

K.11020/03/2017-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: 04<sup>th</sup> July, 2018

To

All State Licensing Authorities/Drug Controllers for ASU Drugs.

**Sub:** Clarification in respect of the requirement of pilot study/clinical trial for the license of Ayurvedic, Siddha or Unani drugs under the provisions of Rule 158B of the Drugs & Cosmetics Rules, 1945- reg:

Whereas it has come to the notice of Central Government that the provisions of Rule 158-B of the Drugs & Cosmetics Rules, 1945 pertaining to the requirements for issue of manufacturing license for Ayurvedic, Siddha or Unani drugs are being interpreted differently and clinical trial reports are reported to be sought from the manufacturers particularly for Patent or Proprietary category of such medicines, resulting in inordinate delay in granting license or renewal of license.

In this regard, it may be hereby clarified, noted and advised to comply that:

- i. the term 'clinical trial' as such is not mentioned in the context of ASU drugs-related provisions of Drugs & Cosmetics Rules, 1945. However, experience or evidence of effectiveness of the ASU drug based on textual rationale, published literature and pilot study is required in support of the claim of indication or use for issue of license in accordance with the provisions of Rule 158(b). Proof of effectiveness in the form of Pilot Study may be required for intended ASU drug, if the textual rationale, published literature and textual (authoritative book-based) indications are not furnished to support the claim of use or indication;
- ii. there is no provision to designate, authorize or notify any particular institution or center for conducting such pilot studies on ASU drugs; and
- iii. license applications for ASU drugs may accordingly be disposed of in a time bound manner within a period of three months provided under Rule 154 (i) of the Drugs & Cosmetics Rules, 1945.

Yours faithfully,



(Shiela Tirkey)

Under Secretary to the Govt. of India