GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:3391
ANSWERED ON:29.07.2009
CENTRAL AUTONOMOUS REGULATORY BODY
Sule Supriya

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

(a) whether the proposal for Central Drug Authority has been shelved;

(b) if so, whether such proposal had been mooted earlier and Mashelkar Committee had also advocated for dynamic transporting system synchronizing with growing pharmaceutical medical devices and clinical trial segments;

(c) if so, the details thereof;

(d) whether a task force was set up for suggesting strategy for increasing exports of pharmaceuticals products; and

(e) if so, the main points submitted by the Committee and the extent to which the Government has considered/implemented them?

Answer

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

(a): No.

(b), (c) & (e): Government had constituted an expert committee under the Chairmanship of Dr. R.A. Mashelkar, DG, CSIR to review the drug regulatory system in the country and the problem of spurious drugs etc in 2003. The Mashelkar Committee recommended inter alia measures to strengthen the drug regulatory infrastructure in Centre and State including setting up of a National Drug Authority, specifically defining 'Medical Devices' and framing relevant rules and guidelines for their proper regulation, setting up of a specific Medical Devices Division, measures for safety of Indian study subjects in drug development including clinical research, assessing the extent of spurious and sub-standard drugs in the country and measures to deal with the problem, etc. In pursuance of the recommendations of the Mashelker Committee, the Drugs and Cosmetics Act, 1940 has already been amended by the Drugs and Cosmetics (Amendement) Act, 2008 to provide for inter alia stricter penalties for offences relating to spurious and sub standard drugs and making offences under the Drugs and Cosmetics Act cognizable and non-bailable, etc. Further, a Bill, namely, the Drugs and Cosmetics (Amendment) Bill, 2007 has been introduce in the Rajya Sabha on 21st August, 2007 with a view to inter alia creation of a Central Drugs Authority, specifically defining Medical Devices in the Drugs and Cosmetics Act, specific provisions for regulating clinical trials, etc.

(d): Yes. The Department of Commerce has constituted a Task Force on increasing export of pharmaceutical products. A Joint Working Group has also been set up by the Department of Pharmaceuticals for implementation of recommendations of the Task Force.