

the Category II and Category IV of the Biopharmaceutical Classification System.

- (ix) On 27.10.2017, the Drugs and Cosmetics Rules, 1945 have been amended *vide* Gazette notification no. G.S.R. 1337 (E) making it mandatory that before the grant of manufacturing license, the manufacturing establishment is to be inspected jointly by the Drugs Inspectors of Central Government and State Government.

The licensed manufacturing premises shall be inspected jointly by the Drugs Inspectors of Central Government and State Government to verify the compliance with the conditions of license and the provisions of the Drugs and Cosmetics Act and Rules for not less than once in three years or as needed as per risk based approach.

- (x) On 10.04.2018, the Drugs and Cosmetics Rules, 1945 have been amended *vide* Gazette notification no. G.S.R. 360 (E), making it mandatory for all drugs, that the applicants shall submit evidence of stability, safety of excipients etc. to the State Licensing Authority before grant of product manufacturing license by the Authority.
- (xi) The Indian Council of Medical Research (ICMR) has also carried out clinical trials to assess the efficacy and safety of certain drugs.

(c) Details of instances of drugs declared as Not of Standard Quality/Spurious by Central Drugs Testing Laboratories are regularly uploaded on monthly basis on CDSCO website (www.cdsc.nic.in), under the heading “Drug Alert”, which includes details of erring drug manufacturers.

Strengthening the Medical Establishment Act

*220. SHRI G. C. CHANDRASHEKHAR: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state whether Government plans to regulate the role of private sector in healthcare in India by strengthening the Medical Establishment Act for private hospitals to ensure quality care and affordable healthcare?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA): The Government of India has enacted the Clinical Establishments (Registration and Regulation) Act, 2010 and notified Clinical Establishments (Central Government) Rules, 2012. These provide for registration and regulation of Clinical Establishments including those in the private sector belonging to Allopathic and AYUSH systems of medicine. Therapeutic as well as diagnostic establishments are covered under this Act. In the States/Union Territories where the said Act is in

force, the clinical establishments are required to meet the norms such as minimum standards of facilities and services, minimum requirement of personnel, maintenance of records and reports and displaying of rates at a conspicuous place. The clinical establishments are also required to follow Standard Treatment Guidelines issued by the Central/State Governments and charge rates for each type of procedure and service within the range of rates determined from time to time. The National Council for Clinical Establishments has approved a standard list of medical procedures and a standard template for costing of medical procedures and shared the same with the States and Union Territories for appropriate action by them. The States are responsible for regulating hospitals including private hospitals in their respective States as per provisions of the Act and rules applicable in the States to ensure quality care and providing affordable healthcare treatment to patients.

Currently, the Act is applicable in 11 States namely Sikkim, Mizoram, Arunachal Pradesh, Himachal Pradesh, Uttar Pradesh, Bihar, Jharkhand, Rajasthan Uttarakhand, Assam and Haryana and all Union Territories except Delhi. Other States may adopt the Act under Clause (1) of Article 252 of the Constitution. The Central Government is continuously persuading the States to adopt the Clinical Establishment Act, 2010 and ensure its strict implementation or consider bringing a State specific legislation in the matter, if they wish.

Homoeopathy hospitals in India

*221. SHRI AMAR SHANKAR SABLE: Will the Minister of AYURVEDA, YOGA AND NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (AYUSH) be pleased to state:

(a) whether Government has any plan to promote Homoeopathy hospitals in India; and

(b) if so, the details thereof?

THE MINISTER OF STATE OF THE MINISTRY OF AYURVEDA, YOGA AND NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (AYUSH) (SHRI SHRIPAD YESSO NAIK): (a) and (b) Yes, the Central Government has launched Centrally Sponsored Scheme of National AYUSH Mission (NAM) which *inter alia* has following provisions for overall promotion of AYUSH including Homeopathy hospitals in the country:—

(i) Financial assistance for Upgradation of Government AYUSH Hospitals including Homoeopathy.