

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

STARRED QUESTION NO:273

ANSWERED ON:15.03.2013

QUALITY OF DRUGS AND COSMETIC PRODUCTS

Gangaram Shri Awale Jaywant;Rana Shri Jagdish Singh

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

- (a) whether the Government has laid down certain quality standards for drugs, tooth pastes, creams and other cosmetic products being manufactured and sold in the country;
- (b) if so, the details thereof;
- (c) the mechanism and infrastructure put in place by the Government for periodical examination of the quality and safety of drugs, tooth pastes, creams and other cosmetic products in the country;
- (d) the steps taken/proposed by the Government to scale up infrastructure and strengthen monitoring mechanism to ensure the quality and safety of drugs, tooth pastes, creams and other cosmetic products in the country; and
- (e) the further measures taken/proposed by the Government to check exaggerated and misleading advertisements of the above products in the country?

**Answer**

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABIAZAD)

(a)to(e): A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO.273 FOR 15TH MARCH, 2013

(a)&(b):Yes. Drugs imported or manufactured for sale in the country are required to comply with the standards prescribed under the second Schedule of the Drugs and Cosmetics Act, 1940. Cosmetics are also required to comply with the standards prescribed under the Drugs and Cosmetics Rules, 1945. The Cosmetics in finished form, included under Schedule S of the said Rules, should conform to the Indian Standards specifications laid down from time to time by the Bureau of Indian Standards (BIS). 29 categories of cosmetics in finished form, are covered under Schedule S including tooth pastes and creams.

(c) The quality of drugs and cosmetics manufactured in the country and their distribution are regulated through the system of licensing and inspection by Licensing Authorities appointed by the State Governments. Inspections of licensed premises are carried out for ensuring compliance to the conditions of licence through the Drug Inspectors appointed for the purpose. Samples of drugs as well as cosmetics marketed in the country are also drawn and treated in the laboratories to check their quality.

(d) The Government has created 216 additional posts in the Central Drugs Standard Control Organisation (CDSCO) since 2008. The Central Drugs Testing Laboratories have also been provided with new sophisticated testing equipments. Two Sub-zones of CDSCO (Hyderabad and Ahmadabad) have been upgraded to full zones and three new sub-zones (Bangalore, Chandigarh and Jammu) have been created. The scheme of regular overseas inspection of manufacturing facilities situated abroad has been initiated to ensure proper compliance of good manufacturing practices guidelines before registering them for import of drugs. Two such inspections have already taken place in China. The National Pharmacovigilance Programme has been launched to capture Adverse Drugs Reaction (ADRs) for safe-guarding public health. ADR Monitoring Centres are already functioning across the country besides the National Coordination Centre at the Indian Pharmacopoeia Commission, Ghaziabad (U.P.) and a Pharmacovigilance Cell at CDSCO (Headquarter).

The State Governments have also been requested to strengthen their manpower and infrastructure. On its part, the Central Government has, during the 12th Five Year Plan, initiated a new scheme for providing financial assistance to the States / UTs for strengthening of State Drug Control Departments. The upgradation/creation of infrastructure is, however, a continuous and ongoing process.

(e) The advertisement of drugs is regulated under the Drugs & Magic Remedies (Objectionable Advertisements) Act 1954. Under this Act, State Governments are empowered to take action in respect of violations of the said Act after making necessary investigations about the claims made. As per Rule 148B of the Drugs and Cosmetics Rules, 1945, false or misleading claims of cosmetics, are prohibited.