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

LOK SABHA
STARRED QUESTION NO. 254
TO BE ANSWERED ON THE 2ND DECEMBER, 2016
MEDICAL DEVICES

***254. SHRI R. GOPALAKRISHNAN:**

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

(a) whether the latest draft rules on medical devices notified by the Government have any deviations from globally accepted practices;

(b) if so, the details thereof and the reasons therefor;

(c) whether the Government has held consultations with the various stakeholders of the medical devices industry before finalising/issuing rules and if so, the details thereof; and

(d) the steps taken/being taken by the Government to benefit the beneficiaries as well as the industry?

ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(SHRI JAGAT PRAKASH NADDA)

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

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 254* FOR 2ND DECEMBER, 2016

(a) & (b):- The draft Medical Devices Rules, 2016 notified vide G.S.R 983 (E) dated 17.10.2016 are broadly based on International guidelines for regulation of Medical Devices, with appropriate modifications.

(c):- An initial draft of the Medical Devices Rules was published on the website of Central Drugs Standard Control Organisation (CDSCO) and shared with all stakeholders. The draft Rules were, thereafter published in the Gazette of India on 17.10.2016 giving a further time of 30 days for comments and suggestions. Comments and suggestions have since been received

(d):- The draft Rules have been published with the objective of ensuring quality, safety and performance of the regulated medical devices, which are imported or manufactured for sale and marketing in the country.

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