

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

STARRED QUESTION NO:15
ANSWERED ON:23.11.2005
EXPORT OF AYURVEDIC MEDICINES
Adhalrao Patil Shri Shivaji;Adsul Shri Anandrao Vithoba

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether the US and Canadian Governments have banned import of Ayurvedic medicines from India as reported in The Hindustan Times dated October 25, 2005;
- (b) if so, the details thereof;
- (c) whether the Union Government has issued any notification for export of such medicines to be complied with by the manufacturers of Ayurvedic, Unani and Siddha medicines;
- (d) if so, the details thereof;
- (e) whether the said notification will also cover medicines meant for use in domestic market;
- (f) if not, the reasons therefor;
- (g) whether the measures taken by the Government will help Indian pharma companies to export Ayurvedic products in the EU markets;
- (h) whether the Government has also taken a decision to withdraw the requirement for industrial licensing on both drugs and pharmaceutical items; and
- (i) if so, the details thereof?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMADOSS)

(a) to (i): A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 15 FOR 23RD NOVEMBER, 2005.

(a) & (b): No report has come to the notice of the Government on ban imposed by USA on the import of Ayurvedic medicines from India. Canadian Health Ministry have banned some specific Indian Ayurvedic and Unani medicinal products of certain companies on the ground that they allegedly contained heavy metals such as lead, mercury and/or arsenic above the permissible limit. Details are as annexed.

(c) to (i): Central Government has issued an order on October 14, 2005, under Section 33 EEB of the Drugs and Cosmetics Act, 1940, to be effective from January 1, 2006, for mandatory testing for heavy metals namely, arsenic, lead, mercury and cadmium for export purposes in respect of every batch of purely herbal Ayurveda, Siddha and Unani (ASU) drugs by every Licensee. Permissible limits for arsenic, lead & cadmium will be as per the WHO guidelines. In the case of mercury, the permissible limit prescribed will be one ppm. Conspicuous display of the words `Heavy Metals within Permissible Limits` on the container of purely herbal Ayurveda, Siddha, Unani drugs to be exported will be mandatory w.e.f. 1.1.2006. ASU Drug manufacturers, who do not have in-house laboratory facility shall get their drugs tested by any approved drug testing laboratory and would be responsible for proper batch-wise testing before self-certification. This process of self-certification would be extended for sale within the country in due course. Mandatory testing of products for export purposes is resorted to meet the import standards of other countries.

Central Government has issued another order dated 10th October 2005, under section 33 P of the Drugs and Cosmetics Act, 1940, directing the State Licensing Authorities of Ayurveda, Siddha & Unani (ASU) Drugs to ensure full compliance by all ASU drug manufacturers of the provisions of Rule 161 (1) and (2) relating to displaying on the label of the container or package of an Ayurveda, Siddha & Unani (ASU) drug, the true list of all the ingredients (official and botanical names) used in the manufacture of the preparation along with the quantity of each of the ingredients incorporated therein. In case all the ingredients cannot be mentioned on the label because of their large number, the same shall be indicated in the leaflet to be inserted in the package. Further, the container of a medicine shall conspicuously display the words `Caution to be taken under Medical Supervision` if the list of ingredients contains a substance specified in Schedule E(1) of the Drugs and Cosmetics Rules, 1945. The State Ayurveda, Siddha & Unani (ASU) Drug Licensing Authorities have been directed to forthwith cancel or suspend the licenses of the defaulting ASU Drug Manufacturers under

Rule 159 of the Drugs and Cosmetics Rules, 1945.

In pursuance of Section 33P of the Drugs and Cosmetics Act, 1940, Central Government has issued another order dated 13.10.05 directing all the State Ayurveda, Siddha & Unani (ASU) Drug Licensing Authority to take action against the defaulting ASU drug manufacturers for revocation of their licenses under Rules 157, 158 & 159 of the Drugs and Cosmetics Rules, 1945, for failure to comply with the Good Manufacturing Practices (GMP) notified under Schedule 'T' of the Drugs and Cosmetics Rules, 1945.

The above measures have been taken by Central Government to improve the quality of ASU drugs and this may help to increase exports of Ayurvedic products to various countries.

Chapter IVA of the Drugs and Cosmetic Act, 1940 and Rules 1945 there under provide for licensing for manufacture for sale of Ayurveda, Siddha & Unani (ASU) drugs. The State Governments have been authorized to issue such licenses. However, the Government has delicensed Drugs and Pharmaceuticals from the list of items for which industrial licensing is compulsory vide Ministry of Commerce and Industry, Department of Industrial Policy and Promotion, Notification S.O.1386(E), dated 23rd September 2005.

ANNEXURE

List of Indian Companies and their Ayurvedic Products banned by Canada

Karela tablets, produced by Shriji Herbal Products, India

Karela capsules, produced by Himalaya Drug Co., India

Maha Sudarshan Churna power, produced by Zandu Pharmaceuticals, Mumbai, India

Maha Sudarshan Churna powder, D&K Pharmacy, Bhavnagar, India

Maha Sudarshan Churna powder, produced by Chhatrishia Lalpur, India

Maha Sudershan Churna powder, produced by Dabur India Ltd., New Delhi, India

SAFI liquid, produced by Hamdard-WAKF-India

Yograj Guggul tablets, produced by Zandu Pharmaceuticals, Mumbai, India

Sudarshan tablets, produced by Zandu Pharmaceuticals, Mumbai, India

Shilajit capsules, produced by Dabur India Ltd., New Delhi, India