

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

UNSTARRED QUESTION NO:762

ANSWERED ON:25.02.2009

HEAVY METALS CONTENTS IN AYURVEDIC PRODUCTS

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

- (a) whether the level of lead, mercury and arsenic in some of the ayurvedic products exported by the Indian manufacturers has been found beyond the permissible limit;
- (b) if so, the details thereof and the response of the Government thereto; and
- (c) the steps taken by the Government in this regard?

Answer

THE MINISTER OF STATE FOR HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a), to (c) The permissible level of lead, mercury and arsenic in Ayurvedic products as per WHO standards, which has been acceptable by the Department is 10 ppm, 1 ppm and 3 ppm respectively.

As per the article published in Journal of American Medical Association (JAMA) dated 27th August 2008, one fifth of the Indian manufactured Ayurvedic products bought on the internet contain detectable levels of lead, mercury and arsenic. After the report is published, Government have taken immediate steps to test the reports appearing in JAMA article by reputed and accredited laboratories. Central Council for Research in Ayurveda and Siddha (CCRAS) has also undertaken a study to test the toxicity/safety profile of metal based bhasmas. The study is jointly being carried out with the Indian Toxicological Research Center (ITRC), Council for Scientific and Industrial Research (CSIR), Lucknow. Pharmacopoeial Laboratory of Indian Medicine (PLIM), Ghaziabad has also been directed to procure samples of all the products mentioned in JAMA article and send them to Indian Institute of Chemical Technology (IICT), Hyderabad for heavy metal analysis by electron spectroscopic chemical analysis as well as X-ray fluorescence spectroscopic.

The manufacturers of Ayurvedic medicines have been directed to get safety/toxicity studies carried out for their products by National Accreditation Board of Laboratories/Good Laboratories Practices (NABL/GLP accredited laboratories and send their report in respect of acute, sub acute and chronic safety/toxicity drugs studies.

After examination it is found that no exported herbal ayurvedic medicine from India contain heavy metals beyond the permissible limit. As far as purely herbal Ayurvedic formulations are concerned presence of heavy metals is not detected. As regard herbo-mineral and herbo- metallic preparations metals are an essential ingredient of these formulations and therefore are bound to be present in these, however they are permitted to be used only after due purification and only in small quantities to act as catalysts for activation of other herbal ingredients in order to increase the efficacy of the medicines. The metallic preparations in the form of compounds of metals triturated in the form of Bhasmas are rendered safe after purification with herbs and burning in fire for a prescribed number of times.

A Press release was issued on 2nd September, 2008 with detailed comments by the Department of AYUSH, after article published in JAMA (U.S.) 27th August, 2008 alleging heavy metals in Ayurvedic medicines.

The following other necessary orders have also been issued by the Central government to ensure safety and efficacy of AYUSH products in the country and abroad.

Government has introduced mandatory testing for heavy metals in all purely herbal Ayurveda, Siddha and Unani medicines to be exported with effect from 01.01.06 onwards. This has been done to meet the regulatory requirements of importing countries.

State Drug Licensing Authorities have been directed 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 in a leaflet to be inserted in the package of an ASU drug, the true list of all the ingredients used in the manufacture of the preparation together with the quantity of each of the ingredients incorporated therein.

A research project has been sanctioned to various laboratories of Council of Scientific and Industrial Research (CSIR) under the Golden Triangle Partnership Project to study the physiochemical characteristics of 8 most widely use Bhasmas and to carry out their toxicity studies.

Good Manufacturing Practices have been made mandatory for all Ayurveda, Siddha and Unani drug manufacturing units in the country.

Department of AYUSH has discussed with Minister of Commerce to set up an AYUSH Export Promotion Council under the Department of AYUSH to take care of critical issues like testing and certification of Ayurveda, Siddha and Unani medicines for export.

Govt. have constituted Pharmacopoeia Committees of Ayurveda, Siddha and Unani systems of medicines for preparation of Pharmacopoeias to ensure the quality of Ayurveda, Siddha and Unani drugs.

Captain Shreeniwasurti Drug Research Institute for Ayurveda, Chennai, India Toxicology Research Centre (presently IITR, Indian Institute of Toxicological Research), Lucknow and Sri Ram Institute for Industrial Research, New Delhi have analyzed about 600 plants and it was found that lead arsenic and mercury levels were within the permissible limit.

State Licensing Authorities have been directed to constitute an Expert Committee under the provision of Rule 154 (2) of the Drugs and Cosmetics Rule, 1945 for streamline the system for licensing of patent and proprietary Ayurveda, Siddha and Unani products.