GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:3400
ANSWERED ON:01.08.2014
COUNTERFEIT MEDICAL PRODUCTS
Shinde Dr. Shrikant Eknath

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

(a) whether substandard, spurious,falsely labelled, falsified and counterfeit drugs are well defined and globally acceptedby the members of the World Health Organisation (WHO), if so, the detailsthereof and if not, the reasons therefor;

(b) whether the Government has takennote of seizure of Indian Generic Drugs insome European countries as counterfeitmedical products in the recent past forviolation of Intellectual Property Rights;

(c) if so, the details thereof and thereaction of the Government thereto;

(d) whether India has brought the matterbefore the WHO to put in place a globallyaccepted mechanism to define counterfeitmedical products and exclude them fromtrade and intellectual propertyconsiderations; and

(e) if so, the details thereof and theprogress made in this regard?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. HARSH VARDHAN)

(a): Substandard, spurious, falsely labelled, falsified and counterfeit drugs are defined differently in different countries.

(b) & (c): In the recent past, no case of seizure of Indian medicines in EU countries has been reported. However, in 2008, the Dutch Authorities detained certain pharmaceutical consignments in transit through the EU on the ground of product being counterfeit and infringing EC`s regulation 1383/2033. India and Brazil made a request to the Dispute Settlement body of the WHO on 11th and 12th May, 2010, respectively seeking consultation with the EU on the issue of detection of Indian generic medicines while in transit through the EU under the DSU mechanism of WHO (DS 408). Pursuant to consultation and subsequent discussions, the EU authorities issued guidelines in February, 2012 for the Customs Authorities to follow the same. Since then, there has been no case of seizure.

(d) & (e): As per the contribution from India and based on the recommendations from the Inter- Governmental Working Group on Substandard/ Spurious/ Falsely labelled/ Falsified/ Counterfeit (SSFFC) medical products, WHO in WHA 65.19 in May 2012, decided to establish a new 'Member StatesMechanism' for international collaboration on the issue among Member States, from a public health perspective, excluding trade and intellectual property considerationsinaccordance with the goals, objectives and terms of reference of the World Health Assembly resolution - WHA65.19, which is now established and functioning.