

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

UNSTARRED QUESTION NO:51
ANSWERED ON:23.11.2005
MEDICAL DEVICES
Rao Shri Sambasiva Rayapati

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

- (a) whether the Government is planning to bring a large number of unregulated medical devices under the purview of the Drugs and Cosmetics Act;
- (b) if so, the details thereof and the reasons therefor ;
- (c) whether this would ensure import of quality devices like stents which are being increasingly used to treat heart patients ;
- (d) whether the CAG of India does not regulate import of these products , and
- (e) if so, the time by which the Government is likely to take a decision to regulate sale of medical devices?

Answer

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

(a) & (b) : The Government of India has notified the following Medical Devices under the purview of Drugs and Cosmetics Act, 1940 for exercising control over their quality.

1. Cardiac Stents.
2. Drug Eluting Stents.
3. Catheters.
4. Intra Ocular Lenses.
5. I.V. Cannula.
6. Bone Cements.
- 7 Heart Valves.
8. Scalp Vein Set.
9. Orthopedic Implants.
10. Internal Prosthetic replacements.

(c): The provisions under the Drugs and Cosmetics Act will ensure that devices imported and marketed in the country are of standard quality.

(d): Control over the quality of these devices will be exercised by the licensing authorities authorized under the said Act and not by CAG.

(e): Does not arise.