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

LOK SABHA STARRED QUESTION NO.381 TO BE ANSWERED ON THE 12TH AUGUST, 2016 CORONARY STENTS UNDER NLEMS

*381. SHRI BIDYUT BARAN MAHATO: SHRI ANANDRAO ADSUL:

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

- (a) whether the Government has accepted and implemented the recommendations made by the sub-committee of expert cardiologists for inclusion of coronary stents under the National List of Essential Medicines (NLEMs) and if so, the details thereof along with the major recommendations made by the sub-committee;
- (b) whether the medical device industry has raised concern about the said move and if so, the details thereof along with the response of the Government thereto;
- (c) whether the inclusion of coronary stents under NLEMs would reduce the cost of the overall treatment procedure to the heart patients; and
- (d) if so, the details thereof along with the other steps taken/being taken by the Government to reduce the overall cost of procedures in the Government as well as private hospitals for heart patients?

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. 381* FOR 12TH AUGUST, 2016

- (a) The Ministry of Health and Family Welfare constituted a Sub-Committee of the Core Committee that reviewed the National List of Essential Medicines (NLEM), 2011 under the Chairmanship of Professor YK Gupta, Professor and Head, Department of Pharmacology, AIIMS, New Delhi on 15.10.2015 to examine issues relating to essentiality of coronary stents. After holding wide consultations with experts and stakeholders including manufacturers and industry associations and considering all relevant aspects, including economic issues, accessibility and affordability, the Sub-Committee, in its report, *inter alia*, recommended that coronary stents be included in NLEM and may be considered under following categories:
 - (i) Bare Metal Stents (BMS)
 - (ii) Drug Eluting Stents (DES)

The Sub-Committee further recommended that various incremental innovations in technology of the coronary stents may be considered for sub categorization if acceptable evidences are produced in terms of safety and benefits.

The Government, after examination of the report, has accepted the recommendations of the Sub-Committee and notified inclusion of stents in the NLEM on 19.7.2016.

- (b) Some representations have been received from the Medical Devices industry associations after inclusion of stents in the NLEM. The decision of the Government has been welcomed by some associations stating that it will enhance accessibility and affordability of medical devices. A few other associations have informed that the decision will stifle innovation and impede introduction of new stents in the country.
- (c) & (d) Inclusion of coronary stents in NLEM by itself does not reduce the cost of overall treatment procedure. However, once the National Pharmaceutical Pricing Authority (NPPA) regulates prices of stents under Drugs (Price Control) Order (DPCO), 2013, the prices are expected to go down.

The Ministry of Health and Family Welfare has further started AMRIT (Affordable Medicines and Reasonable Implants for Treatment) stores where essential life saving medicines and implants including stents are being provided at a substantial discount vis-à-vis the Maximum Retail Price.