GUIDELINES ON IMPORT PROCEDURES FOR
PHARMACEUTICAL PRODUCTS

(May 2018)

DRAFT FOR COMMENT

Should you have any comments on the attached text, please send these to Dr S. Kopp, Group Lead, Medicines Quality Assurance, Technologies Standards and Norms (kopps@who.int) with a copy to Mrs Xenia Finnerty (finnertyk@who.int) by 30 June 2018.

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SCHEDULE FOR THE PROPOSED ADOPTION PROCESS OF DOCUMENT QAS/18.773: GUIDELINES ON IMPORT PROCEDURES FOR PHARMACEUTICAL PRODUCTS

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1. PUBLIC HEALTH CONSIDERATIONS

1.1 Public health considerations demand that medicines 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 high standard quality medicines, and to prevent the infiltration of substandard and suspected falsified medicine into the supply system.

1.2 The availability of pharmaceutical 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 high-quality medicines to patients (1, 2).

1.3 The global economy of scale and scope that characterize modern trade require 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 medicines. 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 (WHA) 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, and were intended to assure not only the quality, but also the safety and efficacy of pharmaceutical products distributed under its aegis.

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 product under consideration for export, notably on its marketing authorization in the country of origin and whether or not the manufacturer complies with WHO guidelines on good manufacturing practices for pharmaceutical products (6).

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1 This was first published in 1996 in the WHO Technical Report Series, No. 863, Annex 12.
1.6 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 with all particulars with the relevant marketing authorization 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 Pharmaceutical 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. 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 These guidelines, which stem from the above considerations, had been developed first in 1996 in consultation with national regulatory authorities (NRAs), the pharmaceutical industry, the World Customs Organization, and the United Nations International Drug Control Programme.2

2.2 The guidelines are directed to all parties involved in the importation of pharmaceutical 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 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 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.

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. falsified product. A product that deliberately/fraudulently misrepresents its identity, composition or source, and which therefore requires testing beyond the routine quality control testing. Such deliberate/fraudulent misrepresentation refers to any substitution, adulteration,

2 Since 1997 part of the UN Office for Drug Control and Crime Prevention.
reproduction of an authorized product or the manufacture of a product that is not an authorized product.

**drug—national regulatory authority.** The national agency responsible for the registration, marketing authorization 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 usually require a marketing authorization and an additional licence to be issued by the national drug regulatory authority (national regulatory authority) if pharmaceutical products are to be imported.

**licence.** See note.

**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.

**registration.** See Note.

**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. For the purposes of this document, a substandard product is an authorized product that fails to meet either its quality standards or its specifications, or both according to the requirements in the territory of use. 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.

unauthorized product. A product that is not in compliance with national and regional regulations and legislation, being unknown to the authorities, and which therefore requires testing beyond the routine quality control testing.

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”.

4. LEGAL RESPONSIBILITIES

4.1 The importation of pharmaceutical products should be done in accordance with national legislation promulgated under the national drugs act or other relevant legislation and should be enforced by the NDAR/RA and other relevant authorities. National guidelines providing recommendations on the implementation of these regulations should be drawn up by the NDAR/RA, or by the ministry of health, or if an NRA is not formally established, in collaboration with the customs authority and other responsible entities/agencies and organizations.

4.2 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 NDAR/RA for this purpose.

4.3 The importation of all consignments of pharmaceutical products should be channelled exclusively through customs posts or ports specifically authorized for this purpose. This is also applicable to pharmaceuticals moving through the networking global commerce (i.e. world wide web/internet).

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

4.5 The customs authority should utilize its discretionary powers to request technical advice and opinions from other appropriately qualified persons, when required. This should be warranted by particular circumstances.

5. LEGAL BASIS OF CONTROL
5.1 Subject to the exemptions specified in paragraph 4.4 below, only pharmaceutical products proved by appropriate documentation to be duly licensed for marketing or specific intended use such as in clinical trials, named patient programs or other means as appropriate etc., within the importing country, should be cleared by customs.

5.2 The NDRANRA should compile comprehensive and frequently updated lists of licensed products authorized for marketing and authorized importing agents, which are frequently updated, and issue notifications of any product licenced withdrawn or temporarily suspended on grounds of safety, quality or efficacy or safety. These withdrawals or suspensions of the latter should be rapidly communicated to health-care providers and patients and presented in a timely manner designed to attract attention. All manner. All lists and notifications of a temporary suspension or withdrawal of a product licenced, marketing authorization should be published accessible, preferably on the NRA or Ministry of Health website through a computerized database, and should be easily accessible for designation customs posts, authorized importing agents and all drug wholesalers. In case of risks to public health, patients should be advised to contact their doctors or practitioners before suspending their treatments and receive appropriate instructions on how to continue their therapy.

5.3 NRAs should be empowered to take legal actions and should closely collaborate closely with customs, police, judiciary and others to detect substandard and falsified products and to avoid the circulation of those products in the local and international trade. Efficient and confidential channels for communicating information on these counterfeit or falsified products and other illicit activities should be established between all responsible interested official bodies without undue delay.

5.4 In countries where no formal system of products licensing marketing authorization has been established, importation of products is most effectively controlled by issuing permits in the name of the NDRANRA to the authorized importing agency or agent. Within the framework of the Certification Scheme framework, the 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 NDRANRA 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 license for sale in the country of export.

5.5 The NDRANRA should reserve discretionary powers to waive product licensing authorization 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.

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:

- certified copies of documents issued by the NDRA/NRA 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; or otherwise so anyway authorized for use in clinical trial or for a named patient use;
- a batch certificate issued by the manufacturer, in line consonant with the requirements of the WHO Certification Scheme, that documents the results of the final quality analytical control of the batch(es) constituting the consignment;
- safety data sheet;
- 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.

7. IMPLEMENTATION OF CONTROLS

7.1 A visual and physical examination should be routinely undertaken by the customs authorities. Where possible, this should be done, if possible in collaboration with an inspector or enforcement officer of the national drug regulatory authority NDRA/NRA. The size of the consignment should be checked against invoices, and particular attention should be accorded 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 indicative of a substandard or falsified product.)

7.2 Arrangements should be made with the inspector or enforcement officer of the national drug regulatory authority NDRA/NRA for the routine physical and chemical sampling and subsequent analysis of exceptionally large and/or valuable consignments and any other consignment that may appear to have has apparently deteriorated, or that is damaged or is of doubtful authenticity. (Note: The external package should be intact and should not show any signs of damages or infiltrations that may change able to alter the inner content.)

7.3 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. In addition, the package should be stored under appropriate conditions as recommended on the label or in the safety data sheet such as; taking care of monitoring the optimal temperature limits (i.e. if the cold chain has to be maintained), protection from light, humidity and temperature excursions.

7.4 A consignment suspected of being substandard, unregistered/unlicensed, or counterfeit falsified or unregistered/unlicensed/authorized 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 and screening technologies are available at the port of entry—customs border.

7.4–5 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.

7.5–6 National regulations should define the responsibilities of the respective interested parties and the precise procedures to be followed by. In particular, the provisions should identify the agency body (i.e., local representatives from the police service, border control, ministry of health, as appropriate), responsible for the relevant coordinating the investigation and legal actions bringing prosecutions.

7.6–7 Counterfeit/Falsified products and 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. Such procedures should be available, recorded and appropriately saved/recorded/archived (9).

7.7–8 The relevant authorities must be indemnified against any consequent legal actions and proceedings.

7.8–9 NDARAs should urge to notify are not later than a working day urged to notify other national authorities of confirmed cases of imported substandard or counterfeit/falsified pharmaceutical products without delay, through the WHO Global Surveillance and Monitoring System, on Division of Drug Management and Policies—Essential Medicines and Health Products of WHO through the appropriate form. The form is provided as a template to trained focal points within NDARAs. The WHO Global Surveillance and Monitoring System collects reports from focal points in the NDARAs national Regulatory Authorities and international procurement agencies which, if necessary, will forward the report. Once the mandatory fields are completed, the document can be saved and sent as an attachment via email to rapidalert@who.int where necessary. Focal points are encouraged to send any photographs, laboratory reports or other relevant documents as attachments. (http://www.who.int/medicines/regulation/ssffc/medical-products/en/)

8. PROCEDURES APPLICABLE TO PHARMACEUTICAL STARTING MATERIALS

8.1 When considering finished pharmaceutical products, in accordance with good manufacturing practices (GMP), the formal responsibility for the quality analytical control of starting materials used in that product is vested in the manufacturer of the finished pharmaceutical product (FPP). Consequently, unfortunately, only a few countries have introduced formal licensing requirements for active pharmaceutical substances—ingredients (APIs) (8).

8.2 Exceptionally, however, some national authorities now exercise documentary and (in some cases) also quality analytical control, through laboratory testing of starting materials, as a prerequisite to customs clearance.

8.3 Each imported consignment of a pharmaceutical starting material should be accompanied by a warranty (or batch certificate) prepared by the manufacturer as
recommend by the WHO Certification Scheme (WHICH SCHEME? Refer to SMACS?) WHO pharmaceutical starting materials certification scheme (SMACS) (10).

9. STORAGE FACILITIES

9.1 Many pharmaceutical products tend to degrade during storage and some need to be stored under specified conditions such as 2–8 degrees Celsius cold storage. All customs posts designated to handle consignments of pharmaceutical products should consequently be provided with secure storage facilities, with the required conditions including cold storage areas, where required, refrigerated compartments. If no pharmaceutical inspector or enforcement officer is employed on site, these facilities should be inspected periodically by the NDRANRA to ensure that all equipment is maintained and in good working order.

9.2 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 out delay and, in appropriate cases, without breaking the cold chain.

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

9.4 When several different consignments await clearance the customs authorities should be guided by the pharmaceutical drug inspector or enforcement officer as to which should be accorded priority.

10. TRAINING REQUIREMENTS

10.1 Performance is. When implementing the guidelines, the performance of the quality system (including but not limited to personnel, documentation, procedures, and equipment) 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 quality systems, and to foster collaborative approaches between the various responsible parties, should be organized at intervals, as circumstances demand, by the NDRANRA in collaboration with the customs authority and other parties.

11. AUDIT AND SELF-INSPECTION

11.1 A self-inspection should be conducted on a routine basis to verify the correct functionality of the quality system, standard operating procedures in place at the entry port. C to allow the introduction of corrective and preventive actions measures should be implemented for any potential deficiencies identified. Audits by third parties are further recommended. Audits and self-inspection records should document compliance of personnel to both the standard operating procedures adopted and the equipment used in the screening technologies (i.e. measuring and monitoring devices, instrument for sampling, testing, etc.) (15).

REFERENCES
APPENDIX

Special import controls for narcotic drugs and psychotropic substances

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 and customs 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 NDRA, 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 (1) (ST/NAR/1 Rev.2ST/NAR/1/REV.4) published by the United Nations in 2006 (sales number M.06.XI) with its Addendum-2015 and Supplement-2016. Furthermore, they 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 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 export authorizations (certificates) should contain the following information:

- the name of the narcotic drug or psychotropic substance (if available, the International Nonproprietary Name (INN));
- 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 exporter 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 they 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 tranquilizers, into illicit traffic.

REFERENCES


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