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

**LOK SABHA**
**UNSTARRED QUESTION NO.1087**
**TO BE ANSWERED ON 22ND JULY, 2016**

**MEDICAL DEVICES AND MEDICINES**

**1087. SHRI SUDHEER GUPTA:**
**KUNWAR HARIBANSH SINGH:**
**DR. SUNIL BALIRAM GAIKWAD:**
**SHRI T. RADHAKRISHNAN:**
**SHRI GAJANAN KIRTIKAR:**
**SHRI S.R. VIJAYAKUMAR:**
**SHRI BIDYUT BARAN MAHATO:**
**SHRI ASHOK SHANKARRAO CHAVAN:**

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

(a) whether the high cost of imported medical devices due to higher import duty thereon making healthcare expensive and if so, the details thereof;

(b) whether the Government proposes to promote indigenous manufacturing of medical devices to reduce its high costs and if so, the details thereof and the action taken thereon;

(c) whether the Government has constituted/proposes to constitute a task force/committee to regulate price of patented medical devices and medicines and if so, the outcome thereof;

(d) whether the Government has put in place a mechanism to improve the quality of drugs/medicines and if so, the details thereof; and

(e) the extent to which said mechanism has enabled to maintain optimum drug quality?

**ANSWER**
**THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE**
**(SHRI FAGGAN SINGH KULASTE)**

(a): Levy of customs duty impacts the price of imported medical devices. It would, however not be correct to state that the prices of medical devices are higher solely due to such duty being levied. In case of life saving drugs and medical devices, the Department of Revenue exempts certain drugs and medical devices from customs duty based on the recommendation of the Department of Health and Family Welfare.

(b): Manufacture of medical devices in the country is an important component of the Action Plan in respect of pharmaceutical sector which is one of the identified sectors under 'Make in India'. In pursuance of this, a series of decisions including identifying suitable locations for Medical Device Parks and formulation of the National Medical Device Policy have been taken.

(c): Based on the report of the Core Committee on National List of Essential Medicines (NLEM), the Government has brought out NLEM, 2015. National Pharmaceutical Pricing Authority (NPPA) has also revised the Schedule under the Drugs Price Control Order (DPCO), 2013 to bring it in conformity with the new NLEM. Presently, there is no proposal with the Government to include all medical devices in the NLEM. However, the Committee set up to examine the essentiality of coronary stents has rendered its report. The recommendation of the Committee for inclusion of cardiac Stents in NLEM, 2015 has been accepted by the Government.

(d) & (e): The manufacturing, sale and distribution of drugs in the country is regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 thereunder through a system of licensing and inspection. Licenses for manufacture, sale and distribution of drugs are granted by the State Licensing Authorities (SLAs) appointed by respective State Governments. SLAs are legally empowered to take action against violations of any provision of the Act.

Further, the Government is committed to ensuring that the quality, safety and efficacy of drugs are not compromised. With this in view, and to check the marketing and manufacturing of spurious, adulterated, misbranded, sub-standard and expired drugs in the country, the Government has taken a series of measures. These include stringent penalties including making certain offences cognizable and non-bailable; establishment of special designated Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal of cases; announcement of a Whistle Blower Scheme to encourage vigilant public participation for detection of movement of spurious drugs in the country; issuance of guidelines to the State Drugs Controllers for taking action on samples of drugs declared spurious, adulterated, misbranded or 'not of standard quality'; maintaining a vigil and draw samples of drugs for test and analysis for monitoring the quality of drugs moving in the country; increase in the number of posts in Central Drugs Standard Control Organisation (CDSCO); re-equipping the drug testing laboratories with the state of the art equipment; large scale nation-wide survey to determine the 'not of standard quality' drugs; conducting workshops and training programmes for skill enhancement in areas such as Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), Good Distribution Practices (GDP), Good Clinical Practices (GCP) and Good Storage and Distribution Practices (GSP) to regulators and industry in partnership with other Departments, industry and regulators of other countries including USA and European Union. Several training programmes have also been conducted for laboratory personnel of State and Central Laboratories to upgrade their analytical capabilities and skill sets. The measures taken have helped in ensuring the quality, safety and efficacy of drugs manufactured in the country as also drugs imported into the Country.