

F.No.K-11020/5/97-DCC (AYUSH)
GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
(Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and
Homoeopathy)
(AYUSH)

Red Cross Building, 1, Red Cross Road,
New Delhi- 110001,

Dated: December 14, 2005

ORDER

Central Government vide its Order of even number dated 14.10.2005 has made testing for heavy metals, namely, Arsenic, Lead, Mercury and Cadmium mandatory for export purposes in respect of every batch of purely herbal Ayurveda, Siddha and Unani medicines by every licensee. Representations have been received from Ayurveda Drugs Manufacturers Association (ADMA) that the exporters may find it difficult to print the certificate "Heavy metals within permissible limit" on the container of the medicines as container and label are to be approved by the regulatory authorities of the importing countries and it may not be possible to get revised containers and labels approved by the regulatory authorities of the importing countries by 1st January, 2006.

In view of the above difficulties brought to the notice of the Central Government, the above mentioned order of even number dated 14.10.2005 is hereby partially modified as follows :

In case any manufacturer of purely herbal Ayurveda, Siddha and Unani medicines finds it difficult to display on the container of purely herbal Ayurveda, Siddha and Unani medicines to be exported the words "Heavy metals within permissible limit" from 1st January, 2006 in view of the regulatory requirements of the importing country, the manufacturer shall submit batchwise testing reports in respect of every purely herbal Ayurveda, Siddha and Unani medicine to be exported from approved laboratories certifying that the medicine contains heavy metals within permissible limits as laid down by the Central Government vide the order of even number dated 14.10.2005. The test report of an approved laboratory will be an essential part of the consignment papers to be submitted by any exporter from 1st January, 2006 which will be examined by the representative of the DCG(I) at the Airport/port of shipment. The manufacturers/exporters of purely herbal Ayurveda, Siddha and Unani medicines shall be responsible for the genuineness of the test report of the approved laboratory submitted along with other consignment papers at the Airport/Port of Shipment. All GLP/NABL accredited laboratories are approved by the Central Government for the above mandatory testing. The list of approved laboratories and the permissible limits

of heavy metals have been posted on the website of the Department of AYUSH, Ministry of Health and Family Welfare, Government of India www.indianmedicine.nic.in.

The order issued by the Central Government under Section 33 EEB of the Drugs and Cosmetics Act, 1940 dated 14.10.2005 as modified hereby shall come into force from 1st January, 2006. All exporters of purely herbal Ayurveda, Siddha and Unani medicines are hereby directed to either conspicuously display on the container of purely herbal Ayurveda, Siddha and Unani medicines to be exported the words “Heavy metals within permissible limit” or furnish the above mentioned certificate from an approved laboratory along with other consignment papers. It will be the responsibility of the representative of DCG(I) deployed at the Airport/port of shipment to examine and ensure that all exporters of purely herbal Ayurveda, Siddha and Unani medicines comply with this Order w.e.f. 1st January, 2006.

(SHIV BASANT)
JOINT SECRETARY TO GOVT. OF INDIA

- **Drug Controller General (India) with request to check the consignments of purely herbal ASU products for ensuring compliance with the above order through their Drug Inspectors and staff of CDSCO available at port offices, shipments, airports, etc.**
- **All State Drug Controllers/All State Drug Licensing Authorities of ASU drugs.**
- **All Ayurveda/ Siddha/Unani Drug Manufacturers Associations.**
- **All State Health Secretaries/ISM Commissioners.**
- **Shri Vipin Saxena – Export Commissioner, DGFT, Udyog Bhavan, New Delhi.**
- **Chairman, Central Board of Excise & Customs, Ministry of Finance, North Block, New Delhi with the request to implement the order through their Excise and Custom Officers available at ports/shipments/airports.**