No. Z.17018/12/2014-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: 26th March, 2019

ADVISORY

Subject:- Assuring quality of ASU & H drugs procured under the Centrally Sponsored Scheme of National AYUSH Mission (NAM).

As you are aware Ministry of AYUSH is implementing a Centrally Sponsored Scheme of National AYUSH Mission (NAM) for the promotion and development of AYUSH systems in the States/UTs. The Scheme inter-alia makes provision for supply of essential AYUSH medicines to AYUSH health care facilities. NAM guidelines already stipulated the procurement of quality essential AYUSH medicines in AYUSH Public Health care facilities.

However, during the review of National AYUSH Mission (NAM) in some States/UTs and also as per the references received from some of the States, it was observed that robust AYUSH drug procurement mechanism is lacking and testing of drugs samples for adhering the quality of essential medicines procured under NAM are not followed scrupulously in certain instances. It is needless to say that this will compromise the trust of the public in AYUSH systems of medicine.

Keeping in view ensuring that only quality essential AYUSH medicines are procured under Centrally Sponsored Scheme of National AYUSH Mission (NAM), following guidelines may also be followed:

i. State Authority should themselves satisfy by inspecting the infrastructure, records, samples, production capacity of the manufacturing units from where the medicines are being procured and share the inspection report with this Ministry.

ii. States/UTs should adhere in letter and spirit to the NAM guidelines and provisions contained in the Drugs and Cosmetics Rules, 1945 in context of quality of drugs procured under the scheme.

iii. Prescribing physicians in all the dispensaries funded through NAM need to exercise utmost caution in immediately reporting to the competent authority about quality related issues and apparently misbranded, spurious or adulterated drugs procured under the NAM scheme.

iv. In case of any discrepancy in test reports for the drugs procured, the State may send such samples in the manner prescribed under Drugs and Cosmetics Rules, 1945 to the appellate laboratory i.e. Pharmacopoeial Laboratory of Indian Medicine (PLIM) or Homoeopathic Pharmacopoeial Laboratory (HPL), as the case may be, before actually procuring/distributing such drugs.

v. States need to exercise utmost vigil in carrying out the procurement of medicines under NAM which includes matching the Certificate of Analysis (CoA) submitted by the manufacturing unit in the tender with that of the actual drugs supplied by the unit. Also, the packaging and labelling requirements of all the drugs need to be strictly in compliance to the extant regulatory provisions.

Shiela Tirkey

(Shiela Tirkey)
Under Secretary to the Govt. of India

To,

All State and UTs Director General/ Mission Director/ Commissioner/ Director/ State Licensing Officer/ Drug Inspector/ Nodal Officer of NAM