

# Consultative Document

## Guidance for small national drug regulatory authorities

### Draft guidelines on import procedures for pharmaceutical products

#### 1. Introductory notes

1.1 Public health considerations demand that pharmaceutical products should not be treated 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 In 1994, the World Health Assembly endorsed the *WHO Guiding Principles for Small National Drug Regulatory Authorities* in resolution 47.17 (1). These principles set out a regulatory basis, attuned to resources available within a small national regulatory authority, to assure the quality, safety and efficacy of pharmaceutical products distributed under its aegis.

1.3 The Guiding Principles emphasize the need for effective use of the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce (2). This scheme constitutes a formal agreement between participating Member States to provide information on any product under consideration for exportation, notably on its registration status in the country of export and whether or not the manufacturer complies with WHO's standards of good manufacturing practices (GMP).

1.4 To be fully effective, the WHO Certification Scheme needs to be complemented by administrative and other safeguards aimed to ensure that consignments of imported products conform in all particulars with the relevant import licence and that they remain securely 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 directed to preventing diversion and illicit interchange of products during transit, could be applied to other pharmaceutical products.

#### 2. Objectives and scope

2.1 The following guidelines have been developed in consultation with national drug regulatory authorities, the pharmaceutical industry, the Customs Cooperation Council, and the United Nations Drug Control Programme.

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

2.3 They are intended to promote efficiency in applying relevant regulations, and to simplify checking and handling of consignments of pharmaceutical products in international transit. *Inter alia*, they 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 they are intended to be adapted to prevailing national conditions and legal requirements.

#### 3. Legal responsibilities

3.1 Importation of pharmaceutical products should be effected in conformity with regulations promulgated under the national drugs act or other statute 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 or organizations.

3.2 All transactions relating to 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 Importation of all consignments of pharmaceutical products should be channelled through one or more customs posts specifically designated for this purpose.

3.4 All formalities undertaken at the port of entry should be coordinated by the customs authorities which should request the services of an official pharmaceutical inspector as occasion demands. When justified by the workload, a pharmaceutical inspector should be stationed full-time at one or more of the designated ports of entry.

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

#### 4. The legal basis of control

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

4.2 The national drug regulatory authority should compile comprehensive and frequently updated lists of licensed products and authorized importing agents. Notification of any product licences withdrawn on grounds of safety should be rapidly and prominently featured. All lists should be accessible — preferably through a computerized system — to designated customs posts, authorized importing agents or agencies and all drug wholesalers.

4.3 Efficient and confidential channels for communicating information on counterfeited 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 implemented, importation of products is most effectively controlled by issuance of permits authorizing importation of specific consignments (in the name of the national drug regulatory authority) to the authorized importing agency or agent.

Additional measures that may be invoked in this circumstance include:

- provision by the national drug regulatory authority to the customs authorities, and to the importing agency and agents, of official listings of pharmaceutical products that are either permitted and/or prohibited for importation;
- provision by the importing agent or agency to the customs authority of certified information generated through the WHO Certification Scheme to establish the registration status of the product in the country of export.

4.5 The national drug regulatory authority should reserve to itself 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. Documentation

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:

5.1 Certified copies of documents issued by the national drug regulatory authority in the importing country, attesting that:

- the importer is duly licensed to undertake the transaction; and
- the product is duly licensed for marketing in the importing country.

5.2 A batch certificate issued by the manufacturer, consonant with the requirements of the WHO Certification Scheme, which documents the results of the final analytical control of the batch(es) constituting the consignment.

5.3 A relevant invoice or bill and, when applicable, an authorization for release of foreign currency granted by the competent national authority in the country of import.

5.4 Any other documentation required by national legislation for customs clearance.

## 6. Implementation of controls

6.1 A visual and physical examination should be undertaken routinely 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 packaging and labelling.

6.2 Arrangements should be made with the inspectorate of the national drug regulatory authority to undertake 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. Materials and reagents needed to undertake simple analytical tests should be provided at the port of entry.

6.3 When samples are taken for analysis to a governmental or 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 analysis of samples and forensic investigation.

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

6.4.2 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.

6.4.3 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.

6.4.4 The relevant authorities must be indemnified against any consequential legal actions and proceedings.

6.4.5 National drug regulatory authorities are urged to notify other national authorities of confirmed

cases of counterfeit pharmaceutical products through the Division of Drug Management and Policies of the World Health Organization.

## 7. Procedures applicable to pharmaceutical starting materials

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

7.2 In accordance with good manufacturing practices (3), formal responsibility for the analytical control of starting materials is vested in the manufacturer of the finished pharmaceutical product. Consequently, few countries have implemented formal licensing requirements for starting materials.

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

7.4 To meet this need, a certifying authority may agree, on a discretionary and voluntary basis, and at the request of a manufacturer, to undertake an inspection of a manufacturer of active ingredients to satisfy specific requirements of a requesting authority. Alternatively, pending the development of specific guidelines for active pharmaceutical ingredients, the certifying authority may be able to attest that the manufacturer is an established supplier of the substance in question to manufacturers of finished dosage forms licensed for marketing under its jurisdiction.

## 8. Storage facilities

8.1 Many pharmaceuticals, and particularly biological products, including vaccines and sera, tend to degrade on storage and some require to be maintained within a cold chain. All customs posts designated to handle consignments of pharmaceutical products should consequently be provided with secure storage facilities including refrigerated areas. 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 customs 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, in order to maintain 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 by the drug regulatory authority 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, in collaboration with the customs authority and other agencies involved.

### **References**

1. *WHO guiding principles for small national drug regulatory authorities*. Technical Report Series, No. 825, Annex 1. World Health Organization, Geneva, 1992. p. 62.
2. *Proposed guidelines for implementation of the WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce*. Technical Report Series, No. 823, Annex 3. World Health Organization, Geneva, 1992. p. 92.
3. *Good manufacturing practices for pharmaceutical products*. Technical Report Series, No. 823, Annex 1. World Health Organization, Geneva, 1992. p. 14.

**The information in this section is subject to consultation prior to definitive publication. Comments, which are invited at this stage, should be referred to:**

**Division of Drug Management & Policies  
World Health Organization  
1211 Geneva 27, Switzerland**