

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

UNSTARRED QUESTION NO:1933
ANSWERED ON:31.07.2015
Manufacturing of Anti-Diabetic Drugs
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

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- (a) whether 80 per cent of diabetic patients in the country belong to low and middle-income groups and over 80 per cent of diabetes deaths occur in developing countries like India, and if so, the details thereof;
- (b) whether the Government has received applications from the Indian drug manufacturers for grant of permission to manufacture certain costly anti-diabetic drugs including saxagliptin to bring down their cost in the country; and
- (c) if so, the details thereof along with the action taken/proposed to be taken by the Government thereon?

Answer

(a): Estimates of distribution of diabetic patients in India based on their income levels are not available. However, as per World Health Organisation (WHO) factsheet, more than 80% of diabetes deaths occur in low and middle income countries.

(b) & (c): Saxagliptin tablet 2.5mg/5mg was approved for import and marketing in the country on 26-10-2009. As per the Drugs & Cosmetic Rules 1945, after four years i.e. from 25-10-2013 onwards, this drug is no more a new drug and any manufacturer can obtain licence from the respective State Licensing Authority to manufacture and market the drug, without any approval/permission from Central Drugs Standard Control Organization (CDSCO). Therefore, application for manufacture of the drug is neither required to be filed with CDSCO nor it has been received in the recent past.

In addition, as informed by Drugs Controller General of India, details of the applications received from and permission granted to Indian Manufacturers during the years 2014 and 2015(till date) for manufacturing and marketing of Anti-Diabetic Drugs is at Annexure.