TESTING OF HEAVY METALS IN HERBAL MEDICINE A MUST

New Delhi - October 24, 2005

Testing for heavy metals in herbal medicines has become compulsory and their labeling for heavy metals within permissible limits' would be mandatory from January 1, 2006.

The Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha] and Homeopathy (AYUSH) has issued a notification under the Drugs and Cosmetics Act 1940 stating that testing be made compulsory and the container of these medicines meant for export must clearly display 'Heavy Metals within permissible limits.' The testing for heavy metals like arsenic, lead, mercury and cadmium has become mandatory for export purposes. The licensee must check every batch of these drugs before exporting them.

The permissible limits for arsenic, lead and cadmium will be as recommended by WHO on 'quality control methods for medicinal plants and materials'. In case of mercury, the permissible limit will be one ppm.

The manufacturers of Ayurveda, Siddha and Unani, who do not have in-house laboratory facilities, will have to get these tested by any approved drug testing laboratory.

The Department of AYUSH has made it clear that such labeling is a process of self-certification for export purposes and the drug manufacturers will be held responsible if proper batch-wise testing has not been done.

The process of self-certification would be extended in due course for medicines being sold within the country.

It has come to the notice of the Department that due to environmental pollution and unsatisfactory agricultural and collection practices, relating to the medicinal plants that are used in the preparation of Ayurveda, Siddha and Unani drugs, the presence of heavy metals above permissible limits, cannot be ruled out.

Hence, it has become necessary to make testing for heavy metals mandatory in every batch of these medicines, before export.

NON-COMPLYING AYURVEDA/SIDDHA/UNANI DRUG PRODUCERS TO LOSE LICENSE

The manufacturers of Ayurveda/Siddha and Unani drugs now stand to lose their license if they fail to comply with good manufacturing practices notified under the Drugs and Cosmetics Rules 1945. The Department of AYUSH, Ministry of Health, while issuing the notification, directed all the State Drug Licensing Authorities of Ayurveda/Siddha and Unani, to take action against the non-complying manufacturers of these drugs, by revoking their licenses.

The State Licensing Authorities have also been asked to ensure full compliance by all manufacturers of these drugs to strictly follow Rule 161 (1) and (2) relating to displayon the label of the container or package of Ayurveda/Siddha and Unani, the true list of all the ingredients (both official and botanical names) used in the manufacture of the preparation together with the quantity of each of the ingredients used. In case, the list of ingredients used is long and cannot be mentioned on the label, the same will have to be indicated in a leaflet to be inserted in the package.

Also the container of a medicine shall clearly display the warning i.e. â•¸caution: to be taken under medical supervisionâ•¸, if the list of ingredients contains any substance specified in schedule E(1) of the Drug and Cosmetics Rule 1945. If non-compliance is found, the State Authorities dealing with the licensing of these drugs will immediately cancel or suspend the license of the defaulting manufacturer, under Provision 159 of the Drugs and Cosmetics Rule 1945.

The Department has made it clear that adherence to good manufacturing practices is essential.

VKS/SR