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

LOK SABHA
UNSTARRED QUESTION NO. 4603
TO BE ANSWERED ON 23RD MARCH, 2018

PHYSIOTHERAPY EQUIPMENTS

4603. SHRI SUNIL KUMAR SINGH:

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

(a) the procedure followed for issuing standardization certificate for electrical equipments used by physiotherapists and if so, the details thereof;

(b) whether there is any authority to examine/check the sale of defective/flawed/ malfunctioned physiotherapy equipments and if so, the details thereof; and

(c) whether any controlling/regulating authority is there to check the safety and infrastructure requirements of the various physiotherapy equipments along with the details of qualificational requirement of Members of the said authorities?

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

(a): Electronics Regional Test Laboratory (South), STQC Directorate under Ministry of Electronics and Information Technology (MeitY) issues certificate for electrical safety testing and calibration of Electro-medical Equipments. However, it has not been made mandatory.

Further, the Bureau of Indian Standards (BIS) has published standard "**IS 13450(Part 2/Sec 5): 2009/ IEC 60601-2-5:2005 Medical Electrical Equipment - Part 2: Particular requirement for the safety: Section 5 Ultrasonic physiotherapy equipment"**. As on date, no licence exist as per IS 13450 (Part 2/ Sec 5): 2009 /IEC 60601-2-5: 2005.

BIS grants a licence to use and apply Standard Mark on the product after verification of manufacturing and testing capability of the firm and ensuring the conformity of the product against relevant Indian Standard.

Contd…….

(b): There are two organisations to examine/ check the sale of defective/flawed/malfunctioned physiotherapy equipments. First comes under Department of Consumer Affairs which receives consumer complaints through National consumer helpline. Second is Indian Pharmacopoeia commission which receives adverse events associated with medical devices through Materiovigilance program of India.

(c): As per Medical Devices Rules, 2017, regulatory authority for all medical devices is Central Drugs Standard Control Organisation (CDSCO) under the Ministry of Health and Family Welfare. CDSCO regulates the Safety, Efficacy and Quality of 15 notified category of medical devices under the provisions of Drugs and Cosmetics Act, 1940 and Rules, 1945 made thereunder. However, Physiotherapy Equipment are not notified as Medical device under section 3(b)(iv) of Drugs and Cosmetics Act, 1940.

……..