GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA

UNSTARRED QUESTION No. 319

TO BE ANSWERED ON THE 19TH July, 2016

Mechanism for Regulating Essential Drugs

319. SHRI RABINDRA KUMAR JENA:

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether the Government has any mechanism to check the manufacturing, sale and use of approximately 350 essential drugs in the country on the basis of a study conducted by an Expert Committee;
(b) if so, the details thereof and the reasons therefor;
(c) whether the ban imposed by the Government on illegal sale of essential drugs has been enforced country-wise; and
(d) if not, the reasons therefor?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF ROAD TRANSPORT AND HIGHWAYS; MINISTRY OF SHIPPING AND MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI MANSUKH L. MANDAVIYA)

(a): Yes, Madam.

(b): The Central Government appointed an Expert Committee to examine the matter of safety and efficacy of those Fixed Dose Combinations (FDCs) which have been granted license for manufacture without the permission of Drugs Controller General (India) (DCG(I)). The Committee was also assisted by eminent experts in different therapeutic areas from premier Medical Institutions and hospitals. The Expert Committee, after detailed examination and deliberations categorized these FDCs into four categories. One of these category is of those FDCs which have been declared as irrational by the Committee on account of

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their lack of therapeutic justification; pharmacokinetically or pharmacodynamically incompatiblity; abuse potential: or possibility of leading to antibiotic resistance in the population etc. The Expert Committee carried out a comprehensive review of the FDCs keeping in view the contemporary Scientific knowledge and expertise and on the basis of the recommendations of the Expert Committee, the Government examined the matter further and requested the Committee to provide specific reasons in respect of each FDC that was found irrational. The Committee, accordingly reviewed the matter further and finalized its recommendations. After careful consideration of the matter, the Government issued show cause notices to the manufacturers whose products were found to be irrational and submitted applications to CDSCO. At the request of the manufacturers, additional time of three months was given to them to respond to the show cause notice. Thereafter, after due consideration of the report and replies, the Government vide Gazette Notifications S.O. Nos. 705(E) to 1048(E) dated 10.03.2016 prohibited the manufacture for sale, sale and distribution for human use of 344 FDCs with immediate effect in public interest as these FDCs were likely to involve risk to human beings and safer alternatives were available to these drugs.

(c) & (d): Subsequent to the prohibition of 344 FDCs by the Central Government, many pharmaceuticals companies have filed various writ petitions in various courts. The matter is sub-judice.

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