

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

UNSTARRED QUESTION NO:5212

ANSWERED ON:27.08.2010

SPURIOUS DRUGS

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

- (a) whether the International Medical Products Anti-counterfeiting Taskforce (IMPACT) constituted by World Health Organisation (WHO) has given any new definition of counterfeit medicines;
- (b) if so, the details thereof;
- (c) whether this new definition given by IMPACT for counterfeit medicine will adversely affect the generic medicines in India;
- (d) if so, the steps taken/being taken by the Government to protect Indian generic medicines;
- (e) if so, the details thereof;
- (f) the details of Whistle Blower Policy initiated by the Government to control the menace of spurious drugs and the success achieved thereby, State-wise; and
- (g) the details of schemes for making the essential medicines affordable to the common man?

**Answer**

THE MINISTER OF STATE FOR HEALTH & FAMILY WELFARE (SHRI DINESH TRIVEDI)

(a) to (e) The International Medical Product Anti-counterfeiting Taskforce (IMPACT) has defined counterfeit medicines thus:

"A medicinal product is counterfeit when there is a false representation in relation to its identity, history or source. This applies to the product, its container, packaging or other labelling information. Counterfeiting can apply to both branded and generic products. Counterfeits may include products with correct ingredients/components, with wrong ingredients/components, without active ingredients, with incorrect amounts of active ingredients or with fake packaging."

Based on the objections raised by the Member Countries on the role of IMPACT in restricting legitimate international trade in generic drugs, the 63rd World Health Assembly held in May, 2010 adopted a resolution on 'Substandard / spurious / falsely labeled / counterfeit medical products' for examining the role of WHO in ensuring availability of quality, safe, efficacious and affordable medical products, its relationship with IMPACT, its role in the prevention and control of counterfeit medical product excluding trade and intellectual property considerations.

(f): A Whistle Blower Scheme was initiated by the Government in 2009 to encourage vigilant public participation in the detection of movement of spurious drugs in the country. Under this scheme the informers would be suitably rewarded for providing concrete information in respect of movement of spurious drugs to the regulatory authorities. A reward of maximum up to 20% of the total cost of consignment seized will be payable to the informer not exceeding Rs. 25 lakhs in each case. The details of the Whistle Blowers / informers are to be kept secret. A total 30 complaints have been received from different zones of Central Drugs Standard Control Organisation till 31.07.2010. So far, no informer has been rewarded and no prosecution has been launched.

(g): For making available medicines at affordable prices, the Department of Pharmaceuticals has launched a campaign by the name of 'Jan Aushadhi'. The aim of this campaign is to ensure making available quality medicine at affordable prices for all, especially the poor and the disadvantaged. Under this campaign, low priced quality unbranded generic medicines are made available through Jan Aushadhi stores which inherently are less priced but are of same and equivalent quality, efficacy and safety as compared to branded generic medicines.