

**GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA**

UNSTARRED QUESTION NO:2760
ANSWERED ON:09.12.2014
ADULTERATION IN COMPOSITION OF MEDICINES
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Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

- (a) the number of essential bulk drugs and their formulations with specified dosages already under price control;
- (b) the mechanisms put in place/ proposed to be put in place by the Government to deter the drug makers to avoid the price control regime by altering the composition of medicines; and
- (c) the present status of the formulation of New Drug Policy in the country?

Answer

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SHRI HANS RAJ GANGARAM AHIR)

- (a) There are 680 (628 net) drug formulations related to 348 bulk drugs/active pharmaceutical ingredients with specified dosages and strengths as listed in the National List of Essential Medicines (NLEM), 2011 and included in the First Schedule of Drug (Price Control) Order, 2013 (DPCO, 2013)
- (b) DPCO, 2013 provides that where an existing manufacturer of a drug of specified dosages and strengths as specified in the National List of Essential Medicines, 2011(NLEM), incorporated in the First Schedule of the said order launches a `new drug` by combining the drug with another drug either listed or not listed in the NLEM or a formulation launched by changing the strength or dosages or both of the same drug specified in the NLEM, such existing manufacturers are required to obtain prior price approval of such `new drug` under DPCO, 2013.
- (c) Pursuant to the announcement of National Pharmaceutical Pricing Policy (NPPP), 2012, the Government has notified DPCO, 2013 on 15.5.2013 in supersession of DPCO, 1995.