GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2632
ANSWERED ON:09.12.2011
USE OF PARACETAMOL/ACETAMINOPHEN
Vinay Kumar Alias Vinnu Shri

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

(a) whether the Government has taken note of some reports of severe liver injury or allergic reactions associated with the use of paracetamol/ acetaminophen containing products;

(b) if so, the details thereof;

(c) whether the Government proposes to limit the content of paracetamol not more than 325 mg. per tablet or capsule in the combination products and also print a statutory warning on the drug boxes;

(d) if so, the details thereof; and

(e) the mechanism put in place by the Government to ensure compliance of above norms in the letter and spirit in the country?

Answer

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

(a) & (b): Yes. Reports appeared that US Food and Drugs Administration, (USFDA) issued instructions to limit Paracetamol content to 325 mg in combination products to reduce risk of hepatotoxicity, in a period of 3 years in a phased manner.

(c) & (d): Yes. On the recommendation of Drug Technical Advisory Board (DTAB), instructions have been issued to State Licensing Authorities (SLAs) not to grant fresh license or renewal of the combination products of Paracetamol containing more than 325mg per tablet or capsule. Further, SLAs have been requested to ask the manufacturers to limit the Paracetamol contents in combination products to 325mg only in a period of 3 years and also to provide a box warning on the label of such combination products containing Paracetamol indicating that taking more than daily dose may cause serious liver damage or allergic reactions.

(e): The required mechanism already exists in the form of Central Drug Standard Control Organisation (CDSCO) and the Drug Controller Departments of the State/Union Territory Governments.