ORDER

It has come to the notice of Central Government that a large number of irrational Ayurveda, Siddha and Unani formulations are being licensed for production by the State Licensing Authorities as Patent & Proprietary medicines. Further, these products are being licensed without insisting on the manufacturers providing testing protocols which can enable the regulatory authorities to get these products tested for their quality and safety.

In view of the above, it has become expedient for the Central Government to issue a direction to the State Licensing Authorities under Section 33P of the Drugs & Cosmetics Act, 1940 to streamline the system for licensing of Patent & Proprietary Ayurveda, Siddha and Unani products under Rule 154 and 154A of the Drugs & Cosmetics Rules, 1945. With this objective in view an Expert Committee shall be constituted as per the provisions of Rule 154(2) for advising the State Licensing Authorities before any Patent & Proprietary Ayurveda, Siddha and Unani medicine is licensed for production by any manufacturing unit. The Expert Committee may be constituted as follows:

1. Commissioner/Director (ISM) of the State - Chairperson
2. Head of the Department of Dravyaguna/IImul Advia of Government/Private Ayurveda/Siddha/Unani College of the State to be nominated by the State Health Secretary. - Member
3. One eminent practitioner of Ayurveda/ Siddha/Unani medicines to be nominated by the State Health Secretary. - Member
4. Senior most CGHS doctor of Ayurveda/ Siddha/Unani posted at the State capital or Director Incharge of CRIs/RRIs of Central Council for Research in Ayurveda and Siddha and Central council for Research in Unani Medicine located in the State to be nominated by the State Health Secretary. - Member
5. Ayurveda/Siddha/Unani Licensing Authority of the State - Member-Secretary

\[Signature\]
2. Submission of ‘Proof of Concept’ and ‘Testing protocols’ along with the application for obtaining license for any new Patent & Proprietary Ayurveda, Siddha and Unani medicines shall be made mandatory. Development of testing protocols for Patent and Proprietary medicine is the responsibility of the manufacturer.

Application received from any Ayurveda, Siddha and Unani manufacturer along with the above documents shall be submitted to the above mentioned Committee and the State Licensing Authority shall take any decision on the application for issue of license on the basis of the advice of the above mentioned Expert Committee. In case of divergence of opinion either within the Expert Committee or between the Expert Committee and the State Licensing Authority, the matter shall be referred to the Department of AYUSH for advice. The State Licensing authority, however, shall be free to take a decision on the application if no reply is received from the Department of AYUSH within 60 days of the reference made to the Department of AYUSH.

All State Drug Controllers/ ASU State Licensing Authorities shall report compliance within 60 days.

(SHIV BASANT)

JOINT SECRETARY TO THE GOVT. OF INDIA

Copies to:

- Chief Secretaries/ Health Secretaries of All States/ U.T.s
- Drug Controller General (India)/ All State Drug controllers/ All State ASU Licensing Authorities/ All State Directors of ISM&H.

Copy for Information to:

- All Ayurveda/Siddha/Unani Drug Manufactures Associations.