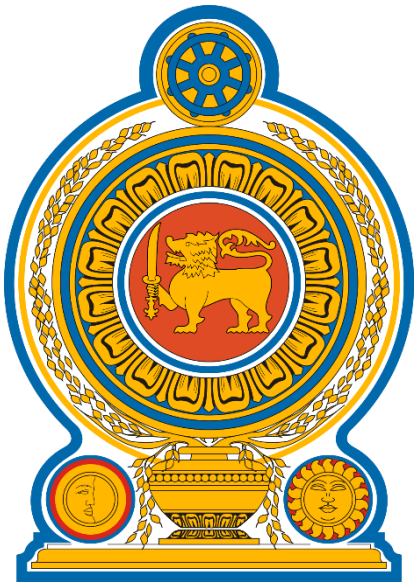

GUIDELINE ON IMPORT CONTROL OF PHARMACEUTICALS PRODUCTS AND RAW MATERIALS

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NATIONAL MEDICINE REGULATORY AUTHORITY
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1. INTRODUCTION

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 medicines into the supply system.

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 levels are deemed crucial to ensure high-quality medicines to patients.

To be fully effective, the scheme needs to be complemented by regulatory, 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.
NMRA regulates the import of medicines in the country in collaboration with Sri Lanka Customs and Ports Authorityand other responsible organizations.

2. SCOPE

This guideline is directed to all parties involved in the importation of pharmaceutical products in Sri Lanka, including NMRA, competent trade ministries, customs authoritiesSri Lanka Customs, Ports authority, and importing agents.
The guideline is intended to promote efficiency in applying relevant regulations, to simplify the checking and handling of consignments of pharmaceutical products in international transit andinter aliato provide a basis for collaboration between the various interested parties.

This guideline is applicable to any pharmaceutical products destined for use within Sri Lanka and are intended to be adopted into prevailing national procedures and legal requirements.

3. ABBREVATIONS AND DEFINITIONS

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).

National Medicines Regulatory Authority(NMRA). The national agency responsible for the marketing authorization of, and other regulatory activities concerning pharmaceutical products.

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Pharmaceutical Product. Any medicine, Medical device ,Borderline product intended for human 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 (SF). 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

4. LEGAL RESPONSIBILITIES

The importation of pharmaceutical products should be done effected in accordance conformitywith national legislation regulations promulgated under the NMRA Act No. 05 of 2015 and other relevant legislations and should be enforced by the NMRA and other relevant authorities. National guidelines providing recommendations on the implementation of these regulations legislation should be drawn up by the NMRA, or by the ministry of Health, in collaboration with the other responsible interested entities agencies and organizations.

All transactions relating to the importation of consignments of pharmaceutical products should be conducted through the governmental drug procurement agency (State Pharmaceuticals Corporation)and through independent wholesale dealers specifically designated and licensed by the NMRA for this purpose.

The importation of all consignments of pharmaceutical products should be channelled exclusively through designated ports specifically authorized for this purpose. This guideline also applicable to medical products moving through the networking global ecommerce (such as the World WideWeb/internet).

All formalities undertaken on importation should be coordinated by Sri Lanka Customswhich should have the authority to request the services of an officiallaw enforcement officers. On arrival at the ports of entry, pharmaceutical products will be inspected by anenforcement officer assigned by NMRA to ensure that they comply with the approved specifications and regulations before they are released.

The customs authority should utilize its discretionary powers to request technical advice and opinions from other appropriately qualified persons, when required.

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5. LEGAL BASIS OF CONTROL

Only pharmaceutical products proved by appropriate documentation to be duly licensed for marketing or specific intended use such as clinical trials, personal use or other means as appropriate should be cleared by customs.

The NMRA should compile comprehensive and frequently updated lists of licensed products authorized for marketing and authorized importing agents, and issue notifications of any product licenses withdrawn or temporarily suspended on grounds of quality or efficacy or safety. These withdrawals or suspensions; the latter should be rapidly communicated to health-care providers, patients and presented in a timely manner designed to attract attention. All lists and notifications of a temporary suspension or withdrawal of marketing authorization should be published on the NMRA website which should be easily accessible for designated customs posts, authorized importing agents and all wholesalers. In case of risks to for 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.

NMRA should be empowered to take legal actions and should closely collaborate with customs, police, judiciary and others etc. to detect SFproducts and to avoid the circulation of those products in the local and international trade. Efficient and confidential channels for communicating information on theseSFproducts and other illicit activities should be established between all responsible interested official bodies.

The NMRA should reserve discretionary powers to waive product authorization requirements in respect of consignments of pharmaceutical products imported in response to emergency situations such as to save a life, to control an outbreak of an infection or an epidemic and, exceptionally, in response to requests from medical practitioner for limited supplies of an unlicensed product needed for the treatment of a specific named patient for personal use. For an emergency and special circumstances, permission is granted on a request made by Ministry of Health or on the request made by an individual or an organization recommended by the Ministry of Health. For personal use pharmaceutical products such person may import the required quantity on a prescription issued by the medical practitioner treating him with the prior approval of the authority.

Products that do not comply with the country requirements may be refused admission. Refused products must be destroyed or exported from the country.

Every licensed importer should obtain an authorization from the NMRA for each consignment of every medicines imported under a license to import a registered medicine. Importer should inform quantity, batch numbers and other required information of each imported products to NMRA.

NMRA regulated products are refused entry if they appear to be or have been found to be:

- adulterated, meaning the product is contaminated, is not safe, unauthorized, or does not otherwise meet applicable standards,
- misbranded, meaning the labels contain false or misleading information, or the product is not registered and listed, if required,
- forbidden or restricted for sale.

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6. IMPORTATION OF PHARMACEUTICAL PRODUCTS

6.1 Categories of importers of pharmaceutical products

Importers of pharmaceuticals shall fall under the following categories:
a) Government and Non- Governmental institutions
b) Pharmaceutical wholesalers
c) Pharmaceutical Manufacturers
d) Clinical trial sponsors and Principal investigators
e) Recipients of donations
However, the following in the special circumstance can be authorized
f) Persons authorized to import pharmaceuticals for personal use
g) Hospitals authorized to import pharmaceuticals for hospital use

6.2 Requirements for importers

6.2.1 All pharmaceutical products to be imported must be registered by NMRA unless given special approval by the Authority.

6.2.2 All importation of pharmaceutical products must be done by importers whose premises are dully registered by NMRA.

6.3 **Required 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:

Certified copies of documents issued by the NMRA attesting that:
6.3.1 Certificate of the registration of medicines- the product is duly authorized by, to be marketed or otherwise so authorized for use in clinical trial or for personal use;
6.3.2 Import license - the importer is duly authorized to undertake the transaction,
6.3.3 A batch release certificate issued by the manufacturer
6.3.4 Safety Data Sheets
6.3.5 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; and
6.3.6 Any other documentation required by national legislation for customs clearance.

7. IMPLEMENTATION OF CONTROLS

7.1 Inspection of imported consignments at ports of entry

(i) A visual examination and preliminary screening should be routinely undertaken by the customs authorities. Where possible, this should be done, in collaboration with an enforcement officer of the NMRAto ensure that they comply with the approved specifications and regulations before they are released. The size of the consignment should be checked against invoices, and particular attention should be given to the nature and conditions of the packaging and labelling. The external package should be compared with the registration certificate when this is possible. (Note: spelling errors, low-quality printing and other defects may be signs indicative of a substandard or falsified product

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(ii) During the process of inspection and release of the consignment, the inspector may sample medicines for further investigations.

7.2 On inspection of the consignment the following actions may be taken:

(a) An approval for release may be given.
(b) A query may arise whereby the consignment may be held at customs warehouse or owner's premises pending further investigation.
(c) An outright rejection of the consignment pending re-export or destruction at owner's expense may be issued.

7.3 Release or rejection of a consignment

a). Conditions for release of consignments:

i) All approved consignments will be released by customs/NMRA Enforcement Officer once satisfied that all importation conditions have been fulfilled.
ii) A customs/NMRA Enforcement Officer will stamp all the supporting documents with an official stamp marked "APPROVED FOR RELEASE".

b). Conditions for rejection

i) Consignments which do not meet importation requirements will be rejected by Customs/NMRA Enforcement Officer and the accompanied documents shall be stamped with an official stamp marked "STOP RELEASE".
ii) Drugs rejected for quality reasons will be CONDEMNED;
iii) Destruction of rejected medicines will be done as per the Customs requirements and NMRA will provide technical advice on mode of destruction according to the guidelines of disposal of unwanted pharmaceutical products.

7.4 Authorized Ports of Entry

Medicines imported into Sri Lanka would be allowed to enter through the Official ports of entry published through gazette notification.

7.5 Sampling for Testing

7.5.1Sampling should be done by the enforcement Officer of the NMRA for imported pharmaceutical products for further investigations based on established procedures following risk based approach and the consignments that may appear to have deteriorated, damage or doubtful authenticity. (Note: The external package should be intact and should do not show any signs of damages or infiltrations that may change able to alter the inner content.

7.5.2 When samples are taken for analysis to National Medicines Quality Assurance Laboratory, the consignment damage or doubtful authenticity 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 temperature limits (i.e. if the cold chain has to be maintained), protection from light, humidity and temperature excursions.

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7.6 Substandard, falsified or unauthorized medical products

A consignment suspected of being substandard, falsified or not authorized should be placed in quarantine pending the analysis of samples and forensic investigation.

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

NMRA regulations should define the responsibilities and the precise procedures to be followed by other law enforcement agencies (i.e representatives from the Sri Lanka Police, Customs, border control, Ministry of Health) as appropriate for the relevant investigation and legal actions.

7.7 Controls for Pharmaceutical raw materials:

7.7.1 Active Pharmaceutical Ingredients and excipients imported to manufacture finished pharmaceutical products require inspections at the borders by an enforcement officer, in addition to customs inspections. This may include physical screening, storage conditions and document checks.

7.7.2 At the customs clearance, the importer should furnish following documentation in respect of each consignment:

a) A batch release certificate prepared by the manufacturer.

b) Raw materials purchased from third party suppliers should be properly labelled as NMRA guidelines and should be accompanied with a certificate of analyses issued by the original manufacturer.

7.7.3 NMRA enforcement officers may be directed to do sampling for testing as and when necessary.

8. STORAGE FACILITIES

8.1 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 ??enforcement officer is employed on site, these facilities should be inspected periodically by the NMRA to ensure that all equipment is maintained and in good working order.

8.2 The importing agency or agent should inform the customs authorities and the enforcement division of NMRA 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.

8.3 Consignments of pharmaceutical products and pharmaceutical starting materials should be accorded high priority for clearance through customs.
When several different consignments await clearance the customs authorities should be guided by the pharmaceutical enforcement officer as to which should be accorded priority.

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9. REFERENCES

1. Guidelines on Import Procedure for medical products, WHO Technical Report Series,No.1019,2019, Annex 5
2. GUIDELINES FOR IMPORTATION AND EXPORTATION OF PHARMACEUTICAL PRODUCTS AND RAW MATERIALS, TANZANIA FOOD AND DRUGS AUTHORITY' Second Edition,2011

10. FEEDBACK

10.1 Staff and customers may provide feedback about this document by emailing info@nmra.gov.lk

11. APPROVAL AND REVIEW DETAILS

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