin WHO Drug Information and its Pharmaceuticals Newsletter...”. Countries with developed systems of drug registration or with similar social and health-care structures can be requested to provide information as to the availability of certain drugs on their markets, and the terms and conditions subject to which such drugs are being imported, manufactured, marketed or exported.

The revised WHO Certification Scheme on the Quality of Pharmaceuticals Moving in International Commerce enables importing countries to request the following types of documents which will provide more information with regard to any product in the country of export:

— Certificate of a Pharmaceutical Product;
— Statement of Licensing Status of Pharmaceutical Product;
— Batch Certificate.

The Certificate of a Pharmaceutical Product requires the following information to be furnished by the designated regulatory authority in the country of export:

— the proprietary name (if applicable) and dosage form;
— active ingredient(s) per unit dose (together with a qualitative listing of other ingredients contained in the dosage form);
— particulars of product licence and of product licence holder (or particulars of applicant for certificate if the product is not licensed to be placed on the market for use in the country of export);
— if the product is not licensed to be placed on the market for use in the country of export, the reason why such authorization is lacking (not required/not requested/under consideration/refused);
— particulars concerning inspection of the manufacturing plant in which the dosage form is produced;
— approved product information and technical summary.

The Statement of Licensing Status, on the other hand, indicates only whether or not the products listed in the certificate are licensed to be placed on the market for use in the country of export. This Statement is essentially intended for use by importing agents who are required to screen bids made in response to international tenders.

Upon request, WHO assists countries with a standardized approach to the computerization of drug regulatory data, for example, processing marketing authorizations and maintaining product lists. Under preparation are additional software products to help in the management of information related to monitoring of imports/exports, reporting on psychotropic and narcotic drugs, and samples in a drug quality control laboratory.

References


6. **International nonproprietary names (INN) for pharmaceutical substances: lists 1–73 of proposed INN and lists 1–35 of recommended INN; cumulative list no. 9.** Geneva, World Health Organization, 1996.

(document WHO/PHARM Si/NOM 1570; available on request from Division of Drug Management and Policies, WHO, 1211 Geneva 27, Switzerland).

