Indian Medical Device Industry seeks Government's attention on upcoming Medical Device Rules 2016

NEW DELHI, 16 November 2016: As Industry associations prepare to submit a detailed representation of Medical Device Industry to the **Central Drugs Standard Control Organisation(CDSCO) and Ministry of Health & Family Welfare,** it has been a winding exercise for last six months involving all stakeholders through consultations over meetings, sharing of industry inputs and waiting for the final draft which was notified on 17 October 2016.

'The Medical device draft rules 2016 though broadly well drafted and aligned with global regulatory practices still leave few critical gaps on issues which were well discussed and deliberated upon but haven't been incorporated in the draft' said **Mr. Probir Das,** Chairman – FICCI Medical Device Forum.

Indian Med Tech Industry currently traversing the inflexion point of growth and value creation through Make in India, needs a scientifically well thought regulatory regime which embodies the essence of Industry growth and Patient safety in equal measure.

Industry experts say , measures to lift current restrictions on shelf life of medical devices are much needed to appreciate the usability of device and establish trust in manufacturers quality systems, these are imperatives to strengthen ease of doing business. On the same lines, redundant regulatory measures like requirement for having both accelerated and real time stability data and clinical investigation of medical devices already approved in GHTF countries must be waived off to facilitate use and reachability of medical devices to needy Indian population.

Attractiveness of a country's industrial sector also lies in the stability of policy decisions and countries are closely watched by global investors on that aspect, India should uphold the provisions of GSR 690E w.r.t the labelling requirements for import of medical devices in India.

Also said **Mr. Das,** '*Industry welcomes the implementation of UDI , however the strategy and timelines need to be well planned as It needs tremendous preparation in entire supply chain and should be explicitly clarified that it shall not be implemented with the notification of rules'*

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