GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2104
ANSWERED ON:24.08.2012
COUNTERFEIT DRUGS
Angadi Shri Suresh Chanabasappa

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

(a) whether there is no uniformity on the constituents of a substandard, spurious, falsely labelled, falsified and counterfeit drug;

(b) if so, the facts in this regard;

(c) whether India has brought the matter before the World Health Organisation (WHO) to put in place a mechanism to define counterfeit medical products;

(d) if so, the details thereof;

(e) whether WHO has evolved any mechanism to define counterfeit drugs; and

(f) if so, the details thereof along with the benefits India can reap through such new mechanism?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD)

(a) to (e): World Health Organisation (WHO) had a defined counterfeit medicines in1992 as per WHO guidelines for development of measures to combat counterfeit drugs. However, due to seizure of Indian Generic Drugs at European Union Ports as counterfeit medical products for violation of Intellectual Property Rights and not for being substandard/spurious, India and other likeminded countries have raised objections regarding restrictions on trade in Generic Medicines leading to access and affordability issues in the rest of the world. Pursuant to 63rd World Health Assembly Resolution, a Working Group was established by WHO in June 2010 which recommended setting up of a Member State Mechanism to examine, from a public health perspective, excluding trade and intellectual property considerations, matters regarding Sub standard, Spurious, Falsely Labelled, Falsified and Counterfeit Medical Products.

(f): India, being a large exporter of good quality and affordable medical products to large number of countries, stands to gain through this mechanism.