

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

UNSTARRED QUESTION NO:890

ANSWERED ON:24.07.2015

Quality of Indian Drugs

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

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

- (a) whether the Government has put in place any mechanism to ensure the safety, quality and efficacy of imported as well as domestically manufactured drugs which are being marketed across the country, and if so, the details thereof;
- (b) whether some countries have banned certain drugs being manufactured and exported from India recently;
- (c) if so, the details thereof and the reasons therefor along with the corrective measures taken/being taken by the Government in this regard;
- (d) whether some drugs reportedly banned by other countries are being imported, manufactured and sold in the country; and
- (e) if so, the details thereof and the reasons therefor along with the corrective measures taken/being taken by the Government in this regard?

Answer

(a): The Drugs and Cosmetics Act, 1940 and Rules made thereunder provide the mechanism for ensuring the safety, quality and efficacy of imported as well as domestically manufactured drugs. The import of drugs into the country is regulated by the Central Drugs Standard Control Organization (CDSCO), while the manufacture, sale and distribution of drugs are regulated by the State Licensing Authorities (SLAs) under the said Act and Rules.

(b) & (c): As per media reports, regulatory actions have been taken by the United States Food and Drugs Administration (USFDA) against a few Indian pharmaceutical companies in cases of non-conformance to USFDA requirements.

(d) & (e): Every country has its own system for evaluation of continued marketing of drugs. The marketing of a drug in a country, which is banned in another country, is decided based on the evaluation of disease pattern, reported side effects and overall safety and efficacy profile of the drug and availability of safer alternatives, etc. Certain drugs like Pioglitazone, Nimesulide and Analgin are banned in certain countries but are allowed to be marketed in India with some restrictions based on their evaluation in the country.