

## **FICCI welcomes Department of Pharmaceutical's move towards broadbased stakeholder consultations**

**NEW DELHI, 24 August 2016:** The Department of Pharmaceuticals has involved hospitals and eminent clinicians, both from the Government and Private sectors in the important discussion on price control of coronary stents.

In this discussion on the subject of coronary stents' inclusion in NLEM (National List of Essential Medicine), several reputed clinicians emphasized on the fact that all Drug Eluting Stents (DES) cannot be considered the same. There is sufficient clinical evidence that generational improvements in DES through incremental innovation has resulted in improved patient outcomes in the form of reduced rate of thrombosis and restenosis reduction for instance, in addition to ease of deliverability thus improving overall safety and efficacy. The suggestion that all DES is similar puts Indian patients and medical care in significant quality disadvantage.

The reputed clinicians' experts present in the meeting have recommended to the Government to consider a DES classification norm through a matrix that involves such key performance parameters as:

- a. Type of drug
- b. Type of alloy
- c. Strut thickness
- d. Polymer profile
- e. Deliverability / Trackability
- f. Published safety & efficacy outcome data in publications of minimum impact factor of 2
- g. Global regulatory approvals

There was consensus amongst Clinicians, Government and Industry that an appropriate Scoring Matrix, with critical patient safety and efficacy parameters, should be designed to determine DES classification. Industry has requested the Government to follow up through a multi stakeholder determination workshop, involving reputed clinicians, to design the matrix before Government activates the pricing mechanism for stents in NLEM.

FICCI, which has always maintained that all DES cannot be considered same and submitted extensive evidence of that to the NLEM Expert Committee in the past, welcomes the Department of Pharmaceutical's latest move towards a science, safety and efficacy based DES price determination process.

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**FICCI Media Division**