सीमाशुल्क आयुक्त का कार्यालय,एन.एस.-II,
मुंबईअंचल-II
OFFICE OF THE COMMISSIONER OF CUSTOMS, NS-II, MUMBAI ZONE-II
जवाहरलाल नेहरूसीमाशुल्कभवन
JAWAHARLAL NEHRU CUSTOM HOUSE
पो:शेवा, ताल: उरण, नवीमुंबई - ४००७०७
PO: SHEVA, TAL: URAN, NAVI MUMBAI-400707
Email: commr-ns2@gov.in

दिनांक /Date: As Signed

दिनांक 07.07.2026 को सम्पन्न 'फेडरेशन ऑफ़ फ़ार्मास्युटिकल एंड एलाइड प्रोडक्ट्स (FPME) & PHARMEXCIL के सदस्यों के साथ हुई बैठक का कार्यवृत्त

MINUTES OF THE MEETING WITH MEMBERS OF FEDERATION OF PHARMACEUTICAL AND ALLIED PRODUCTS (FPME) & PHARMEXCIL HELD ON 07.07.2026

A meeting was held in physical mode on 07.07.2026 at 15:30 hrs at Jawaharlal Nehru Custom House (JNCH), Nhava Sheva Raigad, Maharashtra under the Chairmanship of Shri. Giridhar G. Pai, Commissioner of Customs (NS-II), JNCH in order to resolve the issues raised by the said trade bodies.

2. Ms. Jyoti Agarwal, Additional Commissioner, NS-II, JNCH opened the proceedings by welcoming Commissioner of Customs, NS-II, Mumbai Customs Zone-II and other participants.

3. इस बैठक में व्यापार के निम्नलिखित सदस्यों/प्रतिभागियों ने भाग लिया:

3. The meeting was attended by the following members/participants of the trade:

क्रमसं./ Sr.No.	नाम(सर्वश्री/सुश्री/श्रीमती) Names(Shri/Ms./Mrs.)	संगठन / संघ Organizations/Associations
1.	Kamlesh Shah	FPME
2.	Abhay Shah	FPME
3.	Sandeep Modi	FPME
4.	Ashish Shah	FPME
5.	Atul Balel	FPME
6.	Kamal S Shah	FPME
7.	Hamil Shah	FPME
8.	Yash Patel	Indasi Lifescience Pvt Ltd
9.	Dr. R. K. Singh	Indasi Lifescience Pvt Ltd

10.	Rollins John	Pharmexcil
11.	Bhavin Mehta	Pharmexcil

4. इस बैठक में निम्नलिखित सदस्यों/प्रतिभागियों (PGAs) ने भाग लिया।:

4. The meeting was attended by the following members/participants PGAs:

क्रमसं./ Sr.No.	**नाम(सर्वश्री/सुश्री/श्रीमती) Names(Shri/Ms./Mrs.)**	**संगठन / संघ Organizations/Associations**
1.	Rajesh Verma	Assistant Drug Controller, O/o CDSCO

5. विभाग की ओर से निम्नलिखित अधिकारियों ने बैठक में भाग लिया: -

5. Following Officers from the department attended the meeting:

क्रमसं./ Sr.No.	**नाम(सर्वश्री/सुश्री/श्रीमती) Names(Shri/Ms./Mrs.)**	**पदनाम Designation**
1.	Jyoti Agarwal	Additional Commissioner of Customs
2.	Mahesh Keny	Deputy Commissioner of Customs
3.	Sunil Saththianesan	Assistant Commissioner of Customs
4.	Sangeeta Adhikari	Assistant Commissioner of Customs
5.	Krishna Kumar	Assistant Commissioner of Customs
6.	Rakesh Bainle	Assistant Commissioner of Customs
7.	Santosh Anand	Superintendent of Customs/Docks
8.	Devashish Jangid	Appraiser/Docks
9.	Hunny Bansal	Appraiser/AM(X)
10.	Shubham Choudhary	Examiner/AM(X)
11.	Akash Kumar	Examiner/AM(X)
12.	Rahul Kumar Rai	Examiner/AM(X)

6. Ms. Jyoti Agarwal, Additional Commissioner, NS-II with the permission of Chair; welcomed all for the meeting to discuss issues raised by the members of Federation of Pharmaceutical and Allied Products (FPME) & Pharmexcil regarding export of Drugs and Pharmaceuticals.

<u>कार्यबिन्दु संख्या/POINT NO. 1:</u>

(i) FPME submitted that the SOP as under is being followed by Merchant Exporters, who are all DL holders in Form 20B and 21B:

1. Seek ADC NOC from the port of Shipment by, inter alia, submitting, along with the statutory documents, the Purchase Bills bearing Drug License Nos of the seller and Product scans;
2. Wherever called for, produce sample of the products;
3. Post ADC NOC Put up the documents for Custom Clearance and where necessary permit examination of cargo.

(ii) Despite obtaining ADC NOC, Custom Officers are further seeking following documents:

1) Manufacturing Licence Copy
2) GMP Certificate of the Manufacturer Product Permission
3) Product Permission
4) Export Permission for products bearing Local MRP
5) COA

(iii) FPME submits that once the ADC has granted NOC for the consignment customs should not insist on documents which are already considered by ADC while granting NOC.

(Issue by FPME)

<u>प्रतिक्रिया/Response:</u>

(i) ADC, O/o CDCSO vide letter dated 06.07.2026 informed that they have issued Public Notice No. 04/ADC-NS/Notice/2024-25/71 dated 18.04.2024 prescribing the list of documents required for export of pharmaceutical products at the Office of ADC(I), JNPT Sea Port, Panvel taking into account DGFT Public Notice No. 173 (RE-2008)/2004-2009 dated 13.04.2009 which provides that every exporter of drugs and pharmaceuticals at the time of shipment shall submit, along with other required documents, the following:

1. Copy of Certificate of Analysis issued by the manufacturer for the subject product; or
2. Copy of Certificate of Analysis issued by an approved laboratory of the importing country/FDA; or
3. iii. Copy of Certificate of Analysis issued by a laboratory approved by the Drugs Controller under the Drugs and Cosmetics Act, 1940 and Rules made thereunder.
4. iv. Other required documents may include Manufacturing Licence, Product Permission, Labels, Invoice, Packing List, Purchase Bill, Wholesale Licence, etc.

(ii) Accordingly, ADC/CDCSO verifies the following aspects depending on the category of products to be exported by merchant exporters:

i. Validity of Drug Licence(s) (Form 20B/21B and/or Manufacturing Licence, as applicable);
ii. Batch-wise/Product-wise Certificate of Analysis (COA);
iii. Batch Number, Manufacturing Date, Expiry Date and Manufacturer details appearing on the product labels;
iv. Whether the products are banned, unapproved or fall under the category of new drugs;
v. Any other regulatory parameters examined by CDSCO prior to issuance of the NOC;
vi. Labelling of pharmaceuticals as per rules.

(iii) Docks officers informed that the ADC NOC is issued to the Exporter/Customs Broker through email with a copy to the DC/Docks. It is physically produced during Customs examination as it is not uploaded in e-Sanchit. The NOC presently contains only the Shipping Bill Number/Date and ADC Entry Number. However, it does not specify the scope of verification carried out by the ADC.

(iv) The matter was deliberated amongst the stakeholders. It was felt that if the scope of documentary verification conducted by ADC/CDSCO while granting NOC is clearly laid out

by way of a Public Notice, customs officers need not insist on such documents again for the purposes of eligibility for export from the CDSCO's perspective. Officers may only seek documents that are required for scrutiny from the customs assessment perspective.

Action To be Taken: Accordingly, it was decided that Public Notice will be issued in consultation with ADC/CDSCO prescribing the procedure to be followed for export of drugs and pharmaceuticals, with a view to reducing procedural redundancies, avoiding duplication of document verification, and promoting Ease of Doing Business.

कार्यबिन्दु संख्या/POINT NO. 2:

Excessive Physical Examination and Sample Testing: Almost every pharmaceutical consignment is subjected to physical examination and repeated sample testing, including consignments belonging to AEO-T2, WHO-GMP and USFDA-compliant exporters.

(Issue by Pharmexcil)

प्रतिक्रिया/Response: The Chair informed the members of Pharmexcil that the examination order is generated by the ICES system based on predefined risk parameters, and the examining officer has no role in its selection. The members were advised to submit a representation, along with details of exporters whose past consignments have consistently been subjected to examination, including the Shipping Bill particulars such as description of goods, value, classification, and other relevant details. The same may be forwarded to NCTC for review and re-evaluation of the applicable risk parameters, if considered necessary.

कार्यबिन्दु संख्या/POINT NO. 3:

Product-specific Regulatory Clarifications: Companies reported a lack of clarity regarding the regulatory requirements applicable to Combi Packs containing diluents, particularly in relation to the implementation of Circular No. SND-16011(11)/94/2025-eOffice dated 29.09.2025. Exporters also highlighted that Customs officers frequently raise queries and seek additional approvals for products that have already been approved by the competent regulatory authorities, resulting in avoidable delays, uncertainty and inconsistent implementation of regulatory requirements across Customs formations.

(Issue by Pharmexcil)

प्रतिक्रिया/Response:

In cases where a drug was approved prior to 2018 and is being marketed in India but is not available on the SUGAM Portal, the Chair advised that the Indian Pharmacopoeia may be referred to, wherever applicable. Further, the Chair advised exporters to upload a detailed declaration in e-Sanchit, along with all relevant clarifications and supporting documents, at the time of filing the Shipping Bill so that any minor issues arising during assessment, examination or post clearance audit can be resolved on the basis of the pre-uploaded declaration, thereby minimizing delays in export clearance.

कार्यबिन्दु संख्या/POINT NO. 4:

Repeated Queries on Previously Resolved Issues Customs repeatedly raise identical classification and documentation queries that had already been resolved in previous consignments.

(Issue by Pharmexcil)

प्रतिक्रिया/Response:

The chair informed all trade members to upload all the necessary clarifications; explanation along with details of Previous Shipping Bills for identical goods supporting documents, at the time of filing the Shipping Bill so that any minor issues arising during assessment, examination or post clearance audit can be resolved on the basis of the pre-uploaded declaration.

7. Further, the Chair informed the representatives of all trade associations about the monthly Niryat Samvaad, held on every Wednesday of the 2nd week of each month, which serves as a dedicated platform for addressing exporter-specific grievances under the export grievance redressal mechanism. The Chair also apprised the representatives of the monthly Permanent Trade Facilitation Committee (PTFC) and Customs Clearance Facilitation Committee (CCFC) meetings, which provide a forum for stakeholders to raise trade-related issues and facilitate the expeditious clearance of import and export cargo by resolving inter-agency bottlenecks. The notices for all the aforesaid meetings are regularly circulated to the registered e-mail IDs of the respective trade associations. In case of any issue regarding receipt of such communications, the same may be brought to the notice of the concerned office through e-mail at *apmainexp@jawaharcustoms.gov.in* for Niryat Samvaad and PTFC, and ccu-*cusmum2@nic.in* for CCFC.

8. The meeting ended with a vote of thanks to the Chair.

9. Minutes are placed on the JNCH website and also sent through emails to all members including concerned exporters. Any amendments to these minutes to be provided within the next five working days.

10. This issues with the approval of the Commissioner of Customs, NS-II**.**

(Sunil Saththianesan)
सहायक आयुक्त,सीमाशुल्क/
Asst. Commissioner of Customs,
मूल्य निरूपण मुख्य(निर्यात)/Appraising Main (X),
जे.एन.सी.एच.,न्हावाशेवा/ JNCH, Nhava Sheva.

सेवामें /To,

सभी संबंधित निर्यातक को ईमेल के माध्यम से /All Concerned Exporters (through email)

प्रतिलिपि/Copy to :(ईमेल के माध्यम से)

1) मुख्य आयुक्त,सीमाशुल्क,मुंबईअंचल-II/Chief Commissioner of Customs, MUM Zone-II;

Digitally signed by
Sunil Sathianesan
Date: 13-07-2026
16:24:25

2) प्रधानअपरमहानिदेशक,करदाता सेवा महानिदेशालय,मुंबई/The Principal Add. Director General, Directorate General of Tax Payers Services, Mumbai Zonal Unit, room No 138/139, New Custom House, Mumbai-400001(mzu-dgtps@gov.in);
3) सभी अपर/संयुक्त आयुक्त,एनएस II, जेएनसीएच,न्हावा शेवा /All ADC/JC, NS-II, JNCH, ;
4) सभी उप/सहा.आयुक्त, एनएस II,जेएनसीएच&सहा/उप आयुक्त, ईडीआई न्हावा शेवा /All DCs/ACs,NS-II& AC/DC/EDI, JNCH;
5) सहा/उप आयुक्त, ईडीआई, जेएनसीएच,न्हावा शेवा को अविलंब वैबसाइट में अपलोड करने के लिए/AC/DC, EDI, JNCH, Nhava Sheva, for uploading in JNCH website;
6) कार्यालयप्रति/Office Copy.