

## Annex 12

# **Guidelines on import procedures for pharmaceutical products**

### **1. Introductory notes**

1.1 Public health considerations demand that pharmaceutical products should not be treated in the same way as ordinary commodities. Their manufacture and subsequent handling within the distribution chain, both nationally and internationally, must conform to prescribed standards and be rigorously controlled. These precautions serve to assure the quality of authentic products, and to prevent the infiltration of illicit products into the supply system.

1.2 Within the context of its revised drug strategy, adopted in 1986 by the Thirty-ninth World Health Assembly in resolution WHA39.27, WHO developed "Guiding principles for small national drug regulatory authorities" (1, 2) which established a regulatory approach in line with the resources available within a small national regulatory authority, and were intended to assure not only the quality, but also the safety and efficacy, of pharmaceutical products distributed under its aegis.

1.3 The principles emphasize the need for the effective use of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. This constitutes a formal agreement between participating Member States to provide information on any product under consideration for export, notably on its registration status in the country of origin and whether or not the manufacturer complies with WHO's guidelines on good manufacturing practices (GMP) for pharmaceutical products (3).

1.4 To be fully effective, the Scheme needs to be complemented by administrative and other safeguards aimed at ensuring that consignments of imported products are in conformity in all particulars with the relevant import licence and that they remain secure within the distribution chain. Storage and transit facilities must be proof against tampering and adverse climatic conditions, and relevant controls must be applied at every stage of transportation.

1.5 Pharmaceutical products containing substances controlled under the international conventions have long been subjected to rigorous border controls. Some of these controls, and particularly those designed to prevent the diversion and illicit interchange of products during transit, are relevant to all pharmaceutical products, and are therefore included in these guidelines. Full details of the special import controls required for narcotic drugs and psychotropic substances are given in the Appendix.

## 2. Objectives and scope

2.1 The following guidelines, which stem from the above considerations, have been developed in consultation with national drug regulatory authorities, the pharmaceutical industry, the World Customs Organization, and the United Nations International Drug Control Programme.

2.2 The guidelines are directed to all parties involved in the importation of pharmaceutical products, including national drug regulatory authorities, competent trade ministries, customs authorities, port authorities, and importing agents.

2.3 They are intended to promote efficiency in applying relevant regulations, to simplify the checking and handling of consignments of pharmaceutical products in international transit and, *inter alia*, to provide a basis for collaboration between the various interested parties.

2.4 They are applicable to any pharmaceutical product destined for use within the country of import, and are intended to be adapted to prevailing national conditions and legal requirements.

## 3. Legal responsibilities

3.1 The importation of pharmaceutical products should be effected in conformity with regulations promulgated under the national drugs act or other relevant legislation and enforced by the national drug regulatory authority. National guidelines providing recommendations on the implementation of these regulations should be drawn up by the national drug regulatory authority in collaboration with the customs authority and other interested agencies and organizations.

3.2 All transactions relating to the importation of consignments of pharmaceutical products should be conducted either through the governmental drug procurement agency or through independent wholesale dealers specifically designated and licensed by the national drug regulatory authority for this purpose.

3.3 The importation of all consignments of pharmaceutical products should be channelled exclusively through customs posts specifically designated for this purpose.

3.4 All formalities undertaken on importation should be coordinated by the customs service, which should have the authority to request the services of an official pharmaceutical inspector as occasion demands. When justified by the workload, a pharmaceutical inspector may be stationed full time at one or more of the designated ports of entry.

3.5 The customs authority should have the discretionary powers to request technical advice and opinions from other appropriately qualified persons, should this be warranted by particular circumstances.

#### **4. Legal basis of control**

4.1 Subject to the exemptions specified in paragraph 4.4 below, only pharmaceutical products proved by appropriate documentation to be duly licensed for marketing within the importing country should be cleared by customs.

4.2 The national drug regulatory authority should compile comprehensive and frequently updated lists of licensed products and authorized importing agents, and issue notifications of any product licences withdrawn on grounds of safety; the latter should be rapidly communicated and presented in a manner designed to attract attention. All lists and notifications of withdrawal of a product licence should be accessible, preferably through a computerized database, to designated customs posts, authorized importing agents and all drug wholesalers.

4.3 Efficient and confidential channels for communicating information on counterfeit products and other illicit activities should be established between all interested official bodies.

4.4 In countries where no formal system of product licensing has been established, importation of products is most effectively controlled by issuing permits in the name of the national drug regulatory authority to the authorized importing agency or agent. Additional measures that may be taken under these conditions include:

- the provision by the national drug regulatory authority to the customs authorities, and to the importing agency and agents, of official lists of pharmaceutical products permitted and/or prohibited to be imported;
- the provision by the importing agent of certified information to establish that the product is authorized by licence for sale in the country of export.

4.5 The national drug regulatory authority should reserve discretionary powers to waive product licensing requirements in respect of consignments of pharmaceutical products imported in response to emergency situations and, exceptionally, in response to requests from clinicians for limited supplies of an unlicensed product needed for the treatment of a specific named patient.

#### **5. Required documentation**

5.1 As a prerequisite to customs clearance, the importing agency or agent should be required to furnish the customs authority with the following documentation in respect of each consignment:

- certified copies of documents issued by the national drug regulatory authority in the importing country, attesting that:
  - (a) the importer is duly authorized by licence to undertake the transaction; and
  - (b) the product is duly authorized by licence to be marketed in the importing country;

- a batch certificate issued by the manufacturer, consonant with the requirements of the WHO Certification Scheme, that documents the results of the final analytical control of the batch(es) constituting the consignment;
- a relevant invoice or bill and, when applicable, an authorization for the release of foreign exchange granted by the competent national authority in the country of import;
- any other documentation required by national legislation for customs clearance.

## 6. Implementation of controls

6.1 A visual and physical examination should be routinely undertaken by the customs authorities, if possible in collaboration with an inspector of the national drug regulatory authority. The size of the consignment should be checked against invoices, and particular attention should be accorded to the nature and condition of the packaging and labelling.

6.2 Arrangements should be made with the inspector of the national drug regulatory authority for the routine sampling and subsequent analysis of exceptionally large and/or valuable consignments and any other consignment that has apparently deteriorated, or that is damaged or of doubtful authenticity.

6.3 When samples are taken for analysis to a governmental or other accredited drug quality control laboratory, the consignment should be placed in quarantine. During this procedure, and throughout the time that the consignment is held in customs, particular care must be taken to ensure that packages do not come into contact with potential contaminants.

6.4 A consignment suspected of being counterfeit should be placed in quarantine pending the analysis of samples and forensic investigation. Time is often saved if materials and reagents needed to undertake simple analytical tests are available at the port of entry.

6.5 Representatives of the manufacturer of the authentic product, and/or the owner of the trademark, and the consignee should immediately be advised of such action.

6.6 National regulations should define the responsibilities of the interested parties and the precise procedures to be followed. In particular, the provisions should identify the agency responsible for coordinating the investigation and bringing prosecutions.

6.7 Counterfeit or other products which have been imported in contravention of the law must be forfeited and destroyed, or otherwise dealt with in accordance with legal procedures.

6.8 The relevant authorities must be indemnified against any consequent legal actions and proceedings.

6.9 National drug regulatory authorities are urged to notify other national authorities of confirmed cases of imported counterfeit pharmaceutical products through the Division of Drug Management and Policies of WHO.

**7. Procedures applicable to pharmaceutical starting materials**

7.1 In accordance with good manufacturing practices, formal responsibility for the analytical control of starting materials is vested in the manufacturer of the finished pharmaceutical product. Consequently, few countries have introduced formal licensing requirements for active pharmaceutical substances.

7.2 Exceptionally, however, some national authorities now exercise documentary and, in some cases, analytical control of starting materials as a prerequisite to customs clearance.

7.3 Each imported consignment of a pharmaceutical starting material should be accompanied by a warranty (or batch certificate) prepared by the manufacturer as recommended by the WHO Certification Scheme.

**8. Storage facilities**

8.1 Many pharmaceutical products tend to degrade on storage and some need to be kept in cold storage. All customs posts designated to handle consignments of pharmaceutical products should consequently be provided with secure storage facilities, including refrigerated compartments. If no pharmaceutical inspector is employed on site, these facilities should be inspected periodically by the national drug regulatory authority to ensure that all equipment is maintained in good working order.

8.2 The importing agency or agent should alert the customs authorities in advance of the anticipated arrival of consignments in order that they may be transferred from the international carrier to the designated storage facility with the minimum of delay and, in appropriate cases, without breaking the cold chain.

8.3. Consignments of pharmaceutical products and pharmaceutical starting materials should be accorded high priority for clearance through customs.

8.4 When several different consignments await clearance, the customs authorities should be guided by the drug inspector as to which should be accorded priority.

**9. Training requirements**

9.1 Performance in implementing the guidelines should be reviewed on an open-ended basis and, if necessary, improved in the light of on-site

monitoring and evaluation. Workshops designed to facilitate efficient implementation of the guidelines and to foster collaborative approaches between the various responsible parties should be organized, as circumstances demand, by the national drug regulatory authority in collaboration with the customs authority.

## References

1. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-first report.* Geneva, World Health Organization, 1990:64-79 (WHO Technical Report Series, No. 790).
2. *The use of essential drugs. Model List of Essential Drugs (Seventh List). Fifth report of the WHO Expert Committee.* Geneva, World Health Organization, 1992:62-74 (WHO Technical Report Series, No. 825).
3. Good manufacturing practices for pharmaceutical products. In: *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-second report.* Geneva, World Health Organization, 1992:14-79 (WHO Technical Report Series, No. 823).

## Glossary

The definitions given apply to the terms used in these guidelines. They may have different meanings in other contexts.

### *authorization*

See Note.

### *counterfeit product*

A pharmaceutical product that is deliberately and fraudulently mislabelled with respect to identity and/or source. Both branded and generic products can be counterfeited, and counterfeit products may include products with the correct ingredients, with the wrong ingredients, without active ingredients, with insufficient quantity of active ingredients or with fake packaging.

### *drug regulatory authority*

The national agency responsible for the registration of, and other regulatory activities concerning, pharmaceutical products.

### *import authority*

The national agency responsible for authorizing imports (e.g. the ministry or department of trade or of imports and exports).

### *importation*

The act of bringing or causing any goods to be brought into a customs territory (national territory, excluding any free zone).

*importer*

An individual or company or similar legal entity importing or seeking to import a pharmaceutical product. A “licensed” or “registered” importer is one who has been granted a licence or registration status for the purpose. In addition to a general licence or permit as an importer, some countries require an additional licence to be issued by the national drug regulatory authority if pharmaceutical products are to be imported.

*licence*

See Note.

*pharmaceutical product*

Any medicine intended for human or veterinary use, presented in its finished dosage form, that is subject to control by pharmaceutical legislation in both the exporting state and the importing state.

*registration*

See Note.

*starting material*

Any substance of defined quality used in the production of a pharmaceutical product, but excluding packaging materials.

**Note**

Because of a lack of uniformity in national legal requirements and administrative practices, the terms “registered”, “licenced” and “authorized” have been used in these guidelines as if they were interchangeable. When the guidelines are being used as a basis for drawing up national guidelines, more precise terminology applicable to the country concerned should be used. In some countries, for example, “certificate of drug registration” has been replaced by terms such as “marketing authorization”.

## Appendix

### **Special import controls for narcotic drugs and psychotropic substances<sup>1</sup>**

In accordance with the requirements of the international drug control treaties (i.e. the Single Convention on Narcotic Drugs, 1961, and that Convention as amended by the 1972 Protocol, and the Convention on Psychotropic Substances, 1971, referred to subsequently as the 1961 Convention and the 1971 Convention), each state must adopt national legislation and administrative regulations, and establish administrative structures to ensure the full implementation of the provisions of these treaties on its territory and cooperation with other states.

Most of the requirements specified in these guidelines on import procedures for pharmaceutical products also apply to the border control of narcotic drugs and psychotropic substances. In addition, detailed information on the control of international trade in narcotic drugs and psychotropic substances can be found in Article 31 of the 1961 Convention and Article 12 of the 1971 Convention respectively. The guidelines provided in this Appendix are intended to facilitate the operation of control at entry points, and can be expanded by taking into account the legislation and administrative regulations in force in each country.

The customs authorities and, if applicable, any other law enforcement authorities assigned to border control should cooperate closely with the competent authorities for the control of narcotic drugs and psychotropic substances designated by the government (subsequently referred to as the competent authorities). It should be noted that, while the competent authorities in some countries are different from the national drug regulatory authority, in others they may be one and the same.

The customs authorities, or any other competent law enforcement authorities, should be well trained and equipped (e.g. with drug identification kits) so that they can distinguish consignments of narcotic drugs and psychotropic substances from other pharmaceutical products. They should be provided with lists of narcotic drugs and psychotropic substances under international control, e.g. the "Yellow List" and "Green List" published by the International Narcotics Control Board, which include, *inter alia*, trade names of pharmaceutical products containing narcotic drugs and psychotropic substances. They may also make use of the *Multilingual dictionary of narcotic drugs and psychotropic substances under international control* (ST/NAR/1/REV.1) published by the United Nations (sales number E/F/S.93.XI.2). Furthermore, they

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<sup>1</sup> "Narcotic drug" means any of the substances listed in Schedules I and II of the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol, whether natural or synthetic; "psychotropic substance" means any substance, natural or synthetic, listed in Schedule I, II, III or IV of the Convention on Psychotropic Substances, 1971.



should be provided with lists of narcotic drugs and psychotropic substances whose importation into the country has been prohibited.

Checks conducted during the border control of narcotic drugs and of psychotropic substances listed in Schedules I and II of the 1971 Convention should ensure that each consignment has been duly authorized by the competent authorities of the importing country. The competent authorities express their consent to each import by issuing an import certificate (for narcotic drugs) or an import authorization (for psychotropic substances). When presented with the original of this document, the competent authorities of the exporting country may issue an export authorization permitting the consignment containing narcotic drugs or psychotropic substances to leave the exporting country. In free ports and zones governments should exercise the same supervision and control as in other parts of their territory, provided, however, that they may apply more drastic measures if appropriate.

The competent authorities of the importing country may wish to inform the customs, or any other competent law enforcement authorities, of authorized imports of narcotic drugs and psychotropic substances before the entry of the consignment into the country.

In addition to the other documents referred to in section 5 of the guidelines, the customs authorities should require the importer or importer's agent to provide them with a copy of the respective import authorization (certificate) issued by the competent authorities of the importing country. This document should be compared with the export authorization issued by the competent authorities of the exporting country, a copy of which must accompany each consignment. The authenticity of these documents must be carefully checked. In case of doubt, the competent authorities should be consulted immediately.

Import and export authorizations (certificates) should contain the following information:

- the name of the narcotic drug or psychotropic substance (if available, the International Nonproprietary Name);
- the quantity to be imported/exported, expressed in terms of anhydrous base content;
- the pharmaceutical form and, if in the form of a preparation, the name of the preparation;
- the name and address of the importer and exporter;
- the period of validity of the authorization.

In addition, the export authorization should contain the number and date of the corresponding import authorization/certificate and the name of the competent authority of the importing country by whom it was issued.

The competent authorities of the importing country may wish to specify in the import authorization/certificate the entry point through which the importation must be effected.

During the visual and physical examination of the imported consignment, the quantity of narcotic drugs or psychotropic substances contained in it should be carefully checked. If the quantity exceeds the amount authorized, the consignment should be stopped by the customs and the matter brought to the attention of the competent authorities for the control of narcotic drugs and psychotropic substances in the importing country. If the quantity imported is the same as, or less than, the amount authorized, the quantity should be recorded on the copy of the export authorization accompanying the consignment and communicated to the competent authorities of the importing country.

All consignments containing psychotropic substances included in Schedule III of the 1971 Convention must be accompanied by a separate export declaration. This document should indicate the name and address of the exporter and importer, the name of the substance, the quantity and the pharmaceutical form in which the substance is exported, including, if applicable, the name of the preparation and the date of dispatch.

Pursuant to the recommendations contained in resolutions of the Economic and Social Council of the United Nations, many governments now require import authorizations not only for psychotropic substances in Schedules I and II but also for those in Schedules III and IV of the 1971 Convention. This strengthening of the control requirements has proved to be very useful in preventing attempts to divert psychotropic substances, such as stimulants, sedative-hypnotics and tranquillizers, into illicit traffic.