Circular No. 40/2026-Customs

F. No. CBIC-510401/4/2023
Government of India
Ministry of Finance
Department of Revenue
(Central Board of Indirect Taxes and Customs)
16049, Kartavya Bhavan-1, New Delhi

Date:03-09-2026

To,

1. All Principal Chief Commissioners / Chief Commissioners of Customs /Customs (Preventive) / Customs & Central Taxes
2. All Principal Commissioners / Commissioners of Customs / Customs (Preventive)
3. Pr. Director General, DGARM,
4. Pr. Director General, DG SYSTEMS

Sir/Madam,

Subject: Checklists for mandatory compliance for Cosmetics/Drugs/Medical Devices to be verified by the Customs officer before granting out-of-charge in case of PGA facilitated Bills of Entry– reg.

The Central Drugs Standard Control Organization (CDSCO) in alignment with the Government's objective of enhancing the 'Ease of Doing Business' is taking measures to increase the facilitation of Cosmetics, Drugs and Medical Devices.

2. The said products require certain mandatory compliance in terms of licenses, permissions, registration certificates, etc., as per the provisions of the Drugs and Cosmetics Act, 1940 and Rules made thereunder. Considering the fact that integration of these documents under SWIFT 2.0. is under process, the field formations should exercise due diligence while giving out-of-charge in case of such imports. The CDSCO has provided checklists for the following 7 such categories of products and a list of documents to be verified by the Customs officer against each category of the products. **(Annexure-A** may be referred for document checklist**)**

Checklist I – Cosmetics

Checklist II – Drugs (API i.e. Active Pharmaceutical Ingredient, finished formulation)

Checklist III – Import of Drugs

(a) For personal use.

(b) Import of small quantities of new drug by a Government Hospital or Autonomous Medical Institution for the treatment of patients.

Checklist IV – Import of Drugs for examination, test or analysis

Checklist V - Medical Devices (including IVD's i.e. Invitro Diagnostics Kits/Devices)

Checklist VI – Import of Medical Devices

Checklist VII – Import of raw materials / components (substance, piece, parts, software, firmware, labelling or assembling which is intended to be included as part of the finished, packaged and labelled device) used for manufacture of Medical Devices.

3. Accordingly, it is requested that the field formations may be sensitized to check the documents at the time of out of charge. The trade fraternity may also be informed through a suitable public notice about the requirement of such documents with a request to upload the required documents on e-SANCHIT to facilitate expedited clearance.

4. Difficulty faced, if any, in implementation of this Circular may be immediately brought to the notice of the Board.

Yours Sincerely,

Encl: As above.

V. Kumar
03/09/2026

(Vivek Kumar)
OSD (Customs Policy Wing)

Copy for information to-
Drug Controller General of India, CDSCO, New Delhi.

UNCOMPLICATE Simplifying Compliances

ANNEXURE-A

Checklist for the custom official to be verified before Out-of-Charge

The Checklists I to VII covering various class of commodities are as detailed below:

Checklist I: Cosmetics

S.No.	Particulars
1	*Self-Certified copy of Registration Certificate (RC) in Form COS-2 in case of fresh registration or Form COS-4A in case of subsequent registration issued by CDSCO
2	Self-certified copy of invoice. • The invoice of the consignment shall mention the name of the cosmetics and match with the RC with respect to the Pack size (in case of finished product)
3	Self-certified copy of packing list.
4	Self-certified copy of the certificate of country of origin.
5	Items shall be labelled and match with RC w.r.t. a. Name of the cosmetics b. RC No. of the cosmetics and the name and address of the registration certificate holder for marketing the product in India. c. The name and address of the manufacturer and address of actual premises where the cosmetic has been manufactured. In addition to above each item shall be labelled to include: d. Batch number or lot number or serial number. e. use before or date of expiry ** No cosmetics shall be imported unless the Use Before/expiry is not more than six months from the date of import.
6	Self-Certified copy of the licensed premises where cosmetics are to be stored.
7	Self-Certified copy of Certificate of analysis (COA) or batch release certificate for each batch of cosmetics item.
8	No cosmetic containing hexachlorophene shall be imported. A Declaration from importer/manufacturer in this regard shall be submitted.
9	Declaration by the manufacturer that no animal is used for testing of cosmetics.
10	Undertaking by the importer that the consignment packaging is not damaged/broken/destroyed and the content of cosmetic has not been deteriorated.

Note:

* **In case of New Cosmetics to be imported under Form COS-3, the consignment shall be referred to concerned port office of CDSCO.**

** No cosmetics shall be imported unless the Use Before/expiry is not more than six months from the date of import.

In case of any discrepancies or doubts, the consignment shall be referred to the concerned CDSCO O/o ADC(I), Port Office

Checklist II: Drugs (API i.e. Active Pharmaceutical Ingredient, finished formulation)

S.No.	Particulars
1	Self-Certified copy of Registration Certificate (RC) in Form 41 along with Import License (IL) in Form 10
2	Self-Certified copy of invoice * The invoice of the consignment shall mention the name of the item and match with RC/IL with respect to the Pack size (in case of finished product).
3	Self-certified copy of packing list.
4	Self-certified copy of the certificate of country of origin.
5	Self-certified copy of labels and markings on the consignment. The Drug Items (API, Finished product) should be labelled and match with RC and IL with respect to the following:- a. Name of the drug b. IL No. and the name and address of the Import license holder. c. The name and address of the actual manufacturer where the drug has been manufactured. d. Storage condition. e. Composition of each unit in the case of a finished product.
	In addition to the above, each item should be labelled to include: a. Batch number or lot number, or serial number. b. Manufacturing date c. Expiry date. (re-test date in case of API). The residual shelf life is calculated on the date of import • More than 60% is allowed to import • less than 60%, the consignment should be referred to the concerned CDSCO port office d. The label in the case of API (bulk drugs) must bear a readable QR code which stores and retrieves the following information upon scanning: i. Unique product identification code, ii. Name of the API, iii. Brand name (if any),

	iv. Name and address of the manufacturer, v. Batch no., vi. Batch size, vii. Date of manufacturing, viii. Date of expiry or retesting, ix. Serial shipping container code, x. Import licence no. xi. Special storage conditions required (if any).
6	Self-Certified copy of Certificate of analysis (COA) for each batch imported and shall match with RC/IL w.r.t. - Name and Composition in case of finished product.
7	Self-Certified copy of the licensed premises where Drugs are to be stored (valid wholesale license/manufacturing license)
8	Undertaking by the importer that the consignment packaging is not damaged/broken/destroyed and the content of the drug/cosmetic has not deteriorated.

Note: The residual shelf life calculated on the date of import should be more than 60 %. If the Residual shelf life is less than 60%, the consignment should be referred to the concerned CDSCO port office.

Checklist III: Checklist for Import of Drugs

a. for personal use or,

b. Import of small quantities of the new drug by a Government Hospital or Autonomous Medical Institution for the treatment of patients.

S.No.	Particulars
1	Self-certified copy of Import permission granted in Form 12B or Form 11A/CT-25
2	Self-certified copy of invoice, packing list.
3	The quantity imported should tally with the quantity mentioned in the Import permission granted in Form 12B or Form 11A/CT-25

Checklist IV: Checklist for Import of drugs for examination, test or analysis

S.No.	Particulars
1	Self-certified copy of Import permission granted in Form 11 or CT-17 (to import new drug or investigational new drug)
2	Self-certified copy of invoice, packing list. * The invoice of the consignment shall mention the name of the item(s) and

	quantity same as mentioned in the Import permission.
3	The quantity imported should tally with the quantity mentioned in the Import permission.

Note:

• Registration certificate and Import license are not required for the drugs in transit through India to foreign Countries or Raw material (bulk drug) imported under Advance Authorization and which are not required to be sold or distributed in India.

• If the drugs are imported under 100% EOU/EPZ/SEZ and as are exempted from the condition of registration as per the above ITC Policy Circulars. To control misuse, as a precautionary measure, an undertaking from the importer also to be taken, and the details of the import to be informed to the State Drug Controller / Zonal Officer / DCGI immediately for post-import check.

In case of any discrepancies or doubts, the consignment shall be referred to the concerned CDSCO O/o ADC(I), Port Office.

Checklist V: Medical Devices (Including IVD's i.e., in vitro diagnostics kits/devices)

S.No.	Particulars
1	Self-certified copy of Import License in Form MD-15 issued by CDSCO. *In case of Class A (non-sterile and non-measuring) medical devices, the registration number.
2	Self-Certified copy of invoice, packing list, certificate of country of origin * The invoice of the consignment shall mention the name of the item and match with the Import License (MD-15) with respect to the Pack size (in case of finished product).
3	Self-certified copy of packing list.
4	Self-certified copy of the certificate of country of origin.
5	Self-certified copy of labels and markings on the consignment. The medical devices shall be labelled and match with the import License (MD-15) w.r.t. a. Name of the item(s) b. Import license No. and the name and address of the Import license holder. c. The name and address of the actual manufacturer where the medical devices have been manufactured. d. Storage condition. In addition to the above, each item shall be labelled to include: e. Batch number or lot number, or serial number. f. Manufacturing date. g. Expiry date. (re-test date in case of API).
	If the shelf life applicable item is imported, the Residual Shelf Life (RSL)

6	should be calculated from the date of import. The minimum RSL requirements are: at least 40% for devices with a 90-day shelf life, at least 50% for shelf life between 90 and 365 days, and at least 60% for shelf life exceeding 365 days.
7	Self-certified copy of Certificate of Analysis (COA) or quality certificate for each batch imported, and shall match with the Import license in Form MD-15.
8	Self-certified copy of the licensed premises where medical devices are to be stored.
9	Undertaking by the importer that the consignment packaging is not damaged/broken/destroyed and the content of the drug/cosmetic has not been deteriorated.

Checklist VI: Medical Devices

a. for the purposes of Clinical Investigations Test or Evaluation or Demonstration or Training.

b. For investigational medical device by a Government Hospital or Statutory Medical Institution for the treatment of patients.

c. to import of small quantity of Medical Devices for personal use.

S.No.	Particulars
1	Self-Certified copy of the Import license granted in Form MD-17 or MD-19 or permission in Form MD-21
2	Self-Certified copy of invoice, packing list, certificate of country of origin * The invoice of the consignment shall mention the name of the item(s) and quantity same as mentioned in the Import permission/license.

Checklist VII: Raw material/components (substance, piece, part, software, firmware, labelling, or assembly which is intended to be included as part of the finished, packaged, and labelled device) used for manufacture of Medical Devices

S.No.	Particulars
1	Self-Certified copy of manufacturing license granted in Form MD-05 (for Class A & B) or MD-09 (for Class C & D).
2	Self-Certified copy of copy of invoice, packing list, certificate of country of origin

In case of any discrepancies or doubts, the consignment shall be referred to the concerned CDSCO O/o ADC(I), Port Office.