

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

STARRED QUESTION NO:112
ANSWERED ON:30.11.2005
USE OF BANNED CARDIAC STENTS
Masood Shri Rasheed

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

- (a) whether Cardiac stents which were banned by the manufacturers in foreign countries are being freely used in hospitals in the country as reported in The Navbharat Times dated July 27, 2005;
- (b) if so, the facts of the matter reported therein;
- (c) the steps being taken by the Government to stop the use of these stents in the country;
- (d) whether the Government proposes to enact law to check import of such stents in future; and
- (e) if not, the reasons therefor?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMADOSS)

(a) to (e): A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 112 FOR 30TH NOVEMBER , 2005.

According to the All India Institute of Medical Sciences, New Delhi, there are basically two broad categories of stents in use for coronary artery diseases - medicated and non-medicated. The stents referred in the question pertains to medicated stents - i.e. stents coated with drugs like rapamycin and paclitaxel which help to reduce incidence of restenosis. Two of these stents approved for commercial human use by FDA (USA) are cipher end Taxus made by J & J (Cordis) and Boston Scientific respectively. Besides these Stents, three other stents are being sold under CE mark in Europe. Rest of the medicated stents are neither FDA nor CE marked. However, they are not BANNED and are to be used under investigational category after proper approvals from competent authority.

The cardiac stents are used by the medical specialists on the basis of their experience and knowledge about their functional adequacy. In order to exercise control over certain medical devises of critical nature, the Government of India on 6.10.2005 has published a Gazette notification declaring certain sterile medical devices including cardiac stents as drugs under the Drugs & Cosmetics Act, 1940.