

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

UNSTARRED QUESTION NO:6050

ANSWERED ON:03.05.2013

REGISTRATION OF GENERIC DRUGS

Jagannath Dr. M.;Nagorao Shri Dudhgaonkar Ganeshrao

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

- (a) whether the Indian Pharmaceutical Alliance has urged the Government to ensure that registration of generic drugs does not get affected with their patent status;
- (b) if so, the details thereof along with the reaction of the Government thereto;
- (c) whether there are adequate provisions in the Drug and Cosmetics Act/ Rules to deal with the patent issues while granting approval of generic version of drugs in the country;
- (d) if so, the details thereof; and
- (e) if not, the corrective measures taken/ proposed by the Government in this regard?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABIAZAD)

(a) to (e) The Government is not aware of any request of Indian Pharmaceutical Alliance in this regard. However, registration / licensing of generic drugs does not have any linkage with their patent status because generic drugs are off-patent drugs. As the primary objective of the Drugs & Cosmetics Act, 1940 and the Drugs & Cosmetics Rules, 1945 made thereunder is to ensure the quality, efficacy and safety of any drug, they do not deal with the patent issues for which there is a different Act, namely the patents Act, 1970.