Government of India
Ministry of Ayush

NBCC Office Block-3 (2nd Floor),
East Kidwai Nagar, New Delhi-110023
Dated: 18th April, 2024

Advisory

Subject: Compliance to the labelling provisions for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs/medicines-reg.

It has been come to the notice of Ministry of Ayush that some Ayush drug manufacturers are mentioning following particulars on the label of their drug/ product or in advertisement of their licensed ASU&H products in print and/ or electronic media: -

- Mentioning that the drug/ product is “Approved/Certified by Ministry of Ayush”
- Displaying “Green logo” on the product and mentioning “100% vegetarian".
- Claiming the product as “100% Safe”, “Free from side effects”, “Guaranteed Treatment”, “Permanent cure” etc.
- Claiming nutraceutical value to Ayush drugs/ products.

2. In this regard, it is to inform that –

i. Ministry of Ayush, Government of India does not grant manufacturing license or approval for any Ayush drug/medicine.
ii. Rule 158B of Drugs and Cosmetics Rules, 1945 prescribes guidelines for issue of license with respect of Ayurveda, Siddha and Unani (ASU) drugs.
iii. Licensing by State Drug Licensing Authority shouldn’t be construed as an approval by “Ministry of Ayush”. License issued by state SLA is a permission to manufacturer for sale of the particular drug/ product based on the fulfilment of stipulations laid down under the Drugs and Cosmetics Act, 1940 and Rules thereunder.
iv. Rule 161, 161A and 161B of Drugs and Cosmetics Rules, 1945 have exclusive provisions for labelling of Ayurveda, Siddha and Unani (ASU) drugs. Further, rule 106-A of Drugs and Cosmetics Rules, 1945 have provisions for labelling of

Homoeopathic medicine.

v. Provisions related to advertisement of a drug, including Ayush drugs are prescribed under the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954.
vi. Besides these, the Consumer Protection Act, 2019; the Cable Television Networks Act, 1995; the Emblems & Names (prevention of improper use) Act, 1950 are few acts/ regulations that have provisions to control misleading advertisements.

3. In view of aforementioned facts/ extant Acts and Rules, all Ayush drug manufacturers are hereby advised -

i. To strictly adhere to the aforementioned labelling provisions and advertisements of ASU&H drugs, prescribed under various Acts and Rules.
ii. Any misleading claim/advertisement in any form or on any platform will attract consequent legal actions by the Competent Authorities.
iii. Any claim of “Approved/Certified by Ministry of Ayush” on the label or advertisement of ASU&H drugs, will attract consequent legal action against the alleged manufacturer by the Ministry of Ayush.

4. Further, State Drug Licensing Authorities are hereby advised to examine all such ASU&H drug licensed claiming "approval/certification by Ministry of Ayush" either on label or in the advertisements and ensure compliance to this advisory.

Signed by Madan Lal Meena
Date: 18-04-2024 17:07:27

(Madan Lal Meena)
Under Secretary to the Government of India.

To ,

i. All State Ayush Drug Licensing Authorities - *with a request to forward a copy of this advisory to all the licensees under their jurisdiction.*
ii. All Ayush drugs manufacturers/ Associations.
iii. Coordinator, National Pharmacovigilance Co-ordination Centre - *with a request to ensure reporting of such claims of approval/certification by Ministry of Ayush to concerned State Licensing Authority, under intimation to this Ministry of Ayush.*

Copy to

1. Sr. PPS to Secretary, Ministry of Ayush
2. PPS to J.S. (BKS), Ministry of Ayush
3. PPS to Adv. (Dr. K.U.), Ministry of Ayush
4. Web information manager/ NIC, Ministry of Ayush - to upload this advisory on the website of Ministry of Ayush / e-AUSHADHI portal.