GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1522
ANSWERED ON:13.12.2013
DRUGS AND COSMETICS ACT RULES
Botcha Lakshmi Smt. Jhansi;Das Shri Bhakta Charan;Naik Dr. Sanjeev Ganesh;Patil Shri Sanjay Dina ;Singh Shri Pashupati Nath;Sule Supriya

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether a number of instances of violation of the Drugs and Cosmetics Rules, 1945 such as running chemist shops without pharmacists, sale of medicines without prescription, excess metal contents in medicines etc. have been reported in the country;

(b) if so, the details thereof and the action taken/proposed by the Government thereon during the last three years and the current year, State/UT-wise;

(c) whether the Government has reviewed the Drugs and Cosmetics Act, 1940 and if so, the details and the outcome thereof; and

(d) the steps taken/proposed by the Government to make suitable amendments and new provisions in the said Act/Rules in order to make them relevant to present time?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD)

(a) & (b): Under the Drugs & Cosmetics Act, 1940, the manufacture and sale of drugs come under the purview of the State Drugs Control Authorities appointed by the State Governments. The information in case of violation of the provisions of the Drugs & Cosmetics Rules, 1945 with respect to running of chemist shops without pharmacists and sale of medicines without prescription are, therefore, not maintained centrally. Further, the question of excess metal contents in allopathic medicines does not arise as the same is governed by the Indian Pharmacopoeia and drugs not in conformity with the same are not approved.

(c) & (d): Law making is an evolving process depending upon the needs of the situation / times. The Drugs & Cosmetics Act, 1940 has been amended on several occasions since its enactment. On the last occasion, on the basis of the recommendations of the Mashelkar Committee, the Act was amended by the Drugs & Cosmetics (Amendment) Act, 2008 to provide stringent penalties for manufacture of spurious and adulterated drugs. Certain offences were made cognizable and non-bailable. It also enabled setting up of special designated courts for speedy disposal of cases to deal with the cases of offences under the Drugs and Cosmetics Act. 16 States/UTs have already set up these special Courts.

Recently, the Drugs & Cosmetics (Amendment) Bill, 2013 has been introduced in the Rajya Sabha on 29th August, 2013 to provide for inter alia creation of a Central Drugs Authority with powers to review, suspend and cancel the licenses issued by the Central and States' Licensing Authorities, new Chapters containing regulatory provisions for medical devices and clinical trials, regulatory provisions for exports and centralized licensing in respect of 17 categories of drugs contained in a new Third Schedule.

Similarly, the Drugs & Cosmetics Rules, 1945 have been amended on numerous occasions. Recently, these rules were amended by three notifications, namely, (i) Gazette Notification G.S.R. 53 (E) dated 30-01-2013 specifying procedures to analyze the reports of Serious Adverse Events occurring during clinical trials and procedures for payment of compensation in case of trial related injury or death as per prescribed timelines; (ii) Gazette Notification G.S.R. 63(E) dated 01-02-2013 specifying various conditions for conduct of clinical trials, authority for conducting clinical trial inspections and actions in case of non-compliance; and (iii) Gazette Notification G.S.R No. 72(E) Dated 08.02.13 making registration of the Ethics Committees mandatory and specifying requirements and guidelines for registration of Ethics Committee.