GUIDELINES ON IMPORT PROCEDURES

FOR MEDICAL PRODUCTS

(July 2018)

DRAFT FOR COMMENTS

Please send any comments you may have to Dr. S. Kopp, Group Lead, Medicines Quality Assurance, Technologies Standards and Norms (kopp@who.int), with a copy to Mrs. Xenia Finnerty (finnertyk@who.int) by 30 September 2018.

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GUIDELINES ON IMPORT PROCEDURES FOR MEDICAL PRODUCTS¹

1. INTRODUCTORY NOTE

1.1 Public health considerations demand that medical products should not be treated in the same way as ordinary commodities. Their manufacturing 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 that patients receive quality-assured medical products, and to prevent the infiltration of substandard and suspected falsified medical products into the supply system.

1.2 The availability of medical products is sometimes limited due to economic constraints, difficulty in meeting norms and standards in their production, and lack of resources in their supply chain. The market penetration by substandard and suspected falsified medicines poses hazards for public health and forces the diversion of public health resources from other uses. In light of this, investments towards strengthening strategies at the customs level are deemed crucial to ensure quality-assured medical products to patients (1, 2).

1.3 The global economy of scale and scope that characterizes modern trade requires continuous improvement in border control. This includes a departure from the traditional reactive control system to a risk-based and pro-active approach. The risk-based surveillance scheme should identify risks and define the controls that will protect patients from substandard, falsified and unregulated medical products. A risk-based approach can improve the cost-benefit ratio with existing or reduced resources through more effective and efficient controls.

1.4 Within the context of its revised medicines strategy adopted in 1986 by the Thirty-ninth World Health Assembly in resolution WHA39.27, the World Health Organization (WHO) developed Guiding Principles for Small National Drug Regulatory Authorities (3) which established a regulatory approach in line with the resources available within a small national regulatory authority (NRA), and were intended to assure not only the quality, but also the safety and efficacy of pharmaceutical products distributed under its aegis.

¹ This was first published in 1996 in the WHO Technical Report Series (TRS), No. 863, Annex 12.
1.5 The principles emphasize the need for the effective use of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce (4, 5).

This constitutes a formal agreement between participating Member States to provide information on any medical products under consideration for export, notably on its marketing authorization in the country of origin and whether or not the manufacturer complies with the WHO Guidelines on Good Manufacturing Practices for Pharmaceutical Products (6).

1.6 To be fully effective, the WHO Certification Scheme needs to be complemented by administrative and other safeguards aimed at ensuring that imported products are in conformity with all particulars with the relevant marketing authorization or specific intended use, such as clinical trial, named patient programmes, emergencies or other means, as appropriate, within the importing country and that they remain secure within the distribution chain. Storage and transit facilities must provide protection against tampering and adverse conditions and relevant controls must be applied at every stage of transportation (7, 8).

1.7 Medical products containing substances controlled under international conventions have long been subjected to rigorous border control. 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. Only those pharmaceutical products falling under the category of narcotic and psychotropic substances which are permitted by the relevant authorities shall be allowed to be imported as foreseen in the national and regional legislations and international treaties signed by the country.

2. OBJECTIVES AND SCOPE

2.1 These guidelines, which stem from the above considerations, had been developed first in 1996 in consultation with NRAs, the pharmaceutical industry, the World Customs Organization; and the United Nations International Drug Control Programme. \(^2\)

\(^2\) Since 1997, part of the UN Office for Drug Control and Crime
2.2 These guidelines are directed to all parties involved in the importation of medical products, including NRAs, 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 medical products for import, *inter alia*, to provide a basis for collaboration between the various interested parties.

2.4 They are applicable to medical products destined for use within the country of import and are intended to be adopted into prevailing national procedures and legal requirements.

3. GLOSSARY

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

*falsified medical products.*
Medical products that deliberately or fraudulently misrepresent their identity, composition or source. Any consideration related to intellectual property rights does not fall within this definition. Such deliberate or fraudulent misrepresentation refers to any substitution, adulteration or reproduction of an authorized medical product or the manufacture of a medical product that is not an authorized product.

*import authority.*
The national agency responsible for authorizing imports (for example, 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 for the purpose.

marketing authorization (product license, registration certificate).
A legal document issued by the competent medicines regulatory authority that authorizes the
marketing or free distribution of a pharmaceutical product in the respective country after
evaluation for safety, efficacy and quality. In terms of quality, it establishes, inter alia, the
detailed composition and formulation of the pharmaceutical product and the quality
requirements for the product and its ingredients. It also includes details of packaging,
labelling, storage conditions, shelf life and approved conditions of use.

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

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.

screening technologies.
The qualitative and/or semi-quantitative technologies which could rapidly acquire the
analytical information or data for preliminary identification of suspect medical products in
the field.

standard operating procedure.
An authorized written procedure giving instructions for performing standardized operations
both general and specific.

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

A substandard product is an authorized product that fails to meet either its quality standards or its specifications, or both. ³

unauthorized product.

An unauthorized product that has not undergone evaluation and/or approval by the NRA for the market in which it is marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.

These medical products may or may not have obtained the relevant authorization from the national/regional regulatory authority of its geographical origin.

4. LEGAL RESPONSIBILITIES

4.1 The importation of medical products should be done in accordance with national and regional legislation and should be enforced by the NRA and other relevant authorities.

National and regional guidelines providing recommendations on the implementation of legislation should be drawn up by the NRA or the Ministry of Health, if a NRA is not formally established, in collaboration with the customs authority and other responsible agencies and organizations.

4.2 The import of pharmaceutical products should be undertaken by an importer or agency authorized by the NRA as per national and regional legislation. This normally does not include pharmaceutical products in transit.

4.3 The import of all medical products should be channelled exclusively through custom posts or ports specifically authorized for this purpose. This is also applicable to medical products moving through the networking global commerce (such as, the World Wide Web/Internet).

³ These standards and specifications are normally reviewed, assessed and approved by the applicable national or regional medicines regulatory authority before the product is authorized for marketing.
4.4 All formalities on importation of medical products should be coordinated by the customs authority in close collaboration with the NRAs or the Ministry of Health if a NRA is not formally established. When justified by the workload, NRA officials may be stationed in a full-time position at such designated ports of entry. In carrying out the duties and formalities, the impact of possible delays on, for example, access to medicines and storage conditions of medical products, should be considered (for storage facilities, please see chapter 9 of this document).

5. LEGAL BASIS OF CONTROL

5.1 Subject to the exemptions specified in the national and regional legislation, and mentioned in paragraph 5.5 below, only medical products proved by appropriate documentation to be duly authorized for marketing should be cleared by customs.

5.2 The NRA should publish an updated list of authorized pharmaceutical products and authorized importers permitted to import into the country for marketing. This does not include a list of exempted products and importers as per national or regional legislation. In all cases, close collaboration with the NRA is needed to verify that the product is authorized for importation and that there are no restrictions, temporary suspensions or withdrawals of marketing authorizations.

5.3 NRAs should be empowered to take legal actions and should collaborate closely with customs, police, judiciary and others to detect substandard and falsified products and to avoid the import of such products. Efficient and confidential channels for communicating information on these products and other illicit activities should be established between all responsible official bodies.

5.4 In countries where no formal system of product marketing authorization has been established, the importation of products is most effectively controlled by issuing permits in the name of the NRA to the authorized importing agency or agent. Within the framework of the WHO Certification Scheme, WHO provides a list with names and full addresses of those government organizations authorized to sign and issue a certificate of a pharmaceutical product (CPP). NRAs receiving a CPP can use this list to check and verify if the certificate
they are receiving has been issued by the authorized organization (4, 5). Additional measures that may be taken under these conditions include:

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

5.5 The NRA should reserve discretionary powers to waive product authorization requirements in respect of consignments of pharmaceutical products imported in response to emergency situations, specific intended use as in clinical trials and in response to requests from clinicians for limited supplies of an unlicensed product needed for the treatment of a specific named patient.

6. REQUIRED DOCUMENTATION

6.1 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, except in cases of exemptions as per national or regional legislation (see also 5.5.):

- documents issued by the NRA in the importing country, attesting that:
  - (a) the importer is duly authorized to import the medical products; and
  - (b) the product is duly authorized to be marketed or permitted to be imported into the importing country;
- a batch release certificate issued by the manufacturer;
- safety data sheet;
- relevant invoice, bill or delivery slip for the batch, including product name, batch number, quantity and expiry date; and
- any other documentation required by national or regional legislation for customs clearance, for example a certificate in accordance with the WHO Certification Scheme.
6.2 The NRA may grant exemptions to the above if the distribution is taking place through regional hubs or by international organizations, for example, in case of emergencies.

7. IMPLEMENTATION OF CONTROLS

7.1 A visual examination should be routinely undertaken by the customs authorities. Where possible, this should be done in collaboration with an inspector or enforcement officer of the NRA. The size of the consignment should be checked against invoices, bills or delivery slips, and attention should be given to the nature and conditions of the packaging and labelling. The external package should be compared with a standard when this is possible.

(NOTE: spelling errors, low-quality printing and other defects may be signs of a substandard or falsified product. The external package should be intact and should not show any signs of damages or infiltrations that may change the inner content (2, 13,14,15).)

7.2 Arrangements should be made by the NRA for the sampling and subsequent physical and chemical analysis of medical products based on established procedures following a risk-based approach.

7.3 When samples, prior to the release of the consignment as per national and regional legislation, are taken for analysis to a governmental or other accredited quality control laboratory, the consignment should be placed in quarantine at approved sites. During this procedure, and throughout the time that the consignment is held legally under customs control, particular care must be taken to ensure that packages do not come into contact with potential contaminants. In addition, the package should be stored under appropriate conditions as recommended on the label or in the safety data sheet such as temperature, light and humidity limits (13, 14, 15).

7.4 A consignment suspected of being substandard, falsified or not authorized should be placed in quarantine pending the analysis of samples and forensic investigation. During this procedure, particular care must be taken to ensure that packages do not come into contact with potential contaminants. In addition, the package should be stored under appropriate conditions as recommended on the label or in the safety data sheet such as temperature, light, and humidity limits (13, 14, 15). Time is often saved if materials and reagents needed to
undertake simple analytical tests and screening technologies are available at the customs border. The consignee should immediately be informed of such action, ideally the authorized manufacturer or importer should also be promptly involved in the investigation.

7.5 National or regional regulations should define the responsibilities of the respective parties and the precise procedures to be followed by representatives from the NRA, police, border control, or Ministry of Health, as appropriate, for the relevant investigation and legal actions.

7.6 Falsified medical products and other products which have been imported in contravention of the law must be forfeited and destroyed, or otherwise dealt with in accordance with the procedures established by national and regional legislation, the records of which should be appropriately archived (9). The relevant authorities must be indemnified against any consequent legal actions and proceedings.

7.7 NRAs should notify other national or regional authorities and the WHO Global Surveillance and Monitoring System\(^4\) of confirmed cases of imported substandard or falsified products without delay on the appropriate form.

7.8 The WHO Member State mechanism has prepared an overview on the different field screening devices, authentication and verification technologies, and “track and trace” models that can facilitate responses (11). Overt/covert technologies, forensic chemical markers, bar-coding and other forms of serializations can support the seamless tracking of products through the supply chain. The implementation of these and upcoming new technologies is considered one of the most prominent preventive measures to tackle substandard and falsified medical products.

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\(^4\) The WHO Global Surveillance and Monitoring System collects reports from focal points in the NRAs and international procurement agencies which will forward the report via email to rapidalert@who.int where necessary. Focal points are encouraged to send any photographs, laboratory reports or other relevant documents as attachments.
8. PROCEDURES APPLICABLE TO PHARMACEUTICAL STARTING MATERIALS

8.1 When considering finished pharmaceutical products, the responsibility for the quality assurance of starting materials (active pharmaceutical ingredients (APIs) and excipients) used in that product is vested in the manufacturer of the finished pharmaceutical product (FPP). Few NRAs have introduced authorization requirements for APIs and excipients (8).

8.2 Some national and regional authorities also exercise documentary and (in some cases) quality control through laboratory testing of APIs as a prerequisite to customs clearance.

8.3 Each imported pharmaceutical starting material should be accompanied by a warranty (or batch certificate) prepared by the manufacturer, for example, as recommended by the WHO pharmaceutical starting materials certification scheme (SMACS) (10).

9. STORAGE FACILITIES

9.1 Many medical products tend to degrade during storage and some need to be stored under specified conditions, such as 2–8 degree Celsius. All customs posts designated to handle consignments of medical products should be provided with secure storage facilities, with the required conditions including cold storage areas.

Customs and NRA officials shall ensure that the appropriate environmental conditions are maintained for storage and shall monitor that the equipment is maintained and in good working order. The facilities should be inspected periodically by the NRA.

9.2 The importer should inform the customs authorities in advance of the anticipated arrival of medical products in order that they may be transferred from the international carrier to the designated storage facility without delay and, in appropriate cases, without breaking the cold chain.

9.3 Consignments of medical products and pharmaceutical starting materials, especially those requiring cold chain, should be accorded high priority for clearance through customs to avoid extended storage.
10. TRAINING REQUIREMENTS

10.1 When implementing these guidelines, the performance of the established procedures (including but not limited to personnel, documentation, procedures, and equipment) should be reviewed on an open-ended basis and improved in the light of on-site monitoring and evaluation. Workshops designed to facilitate efficient implementation of the guidelines and established procedures, and to foster collaborative approaches between the various responsible parties, should be organized at intervals by the NRA in collaboration with the customs authority and other parties.

REFERENCES


11. Member State Mechanism on Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit Medical Products (Seventieth World Health Assembly A70/2320, Appendix 2).


