

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

UNSTARRED QUESTION NO:3715
ANSWERED ON:16.12.2011
SALE OF NICOTINE
Bishnoi Shri Kuldeep

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

- (a) whether highly toxic addictive drug Nicotine is being manufactured, stored, distributed and sold in the country outside the purview of Drugs and Cosmetics Act;
- (b) if so, the details thereof and the reasons therefor;
- (c) the steps taken/proposed by the Government, for sale of Nicotine on prescription;
- (d) whether the Government proposes mandatory labelling indicating amount of nicotine available in a product: and
- (e) if so, the details thereof?

Answer

THE MINISTER OF HEALTH & FAMILY WELFARE (SHRIGHULAM NABIAZAD)

(a)to(c): The manufacture and sale of nicotine formulations as a drug are regulated under the Drugs and Cosmetics Act, 1940. Nicotine based drug formulations can, therefore, be manufactured under a valid drug manufacturing license. However, sale of formulation of nicotine gum containing 2mg of nicotine only is exempted from the requirement, of a sale license under the Drugs and Cosmetics Rules. This exemption was provided as the nicotine gum is used as nicotine replacement therapy for smoking cessation. There is no proposal to withdraw this exemption.

(d) & (e): It is mandatory under the Drugs and Cosmetics Rules, 1945 to indicate contents of active ingredients on the label of drug formulations.