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GOVERNMENT OF KERALA

Abstract

Health & Family Welfare Department-Drugs Control Department-Expert Committee for the approval of new patent or Proprietary Ayurvedic Siddha Unani Drugs in Kerala - reconstituted-orders issued

HEALTH & FAMILY WELFARE (F) DEPARTMENT

G.O.(Rt)No.861/2023/H&FWD Dated,Thiruvananthapuram, 11-04-2023

- Read:- 1. GO(Rt) No.2540/2019/H&FWD dated 24/10/2019
 2. GO(Rt)No.1377/2020/H&FWD dated 28/07/2020
 3. Order No.T-20020/9/2020-DCC dated 31/10/2022 from the Ministry of AYUSH(Drug Policy Section), Government of India.
 4. Letter No.DC/9883/2020-L dated 23/12/2022 from the Drugs Controller, Thiruvananthapuram.

ORDER

Government in supersession of order read as 2nd paper above are pleased to reconstitute the Expert Committee with the following members as per provisions of Rule 154(2) of Drugs & Cosmetic Rules, 1945, for advising the State Licensing Authority for granting licence on production of Patent & Proprietary Ayurvedic products by manufacturing units and for streamlining the licensing procedure in the State.

S.No	Name/Designation	Role
1	Deputy Drugs Controller(Ayurveda), O/o Deputy Drugs Controller(Ayurveda) Thiruvananthapuram	Chairperson
2	Dr.Indulekha VC, Associate Professor, Dravyaguna Vijnana Department, Government Ayurveda College	Member

	Thiruvananthapuram	
3	Dr.Thara Lakshmi S, Professor & HOD, Department of Rasashastra and Bhaishajya Kalpana, Government Ayurveda College, Tripunithura	Member
4	Dr.Kavitha S Gireesh, Senior Drugs Inspector(Ayurveda) O/o Deputy Drugs Controller, Thiruvananthapuram	Member-Secretary

The Terms of Reference of the Expert Committee shall be as follows:

- i. To examine the license application & associated documents, proof of concept and testing protocols of intended Patent or Proprietary ASU drug as provided in Section 3(h) (i) of the Drugs & Cosmetics Act, 1940 and Rules thereunder.
- ii. 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 provisions of Rule 169 of Drugs & Cosmetic Rules, 1945.
- iii. To ascertain that the supporting evidence or proof of safety effectiveness for the classical/shastriya ASU Drug with new dosage form or new indication and Patent or Proprietary ASU drug is in accordance with the provisions of Rule 158-B of Drugs & Cosmetic Rules, 1945; and
- iv. The Expert Committee shall examine the proposals 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 formulation.
- v. Meeting of EPC (Expert Penal Committee) should be held in every three weeks (21 days) for the timely disposal of license applications.
- vi. ASU Drug Inspector/Member Secretary of expert committee shall be responsible for convening meetings, to prepare and keep the

minutes of Expert Committee and forward them to the Licensing Authority after approval of the Chairperson.

(By order of the Governor)
TINKU BISWAL
PRINCIPAL SECRETARY

Drugs Controller, Thiruvananthapuram.

Director, Ayurveda Medical Education Department,
Thiruvananthapuram.

Principal, Government Ayurveda College, Thiruvananthapuram.

Principal, Government Ayurveda College, Tripunithura.

Deputy Drugs Controller, O/o Deputy Drugs Controller, Arogyabhavan,
Thiruvananthapuram-01.

Dr.Indhulekha VC, Associate Professor, Dravyaguna Vijnana
Department, Government Ayurveda College, Thiruvananthapuram.

Dr.Thara Lakshmi S, Professor & HOD, Department of Rasashastra and
Bhaishajya Kalpana, Government Ayurveda College, Tripunithura.

Dr.Kavitha S Gireesh, Senior Drugs Inspector(Ayurveda) O/o Deputy
Drugs Controller, Thiruvananthapuram.

Information & Public Relations (Web & New Media)Department.

StockFile/Office Copy(To File F1/5/2023-Health).

Forwarded /By order

Signed by

Vilasini K.V
Section Officer

Date: 17-04-2023 11:17:45

Copy to :-1.Private Secretary to Minister H,W&CD

2.PA to Principal Secretary H&FWD