

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

UNSTARRED QUESTION NO:2161
ANSWERED ON:06.12.2012
ESSENTIAL DRUGS UNDER NLEM
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Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

- (a) the details and number of essential drugs covered under the National List of Essential Medicines (NLEM);
- (b) the year-wise coverage since 2005;
- (c) the market size of essential drugs which are not covered in the list so far in the country;
- (d) whether the Hon`ble Supreme Court in a directive had wanted the Government to formulate appropriate criteria to bring all essential and life-saving medicines under the price control;
- (e) if so, whether the drug regulator of the country National Pharmaceutical Pricing Authority (NPPA) is exploring the responsibility of invoking the `public interest` clause enshrined in the (Drug Prices Control) Order, 1995 to take charge in the pricing of these drugs; and
- (f) if so, the details thereof?

Answer

MINISTER OF STATE (INDEPENDENT CHARGE) OF THE MINISTRY OF STATISTICS AND PROGRAMME IMPLEMENTATION AND MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI SRIKANT KUMAR JENA)

- (a): National List of Essential Medicine (NLEM) 2011 includes 348 medicines, broadly categorized within 27 therapeutic categories such as antineoplastic, immunological, anti-infective cardiovascular, diuretics, anti allergic, ophthalmological preparation etc.
- (b): The National List of Essential Medicines(NLEM)-2003 which was having 354 drugs with 663 formulations was revised in 2011 as NLEM-2011 as stated in part (a) above.
- (c): The total Indian Pharma Market, as per IMS data as on March 2011, was Rs. 48, 239 crores (on price to retailer basis) and the market share of medicines as under National List of Essential Medicines-2011 was Rs. 10, 159 crores.
- (d): The Government announced the `Pharmaceutical Policy 2002` in February 2002. However, a public interest litigation filed in the High Court of Karnataka at Bangalore in WP No. 2168 of 2002 resulted in an Order dated 12-11-2002 which stopped the Government from implementing the price control regime of the Pharmaceutical Policy 2002. This Department filed a Special Leave Petition (SLP) before the Supreme Court of India against the Order of the Karnataka High Court. The Supreme Court vide its order dated 10.3.2003 directed the Government, inter-alia, that, `we suspend the operation of the order to the extent it directs that the Policy dated 15.2.2002 shall not be implemented. However we direct that the petitioner shall consider and formulate appropriate criteria for ensuring essential and life saving drugs not to fall out of the price control and further directed to review drugs, which are essential and life saving in nature till 2nd May, 2003`.
- (e) & (f): The National Pharmaceutical Pricing Authority (NPPA) monitors the prices of formulations regularly and wherever a price increase beyond 10% per annum is noticed, the manufacturer is asked to bring down the price voluntarily failing which, subject to prescribed conditions, action is initiated under paragraph 10(b) of the DPCO, 1995 for fixing the price of the formulation in public interest.