Importation and Customs of Medical Items

In addition to the regular procurement policies and procedures used for importing goods in any humanitarian context, there are additional components specific to the importation process of pharmaceuticals and health items that humanitarian organisations should be aware of. The importation of pharmaceutical products is normally done in compliance with national regulations established under the National Medicines Regulatory Authority (NMRA). In most countries, NMRA is the national agency responsible for the marketing authorisation of, and other regulatory activities concerning pharmaceutical products.

In principle, the NMRA will restrict the importation of unapproved and substandard medicines, as this poses a serious risk to public health. For controlling purposes, specific requirements are expected for the importation of goods such as medicines, vaccines and biologics and medical devices and other health supplies (not exhaustive: will depend on local regulations):

- Only designated ports or points of entry specifically authorised for importation may be used to channel consignments of pharmaceutical products.
- 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. When new products are required for importation, an emergency authorisation must be released by the local authorities.
- All importation of pharmaceutical products may be done by authorised importers only.
- Quality sample testing may be required, being unable to release the goods until the results are provided. In some cases, testing occurs at the time the goods arrive, or even after they have cleared customs.
- Specific requirements may be put in place related to minimum shelf life on importation.
- Additional restrictions and licenses may be imposed for importing different narcotics (controlled substances) and dangerous goods.

In addition to restrictions on importation, many times NMRAs or other authorities might also restrict the export of certain heal items as well. Requirements for restriction of exportation may vary, depending on sensitive local markets, politics, or regulations on controlled substances. Exportation restrictions may impact reverse logistics of removing drugs but may also impact drugs exported from manufacturing or prepositioning facilities in more developed countries as well. Importers/exporters should review legislation requirements prior to exporting any items and should consult with a knowledgeable customs broker.

Emergency Procedures for Import

In emergencies, import regulations may change. Depending on the type of emergency and the political climate, the regulations on import might change substantially; when confronting a major natural disaster or health emergency such a pandemic, the authorities are prone to be more flexible with their importation procedures. By contrast, emergencies caused by political instability may cause the rules and regulations may become more challenging and the paperwork more burdensome.

The type of registration obtained by the humanitarian organisation may affect its ability to import medicines in case of an emergency.

- If organisations are registered under the ministry of health as a medical NGO, importation of medicines and health products may become easier.
- Declaration of non-commercial use of the products, or the donation to the Ministry of Health may also ease the process.

Waivers in emergencies specific to health supply importation (depending on the context) may include:

- Waivers on importation based on NDMO.
- Waivers on importation based on national registration.
- Reduction on documentation and testing requirements.
- Waivers on restrictions to country of origin.
- Waivers on restrictions of import to specific ports of entry.
- Waivers on restrictions of authorised importers.
- Waivers on minimum shelf life requirements (If required for advocacy: see attached Appendix 2 to the WHO Points to consider for setting the remaining shelf-life of medical products upon delivery, which specifies for governments examples of minimum remaining shelf-life for emergency health kits for use as part of humanitarian response).

Customs Concepts Common to Health Items

Banned/Allowed Items

Prior to attempting to import any pharmaceutical or health item into any country, humanitarian organisations should research regulations on what can and cannot be imported. This is especially important in rapid emergencies where organisations may wish to import pre-made kits or prepositioned stock or undertake a rapid procurement that may or may not contain items that are not permitted to be imported for whatever reasons.

Methods that humanitarian organisations can use to identify banned/allowed items for import include:

- Speak with a registered customs broker.
- Consult ministry of health websites or other online sources.
- Reference the database of approved essential medicines per country.

Documentation:

In addition to the regular documentation required to import any item, there are additional documentation or steps that may relate to health items, with particular emphasis on pharmaceutical and live vaccines. These might include:

- **Certificate of Registration** – Proof that the medicinal product is duly authorised by, to be marketed or otherwise so authorised for use in clinical trial or for personal use.
- **Import License** - Proof the importer is duly authorised to undertake the transaction.
- **Certificates of Analysis (CoA)** – CoAs include information on laboratory testing for specific batches or lots of pharmaceuticals and other health items. Sometimes CoAs can be provided by the manufacturer, but some national authorities require CoAs from recognised outside sources to prevent fraud.
- **Laboratory Samples** – Some customs and health authorities require laboratory testing on imported goods once they arrive in-country. This usually entails samples taken from supplies prior to clearing customs and being sent to state managed or mandated laboratory testing sites.
- **Other Common Forms** – Safety Data Sheets (SDS), Certificates of Origin (CoO), Certificates of Inspection (CoI), Certificates of Conformity (CoC), Pre-shipment Inspection (PSI) as applicable. More information on other common forms can be found here.

Cold Chain Items:

For cold chain products, there may be fast track procedures, enabling a preliminary reception of the goods while clearance procedures are concluded at a later stage. In any case, for any temperature-controlled range, it is strongly recommended to assess the customs facilities for their capacity to receive and properly handle items.

Transit Regimes:

Many countries now have strict regulations on handling health items under their own national GDP, and health items may only be released to a limited number of pre-identified entities, such as central medical stores or state appointed companies. In instances where humanitarian organisations may wish to transit health items through one country into another neighbouring country, there may be limitations on the types, quantities, or time frame in which some or all health items can transit.

Physical Considerations:

Depending on the port of entry used for importation of medical items, there will be different infrastructure available and different levels of knowledge on the handling staff related to medical supplies.

In larger centralised airports and sea ports, where the private/public sector have already been importing medical supplies, the likelihood is higher that the correct temporary storage infrastructure, handling equipment, standard operating procedures and capacity of handling staff is in place.

In smaller air and sea ports, or in locations where the entry point operation has been impacted by the emergency - such as damage to infrastructure or displacement of handling staff - there may be gaps in the proper infrastructure, capacity, and processes related to maintaining the safeguarding and quality of medical supplies.

Bottlenecks or gaps, which need to be mitigated for, may include:

- Lack of available (or insufficient space in) covered storage location.
- Lack of available (or insufficient space in) temperature-controlled storage (or reefer connectors in sea ports).
- Lack of available (or insufficient space in) keep cool storage locations (or reefer connectors in sea ports).
- Lack of knowledge of handling staff on fragile goods handling.
- Lack of proper handling equipment.
- Lack of special operating procedures within standard operating procedures dedicated to offloading and immediate temporary storage of medical supplies in relevant storage locations.
- Lack of controlled access storage for controlled substances.
- Lack of process or infrastructure for segregation, destruction or movement of damaged/expired medical supplies (pre or post clearance).
- Lack of knowledge on preparation of keep cool items for onward dispatch when cleared.

Solutions, which will often require engagement with relevant national authorities and port operating agents may include capacity development of personnel, procurement of ad hoc infrastructure/equipment (temperature controlled MSUs, refrigerated containers, freezers, generators, etc.), or deployment of dedicated specialised personnel to the entry point.