

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

UNSTARRED QUESTION NO:1982
ANSWERED ON:08.03.2013
QUALITY OF IMPORTED DRUGS
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) the mechanism put in place by the Government to ensure the quality of drugs being imported in the country;
- (b) whether instances of import of spurious and sub-standard drugs have been reported in the country;
- (c) if so, the details thereof along with the action taken/proposed by the Government thereon during each of the last three years and the current year;
- (d) whether India has recently participated in an global discussion in Buenos Aires to frame an international treaty to prevent spurious drugs from reaching the market; and
- (e) if so, the details thereof and the stand taken by the Government on the matter?

Answer

THE MINISTER QF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABIAZAD)

(a) The quality of the drugs imported into the country is regulated under the provisions of the Drugs and Cosmetics Act, 1940 and Rules made thereunder, through a system of registration, import licence and checking of the consignments at the time of their import at the designated ports.

(b) The number of cases of import of spurious and sub-standard drugs which have come to the notice of the Government during the last three years and the

current year are given below:

Year	Spurious	Sub-standard
2009-2010	7	35
2010-2011	Nil	35
2011-2012	Nil	34
Current year	Nil	18

(c) Drugs found spurious and sub-standard are not permitted to be released for import by the customs authorities. The cases of import of spurious drugs in 2009-2010 were investigated by the Central Bureau of Investigation (CBI) and prosecutions launched on the basis of evidences available as per the provisions of law.

(d) Yes.

(e) The first meeting of the Member State Mechanism (MSM) on substandard/spurious/false- labeled/falsified/counterfeit (SSFFC) medical products met from 19 to 21 November 2012 in Buenos Aires. The meeting decided to establish an open-ended working group to identify the actions, activities and behaviours that result in SSFFC medical products. In order to actively participate in the working group, the Ministry of Health and Family Welfare set up a Cell comprising three experts in the Indian Pharmacopoeia Commission on 15 January 2013 to, address the issues pertaining to strengthening international cooperation for harmonisation of practices on SSFFC.