

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:3557

ANSWERED ON:14.12.2012

FIXED DOSE COMBINATIONS DRUGS

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

- (a) whether attention of the Government has been drawn to manufacturing and marketing of certain fixed dose combinations/drugs in certain parts of the country which have been prepared in an unscientific manner;
- (b) if so, the details thereof indicating the number of such cases which have come to the notice of the Government during each of the last three years and the current year, State/UT-wise;
- (c) the action taken/proposed by the Government against the offenders and also to check the recurrence of such cases;
- (d) whether the Government proposes certain amendments in the labelling of drugs keeping in mind that the majority of people do not understand English in which the price, expiry date and drug formulations are printed; and
- (e) if so, the details thereof and if not, the reasons therefor?

Answer

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

(a) to (c): Information pertaining to preparation of contain fixed dose combinations/drugs in an unscientific manner is not maintained centrally. However, a Statement containing the details of cases of new Fixed Dose Combinations (FDCs) licensed by State Licensing Authorities (SLAs) without the approval of the Drugs Controller General (India) [DCG(I)] is annexed. In all such cases the matter was taken up with the respective SLA. The State Licensing Authorities have been requested in the meetings of the Drugs Consultative Committee to ensure that New Drugs and FDCs without approval of DCG (I) should not be licensed. Further, on 1st October 2012, the Central Government issued directions under sections 33P of the Drugs and Cosmetics Act, 1940 to all State / UT Governments to instruct their respective drug licensing authorities to abide by the provisions prescribed under the Drugs and Cosmetics Rules in respect of grant of manufacturing licenses for the drugs falling under the definition of the term "New Drug" and not to grant licenses for manufacture for sale or for distribution or for export of such new drugs, except in accordance with the procedure laid down under the said rules i.e. without prior approval of the DCGI.

(d) & (e): There is no such proposal for amendments in Drugs and Cosmetics Rules in the labeling of drugs. The proposal of printing of labels and wrappers of drugs in other languages also in addition to English was discussed in the 34th meeting of the Drugs Consultative Committee held on 8-9 April, 2002. The Committee was not in favour of the proposal as same drugs are sold all over the country and to cater to the needs of every linguistic region, printing of labels in different languages will be needed.