



ABSTRACT

Indian Medicine and Homoeopathy – State licensing Authority – Reconstitution of Expert Committee for advising Licensing Authority – Orders-Issued.

HEALTH AND FAMILY WELFARE (IM2-2) DEPARTMENT

G.O.(D) No.1255

Dated:29.11.2021

திருவள்ளூர் ஆண்டு 2052

பிலவ, கார்த்திகை -13

Read:

1. G.O.(Ms).No.1481, Health and Family Welfare (IM2-2) Department, dated:30.09.2019.
2. From the Director of Indian Medicine and Homoeopathy letter Ref No.10727/A2/2021, dated: 23.9.2021.

ORDER:

In the Government order first read above, the Expert Committee has been reconstituted as per the provision of Rule 154 (2) of the Drugs and Cosmetic Rules, 1945 for advising the State Licensing Authority before any patent and proprietary of Ayurveda, Siddha, Unani Medicine is licensed for production by any manufacturing Unit.

2. The Director of Indian Medicine and Homoeopathy, in his letter 2nd read above, has stated that the Government of India in the letter No.11027/C2/2007-DCC (Ayush), Ministry of Health and Family Welfare Department, dated 04.01.2008 has requested the State Government to constitute an Expert Committee as per the provision of Rule 154(2) of the Drugs and Cosmetics Rule, 1945 for advising State Licensing Authority before any patent/proprietary Ayurveda, Siddha, Unani Medicines are licensed for production by any manufacturing units.

3. He has also stated that the State Licensing Authority (IM), Chennai has requested to issue orders, as per the new guidelines of Government of India, to facilitate the licensing or approval of ASU drugs, to constitute expert committee of reference as under;

Expert Committee shall consist of;

- i. Senior most Ayurved/Siddha/Unani Officer in the Office of State Licensing Authority or Director (AYUSH)
- ii. Expert of Dravyaguna / Ilmul Advia / Gunapadam
- iii. Expert of ASU Pharmacy or of Ras-Shastra/Saidala/Marunthu – Alunur
- iv. ASU Drug Inspector.

4. The Director of Indian Medicine and Homoeopathy has also stated that Government of India has instructed all State ASU (Ayurveda, Siddha, Unani) Drug Controllers / Licensing Authorities shall comply with the order from immediate effect. He has also stated that the lifetime of the expert committee reconstituted in the Government order first read above was expired on 29.09.2021 and requested the Government to re-constitute the Expert Committee with the following members:-

Sl. No	Department	Newly appointed members of Expert Committee
1	Senior most Ayurveda / Siddha/ Unani Officer in the Office of State Licensing Authority or Director (AYUSH)	The Director, Indian Medicine and Homoeopathy, Department, Chennai-106.
2	One Expert of Dravyaguna / Ilmul Advia / Siddha Gunapadam (as per need)	1.Head of Department - Dravyaguna – Government Ayurveda Medical College, Nagercoil. 2. Head of Department – Ilmul Advia – Government Unani Medical College, Chennai. 3.Head of Department – Gunapadam – Government Siddha Medical College, Chennai.
3	Expert of ASU pharmacy or of Ras - Shastra / Saidala / Marunthu - Alunur	Medical Officer, Pharmacy attached to Arignar Anna Government Hospital of Indian Medicine, Chennai.
4	ASU (Ayurveda, Siddha, Unani) Drug Inspector	The Drugs Inspector (IM), Chennai District, Directorate of Indian Medicine & Homoeopathy.

5. The Government, after careful examination, have decided to accept the proposal of the Director of Indian Medicine and Homoeopathy, Chennai and to re-constitute an Expert Committee as per the provisions of Rule 154 (2) of the Drugs and Cosmetics Rule 1945 for advising State Licensing Authority (IM) before any Patent/Proprietary Ayurveda, Siddha, Unani Medicines are licensed for production by any manufacturing unit, with the following Members and orders accordingly:-

1	The Director, Indian Medicine and Homoeopathy, Department, Chennai-106.	Chairperson
2	1.Head of Department - Dravyaguna – Government Ayurveda Medical College, Nagercoil. 2.Head of Department – Ilmul Advia – Government Unani Medical College, Chennai. 3.Head of Department – Gunapadam – Government Siddha Medical College, Chennai.)	Member
3	Medical Officer, Pharmacy attached to Arignar Anna Government Hospital of Indian Medicine, Chennai	Member

4	The Drugs Inspector (IM), Chennai District, Directorate of Indian Medicine & Homoeopathy.	Member
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The terms of reference of the Expert Committee are as follows:-

- a) To examine the license application & associated documents, proof of concept and testing protocols of intended Patent or Proprietary ASU Drugs as provided in section 3 (h) (i) of the Drugs & Cosmetics Act, 1940 and Rules there under;
- b) To verify the reference of the proposed ASU drug and its ingredients from authoritative books and to ascertain that the excipients used in the formulation are in accordance with the provision of Rule 169;
- c) To ascertain that the supporting evidence or proof of safety and effectiveness for the classical / shastric ASU drug with new dosage form or indication and patent or proprietary ASU Drug is in accordance with the provision of Rule 158-B of Drugs & Cosmetic Rules, 1945.
- d) The Expert Committee shall examine the proposal and send its advice & recommendations to the Licensing Authority within 15 days of the receipt of application for consideration of granting approval to the intended ASU formulations.
- e) The Committee shall be categorized as first class committee for the purpose of drawal of sitting allowance.
- f) The Committee would meet twice in a month normal course and in extraordinary circumstances or whenever the necessity so demands, the Committee would meet more than 2 occasions in a month.

(BY ORDER OF THE GOVERNOR)

J. RADHAKRISHNAN
PRINCIPAL SECRETARY TO GOVERNMENT

To

The Director of Indian Medicine and Homoeopathy, Chennai- 600 106.

The Director of Drugs Control, Chennai- 600 006.

The State Licensing Authority, Arumbakkam, Chennai- 600 106.

Arignar Anna Government Hospital of Indian Medicine, Chennai – 600 106.

The Pay and Accounts Officer (South), Chennai- 600 035.

The Members of the Committee through the Director of Indian Medicine and Homoeopathy, Chennai- 600 106.

Copy to:

The Finance (Health-1) Department, Chennai- 600 009.

The Secretary to Government, Government of India, Ministry of Health and Family Welfare, Department of AYUSH, New Delhi-110 001.

The Special Personal Assistant to Hon'ble Minister (Health and Family Welfare Chennai- 600 009.

✓ The Health and Family Welfare (Data Cell) Department, Chennai- 600 009.
Stock file/Spare copies.

// Forwarded by Order //

N. Manjil
20/11/21
SECTION OFFICER

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