## GOVERNMENT OF INDIA MINISTRY OF HEALTH AND FAMILY WELFARE DEPARTMENT OF HEALTH AND FAMILY WELFARE

## RAJYA SABHA UNSTARRED QUESTION NO. 1868 TO BE ANSWERED ON 19<sup>TH</sup> DECEMBER, 2023

## IMPLANTATION OF SUB-STANDARD PACEMAKERS

1868: SHRI SANJAY RAUT:

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

- (a) whether Government's attention has been drawn towards the report about a cardiologist from a Government hospital in Uttar Pradesh, who allegedly implanted sub-standard pacemakers in his patients, while charging as much as nine times the cost of a standard one;
- (b) if so, the details thereof and Government's reaction thereto;
- (c) whether Government has received similar cases in the country during the last three years, if so, the details thereof; and
- (d) the details of steps taken or proposed to be taken by Government in this regard, particularly against the manufacturers of sub-standard and fake pacemakers in the country?

## ANSWER THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (DR. BHARATI PRAVIN PAWAR)

(a) to (d): Health is a State subject, hence it is the primary responsibility of the State/Union Territory (UT) Government to take appropriate steps to protect patients from instances of exploitation by health facilities.

Pacemakers are regulated under Medical Devices Rules, 2017 and it should conform to the standards laid down by the Bureau of Indian Standards. As and when such complaints are received, based on merit, the matter is taken up by the CDSCO in coordination with State/UT Drugs Controller for action as per the provisions of the Drugs & Cosmetics Act, 1940 and Medical Devices Rules, 2017.

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