

**GOVERNMENT OF INDIA  
HEALTH AND FAMILY WELFARE  
LOK SABHA**

UNSTARRED QUESTION NO:5901

ANSWERED ON:11.05.2012

QUALITY AND SAFETY OF AYURVEDIC/HOMOEOPATHY DRUGS

Bapurao Shri Khatgaonkar Patil Bhaskarrao;Chowdhury Shri Adhir Ranjan;Gaikwad Shri Eknath Mahadeo;Mahendrasinh Shri Chauhan ;Mandlik Shri Sadashivrao Dadoba;Paranjpe Shri Anand Prakash

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

- (a) whether the Government has taken note of a recent study which revealed that a large number of ayurvedic drug manufacturers do not conduct any safety tests on their drugs/products;
- (b) if so, the details alongwith the facts in this regard;
- (c) the corrective measures taken/proposed by the Government to enforce strict compliance of quality and safety standards by ayurvedic drug manufacturers;
- (d) whether there is shortage of laboratories for testing of ayurvedic and homoeopathic drugs in the country;
- (e) if so, the details thereof indicating the details of such laboratories presently functioning in the country, State/UT-wise; and
- (f) the steps taken/proposed by the Government to set up new laboratories for testing of ayurvedic and homoeopathy drugs in the country, State/UT-wise?

**Answer**

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI S. GANDHI SELVAN)

(a) to(c): Department of AYUSH has not conducted any such study nor any recent study revealing that a large number of Ayurvedic drug manufacturers do not conduct safety tests on their drugs and products has come to the notice of this Department. As per the Drugs & Cosmetics Act, 1940 and the Rules thereunder, the manufacture of Ayurveda, Siddha, Unani and Homoeopathy drugs is licensed by the State Drug Licensing Authorities and compliance to Good Manufacturing Practices (GMP) is mandatory for the licensees to provide facility for quality control section in the drug manufacturing premises or through Government approved drug testing laboratory. The testing of drugs has to be done as per the pharmacopoeial standards and the manufacturers are required to verify the raw materials, monitor in-process, product quality checks and control the quality of finished products. Further, the Department of AYUSH has taken a number of measures for ensuring quality control and regulation of Ayurvedic, Unani and Homoeopathic medicines. The major initiatives to enforce quality and safety of Ayurvedic drugs are as follows-

- 1) Publication of Ayurvedic Pharmacopoeia containing quality standards of 600 single drugs and 152 compound formulations of Ayurveda.
- 2) Pharmacopoeia Commission for Indian Medicine (PCIM) has been established to augment standardization and quality control parameters of Ayurveda, Siddha and Unani medicines.
- 3) Department of AYUSH in collaboration with the Quality Council of India has launched a scheme for voluntary quality certification of drugs.
- 4) Shelf life of various categories of Ayurveda drugs and the use of preservatives, additives etc. in the manufacture of these drugs have been notified.
- 5) Regulatory guidelines under Drugs & Cosmetics Rule 158 (B) have been notified for issue of license to certain categories of Ayurveda, Siddha and Unani drugs with the requirement of safety study and experience or evidence of effectiveness.

(d) to (f): The following two Central Govt. laboratories have been established under the Drugs & Cosmetics Rules 1945;

- i) Pharmacopoeial Laboratory of Indian Medicine (PLIM), Ghaziabad.
- ii) Homoeopathic Pharmacopoeia Laboratory (HPL), Ghaziabad

These laboratories have the mandate for the development of pharmacopoeial standards and testing of ASU&H Homoeopathic drugs and are the appellate laboratories for the purpose of testing or analysis of drugs.

Besides, 29 State Drug Testing Laboratories have already been supported for strengthening of infrastructure for quality testing of drugs and 47 laboratories are recognized under the Drugs & Cosmetics Rules. State/UT wise details of existing laboratories have been enclosed as annexure. By and large there is no shortage of drug testing laboratories. There may be non-availability of drug testing laboratory near to a particular place due to market forces.