Custom Clearance of Medical Device

Industry Questions and Concerns

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Agenda

- Presentation from MDA
- Presentation from Custom/DagangNet
- Industry Questions and Concerns Presentation

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How will this impact the industry

- Additional administrative layer – custom clearance
- Additional lead-time due to custom procedure
- Additional cost of doing business (DagangNet e-permit system)
- Additional manpower / engaging third party for permit application
- Import permit requirements for products for re-export devices will add complexity for operations in regional distribution hub

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Overview of SG Custom Declaration Approach to custom clearance

TradeNet set up

HSA product code creation → importer/freight forwarder/declaring agency to populate HS codes, HSA Product codes, Product registration number or other agency registration number etc. according to the type of import in TradeNet

During Importation

importer/freight forwarder/declaring agency fill in HS codes → Other fields are auto-populated. → Custom Clearance

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Information required by Industry

- **HS Code that is planned to be listed in Customs Order [Customs (Prohibition of Imports) Order 2017]**
- Information required for permit application to ensure industry is prepared and able to comply with the requirements.
- Demo and UAT to the industry including custom broker/ freight forwarder
- Training to industry to facilitate the set up of DagangNet accounts.

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Joint proposal from industry

Topics	Feedback for MDA / Custom
Target enforcement timeline	**Test run the new policy/system for minimum of 1 year without charge**.
Grace period for the transition upon Order Gazette for the medical device industry and related enforcement body	**Transition period to conduct awareness program** to industry before full implementation **Will the Custom Prohibition Order have any provision for transition period?** For Establishment to set up the process - DagangNet account - Appoint 3rd party or/and obtain additional resources
Clarity on requirements for import permit for each importation/shipment/consignment and/or identifier of medical device	Depending on the mechanism of import permit application/custom clearance process; - One-Time annual application for all registered devices Or - One application per shipment/consignment (regardless the number of product identifier)
Turnaround time for each import permit approval Expected approval lead time for each permit as this might impose risk to supply to market & healthcare service level	Import permit application and approval should be allowed prior to shipment arrival. **Process to be available during public holidays and weekend.** Import Permit should have a suitable validity to allow flexibility for pre-shipment application e.g. changes for last minute changes **A 24/7 hotline available to assist to resolve challenges on the spot.** The import permit approval should not add additional clearance time upon shipment arrival, especially in the following scenario: - Importation of temperatures sensitive products that is packed with dry ice and some needs to refrigeration. - Product that has only has 4-6 weeks shelf life. - Limited time allowable for free storage of goods awaiting custom clearance. Could be as short as 3 working days.

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Joint proposal from industry

Topics	Feedback for MDA / Custom
Application/processing fees	**Charges to be minimum to facilitate the process while continue to promote the growth of the industry**. Industry noted that AELB as a regulatory body do not impose any charge for import permit whilst SIRIM as a private certification body imposed a charge. In view of this, MDA as a regulatory body with charges for product license and establishment license, any additional import permit charges is burdensome for the industry. If import permit charges is inevitable, propose to have charges/invoice on monthly basis instead of with every application to facilitate seamless import process,
Information required for each application	Minimum information that has an easy mechanism of uploading / entering of device to be imported and quantity rather than manual entry of each model. **Information required should be minimum to allow for import permit application and approval prior to shipment arrival.** Need to ensure DagangNet HS code list is identical to the HS code in custom prohibition order. No need to upload any documents e.g. only input invoice number for custom to match To include the all notification approved manually (notification ID) no. as part of DagangNet as an alternative to Medical device registration certificate number/ listing to cover all transactions e.g. the regional distribution center business nature. Based on the application flow for import permit, the necessary information are medical device registration number which is not applicable to product that is only meant for import for re-export.

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Topics	Feedback for MDA / Custom
System interface between Medcast / DagangNet / Custom Products like Clinical Reserch; Custom Made devices and special access products; Export products are not linked in Medcast. Public register Also Combination products where main agency is NPRA, however, importation for device component is imported separately. e.g. device component is under MD HS code. However, the primary agency is NPRA, Medcast Public portal will not reflect the registration status of the device component. Shipments with medical devices mixed with non-Medical devices e.g. pharma products or spare parts, and hence appears in same packing list.	It is important that **Medcast public portal database reflect real time upon product / Change Notification (CN) approval.** e.g. Medcast public portal with missing product identifier information **Contingency process is required in case of MDA server issues.** Not all approved products are listed in Medcast public portal. • Need to ensure all manual approvals are linked to custom portals • Industry need time to align information in MDA license with importation documents. • HS Code alignment with manufacturers Provide special clearance for circumstance with minor differences in approved MDA license and shipping information. e.g. If one of the model number in the license has typo in MDA system, or new model via amendment wasn't updated to database **To allow upload of only HS code that requires MDA import permit.** To include export notification ID no. as part of e-dagang net on top of Medical device registration certificate number/ listing to cover the regional distribution center business nature.
Urgent custom clearance for life-saving medical devices	**Urgent pathway is required to be set up** - if TAT is >24 hours or - if import permit application and approval is not allowed prior to shipment arrival A 24/7 hotline available to assist to resolve challenges on the spot

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Topics	Feedback for MDA / Custom
3rd part importers LAR frequently appoints freight forwarder as importer.	**To allow 3rd parties to act on behalf of the applicant (LAR) for importation matters/clearance/tariff payment.** Allow authorized freight forwarder to use their DagangNet account to apply for import permit. (LAR to authorize the appointed freight forwarder via their own DagangNet account) to prevent parallel import
Import permit requirements for medical device do not intend to be place on the Malaysian market (import for re-export)	**To exclude medical device that intend to import for re-export** (especially for companies approved as Regional Distribution Centre)

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Topics requiring clarification from MDA and Custom

Topics
To confirm the scope of the Custom Prohibition Order.
Mechanism for custom clearance for products which are not medical device but may be mistaken as medical devices e.g spare parts and use Medical Device HS code
How will the new e-permit system impact Medical Devices Spare-Part & Accessories in **terms of tariffs** (due to unavailability of separate registration approval – if registered under group/system)
Products requiring import permit from other authorities currently e.g. AELB and SIRIM Will companies need to apply for multiple DagangNet import permit for an importation?
For holder of Licensed Manufacturing Warehouse (LMW license) and is there exemption or special platform toget a blanket approval from MDA and custom import.
What the import permit look like e.g. validity. Transaction basis (to cater ofr multiple shipments in one application), changes to the shipment vs import permit.
Medical device that is imported for the purpose of re-export/transit, imported for re-work and re-export are not within the MDR 2012 scope. This should apply the same for any E-Permit process.
Intellectual properties on information provided in Medcast – How will MDA ensure that the Medcast database are protected from unauthorized access.

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Thank you


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