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IN THE HIGH COURT OF JUDICATURE AT BOMBAY
ORDINARY ORIGINAL CIVIL JURISDICTION

WRIT PETITION NO. 3079 OF 2026

MUMBAI TRAVEL RETAIL LIMITED,
A Company existing under the Companies Act, 2013 and having its registered office at Adani Corporate House Shantigram, Near Vaishno Devi Circle, S. G. Highway, Khodiyar, Ahmedabad 382 421, Gujarat, and office in Mumbai at Chhatrapati Shivaji Maharaj International Airport, Mumbai 400 009
Through its Authorized Signatory
Mr Ajay Kaul ...PETITIONER

~ versus ~

1. **UNION OF INDIA,**
   Through the Secretary,
   Ministry of Health and Family Welfare of India, Nariman Bhawan, C-Wing,
   New Delhi 110 001
2. **THE DRUG CONTROLLER GENERAL (I),**
   CDSCO, FDA Bhawan, Near Bal Bhavan, Kotla Road, New Delhi 110 00, India
3. **ASSISTANT DRUGS CONTROLLER (I),**
   Room No.10, International Air Cargo Complex, Sahar, Andheri,
   Mumbai 400 099,
4. **PRINCIPAL COMMISSIONER OF CUSTOMS,**
   Chharapati Shivaji Maharaj International Airport, Mumbai 400 099. ...RESPONDENTS

SHEPHALI SANJAY MORMARE

Digitally signed by SHEPHALI SANJAY MORMARE
Date: 2026.09.22 17:59:22 +0530

WITH
WRIT PETITION (L) NO. 20740 OF 2026

FLEMINGO DUTYFREE SHOP PRIVATE LIMITED,
A company existing under the Companies Act 2013 and having its registered office at D-72, TTC Industrial Area, MIDC Turbhe, Navi Mumbai 400 705, through its Authorized Signatory Assistant Manager,
Mumbai Seaport **...PETITIONER**

~ versus ~

1. **UNION OF INDIA,**
Through the Secretary,
Ministry of Health and Family Welfare of India, Nariman Bhawan, C-Wing,
New Delhi 110 001

2. **THE DRUG CONTROLLER GENERAL (I),**
CDSCO, FDA Bhawan, Near Bal Bhavan, Kotla Road, New Delhi 110 00, India

3. **ASSISTANT DRUGS CONTROLLER (I),**
Office of the ADC (I), CDSCO, Central Drugs Standard Control Organization, M/s. JWR Logistic Pvt. Ltd. 15-45, National Highway, 4BPanvel-JNPT Highway, Village Padeghar, Post-Vahal, Panvel 410206, Maharashtra.

4. **COMMISSIONER OF CUSTOMS (IMPORT II),**
New Customs House, Bond Section,
New Customs House, Ballard Estate, Mumbai 400 001. **...RESPONDENTS**

APPEARANCES

For the Petitioner in **Mr Janak Dwarkadas, Senior Advocate**,

WP/3079/2026	with Mr Arunabh Chowdhury, Senior Advocate, Mr Ashish Kamat, Senior Advocate, Mr Prakash Shah, Senior Advocate, Simantini Mohite, Abhay Jadeja, Dhanyashree Jadeja, Urvi Gulechha and Ishani Saxena, i/b Jadejas & Partners.
For Petitioner in WPL/20740/2026	**Mr Arunabh Chowdhury, Senior Advocate**, with Abhay Jadeja, Dhanyashree Jadeja, Urvi Gulechha and Ishani Saxena, i/b Jadejas & Partners.
For the Respondents Nos. 1 to 3, UoI.	**Mr Anil Singh, Additional Solicitor General**, with Rui Rodrigues, Jainendra Sheth, Adiya Vyas and Leena Patil.
For Respondent No. 4	**Mr Siddharth Chandrashekhar**, with Abhishek R Mishra.

CORAM : SUMAN SHYAM &
ADVAIT M. SETHNA, JJ.

RESERVED ON : 7th AUGUST 2026.

PRONOUNCED ON : 22nd SEPTEMBER 2026.

JUDGMENT (*Per Suman Shyam, J*):-

1. Rule. Rule made returnable forthwith. By consent of the parties, both these Writ Petitions are taken up for final hearing and disposal.

2. The Writ Petitioners are operating their respective Duty Free Shops (DFSs) in the Departure Terminal of the Chhatrapati Shivaji

Maharaj International Airport Terminals at Mumbai. The Petitioners in Writ Petition No. 3079 of 2026 and Writ Petition (L) No. 20740 of 2026 are both *inter alia* selling an imported product called “Nicotine pouch” in the DFS under the brand names, “ZYN” and “FOX”, the sale of which has been banned by the authorities, apparently due to want of licence issued under The Drugs and Cosmetics Act, 1940 (hereinafter referred to as “the Act of 1940”) and the Rules framed thereunder. Aggrieved thereby, both the Writ Petitioners have approached this Court by filing these Writ Petitions seeking identical reliefs. Since both these Writ Petitions raise common questions of law and are based on identical facts, hence these are being disposed of by this common judgment and order.

3. For the purpose of these proceedings, the facts involved in Writ Petition No. 3079 of 2026 are being referred to hereinbelow, for ready reference:-

4. As noted above, the Writ Petitioner is operating a Duty Free Shop (“DFS”) viz. M/s. Mumbai Travel Retail Ltd., in the Departure Terminal of the Chhatrapati Shivaji Maharaj International (“CSMI”) Airport at Mumbai. The Petitioner imports a product under the brand names "ZYN" and "FOX" for sale in the Duty Free Shop (DFS) at the International Departure Terminal of the Airport. According to the Petitioner, the product in question is "Tobacco free nicotine pouch". These products are stored in a Special Warehouse operated under a licence obtained from the Jurisdictional Commissioner of Customs under section 58-A of the Custom Act, 1962 (hereinafter referred to as the "Act of 1962"). However, it is the admitted factual position that the Petitioner is not holding any import licence or Registration Certificate issued by the authority under the Drugs and Cosmetics Act, 1940 either for importing or for selling the product. The Petitioner claims that "Nicotine pouches" are imported from reputed international suppliers and are not meant to be sold in the domestic market or for consumption in India but are meant only for consumption by the outbound travellers in the International Departure Terminal and therefore, it was a case of re-export. As such, there is no necessity for the Petitioner to obtain any licence under the Act of 1940 for dealing with such product.

5. On 3rd October 2025, a complaint was lodged by an entity called "Mothers Against Vaping" ("MAV"), raising concerns about the sale of the "Nicotine Pouch" *inter-alia* on the ground of a potential health hazard associated with the use of the product. Based on such complaint, the Respondent No. 4 had issued a Notice dated 10th October 2025 bearing No. F.No.ARPT/WH/MISC/81/2025-DFS, calling upon the Petitioner to furnish details concerning the legality and authorization of sale of the Nicotine pouches. On receipt of the said notice, the Petitioner had submitted a Reply dated 15th October 2025, addressed to the Respondent No. 4, thus, asserting that since the DFS is situated within the customs frontier of the International Airport, hence, the domestic regulatory regime would not apply to the sale of "Nicotine pouches". Having taken the above stand, the Petitioner, while questioning the *bonafide* of the complaint made by MAV, had also sought an opportunity of hearing before the authorities. On 10th November 2025, the Respondent No. 4 had called upon the Petitioner to furnish (i) the Bill of Entry under which the product was imported/warehoused as well as the documents connected therewith including the exemption Notification, if any; and (ii) NOC/Exemption from the concerned government agencies. In response to the communication dated 10th November 2025, on 13th November 2025, the Petitioner had forwarded the relevant Bill of Entry, while reiterating its earlier stand that since the DFS operates beyond the customs frontier and the product fell under the DGFT's (Directorate General of Foreign Trade) "free classification" policy, no NOC/Exemption was legally required to sell the product in the DFS. The Respondent No. 4 had, however, not accepted such claims of the Petitioner and instead, issued a communication dated 15th December 2025 alleging that in the Bill of Entry, only the brand name of the product, viz., "ZYN" has been reflected instead of specifically mentioning "Nicotine Pouches" and, therefore, called upon the Petitioner to show cause as to why, such specific description was avoided in the Bill of Entry. Since the Petitioner did not submit any Reply to the said communication, hence, on 26th December 2025, the Respondent No. 4 had also issued a reminder notice. On 2nd January 2026, the Petitioner addressed a letter to the Respondent No. 4 stating that the description of the product in the Bill of Entry was based on the invoice of the supplier/ manufacturer. It was mentioned that the product was classified under the head '24049100' of the Notification dated 9th February, 2022 issued by the DGFT. It was further contended that since there was a specific mention in the Bill of Entry to the effect that the same was " For

Duty Free Shop Sale" and the customs authorities had physically examined the products and permitted warehousing of the same, hence, no further action was called for in the matter. On 5th March 2026, the Respondent No. 3 conducted an investigation at the Petitioner's DFS pertaining to the sale of the nicotine pouches, whereafter, investigation report dated 5th March 2026 was prepared. Taking note of the findings of the investigation report dated 5th March 2026, the Respondent No. 3 had issued the impugned order dated 2nd April 2026 banning the sale of the product (Nicotine Pouch) in the Duty Free Shops located at the International Departure Terminal 2 of Chhatrapati Shivaji Maharaj International Airport at Mumbai, by holding that the sale of the product in the terminal was in contravention of the provisions of the Drugs and Cosmetics Act, 1940 and the Rules framed thereunder. Accordingly, a request was made by the Assistant Drug Controller, i.e., the Respondent No 3 to the Customs Authorities to take appropriate action in the matter. On 8th April, 2026, the Assistant Commissioner, DFS Bond, C.S.M.I Airport had issued a communication to the Petitioner informing that the nicotine pouches imported for sale in the DFS were "Drugs" as per section 3(b) of the Drugs and Cosmetics Act, 1940 and therefore, valid

Registration Certificate and import licence were mandatory for their import and sale in India. The Petitioner was accordingly, advised to take up the matter with the CDSCO (Central Drug Standard Control Organization) and obtain the necessary documents, pending which, the sale of the product be stopped. Aggrieved thereby, the Writ Petitioner has approached this Court by filing the present Writ Petition with the following prayers:

> "(a) that this Hon'ble Court be pleased to issue a writ of mandamus or a writ in the nature of mandamus or any other writ, order and direction:
>
> (i) ordering and declaring that the Drugs and Cosmetic Act 1940 and Drugs and Cosmetics Rules 1945 do not apply to the Petitioner in relation to its business and activities conducted at the Petitioner's Duty Free Shops and/or the nicotine pouches available, displayed and/or sold at the said Duty Free Shops and as such the impugned Communications dated 08 April 2026 read with 02 April 2026 (at Exhibit "K" hereto) are without jurisdiction and legal authority;
>
> (ii) restraining, injuncting and/or prohibiting Respondents No.1 to 4, their respective servants, officers and/or agents from in any manner (directly and/or indirectly) applying the Drugs and Cosmetic Act, 1940 and Drugs and Cosmetics Rules, 1945 to the Petitioner for and in respect of their business and activities conducted at the Duty Free shops and/or nicotine pouches sold at the Petitioner's Duty Free Shops; and
>
> (ii) restraining, injuncting and/or prohibiting Respondents No.1 to 4, their respective servants, officers and agents from in any manner (directly and/or indirectly) interfering with, disturbing and/or in any manner disturbing the Petitioner's supply, display, distribution and/or sale of the nicotine pouches at the Petitioner's Duty Free Shops and/or acting upon on the basis of

and/or taking any coercive measures against the Petitioner on the basis of the impugned Communications dated 08 April 2026 read with 02 April 2026 (at Exhibit "K" hereto) in relation to the business and/or activities of sale conducted by the Petitioner at its Duty Free Shops;

(b) this Hon'ble Court be pleased to issue a writ of certiorari or writ in the nature of certiorari or any other appropriate writ, order and direction calling for the record of the case from Respondents No. 1 to 4 and after perusing the legality, correctness and veracity, this Hon'ble Court be pleased to quash and set aside the impugned Communications dated 08 April 2026 read with 02 April 2026 (at Exhibit K hereto);

(c) that pending the hearing and final disposal of the present Petition, this Hon'ble Court be pleased to:

(i) restrain, injunct and/or prohibit Respondents No.1 to 4, their respective servants, officers and/or agents from in any manner (directly and/or indirectly) applying the Drugs and Cosmetic Act, 1940 and Drugs and Cosmetics Rules, 1945 to the Petitioner in relation to the Petitioner's business and/or activities conducted at its Duty Free Shops and more particularly, the storage, display and/or sale of nicotine pouches at the Petitioner' Duty Free Shops;

(ii) stay the effect, implementation and operation of the impugned Communications dated 08 April 2026 read with 02 April 2026 (at Exhibit K hereto); and

(iii) restrain, injunct and/or prohibit Respondents No.1 to 4, their respective servants, officers and agents from in any manner (directly and/or indirectly) interfering with, disturbing and/or in any manner disturbing the Petitioner' supply, display, distribution and/or sale of the nicotine pouches at the Petitioner' Duty Free Shops and/or acting upon and/or in furtherance of and/or otherwise taking any coercive measures against the Petitioner on the basis of the on the basis of the impugned Communications dated 08 April 2026 read with 02 April 2026 (at Exhibit "K" hereto)."

6. On 24st June 2026, this Court had passed an ad-interim order restraining the Respondents from initiating any coercive action against the Petitioner pertaining to the existing stock of Nicotine Pouches held in its Duty Free Shop. However, further import of the product has remained suspended in view of the communication dated 2nd April 2026 issued by the Respondent No. 3.

7. As noted above, the pleaded case of the Petitioner is that since the purchase of the product is from foreign suppliers and the product is being sold only in the Duty Free Shops at the Departure Terminal of the International Airport and within the customs barrier of the Airport, hence, the domestic municipal laws, including the Rules and Regulations framed under the Drugs and Cosmetics Act, 1940, would not have any application to such products. Therefore, there was no requirement on the part of the Petitioner to obtain any licence under the Drugs and Cosmetics Act or the Rules framed thereunder.

8. The stand of the Respondents, on the other hand, has been that, although the product is being sold in the Departure Terminal of the International Airport, yet, the passengers take possession of the goods immediately after the sale and are also free to consume the same even on the Indian soil. Considering the health hazard associated with consumption of nicotine, the stoppage and /or sale of the product on Indian soil would come within the domain of the Indian regulatory agencies. It is also the case of the Respondents that the expression "Outside customs frontier" would be applicable to the DFS only for the customs tariff/ taxation purposes and the same would not extend any immunity to the DFS from the regulatory control of domestic agencies, particularly when the matter pertains to an issue of health hazard.

9. While advancing arguments in support of the pleadings in the Writ Petition, Mr. Janak Dwarkadas, learned Senior Counsel has submitted that in view of the decision of the Supreme Court rendered in the case of ***M/s. Hotel Ashoka (Indian Tour Dev. Cor. Ltd) Vs. Assistant Commissioner of Commercial Taxes & Anr.***[1] as well as ***Garden Silk Mills Limited & Anr. v. Union of India & Ors.,***[2] the law is well settled that goods stored in the customs warehouses are later on, sold in the Duty Free Shops, would not attract customs tariff and/or indirect tax since the transaction takes place within the customs barrier. According to Mr. Dwarkadas, since the Nicotine Pouches sold in the DFS, are not

1 (2012) 3 SCC 204.

2 (1999) 8 SCC 744.

sold to the domestic consumers, the same do not merge with the "mass of goods" in India. As such, the product would neither attract customs duty and/or tax on sale nor can the same be subjected to the domestic regulatory regime. Mr. Dwarkadas has further argued that unless the product transcends the customs barrier, none of the Regulatory Authorities, including the Respondent No. 3, would have any authority or jurisdiction under the law to either seize the product or to insist on any licence for trading of the same.

10. In his attempt to distinguish the recent decision of a coordinate Bench of this Court in the case of ***Glamstone Cosmetics Pvt. Ltd. Vs. Union of India & Ors.***,[3] Mr. Dwarkadas has further argued that it was a case where the Court had found that there was a fraudulent declaration of the cosmetics imported by the DFS and, accordingly, the Court had upheld the seizure of such goods. However, submits Mr. Dwarkadas, in the present case, the product having been imported under a valid Bill of Entry and stored in the customs warehouse with the full knowledge and understanding of the customs authorities that the product was imported for the

3 2026 SCC OnLine Bom 1861.

purpose of re-export, the provisions of the Act of 1940 and the Rules framed thereunder, would have no application in case of such product. In support of his above arguments, Mr. Dwarkadas has relied upon and referred to the following decisions: -

1. *Garden Silk Mills Limited & Anr. v. Union of India & Ors. — (1999) 8 SCC 744.*

2. *Flemingo Dutyfree Shop Private Limited v. The State of Karnataka — ILR 2009 KAR 3462.*

3. *DFS India Private Limited v. Commissioner of Custom — Special Leave Petition (C) No. 2436 of 2010.*

4. *DFS India Private Limited & Anr. v. The Commissioner of Customs—Writ Petition No. 2578 of 2009.*

5. *Indian Tourist Development Corporation Limited v. Assistant Commissioner of Commercial Taxes & Anr. —(2012) 3 SCC 204.*

6. *DFS India Private Limited & Anr. v. Union of India & Ors.—rit Petition (L) No. 975 of 2014.*

7. *DFS India Private Limited & Anr. v. Union of India & Ors.—Writ Petition (L) No. 2136 of 2014 (renumbered as Writ Petition No. 2680 of 2014).*

8. *DFS India Private Limited & Anr. v. Union of India & Ors.—Writ Petition No. 2680 of 2014.*

9. *DFS India Private Limited & Anr. v. Union of India & Ors.—Writ Petition (L) No. 3003 of 2017 (renumbered as Writ Petition No. 215 of 2018).*

10. *Commissioner, Service Tax-VII v. Flemingo Dutyfree Shop Private Limited—2017 SCC OnLine CESTAT 10531.*

11. *Aarish Altaf Tinwala—Order No. 634/2018-CUS (WZ)/ASRA/MUMBAI dated 31.08.2018.*

12. *A-1 Cuisines Private Limited v. Union of India—2018 SCC OnLine Bom 21238.*

13. *A-1 Cuisines Private Limited v. Union of India and Anr.—Special Leave Petition (C) No. 33011 of 2018.*

14. *Sandeep Patil v. Union of India & Anr.—Cri. Public Interest Litigation (St.) No. 3 of 2019.*

15. *Atin Krishna v. Union of India—2019 SCC OnLine All 7064*

16. *Sandeep Patil v. Union of India & Anr. along with another connected matters—2019 SCC OnLine Bom 2483.*

11. Mr. Arunabh Chowdhury, learned Senior Counsel, appearing for the Petitioner in Writ Petition (L) No. 20740 of 2026, while adopting the submissions made by Mr. Dwarkadas, has further argued that the impugned communication dated 2nd April 2026 is wholly arbitrary and without jurisdiction since there is nothing on record to show that the product (Nicotine Pouch) would come within the definition of "drug" within the meaning of Section 3(b) of Drugs and Cosmetics Act, 1940 requiring an import licence. According to Mr. Chowdhury, the product is not a prohibited item, rather, it enjoys "free import" status as per the Notification No. 54/2015-2020 dated 9th February 2022 issued by the DGFT.

Therefore, submits Mr. Chowdhury, there is no justifiable ground for the Respondent No. 3 to either insist on an import licence or a Registration Certificate for selling the product in the DFS of the International Airport as there was no requirement under law to hold such a licence.

12. Resisting the above arguments, Mr. Anil Singh, learned Additional Solicitor General of India, appearing for the Respondents, has submitted that any transaction involving the product taking place on the Indian soil and within the territorial waters of India would be subject to the regulatory regime of the country. Therefore, a product which requires licence outside the customs frontier would also require a licence, even if transacted within the DFS. According to Mr. Singh, selling the product in the DFS would be deemed to have been done within India.

13. Mr. Singh has further argued that since 'Nicotine' is considered as an API (Active Pharmaceutical Ingredient) Agent and/or a pharmaceutical ingredient within the meaning of Section 3(b) of the Act of 1940, hence, its import, sale or stocking in India, without a valid licence, would be prohibited under Section 11 of the Act of 1962 as well. On such count, Mr. Singh has, therefore, submitted that the Respondent No. 3 was not only justified in insisting on a licence but the Customs Authorities were also well within their authority and jurisdiction to ban the sale of the product unless the DFS complies with the regulatory regime. It is also the contention of Mr. Singh that the present case will be squarely covered by the judgment of this Court in the case of ***Glamstone Cosmetics Pvt. Ltd. Vs. Union of India & Ors.*** (Supra) and, therefore, the Writ Petition(s) is/ are liable to be dismissed.

14. We have considered the submissions made at the Bar and have also gone through the material available on record.

15. After a careful analysis of the projections made by the contesting parties, we are of the view that, two important questions, having a substantial bearing in the outcome of the proceeding(s), would arise for consideration by this Court, are as follows:-

I. Whether all transactions conducted within a DFS, beyond the customs barrier, would enjoy absolute immunity from the domestic regulatory regime or whether such immunity/exemption would be restricted solely to fiscal levies such as customs duty, indirect tax, etc.?

II. Whether “Nicotine Pouch” falls within the definition of “drug” under section 3(b) of the Drugs and Cosmetics Act, 1940, making import licence and/or registration mandatory even for dealing with the product within the customs barrier of the International Departure Terminal of the Airport?

16. In order to answer the aforementioned questions, it would be necessary for us to refer to and rely upon certain provisions of the Act of 1962 as well as the Act of 1940 and the Rules framed thereunder.

17. The following provisions of the Customs Act, 1962 would be relevant for the purpose of this case and therefore are being quoted herein below for ready reference:-

> “**2. Definitions.—**In this Act, unless the context otherwise requires,—
>
> (10) “customs airport” means any airport appointed under clause (a) of section 7 to be a customs airport 6 [and includes a place appointed under clause (aa) of that section to be an air freight station;

(11) "customs area" means the area of a customs station 7 [or a warehouse] and includes any area in which imported goods or exported goods are ordinarily kept before clearance by Customs Authorities;

(23) "import", with its grammatical variations and cognate expressions, means bringing into India from a place outside India;

(25) "imported goods" means any goods brought into India from a place outside India but does not include goods which have been cleared for home consumption;

(27)"India" includes the territorial waters of India;

(28) "Indian Customs Waters" means the waters extending into the sea up to the limit of 4 Exclusive Economic zone under section 7 of the Territorial Waters, Continental Shelf, Exclusive Economic Zone and other Maritime Zones Act, 1976 (80 of 1976),] and includes any bay, gulf, harbour, creek or tidal river;

(33) "prohibited goods" means any goods the import or export of which is subject to any prohibition under this Act or any other law for the time being in force but does not include any such goods in respect of which the conditions subject to which the goods are permitted to be imported or exported have been complied with;

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Section 11:

11. Power to prohibit importation or exportation of goods.

(1) If the Central Government is satisfied that it is necessary so to do for any of the purposes specified in sub-section (2), it may, by notification in the Official Gazette, prohibit either absolutely or subject to such conditions (to be fulfilled before or after clearance) as may be specified in the notification, the import or export of goods of any specified description.

(2) The purposes referred to in sub-section (1) are the following:—

(a) the maintenance of the security of India;

(b) the maintenance of public order and standards of decency or morality;

(c) the prevention of smuggling;

(d) the prevention of shortage of goods of any description;

(e) the conservation of foreign exchange and the safeguarding of balance of payments;

(f) the prevention of injury to the economy of the country by the uncontrolled import or export of gold or silver;

(g) the prevention of surplus of any agricultural product or the product of fisheries;

(h) the maintenance of standards for the classification, grading or marketing of goods in international trade;

(i) the establishment of any industry;

(j) the prevention of serious injury to domestic production of goods of any description;

(k) the protection of human, animal or plant life or health;

(l) the protection of national treasures of artistic, historic or archaeological value;

(m) the conservation of exhaustible natural resources;

(n) the protection of patents, trademarks, copyrights, designs and geographical indications];

(o) the prevention of deceptive practices;

(p) the carrying on of foreign trade in any goods by the State, or by a Corporation owned or controlled by the State to the exclusion, complete or partial, of citizens of India;

(q) the fulfilment of obligations under the Charter of the United Nations for the maintenance of international peace and security;

(r) the implementation of any treaty, agreement or convention with any country;

(s) the compliance of imported goods with any laws which are applicable to similar goods produced or manufactured in India;

(t) the prevention of dissemination of documents containing any matter which is likely to prejudicially affect friendly relations with any foreign State or is derogatory to national prestige;

(u) the prevention of the contravention of any law for the time being in force; and

(v) any other purpose conducive to the interests of the general public.

(3) Any prohibition or restriction or obligation relating to import or export of any goods or class of goods or clearance thereof provided in any other law for the time being in force, or any rule or regulation made or any order or notification issued thereunder, shall be executed under the provisions of that Act only if such prohibition or restriction or obligation is notified under the provisions of this Act, subject to such exceptions, modifications or adaptations as the Central Government deems fit.

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18. The following provisions of the Drugs and Cosmetics Act, 1940 and the Rules framed thereunder would be relevant for the purpose of this case and therefore are being reproduced hereinbelow for ready reference:-

"**3. Definitions.—**In this Act, unless there is anything repugnant in the subject or context,

(b) "drug" includes—

(i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;

(ii) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of [vermin] or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;

(iii) all substances intended for use as components of a drug including empty gelatin capsules; and

(iv) such devices* intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board;

Section 10:

10. Prohibition of import of certain drugs or cosmetics.— From such date as may be fixed by the Central Government by notification in the Official Gazette in this behalf, no person shall import—

(a) any drug or cosmetic which is not of standard quality;

(b) any misbranded drug or misbranded or spurious cosmetic;

(bb) any adulterated or spurious drug;

(c) any drug or cosmetic for the import of which a licence is prescribed, otherwise than under, and in accordance with, such licence;

(d) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of active ingredients contained in it, together with the quantities thereof;

(e) any drug which by means of any statement, design or device accompanying it or by any other means, purports or claims to cure or mitigate any such disease or ailment, or to have any such other effect, as may be prescribed;

(ee) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;

(f) any drug or cosmetic the import of which is prohibited by rule made under this Chapter:

Provided that nothing in this section shall apply to the import, subject to prescribed conditions, of small quantities of any drug for the purpose of examination, test or analysis or for personal use:

Provided further that the Central Government may, after consultation with the Board, by notification in the Official Gazette, permit, subject to any conditions specified in the notification, the import of any drug or class of drugs not being of standard quality.

Section 18:

18. Prohibition of manufacture and sale of certain drugs and cosmetics.—From such date as may be fixed by the State Government by notification in the Official Gazette in this behalf, no person shall himself or by any other person on his behalf—

(a) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale] or distribute—

(i) any drug which is not of a standard quality, or is misbranded, adulterated or spurious;

(ii) any cosmetic which is not of a standard quality or is misbranded or spurious;

(iii) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of active ingredients contained in it together with the quantities thereof;

(iv) any drug which by means of any statement, design or device accompanying it or by any other means, purports or claims [to prevent, cure or mitigate] any such disease or ailment, or to have any such other effect as may be prescribed;

(v) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;

(vi) any drug or cosmetic in contravention of any of the provisions of this Chapter or any rule made thereunder;

(b) sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic which has been imported or manufactured in contravention of any of the provisions of this Act or any rule made thereunder;

(c) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic, except under, and in accordance with the conditions of, a licence issued for such purpose under this Chapter:

PROVIDED that nothing in this section shall apply to the manufacture, subject to prescribed conditions, of small quantities of any drug for the purpose of examination, test or analysis:

PROVIDED FURTHER that the Central Government may, after consultation with the Board, by notification in the Official Gazette, permit, subject to any conditions specified in the notification, the manufacture for sale, or for distribution, sale, stocking or exhibiting or offering for sale or distribution of any drug or class of drugs not being of standard quality.

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Rule 123

123. The drugs specified in Schedule K shall be exempted from the provisions of Chapter IV of the Act and the Rules made thereunder to the extent and subject to the conditions specified in that Schedule.

SCHEDULE K

Class of Drugs	**Extent and Conditions of Exemption**
33. Nicotine gum and Lozenges containing upto 2 mg of nicotine	The provisions of Chapter IV of the Act and the Rules made thereunder which require them to be covered by a sale licence subject to the condition that such a product has been manufactured under a valid drug manufacturing licence.”

19. At the very outset, we propose to deal with the argument advanced on behalf of the Petitioner(s) to the effect that the product, “Nicotine Pouches” being sold to the customers in the departure terminal of an International Airport, which is beyond the customs frontier, no import licence or Registration Certificate would be necessary for importing the product nor would the domestic regulatory agencies have any jurisdiction to interfere in the matter. Such a contention has been raised primarily by relying upon the decisions of the Hon’ble Supreme Court in the case of ***Garden Silk Mills Limited & Anr. v. Union of India & Ors.*** *(Supra)* as well as ***M/s. Hotel Ashoka (Indian Tour Dev. Cor. Ltd) Vs. Assistant Commissioner of Commercial Taxes & Anr.*** *(Supra).*

20. In ***Garden Silk Mills Limited & Anr. v. Union of India & Ors.*** *(Supra)*, the core issue was pertaining to the question as to whether, while assessing customs duty payable in respect of imported goods, the customs authorities could add/include landing charges in arriving at the value of those goods. That was a case where the Appellants had imported polyester yarn from abroad and the sale transaction involving a domestic purchaser and the foreign supplier was in the nature of CIF contract, i.e., price-included cost, insurance and freight charges contract. Under the contract, the price paid by the purchaser included not only the cost of the goods but also the insurance and the freight charges. Notwithstanding the same, the customs authorities, while determining the value of the goods for the purpose of ascertaining the amount of duty payable, had added to the CIF price, the landing charges which were paid to the Port Trust Authorities. In that case, the Apex Court had considered the concept of import in the context of the assessment and payment of import duty under the Customs Act, particularly when goods are cleared for home consumption under Sections 47 and held that import is completed when the goods become part of the goods within the country. Therefore, the taxable event is reached when the goods cross the customs barriers and the Bill of Entry for home consumption is filed. It is in such factual backdrop, the Supreme Court had made the following observations in paragraph 18 which are reproduced hereinbelow for ready reference: -

> "18. It would appear to us that the import of goods into India would commence when the same cross into the territorial waters but continues and is completed when the goods become part of the mass of goods within the country; the taxable event being reached at the time when the goods reach the customs barriers and the bill of entry for home consumption is filed".

21. In ***M/s. Hotel Ashoka (Indian Tour Dev. Cor. Ltd) Vs. Assistant Commissioner of Commercial Taxes & Anr.*** *(Supra)*, the Appellant-Corporation, which was having its Duty Free Shops ("DFS") at all the major International Airports, which were selling several articles including liquor, cigarettes, perfumes and food articles to foreigners and also to Indians travelling abroad or coming to India by air. The controversy in that case pertained to the transactions that took place in the Duty Free Shops ("DFS") situated at the International Airport at Bangalore. The Appellant-Corporation, which was a registered dealer under the Karnataka Value Added Tax Act, 2003 as well as the Central Sales Tax Act, 1956, had taken the plea that no tax was payable by the Appellant since the goods which have been sold at the Duty Free Shops were sold directly to the passengers and even the delivery of goods at the Duty Free Shops was made before importing the goods or before the goods had passed the customs frontier of India. As such, it was the case of the Appellant that the Assessment Order issued by the Assistant Commissioner of Commercial Tax (Transition-12), Bangalore, directing the Appellant to pay a sum of Rs. 4,20,70,900/- by way of Sales Tax was illegal. The core question arising in that case was as to whether, the State would have the authority under Article 286 of the Constitution to levy sales tax / VAT on transactions taking place in the DFS at the International airport terminal before such goods had crossed the customs frontier. By referring to Section 5(2) of the Central Sales Tax Act, 1956, the Hon'ble Supreme Court has held that no tax on sale or purchase of goods can be imposed by any State when the transaction takes place in the course of import of goods or export of goods outside the territory of India. In other words, the decision in ***M/s. Hotel Ashoka (Indian Tour Dev. Cor. Ltd) Vs. Assistant Commissioner of Commercial Taxes & Anr.*** *(Supra)* deals with the power of a State to impose duty on such goods in course of export or import.

22. From a careful reading of the judgments rendered in the case of ***Garden Silk Mills Limited & Anr. v. Union of India & Ors.*** *(Supra)* as well as in ***M/s. Hotel Ashoka (Indian Tour Dev. Cor. Ltd) Vs. Assistant Commissioner of Commercial Taxes & Anr.*** *(Supra),* it is thus apparent that those precedents exclusively deal with the taxable events for assessing customs duty and sales tax/VAT. The decisions do not extend any blanket immunity to the DFS operators from the domestic regulatory or public health laws of the country. The aforesaid decisions relied upon by the learned Senior Counsel for the Petitioner(s) are also not the authorities for the proposition that all transactions taking place in the DFS, beyond the Customs frontier, would enjoy blanket exemption/immunity from the domestic regulatory regime. On the contrary, the issue appears to be squarely covered by the decision of a co-ordinate Bench of this Court in ***Glamstone Cosmetics Pvt. Ltd. Vs. Union of India & Ors.*** *(Supra).*

23. In ***Glamstone Cosmetics Pvt. Ltd. Vs. Union of India & Ors.*** *(Supra),* the Petitioner (therein) was engaged in the import and trading of cosmetics. Accordingly, consignments of cosmetics and FMCG (Fast Moving Consumer Goods) were imported to India for re-export. The Petitioner had filed warehousing Bills of Entry pertaining to those consignments. However, the product, despite being 'cosmetics' coming within the ambit of the Act of 1940, did not have any licence from the Central Drugs Standard Control Organization ("CDSCO"). Although the Petitioner had applied for the licence, no such licence was granted by the CDSCO *qua* the products. Notwithstanding the same, the goods were imported to India. According to the Petitioner, the warehousing Bills of Entry were filed only to hold the goods in the bond, pending regulatory clearance. Since the goods were not meant to be sold in India, hence, those could not have been seized by the authorities due to want of licence. The plea of the authority, on the other hand, was to the effect that the goods were being imported based on mis-declaration of value and other particulars in order to circumvent the restrictions imposed on the goods under the import policy since a licence from CDSCO was mandatory under the Act of 1940 and the Rules framed thereunder before which the goods could be imported in India. Hence, import of these goods to India was in violation of the relevant Act, Rules and the Foreign Trade Policy.

24. After taking note of the contentions of both the sides and on an assessment of the relevant provisions of the Act of 1962 as well as the Act of 1940, the co-ordinate Bench has observed in ***Glamstone Cosmetics Pvt. Ltd. (Supra)*** as follows:-

> "32. However, something which is at the very threshold needs to be discussed, namely, when the goods are sought to be imported into India from a place outside India, necessarily the provision of Section 2(23) defining 'import' which mean "bringing into India from a place outside India", would become applicable. Such goods would be imported goods within the meaning of Section 2(25) being any goods brought into India from a place outside India, prior to their clearance for home consumption. Thus, in the context of bringing of the goods into India as ordained by Section 2(23) and Section 2(25) (supra), Section 2(27) and Section 2(28) become relevant which means "the territorial waters of India" and the "Indian customs water" to inter alia mean waters extending into the sea, up to the limit of 'exclusive economic zone...'. Further Section 2(33) when speaks about 'prohibited goods' it means any goods, the import or export of which is **"subject to any prohibition"** under the Act **"or any other law for the time being in force".** Also Section 11 A(a) defines "illegal import" to mean the import of any goods in contravention of the provisions of the Act or "any other law for the time being in force". It is in the context of the said provisions, Chapter VII of the Customs Act which inter alia provide for clearance of imported goods are required to be considered in Section 46 provides for 'Entry of goods on importation.'
>
> 33. On a cumulative application of the provisions of the Customs Act (supra) read with the provisions of the Drugs and Cosmetics Act, 1940 and the Cosmetics Rule 2020, qua the goods in question, the following appears to be the apparent requirement of law:

(i) The import of the goods in question which are Cosmetics certainly falls within the expression of import as defined under Section 2(23) i.e., bringing into India from a place outside India and the term India as defined under Section 2(27) includes the territorial waters of India and not the port of arrival or the goods being warehoused, the warehouse being on Indian territory, meaning thereby that the goods are imported goods once they enter the territorial waters of India.

(ii) Such goods would be imported goods within the meaning of Section 2(25) being brought into India from a place outside India, not cleared for home consumption.

(iii) The goods are prohibited goods within the meaning of Section 2(33), the import of which is subject to any prohibition under the Customs Act or “any other law for the time being in force”;

iv) Also an ‘illegal import’ within the meaning of Section 11A(a) means the import of any goods in contravention of the provision of the Customs Act “or any other law for the time being in force”.

34. Thus, necessarily by incorporation of the words “any other law” in the provisions of Section 2(33) of the Customs Act, read with the Drugs and Cosmetics Act 1940 and the Rules framed thereunder become ipso facto applicable to any imports apart from the applicability of the provisions of the Customs Act. In such context, Section 10 of the Drugs and Cosmetics Act (supra) is a provision which prescribes prohibition on import of certain drugs or cosmetics, when such provision ordains that no person shall import any Drug or Cosmetic for the import of which a licence is prescribed, and otherwise than under such licence thereby making a prior licence mandatory for the imports.

35. Further, Section 10 of the Drugs and Cosmetics Act, 1940 is required to be read with the Cosmetics Rules 2020, and more particularly, Rule 12 providing for import of Cosmetics which clearly provide that no cosmetic shall be *inter alia* imported into India, unless the product has been registered in accordance with these rules by the the Central Licensing Authority and making further provisions for application for registration of a Cosmetic product intended to be imported into India.

36. It is, thus as clear as the daylight, that as per the provisions of Section 10 of the Cosmetics Act, no import of Cosmetics could have been undertaken by the petitioner without a licence, as rightly contended on behalf of the Respondent. Admittedly the goods in question were imported into India without a licence. This was not permissible, considering the conjoint effect of the aforesaid provisions. Thus, the provisions of Section 2(33) which define prohibited goods to inter alia mean any goods the import of which is subject to the prohibition either under the Customs Act or “any other law for the time being in force”, stand breached and/or not complied thereby rendering the goods, in question “prohibited goods”.

37. Thus, the goods in question as imported by the petitioner being prohibited goods, the provisions of Section 110 of the Customs Act providing for seizure and the provision of Section 111 providing for confiscation of improperly imported goods, would stand attracted and applicable. This more particularly, clause (d) of Section 111 which provides that the goods would be liable for confiscation when goods which are imported or attempted to be imported or are brought within the Indian Customs Waters for the purpose of being imported, contrary to any prohibition imposed by or under the Customs Act or any other law for the time being in force. In such circumstances, applying the statutory provisions as discussed hereinabove, to the goods in question, which were imported by the petitioner without a licence, the legal character of the goods certainly is of these goods being "prohibited goods" as defined under Section 2(33) of the Customs Act.

38. On the aforesaid complexion, the contentions as urged on behalf of the petitioner are now required to be considered. The case of the petitioner is that the petitioner had imported the goods only for the purpose of warehousing, as seen from Bills of Entry for warehousing, presented by the petitioner for the goods to be kept in the warehouse and thereafter to be re-exported being its contention. The petitioner has also contended that for such reason there was no requirement of a licence to be obtained before the said import. We do not agree on such case of the petitioner. Moreover, such contention of the petitioner militates against the clear provisions of Section 10 of the Drugs and Cosmetics Act read with the Cosmetics Rules 2020 which stand clearly attracted nay incorporated in the provisions of the Customs Act, as noted by us hereinabove. Thus, merely for the purpose of warehousing, such goods

> could be imported, i.e., brought into the Indian territorial waters, is an untenable contention, which has no legs to stand, considering the effect of the aforesaid provisions of the Customs Act read with the Drugs and Cosmetics Act, 1940 read with the Cosmetics Rules, 2020.
>
> 39. We are hence in agreement with Mr. Mishra, learned counsel for the Revenue drawing the Court's attention to the reply affidavit, to contend that there was never an intention of the petitioner that the goods be imported only for the purpose of warehousing and/or re-export. Such case of the petitioner appears to be a complete afterthought being presented before the Customs Authorities as also before this Court, that the goods be permitted to be re-exported as they were not meant to be cleared for home consumption. We do not find any material whatsoever to the effect that there was any prior intention before the imports were undertaken, that the goods were meant to be only stored i.e., being imported only for warehousing in India and thereafter to be re-exported. This is not recognized in law. If this was to be the sole intention, the petitioner could not have applied for a CDSCO licence in May, 2025. The clear provisions of the Drugs and Cosmetics Act and the Cosmetics Rules 2020 as applicable to the imports of Cosmetics do not conceive a situation, that such goods can be brought into territorial waters merely for the purpose of warehousing and/or on that basis, that after the arrival of the goods, a licence can be applied. This is totally unacceptable and in fact illegal. The provisions of law as discussed hereinabove do not permit that these goods can be brought into the Country only for the purpose of warehousing and that too contravening and/or circumventing the provisions of law. The consequence of such contentions as urged on behalf of the petitioner, would be to the effect that Indian territory permits prohibited goods to be brought into India, merely for the purpose of warehousing, on a specious consideration that warehousing is cheaper in India than in other countries, and therefore such unlicenced imports be permitted, for the goods to be ultimately re- exported. This would be too far fetched. We do not gather any such intention under any provisions of law as urged before us. The imports in question being per se illegal cannot be labelled to be legitimate or legal, merely because the petitioner intends to re-export the goods and for which no duty according to the petitioner is attracted.”

25. The decision in ***Glamstone Cosmetics Pvt. Ltd.*** *(supra)*, has established that goods brought into India from outside the country would mean and include goods brought within the "territorial waters of India". The term 'India', as defined under Section 2(27) of the Act of 1962, would include territorial waters and not merely the port of arrival or the warehousing of the goods. "Import" under Section 2(23) takes place once the goods enter the "territorial waters of India". Upon entering the territorial waters in India, the goods would be deemed to be imported goods within the meaning of Section 2(25) even if the same are not cleared for home consumption. Consequently, the prohibition under Section 2(33) would also be applicable to such imported goods if the same is otherwise prohibited under the Customs Act or any other law for the time being in force. Therefore, the prohibition under Section 10 of the Act of 1940 would also apply to such goods.

26. It is not in dispute that the decision in ***Glamstone Cosmetics Pvt. Ltd.*** *(supra)*, which has duly considered ***Garden Silk Mills Limited & Anr.*** *(supra),* has attained finality in the eyes of the law. We do not find any justifiable ground to take a different view in the matter, in the facts and circumstances of the case. We are, therefore, of the opinion that the *ratio* laid down in the said decision would constitute a binding precedent for this Court to follow. In view thereof, the first question framed by this Court is answered against the Petitioner(s) and in favour of the Respondents.

27. We, accordingly, hold that import of goods into India, even if it is for the limited purpose of warehousing or re-export, would not enjoy any immunity from the application of the domestic laws. Such goods would be subject to the law of the land and would be governed by the regulatory regime in force even if the transaction takes place in the DFS, beyond the customs barrier. The exemption, if any, would be limited to the fiscal measures such as levy of customs duty/tax/MVAT etc. As such, if an item is restricted or prohibited under "any other law for the time being in force" it would constitute "prohibited goods" under Section 2(33) of the Act of 1962 and hence, the domestic regulatory regime will apply in full force to such goods brought into the DFS within the Indian territorial jurisdiction.

28. Coming to the next question, as framed above, it is to be noted herein that Section 3(b)(i) of the Act of 1940, covers all medicines for internal or external use and all the substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of disease or disorder. Under Section 3(b)(i) of the Act of 1940, a substance will qualify as a drug if its intended use is in diagnosis, treatment, mitigation or for prevention of any disease / disorder (e.g. Nicotine Replacement Therapy).

29. Section 3(b)(ii) covers substances, other than food, intended to affect the structure or function of the human body *"as may be specified from time to time by the Central Government by notification in the Official Gazette."* Therefore, substances which come within the definition of 'drug' under Section 3(b)(ii) must be included in a Central Government Notification published in the Official Gazette.

30. An import licence is required for importing all drugs into India but the requirement is subject to the exemptions prescribed under the Act of 1940 and the Drugs and Cosmetics Rules, 1945. Section 10(c) of the Drugs and Cosmetics Act, 1940, prohibits the import of *"any drug or cosmetic for the import of which a licence is prescribed, otherwise than under, and in accordance with, such licence."*

31. Section 11 of the Act of 1962 confers power on the Central Government to prohibit importation or exportation of goods by issuing notification in the Official Gazette.

32. The Supreme Court in ***Chimanlal Jagjivandas Sheth v. State of Maharashtra***[4] gave the expression "drug" a comprehensive meaning and held that the word "substances" can include things other than conventional medicines, provided those are used for treatment. This was further explained in ***State of Andhra Pradesh v. Linde India Ltd.***[5] wherein the Supreme Court has held that a substance other than a conventional medicine can fall within Section 3(b)(i), but there must be the requisite connection with diagnosis, treatment, mitigation or prevention of disease/disorder.

33. In the above context, it would be worth noting herein that the available literature on the subject goes to indicate that purified or chemical nicotine is a regulated product which requires a licence from the CDSCO. Although, import of nicotine in its chemical compound cannot be said to be completely banned in India and its legal entry into the country would depend largely on

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4 AIR 1963 SC 665

5 (2020) 16 SCC 335

the product form and its intended use which would determine the necessity of its statutory licensing. “Nicotine” in its pure/chemical form is used as an active substance in pharmaceutical formulations such as nicotine replacement products for smoking cessation. Therefore, “Nicotine” when used in such form, would come within the definition of ‘Active Pharmaceutical Ingredient’ (“API”). As per Rule 2(1)(c) of the New Drugs and Clinical Trials Rules, 2019 an “Active Pharmaceutical Ingredient” (“API”) is defined as follows:

> “active pharmaceutical ingredient" means any substance which can be used in a pharmaceutical formulation with the intention to provide pharmacological activity; or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease; or to have direct effect in restoring, correcting or modifying physiological functions in human beings or animals.”

34. From the above discussion, it is evident that in order to qualify as an API, the use of the substance must be in pharmaceutical formulation with the intention to provide pharmacological activity, having a bearing in diagnosis, cure, mitigation, treatment, etc.

35. An import license may be required for importing “Nicotine” if the same falls within the definition of “Drug” under Section

3(b). However, what is to be noted herein is that Rule 43 read with Schedule-D of the Act of 1940 exempts substances that are not intended for medical use, from the application of Chapter III (Import of Drugs and Cosmetics). In those cases, requirements of registration and import licence may not apply, subject to the fulfillment of the prescribed conditions.

36. Under the DGFT Notification dated 9th February 2022, specified finished Tobacco products including those containing nicotine have been declared as falling under the "prohibited" category. However, the product description does not include products licensed under the Act of 1940. We also find that "Nicotine" under ITC (HS) 24049100 "for oral application" is "free" under the DGFT framework. Therefore, by necessary implication, it is apparent that all forms of Nicotine may not necessarily be "restricted" or "prohibited" and hence may not come within the ambit of definition of "drug" under Section 3(b) of the Act of 1940. A licence would be required only in case of a "drug" under Section 3(b) of the Act of 1940. It is only in such cases that import of the product without a valid import licence would be prohibited under Section 10 of the Act of 1940.

37. Likewise, manufacture and sale of such a product would also be prohibited under Section 18 of the Act of 1940, unless specifically exempted under Rule 123, in which event, such drugs shall stand exempted from applicability of the provisions of Chapter IV of the Act and Rules made thereunder to the extent and subject to the conditions specified in the schedule.

38. Rule 123 does not offer a blanket exemption from import licensing under Chapter III. The object of Rule 123 appears to exempt certain specified drugs in Schedule K from specified provisions of Chapter IV, subject to the fulfillment of the conditions contained in Schedule K. The nicotine-specific Entry 33 in Schedule-K pertains to nicotine gum (e.g. Nicotex) and lozenges, containing up to 2 mg nicotine. It does not expressly include nicotine pouches. Therefore, although statutory exemptions exist for certain variety of nicotine based product, yet, they operate only in specific instances.

39. The requirement of CDSCO licence, however, may not be an absolute requirement, applicable to every "drug" and in every circumstance. Rule 43 provides that the drugs specified in Schedule D are exempted from the provisions of Chapter III

(Import of Drugs and Cosmetics) of the Act and the Rules, to the extent and subject to the conditions specified in Schedule D. Schedule D deals with substances not intended for medicinal use thus, excluding those intended to be used as drugs after purification for rendering them sterile. As such, where a particular product falls within prescribed Schedule D exemption, the ordinary import licensing requirements may not apply.

40. CDSCO approval/licensing is required where the product falls within the definition of "drug" under Section 3(b) of the Drugs and Cosmetics Act, 1940. For ordinary import of a drug, Rule 23 of the Drugs Rules, 1945 requires an import licence in Form 10 or Form 10-A, subject to the exemptions under the Rules. When the product is a "new drug", an additional regulatory requirement arises under the New Drugs and Clinical Trials Rules, 2019. Rule 74 of the Rules of 2019 prohibits import or manufacture for sale or distribution of a new drug except in accordance with the provisions of the Act and those Rules. Rule 75 lays down the procedure for obtaining the permission to import a new drug and Rule 76 provides for grant of permission by the Central Licensing Authority. The NDCT Rules also, *inter alia*, treat a drug proposed to be marketed in a new dosage form or through a new route and certain novel drug-delivery systems, as a "new drug" under Rule 2(w).

41. Tobacco-free nicotine, which is specifically intended and marketed as a smoking cessation/NRT (Nicotine Replacement Therapy) has a substantially wider basis for classification under Section 3(b)(i) of the Act of 1940, because its intended use can also be connected with treatment. However, a nicotine pouch marketed purely as a recreational nicotine product, without any therapeutic or cessation claims, may not automatically come under the purview of Section 3(b)(i) merely because nicotine has physiological effects. Therefore, a tobacco-free nicotine pouch may not necessarily be a "drug" within the meaning of Section 3(b) merely because it contains pharmacologically active nicotine/ tobacco-free nicotine. Unless it is found that the product is used in the diagnosis, treatment, mitigation or prevention of any disease or disorder, it may not qualify as a "drug". Whether or not a particular composition/ formulation in the form of "Nicotine Pouch" would satisfy the requirement of any of the clauses of Section 3(b) of the Act of 1940, so as to be treated as a "drug" would depend on the composition of the product and its intended use.

42. The legal position, that can, therefore, be culled out from the above analysis is that any product which is a “drug” under Section 3(b) of the Act of 1940 is ordinarily subject to the import-licensing regime. This requirement is, however, subject to specific exemptions, if any, provided under the Act and Rules.

43. In the case at hand, the question as to whether an import licence is required for import and sale of “Nicotine Pouch” would essentially depend upon whether the particular product falls within the definition of “drug” under any of the clauses of Section 3(b) and if so, whether any specific exemption is applicable to the product.

44. We have noted the stand of the Respondents that “Nicotine pouches”, which are sold by the Petitioner in its DFS under the brand names “ZYN” and “FOX”, contain a specified amount of Nicotine, i.e. 3 mg to 6 mg per pouch and, therefore, those products would fall under the definition of “drug” under Section 3(b)(i) of the Act of 1940. At the same time, it is also the case of the Respondents that save and except mentioning the brand names, the Petitioner(s) has not furnished any other particulars pertaining to the product in question. A perusal of the Bill of Entry of warehouse also goes to show that only the brand name "ZYN" is mentioned against the relevant Customs Tariff Heading (CTH). If that be so, it is not understood as to on what basis the Respondent No. 3 has reached the conclusion that the product "Nicotine Pouch" is a "Drug" with the meaning of Section 3(b) of the Act of 1940.

45. We have also noted that, in the impugned order dated 2nd April 2026, although it has been mentioned that "Nicotine pouches" would fall under the definition of "drug" as per Section 3(b) of the Act of 1940, yet, no cogent reason has been furnished in support of the conclusion. There is also no indication in the communication dated 2nd April 2026, as to under which of the four categories envisaged by clauses (i) to (iv) of Section 3(b) of the Act of 1940 would "Nicotine Pouch" fall so as to qualify as "drug". The contents of the order dated 2nd April 2026, issued by the Assistant Drug Controller (I), CDSCO, Air Cargo Complex, Mumbai, would be relevant and, therefore, is reproduced herein below for ready reference:-

> "Sir,
>
> With reference to the subject cited above, it is to inform that the Drugs Inspector from this office inspected the duty-free shops at Terminal 2 (Arrival & Departure) on 05-03-2026. The inspection report, along with supporting documents, has been submitted (copy enclosed).
>
> As per the findings of the inspection, nicotine pouches (3 mg and 6 mg) marketed under the trademark "FOX" are being imported by M/s Mumbai Travel Retail Private Limited vide Bill of Entry No. 5386403 dated 29-10-2025. These products are supplied by M/s Swedish Smokeless Solutions AB, Sweden, and are currently being sold at the duty-free shop located at Terminal 2 Departure, Mumbai International Airport.
>
> It is pertinent to note that certain nicotine-containing formulations are approved for sale in India, such as Nicotine transdermal patches (36 mg, 78 mg, 114 mg), Nicotine lozenges (2 mg, 4 mg), and Nicotine gums. These formulations fall under the definition of "Drug" and are regulated under the Drugs and Cosmetics Act, 1940.
>
> In this context, the said Nicotine pouches also fall within the definition of "Drug" as per Section 3(b) of the Drugs and Cosmetics Act, 1940. Accordingly, a valid Registration Certificate and Import Licence are mandatory for their import and sale in India, under provisions of Drugs & Cosmetics Act 1940 and Rules thereunder.
>
> Therefore, the import and sale of these nicotine pouches at the duty-free shops located at Terminal 2 Departure, Mumbai International Airport are in contravention to the provisions of the Drugs and Cosmetics Act, 1940 and the rules thereunder.
>
> In view of the above, it is requested to take deemed fit action including directing to stop the sale and distribution of the said drug products at Mumbai International Airport.
>
> The action taken in this regard may kindly be intimated to this office at the earliest."

46. As has been noted above, Section 3(b) of the Act of 1940 contemplates four different categories of substances. In order to fall in the category of “drug” under Section 3(b)(i), the substance must have intended use in diagnosis, treatment, mitigation or prevention of any disease or disorder. In order to qualify as “drug” under Section 3(b)(ii) or (iv), the substances/devices must be specified in a Central Government Notification published in the Official Gazette. No such Central Government Notification is admittedly available covering the product “Nicotine Pouch”. In so far as Section 3(b)(iii) is concerned, here also, the intended use of the substance must be as a component of a drug. There is, however, no reflection in the impugned order/communication dated 2nd April 2026 that “Nicotine Pouch” contains and/or is a substance which is used as a component of a drug. Before concluding that “Nicotine Pouch” is a “drug” under the Act of 1940, it was incumbent upon the authority to clearly indicate as to under which of the four categories/clauses of Section 3(b) of the Act of 1940 the product would fall. No such indication is available in the impugned communication dated 2nd April 2026.

47. It would be significant to note herein that the Respondent No. 3 would have jurisdiction to impose and/or insist on a ban on the sale of the product without a valid licence only if it is a “drug” within the meaning of Section 3(b) of the Act of 1940 and not otherwise. Therefore, the requisite jurisdictional facts would have to be clearly established by the Drug Controller before invoking its powers under the Act of 1940 and the Rules framed thereunder. In the present case, we find that such particulars are completely missing.

48. Whether import licence and/or Registration Certificate would be required or not will depend on whether the composition of the product legally constitutes a “drug” under Section 3(b). Such determination would require detailed factual verification of the product specification. However, it is an admitted fact that the Petitioner has not furnished the product specification to the Respondents. It is also not clear from the material on record, as to what is the exact nature of composition of the product, insofar as its Nicotine content is concerned. Therefore, it is not possible for this Court to record a finding on the above issue.

49. Whether a specific composition is a “drug” under Section 3(b) having a therapeutic use or if it qualifies under Schedule-D/ Schedule K exemptions would require factual inquiry. This Court does not have the expertise either to embark on such a factual inquiry or to express any opinion in the matter. Therefore, these are not matters that can be determined or adjudicated in a Writ Petition in exercise of jurisdiction under Article 226 of the Constitution.

50. For the aforestated reasons, this Court is not in a position to answer the second question, i.e., “Whether Nicotine Pouch falls within the definition of “drug” under section 3(b) of the Drugs and Cosmetics Act, 1940, making import licence and/or registration mandatory even for dealing with the product within the customs barrier of the International Departure Terminal of the Airport?” The said question is, therefore, kept open to be answered/decided in an appropriate proceeding.

51. Since the Petitioner(s) has not provided the product specification to the Respondents, hence, the impugned communication cannot be faulted for not furnishing proper reasons, meriting interference by this Court. However, that alone may not be a valid ground for the authority not to suitably review and/or revoke the communication dated 2nd April 2026, if full and better particulars, regarding the product, are placed before them.

52. For the reasons stated hereinabove, we are of the view that, notwithstanding the determination made here-in-above, ends of justice would be met, if these Writ Petitions are disposed of with the following:-

ORDER

(a) The Petitioner(s) would be at liberty to make representation(s) before the appropriate authority including the CDSCO, with supporting material, to show that the product in question is either not a "drug" within the meaning of Section 3(b) or is covered under Schedule "D" and/or Schedule "K" exemptions of the Act of 1940 and the Rules framed thereunder and, therefore, can be imported and transacted in India in the DFS without a valid import licence and/or Registration Certificate.

(b) If any such representation is filed within a period of 4 (four) weeks from the date of uploading this Judgment, the same shall be considered on its own merit and disposed of by a reasoned order, in the light of the observations made hereinabove, if necessary, by giving a personal hearing to the representative(s) of the Petitioner(s).

(c) The aforesaid exercise be carried out and completed within a period of 30 (thirty) days' from the date of receipt of the representation(s), if any, to be submitted by the Petitioner(s).

(d) In the facts and circumstances of the case, there would be no order as to costs.

(e) The Writ Petitions are disposed of accordingly.

(ADVAIT M. SETHNA, J.) **(SUMAN SHYAM, J.)**