GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:3054
ANSWERED ON:15.03.2013
ISSUANCE OF DRUG LICENCES
Abdulrahman Shri ;Ponnam Shri Prabhakar

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

(a) whether certain instances of grant of licence to certain drugs by State Licensing Authorities (SLAs) without approval of the Drug Controller General (India) have been reported in the country;

(b) if so, the details thereof and the action taken/proposed by the Government thereon;

(c) the existing mechanism to coordinate approval of drugs between the DCG(I) and SLAs;

(d) whether the Government proposes to set up a Central Drug Authority to enable centralised issuance of licences for manufacture and sale of drugs; and

(e) if so, the details thereof and if not, the reasons therefor?

Answer

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

(a) to (c): The Drugs & Cosmetics Act, 1940 empowers the State Licensing Authorities (SLAs) to issue licenses for manufacture and sale of drugs in the country. However, the drugs falling under the category of New Drugs require prior approval from the Licensing Authority defined under Rule 21(B) of the Drugs & Cosmetics Rules, 1945 i.e. the Drugs Controller General (India) [DCG(I)] before grant of a licence by the State Licensing Authority.

In twenty three cases of new Fixed Dose Combinations (FDCs), considered as New Drugs, licenses have been granted by the SLAs without the mandatory approval of the DCG(I). The State Drugs Controllers were asked to take action under the Drugs and Cosmetics Act 1940 in all these cases. Further, on 1st October 2012, the Central Government issued directions under sections 33P of the Drugs and Cosmetics Act, 1940 to all State / UT Governments to instruct their respective drug licensing authorities to abide by the provisions prescribed under the Drugs and Cosmetics Rules in respect of grant of manufacturing licenses for the drugs falling under the definition of the term "New Drug" and not to grant licenses for manufacture for sale or for distribution or for export of such new drugs, except in accordance with the procedure laid down under the said Rules i.e. without prior approval of the DCGI.

The statutory mechanism of Drugs Consultative Committee provided for in the Drugs and Cosmetics Act, 1940 ensures regular interaction among the State Drug Control Authorities and the Central drug regulator for uniform implementation of the provisions of the Act and Rules made thereunder.

(d) and (e): The Drugs and Cosmetics (Amendment) Bill, 2007 introduced in the Rajya Sabha on the 21st August, 2007 already contains the provisions for inter alia creation of a Central Drugs Authority and Centralised Licensing of Drugs.