

GOVERNMENT OF INDIA  
MINISTRY OF CHEMICALS AND FERTILIZERS  
DEPARTMENT OF PHARMACEUTICALS

**LOK SABHA**

**UNSTARRED QUESTION No. 1116**

**TO BE ANSWERED ON THE 22<sup>nd</sup> November, 2016**

**Drug Literature**

1116. SHRI KONDA VISHWESHWAR REDDY:

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

(a) whether it is mandatory for a drug manufacturer to provide drug literature along with their products and if so, the details thereof;

(b) whether the Government is aware of the fact that drug manufacturers have stopped providing drug literature along with their products and if so, the details thereof; and

(c) the action taken by the Government in this regard?:

**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. As per Schedule Y of Drugs and Cosmetics Act, 1940 and Rules, 1945, manufacturer of new drug is required to submit product literature as a part of new drug application for marketing. The drafts of label and carton texts should comply with the provisions of Rules, 96 and 97.

(b): No incidence of not providing product literature with their product has been reported to Central Drugs Standard Control Organization (CDSCO).

(c): In view of reply to (b) above, does not arise.

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