Circular No. 28/2016-Cus

F.No.450/147/2015-Cus-IV
Government of India
Ministry of Finance
Department of Revenue
(Central Board of Excise and Customs)

New Delhi, dated the 14th June, 2016

To,

All Chief Commissioners of Customs / Customs (Preventive),
All Chief Commissioners of Customs and Central Excise,
All Commissioners of Customs / Customs (Preventive),
All Commissioners of Customs and Central Excise.

Sir/Madam,

Subject: Single Window Project – Simplification of procedure in SWIFT for clearance of consignments related to drugs & cosmetics reg.

Kind reference is invited to Board's Circular No. 03/2016 dated 03.02.2016 and Circular No. 10/2016 dated 15.03.2016 regarding the Indian Customs Single Window. Central Board of Excise and Customs (CBEC) has operationalised the 'Indian Customs Single Window Project' to facilitate trade from 01st April 2016 at all EDI locations throughout India. As a result the importers and exporters electronically lodge their Customs clearance documents at a single point only with the Customs. The required permission, if any, from Partner Government Agencies (PGAs) such as Animal Quarantine, Plant Quarantine, Drug Controller, Food Safety and Standards Authority of India, Textile Committee etc. is obtained online without the importer/exporter having to separately approach these agencies. This has been made possible through a common, seamlessly integrated IT systems utilized by all regulatory agencies, logistics service providers and the importers/exporters. The Single Window Interface for Trade (SWIFT) thus provides the importers/exporters a single point interface for clearance of import and export goods thereby reducing dwell time and cost of doing business.

2. Since its implementation, reports have been received highlighting problems faced by trade in relation to the import of drugs, cosmetics and medical equipment. The Board has examined these issues and in consultation with the Drug Controller General of India the following decisions have been taken to simplify the procedure for clearance of such goods:

Items that are Chemicals and Not drugs

2.1 Several items falling under different Customs Tariff Heads which have been mapped in SWIFT as requiring clearance from Assistant Drug Controller's (ADC) office are chemicals and not drugs. These are being routed for ADC's clearance by virtue of the Customs Tariff Heads under which they are declared, and the ADC's office routinely declares them as "out of scope". In this regard, a list of such items have been prepared and published on the ICEGATE website as part of PGA Exemption Category (PEC).

Importers of such goods should identify their items on this PEC list and include them as part of the Integrated Declaration in order to avoid unnecessary references to the ADC. If any more items deserve to be part of the PEC list, importers/ Customs Brokers may bring it to the notice of the respective Commissioners. The Board has already established a Working Group to examine all such items. The PEC will be duly updated after holding consultations in the Working Group and with the approval of the concerned PGAs (DCGI – in case of drugs and cosmetics items).

Dual Use Items & Excipients

2.2 Several items falling under different Customs Tariff Heads which have been mapped in SWIFT as requiring clearance from Assistant Drug Controller's (ADC) office have dual use (use for medicinal and non-medicinal purposes) and excipients (an inactive substance that can serve as the vehicle or medium for a drug or other active substance). A large number of importers are importing them for purposes other than drugs or medicinal use. Presently, for the clearance of dual use items, the importers have to first seek a permit from Deputy Drug Controller's office and then to obtain an NOC from ADC office. To simplify the clearance of dual use items, it has been decided in consultation with the DCGI that items that are not pharmaceutical grade or items that do not contain any Active Pharmaceutical Ingredients (API) need not be referred to the ADC for NoC. Therefore, in respect of the category of dual-use items or excipients, in the Integrated Declaration, the items will normally not be referred to the ADC clearance if the importers or their Customs Brokers declare as follows:

(i) While providing the item details, it must be declared that the item is not pharmaceutical grade and does not contain any Active Pharmaceutical Ingredient.
(ii) The 'intended end use/ purpose of import' that is declared as part of item details should not be for human or veterinary medicinal purposes.

Risk-based testing & procedure for drawing of samples

2.3 Samples will be drawn for testing of products based on risk. In this regard, the DCGI has already outlined the criteria for risk-based testing under which intervention for inspection and sampling by ADC officers will be significantly reduced. Further, the procedure for drawing of samples for drugs has been streamlined. Customs officers may carry out the inspection of all drug/cosmetics consignments. They shall forward copies of authenticated labels of consignments for verification by the ADCs office. In cases where the consignments have to be opened for the drawing of product samples, an officer from the ADC's office shall draw the samples. The ADC's office reserve the right to inspect any drugs/cosmetics consignment.

2.4 It was reported that in respect of import of drugs & cosmetics items, the ADC's office draws samples for testing irrespective of whether the same batch to which the item belongs has undergone testing in previous consignments. Considering that this causes unnecessary hardship to the importer, it has been decided that if the product sample from a particular batch has been tested, and based on that sample, the consignment/item has been granted NOC by ADC's office, then a product sample shall

not be drawn again for subsequent consignments/items pertaining to the same batch for the purposes of giving NOC.

Letters of Guarantee and Undertakings

2.5 For different situations of clearance, the DCGI requires the importer to present letters of declarations, undertaking and letters of guarantee in formats prescribed in its Guidance Document. It was decided that wherever the text of these declarations, undertakings, and letters of guarantee are provided as part of the integrated declaration and digitally signed by the declarant, the importer may not produce separate hardcopies of the same declarations undertakings and letters of guarantee. These shall be subsumed as part of the Integrated Declaration.

Mapping ADC's office to ICES locations

2.6 Drugs, cosmetics, medical devices, non-critical diagnostics, dual use items, feed grade items etc, which require ADC clearance shall be imported only at the ports notified by CDSCO/DCGI. However, if consignments landed from vessel or aircrafts at a notified port are subsequently transshipped to another Customs location, the consignment will be referred for regulatory clearance purposes to the nearest ADC for clearance. For this purpose, when SWIFT was launched, all ICES locations were already mapped in the system to the nearest ADC's office for routing the consignments for ADC's clearance. Commissioners of Customs may report to the Board in case there are any problems with the mapping.

3. For implementation of the above decisions, DG (Systems) shall introduce necessary qualifiers in respect of the existing data fields in the Integrated Declaration. In regard to information required by ADC relating to supporting documents, CBEC is carrying out necessary upgrades to its IT infrastructure. Access by ADC's office to data fields or images of supporting documents and labels etc will be enabled once the CBEC IT infrastructure is upgraded.

4. Commissioners of Customs may kindly issue public notices to bring to the notice of the Trade the above changes. Importers and Customs Brokers may be advised to correctly declare all information in the Integrated Declaration including product details required by for Single Window and their intended end-use, especially since their declaration will determine how the consignments are handled in respect of regulatory clearances.

5. Any problems faced by field formations pertaining to above may kindly be reported to Single Window Project team, CBEC.

(Zubair Riaz)
Director (Customs)