

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

**LOK SABHA  
UNSTARRED QUESTION NO. 4094  
TO BE ANSWERED ON 04<sup>TH</sup> JANUARY, 2019**

**MEDICAL DEVICES**

**4094. SHRI ASHOK SHANKARRAO CHAVAN:  
SHRI SUDHEER GUPTA:  
KUNWAR HARIBANSH SINGH:  
SHRI S.R. VIJAYAKUMAR:**

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

- (a) whether India is the fourth largest medical devices market in Asia and if so, the details thereof;
- (b) whether it is fact that there are no specific rules or a law that allows the Government to direct a medical device company to give compensation to a victim after the device has been found faulty;
- (c) if so, the details thereof and the reasons therefor; and
- (d) the corrective measures taken/being taken by the Government in this regard?

**ANSWER  
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND  
FAMILY WELFARE  
(SHRI ASHWINI KUMAR CHOUBEY)**

(a): Yes. As informed by Department of Pharmaceuticals, a task force was constituted under the chairmanship of Secretary, Department of Pharmaceuticals and as per the report of the task force published in 2015, India is the 4<sup>th</sup> largest manufacturer of medical device in Asia. This report is available on the website of Department of Pharmaceuticals and they have not conducted any further study.

(b) to (d): Medical Device are regulated under Drugs and Cosmetic Act, 1940 and Medical Devices Rules 2017. Import, sale and manufacture of notified Medical devices are regulated as drugs under the provisions of the said Act & Rules. However, there is no specific provision in the said Act and Rules for compensation to a victim after the devices has been found faulty.

Drugs Technical Advisory Board (DTAB) in 81<sup>st</sup> meeting held on 29<sup>th</sup> November, 2018, has deliberated the issue for inclusion of provisions for compensation in case of injury or death due to any medical device found unsafe, malfunctioning etc., in Medical Devices Rules, 2017. The Board has decided on constitution of a Sub-Committee.