IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED: **26.06.2025**

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THE HONOURABLE **MR.JUSTICE SENTHILKUMAR RAMAMOORTHY**

W.P.Nos.8920, 8924 & 8928 of 2025
and W.M.P.No.10028 of 2025

M/s.Axeon Marketing India,
Represented by its Managing Partner,
Mr.M.H.Jiffry Kasim,
Old No.120, New No.249,
"Vikas Mantra Tower", 2nd Floor,
R.K.Mutt Road, Mandaveli,
Chennai 600 028. ... Petitioner in all WP's

-vs-

1.The Assistant Commissioner of Customs (Group 2),
Import Commissionerate,
Custom House, No.60, Rajaji Salai,
Chennai 600 001.

2.The Deputy Commissioner of Customs,
Docks-Admin Section, Export Commissionerate,
O/o. The Commissioner of Customs, Chennai-IV,
Custom House, No.60, Rajaji Salai,
Chennai 600 001.

3.The Assistant Drugs Controller (India),
Office of the ADC (I), CDSCO, Seaport,
Custom House, 60 Rajaji Salai,
Chennai 600 001.

4.The Drug Controller General of India (DCGI),
Central Drugs Standard Control Organization (HQ),
FDA Bhavan, ITO, Kotla Road, New Delhi 110 002.

5.The State Licensing Authority (IM),
Office of the State Licensing Authority (IM),
Arumbakkam, Chennai 600 016.

6.The Secretary to Government,
Government of India, Ministry of AYUSH,
NBCC Office, Block-III (2nd Floor),
East Kidwai Nagar, New Delhi 110 023.

... Respondents in all WP's

(R6 – suo motu impleaded as per Order
dated 04.04.2025 in all WP's by AQJ)

PRAYER in W.P.No.8920 of 2025: Writ Petition is filed under Article 226 of the Constitution of India praying that this Hon'ble Court be pleased to issue a Writ of Mandamus to direct the 1st and 2nd respondents to permit the petitioner to clear all the goods covered by bill of entry no.8438669 dated 19.02.2025.

PRAYER in W.P.No.8928 of 2025: Writ Petition is filed under Article 226 of the Constitution of India praying that this Hon'ble Court be pleased to issue a Writ of Prohibition prohibiting the 5th respondent from conducting any enquiry with regard to the notices dated 21.05.2024 and 29.11.2024 alleging violation of Section 33EEA of the Drugs & Cosmetics Act, 1940,

and Rule 154 of the Drugs and Cosmetics Rules, 1945, on the ground that the petitioner had allegedly failed to remove the words "Ayurvedic Proprietary Medicine" on the Axe Brand Medicated Oil imported by the petitioner.

PRAYER in W.P.No.8924 of 2025: Writ Petition is filed under Article 226 of the Constitution of India praying that this Hon'ble Court be pleased to issue a Writ of Mandamus to direct the 1st and 2nd respondents to remove the alert appearing against the petitioner in the Indian Customs Electronic Data Interchange System as *"Importing proprietary items under the guise of Ayurvedic medicines"*.

For Petitioner in all WP's : Mr.Hari Radhakrishnan

For Respondents : Ms.Revathi Manivannan for R1 & R2
Mr.ARL.Sundaresan, Assisted by
Mr.V.Chandrasekaran, SPC for R3, R4 & R6
Ms.M.Sneha, Spl. Counsel for R5

COMMON ORDER

By these writ petitions, the petitioner seeks a direction to the first and second respondents to permit the petitioner to clear all goods covered by bill of entry No.8438669 dated 19.02.2025 and for other remedies ancillary or incidental thereto.

2. The petitioner states that it is an authorized importer and distributor of Axe Brand Medicated Oil products in India and that it has been importing the same from the parent company, Leung Kai Fook Medical Company Private Limited, Singapore, since 2007. The petitioner received notices from the 5th respondent alleging violation of Section 33EEA of the Drugs and Cosmetics Act, 1940 (Drugs & Cosmetics Act) and Rule 154 of the Drugs and Cosmetics Rules, 1945 (Drugs & Cosmetics Rules) and replied thereto on 06.12.2024 and 18.01.2025. Thereafter, the petitioner requested the Additional Commissioner of Customs (Group-2) to release the goods, but was informed on 07.03.2025 that the file had been transferred to the office of the 4th respondent. The present writ petitions were filed in the said facts and circumstances.

3. The contentions of learned counsel for the petitioner may be summarized as under:

(i) The products imported by the petitioner have been held to be classifiable as ayurvedic drugs under chapter 30 of the CTH by the Customs Excise and Service Tax Appellate Tribunal (CESTAC), Chennai, in *Commissioner of Customs, Chennai v. M/s. SMA Trading Company, 2022(8) TMI 558 ('SMA Trading Company').*

(ii) Although the definition of "drug" read with the definition of ayurvedic, siddha or unani drug in the Drugs and Cosmetics Act indicates that the statute applies to ayurvedic drugs, the provisions in relation to import of drugs is inapplicable to ayurvedic drugs.

(iii) Rule 23 prescribes that an import licence should be issued in Form-10 or Form 10A and Rule 24 prescribes that the application for import licence should be made in Form-8 or Form-8A with an undertaking in Form-9. None of these forms are appropriate or applicable to ayurvedic drugs. Therefore, the petitioner should be permitted to import goods under the above mentioned bill of entry without a licence.

(iv) Without prejudice, the Central Drugs Standard Control

Organization (CDSCO) has framed guidelines permitting the import of ayurvedic drugs subject to the manufacturer's test report, samples, etc. being examined and a no objection certificate being issued. This process may be followed on an expedited basis to grant clearance.

(v) The Health Sciences Authority, Singapore, has certified on 15.03.2022 that the manufacturer has maintained an acceptable level of compliance with the Pharmaceutical Inspection Convention/Cooperation Scheme Guide to Good Manufacturing Practices for Medicinal Products.

(vi) The import policy provides that import of ayurvedic drugs may be undertaken “free”, i.e without a licence.

(vii) In response to a question in Parliament, the Minister of AYUSH provided the import value of ayurvedic drugs for multiple financial years commencing from financial year 2021-22 to financial year 2023-24.

4. Learned Additional Solicitor General made submissions in reply on behalf of respondents 3 to 4 and 6. His contentions may be summarized as under:

(i) Drug is defined inclusively in Section 3(b) of the Drugs and

Cosmetics Act and therefore encompasses ayurvedic drugs.

(ii) While the Drugs and Cosmetics Act and the rules framed thereunder deal with the manufacture of ayurvedic drugs in India and prescribe licensing requirements in relation thereto, licensing requirements have not been specifically prescribed for ayurvedic drugs. In the absence thereof, import of ayurvedic drugs is prohibited.

(iii) In the absence of provision in the rules, in exercise of judicial review, the Court should not prescribe licensing norms or rules.

(iv) Without prejudice, if the Court were inclined to permit clearance of this consignment, it should be subject to the products satisfying norms prescribed for manufacturing ayurvedic drugs in India, and other requirements for imported drugs, as prescribed in the rules.

5. Learned counsel for the 5th respondent submits that the said respondent is the licensing authority only in respect of the manufacture of ayurvedic drugs and not for the import thereof.

6. The petitioner has placed on record the judgment in SMA Trading Company. The said judgment records a finding that Axe Brand Universal Oil is classifiable under chapter 30 of the CTH. The said judgment does not appear to have been carried in appeal and holds the field as on date. Therefore, one should proceed on the basis that the goods sought to be imported qualify as ayurvedic drugs. On examining the definition of drug and ayurvedic, siddha or unani drug in Section 3(b) and Section 3(a), respectively, of the Drugs and Cosmetics Act, it appears that ayurvedic drugs clearly fall within the ambit of the statute. Indeed, Parliament's intention to regulate this category is expressed beyond doubt in Part XVI of the Drugs and Cosmetics Rules, which expressly regulate ayurvedic drugs. Rule 23 of the Drugs & Cosmetics Rules provides for an import licence to import drugs. No carve out has been made in the said rule in relation to ayurvedic or any other drugs. Therefore, it appears *prima facie* that the intention of Parliament was to provide for an import licence for all drugs. Rules 23 and 24, however, prescribe forms in which the application is required to be made and the licence is to be issued. On examining these forms, they appear to be inappropriate for ayurvedic drugs and appropriate

only for drugs used in allopathy.

7. The petitioner has placed on record guidelines framed by the CDSCO. With regard to ayurvedic drugs, in relevant part, it is stated as under:

> ***"Ayurvedic Drugs***
>
> *1. In case of import of ayurvedic drugs also, invoice, packing list, manufacture's test report, mfg, license, specimen sample, label may be examined before giving "NOC" by port office, samples may be drawn from import consignment ayurvedic drugs and tested for the presence of heavy metals like, lead, arsenic, cadmium, mercury as per ayush guideline in case of dought. Labelling of imported ayurvedic drugs should comply with rule 161 (part VII, labelling, packing, and limit of alcohol in ayurvedic including siddha or unani drugs) of D & C Rule."*

8. The petitioner has also referred to the answers of the Minister of AYUSH in Parliament providing details of import of ayurvedic drugs from financial year 2021-22 to financial year 2023-24. The above indicates that ayurvedic drugs have been imported into the country. From the material on

record, it is not possible to discern whether licensing requirements were imposed in relation to such imports.

9. There is a strong public interest element, specifically public health element, in relation to the import of drugs. The drug involved in this case is Axe Medicated Oil and, in that specific context, the public health threat may not be significant. It is conceivable, however, that other non-allopathic medicines could have, for example, heavy metal content and, therefore, the need for regulation cannot be disregarded. As held above, the statute and rules framed thereunder apply to ayurvedic drugs. As regards import, while Rule 23 uses the expression “drugs” and not drugs used in allopathy, the forms referred to therein and in Rule 24 do not apply to the import of ayurvedic or non-allopathic drugs. Therefore, it is necessary for the rule making authority to modify existing rules, prescribe standards and prepare appropriate forms in which applications may be made and import licenses granted to persons importing ayurvedic drugs. In the alternative, as a policy measure, it is always open to Parliament to amend the law and prohibit the import of ayurvedic or other classes of drugs, if deemed fit.

10. Meanwhile, given the fact that the statute clearly applies to ayurvedic drugs and does not currently contain a prohibition or exemption in respect of import of ayurvedic drugs, as a pre-condition for clearance, it is necessary that the products imported by the petitioner are in conformity with standards prescribed for similar products manufactured in India. For such purpose, it is necessary that this consignment be tested by one of the laboratories accredited to the CDSCO. This process shall be overseen by the 5th respondent, which is the licensing authority for the manufacture of ayurvedic drugs. All expenses relating to such testing shall be borne by the petitioner. If a satisfactory report is received from such laboratory, the 5th respondent shall certify that the manufacturing process is in conformity with the process prescribed for the manufacture of ayurvedic drugs in India. A copy of such certificate shall be provided to the first and second respondents, who, on receipt thereof, shall permit the release of goods covered under bill of entry No.8438669. This entire process shall be completed within a maximum period of eight weeks, preferably within six weeks from the date a copy of this order is uploaded on the website. Other conditions in the Drugs and Cosmetics Rules relating to the import of drugs shall apply *mutatis*

mutandis.

11. These writ petitions are disposed of on these terms without any order as to costs. Consequently, the connected writ miscellaneous petition is closed.

26.06.2025

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Index : Yes / No
Internet : Yes / No
Neutral Citation: Yes / No

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