

**GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

LOK SABHA
UNSTARRED QUESTION No. 2391
TO BE ANSWERED ON THE 2nd January, 2018

Quality of Drugs

2391. DR. KIRIT P. SOLANKI:

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

- (a) whether the new pharmaceutical policy aims to address the quality concerns of indigenously manufactured drugs and if so, the details thereof;
- (b) whether the new policy aims to encourage the domestic manufacturing of drugs and if so, the details thereof; and
- (c) whether the new policy includes provisions to make drugs affordable and accessible and if so, the details thereof?

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): The draft National Pharmaceutical Policy aims to ensure world class quality of drugs for domestic consumption & exports. The draft policy addresses the issue of quality assurance of indigenously manufactured drugs by proposing a road map for effective Bio-availability and Bio-equivalence (BA/BE) implementation, inspection of manufacturing units through an accredited network of third party inspectors/agencies, ensuring World Health Organisation's Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) being adopted by all manufacturing units etc.

(b): The draft National Pharmaceutical Policy proposes to make India sufficiently self-reliant in end to end indigenous drug manufacturing. The various steps suggested in the draft policy in this regard inter alia include encouraging indigenous drug manufacturing by providing an enabling environment for setting up mega bulk drug parks where benefits of scale can be availed of by using common facilities for pollution control, effluent treatment etc.

(c): In order to make essential drugs accessible at affordable prices to the common masses the draft National Pharmaceutical Policy proposes various measures including encouragement for API industry, generic drug, e-pharmacy, trader margin reforms etc.

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