

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

STARRED QUESTION NO:153
ANSWERED ON:01.03.2006
SALE OF LOW GRADE/ SECOND HAND STENTS
Gandhi Smt. Maneka

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

- (a) whether low grade stents and second hand stents are being sold by foreign companies in the country;
- (b) whether there are any regulatory agencies looking into import and use of these medical items;
- (c) whether no agency conducts a health test of the stents imported into the country putting heart patients at grave risk;
- (d) if so, the details thereof; and
- (e) the steps taken/being taken by the Government in this regard?

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. 153 FOR 1ST MARCH, 2006.

A Stent is a small, lattice-shaped, metal tube that is inserted permanently into an artery. The stent helps hold open an artery so that blood can flow through it and is considered as medical device. Majority of such products are import based and are used by the medical specialists/Cardiac Surgeons on the basis of their experience in the use of the device and its functional adequacy. No specific complaints about the use of low grade or second hand stents from the surgeons using the device or the consumers have been received by the Drugs Controller General of India.

No separate mechanism to regulate the quality of such medical devices existed earlier. However, the Government have now widened the scope of Drugs and Cosmetics Act by notifying certain medical devices including Cardiac Stents as drugs for the purpose of exercising control over the import, manufacture and sale for these devices. Detailed guidelines have been drawn for initiating regulatory procedures for exercising control over their import, manufacture and conformity assessment.