

F. No. Z.25022/01/2015-DCC (AYUSH)
Government of India
Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH)

AYUSH Bhawan
B-Block, GPO Complex
INA, New Delhi-110023.


Dated: 16th April, 2015.

Subject: Online RTI Application, Registration No. AYUSH/R/2015/60076 dated 19.3.2015.

Reference: Letter dated 13th April 2015 requesting to send the scan or hard copy of signed letter.

This has reference to the above-mentioned RTI Application and the request dated 13th April 2015.
Point-wise information is provided as follows-

- I) As per the Drugs and Cosmetics Act, 1940, which is introduced by the Government of India, there are two categories of ASU drugs defined under Section 3(a) and Section 3(h) (i) respectively, which can be approved/licensed by the State Licensing Authorities for manufacturing. Central Government does not issue license for manufacturing of ASU drugs.
- II) Presently, license is required for commercial manufacturing of ASU drugs. Rule 153 and Rule 158 B of the Drugs and Cosmetics Rules, 1945 provide the guidelines and requirements for licensing of ASU drugs.
- III), IV), V) There are no provisions in the Drugs & Cosmetics Act, 1940 and Rules thereunder for license to sell the ASU drugs in wholesale or retail. Therefore, the question of applying for license and amount of license fee does not arise.
- VI) Registration system for selling ASU medicines is not in place in India. However, license is required for manufacturing of ASU medicines/food supplements (as described in Rule 158 B of the Drugs and Cosmetics Rules, 1945) for sale .


Dr D.C. Katoch
Adviser (Ay.) cum CPIO

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Copy to:

Sh Ram Lakhan, Deputy Secretary cum CPIO, RTI Cell, Ministry of AYUSH.