GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:352
ANSWERED ON:03.12.2010
UNAPPROVED DRUGS VACCINES
Kumar Shri P.;Singh Shri Murarilal

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

(a) whether a number of unapproved Fixed Dose Combinations and drugs/vaccines including some anti-obesity drugs banned in Europe and anti-cervical cancer vaccines under examination are reportedly available in the market;

(b) if so, the details thereof alongwith the reasons therefor;

(c) the corrective measures takeiiy`proposed in this regard indicating the drugs examined and banned in the country` during the last three years and the current year;

(d) whether instances of State Drugs Controllers having allegedly exceeded their authority by issuing manufacturing licenses without prior approval of the Drugs Controller General (India) been reported;

(e) if so, the facts in this regard; and

(f) the action taken/proposed to be taken in the matter?

Answer

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

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

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 352 FOR 3RD DECEMBER, 2010

Some State Licensing Authorities (SLAs) have been granting licenses in the past for manufacturing of new Fixed Dose Combinations (FDCs) without the required approval from the Drugs Controller General (India) [DCG (I)]. These new FDCs are considered New Drugs under the provisions of the Drugs and Cosmetics Rules, 1945 and the SLAs are required to seek prior approval of the DCGÂ® before issuing licenses for them. The matter was deliberated and discussed with the SLAs by the DCG(I) on many occasions in different forums. The Ministry of Health & Family Welfare has also issued statutory directions under Section 33(P) of Drugs & Cosmetics Act, 1940, to all State Governments on 20.7.2000 and again on 6.5.2004, to advise their SLAs to refrain from issuing such manufacturing licenses without the mandatory approval from the DCG(I). Further, to introduce more clarity on the requirement of the written approval from Drugs Controller General (I) for all such products falling under the purview of New Drugs, Rule 71 and Rule 75 of the Drugs and Cosmetic Rules, 1945, were also amended in May, 2005.

In the year 2007, the office of DCG (I) prepared a list of 294 such FDCs which was communicated to the State Drugs Controllers on 14.8.2007 asking them to take necessary action with respect to these FDCs. However, some of the manufacturers` associations filed a writ petition in the Hon`ble High Court of Madras and obtained an order of stay dated 14.11.2007 against all further proceedings in the matter. The DCG (I) then issued a statutory direction vide his letter dated 28.11.2007 to all the State Drugs Controllers under the provisions of Section 33P of the Drugs and Cosmetics Act, 1940, asking them to comply with the decision taken in the meeting dated 26.10.2007 of the Drugs Consultative Committee, a statutory committee of Central and States` drugs regulators, including suspension of licenses of these FDCs under reference and also not to issue any further licenses for such drugs. However, the Hon`ble High Court of Madras again granted the stay by its order dated 4.12.2007 on the above direction. The matter is subjudice.

There is no report of any of unapproved drug formulation withdrawn / restricted in some foreign countries but available in the country. Similarly, there is no unapproved anti-cervical cancer vaccine reportedly available in the market.

Any drug prohibited under the provisions of the Drugs & Cosmetics Act, 1940, is not permitted to be imported, manufactured or sold in the country, which is punishable under the provisions of the said Act.