

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

UNSTARRED QUESTION NO:3539
ANSWERED ON:15.12.2011
DEVELOPMENT OF PATENTED MEDICINES
Patil Shri A.T. Nana

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

- (a) whether the production of a medicine patented in the country is banned as per the international law;
- (b) if so, the details thereof;
- (c) whether the development of generic medicines is likely to be affected adversely as a result thereof;
- (d) if so, the details thereof;
- (e) whether the Indian drug manufacturing companies are suffering losses due to the ban imposed on production of generic medicines;
- (f) if so, whether the Government is taking any other steps to control the prices of generic medicines; and
- (g) 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) & (b): As per the Article 33 of agreement on Trade Related Aspect of Intellectual Property Rights, the terms of protection available shall not end before the expiration of a period of twenty years counted from the filing date.

(c),(d),(e),(f) & (g): The generic producers are free to produce patented medicines on the expiry of the patent.

As per the exciting policy, National Pharmaceutical Pricing Authority (NPPA)/ Government fixes or revises prices of 74 scheduled drugs and formulations containing any of these bulk drugs as per the provisions of the Drugs (Prices Control) Order, 1995 (DPCO` 95). The bulk drug price is also taken into consideration while fixing/revising the prices of these schedule drugs/formulations. No person can sell any scheduled drug/formulation (medicine) of price controlled category to a consumer at a price exceeding the price notified/approved by the NPPA/Government.

In respect of drugs - not covered under the Drugs(Price Control) Order, 1995 i.e. non-scheduled drugs, manufactures fix the prices by themselves. As a part of price monitoring activity, NPPA regularly examines the movement in prices of non-scheduled formulations. The monthly report of ORG IMS(now renamed as IMS Health) and the information furnished by individual manufacturers are utilized for the purpose of monitoring prices of non-scheduled formulations. Wherever a price increase beyond 10% per annum is noticed, subject to prescribed conditions, the manufacturer is asked to bring down the price voluntarily failing which action is initiated under paragraph 10(b) of the DPCO, 1995 for fixing the price of the formulation in public interest. This is an ongoing process.