Submission on the Drugs & Cosmetics (Amendment) Bill (dated December 31, 2014)
AMCHAM High-Level Recommendations

- **Global harmonization:** The Ministry must ensure that all the regulations for medical devices are harmonized with international best practices such as the International Organization for Standardization (ISO) and IMDRF. This effort would help medical device manufacturers achieve the highest standards of safety and efficacy, and also allow indigenous industry to become globally competitive. For example:
    - "**Manufacture**" should exclude any activities carried out for the sole purpose of research & development and India specific labeling requirements.
    - "**New medical device**" should be defined as a device which does not have a predicate device or a device that does not have a substantially equivalent device already approved by the Central Licensing Authority.

- **Risk-based approach:** *We recommend that CLA should adopt and mention a risk based classification based on GHTF guidance and include the following text in the body of Act in Section 7B with criteria to notify medical devices with higher risk devices to be notified first followed by lower risk medical devices. Medical devices shall be classified into the following four classes, in accordance with risk classification rules that will be stated later:*

  Class Risk Level
  A Low risk
  B Low-moderate risk
  C Moderate-high risk
  D High risk

- **Separate Section for Clinical Trials of Medical Devices and Performance Evaluation of IVDs within Chapter IA:** Currently, the proposed Bill has a chapter on clinical trials, which is common for drugs, devices and cosmetics. However, for the sake of patient safety, it is critical to understand the differences between drugs, IVDs and devices: each step in a medical device clinical trial uses different terminology (e.g. pivotal, pilot and feasibility trials); involves physician techniques and device modifications; and involves a different concept of "substantial equivalence". In light of these differences, the government must create a separate section for clinical trials of medical devices. It is also important to differentiate the clinical trials of medical devices from that of performance evaluation of IVDs. Therefore, it is recommended that the section on clinical trials of medical devices be consistent with the ISO 14155 and the section on clinical trials of IVDs be consistent with the GHTF document – **GHTF/SG5/N7-2012 – Title: Clinical Evidence for IVD medical devices**. We are concerned that the provisions as currently written could significantly limit the potential for clinical research in India. For the sake of patient confidentiality, the point of contact for disclosures related to clinical trials (Section 4-I) should be the investigators. We recommend ISO 14155 should be adopted for clinical investigation of Medical Devices and Performance Evaluation criteria for IVDs.

- **Implementation of the Bill:** The government must ensure that provisions are made for a fair and reasonable transition timeline for the industry to implement new changes. As a practical matter, there are thousands of types of medical devices, and it will take time for the regulatory staff to build resources and expertise to address them all. Therefore, an adequate transition time should be provided to create the requisite capacity and capability both in case of Industry as well as Regulators and **phased implementation** of the legislation over the period of 5 years should be provided for.

- **We request inclusion of following suggestions under Section 3 of the Act :**
    - **Notified Body -** *A notified body means a certification organization, notified by the Central Government as competent to carry out one or more of the conformity assessment procedures for medical devices and IVD devices as per the requirements mentioned in the Act.*
    - **Medical Device Control Officer:** The proposed Bill seeks to replace the word "Inspector" with "Drugs Control Officer" without defining Medical Device Officers. We request that the post of Medical Device Control Officer be created and defined in the Act as the efficient functioning of the Act needs medical device officers with domain knowledge.
    - **Central Medical Device Laboratory:** The proposed Bill defines a Central Drugs Laboratory without mentioning a Central Medical Devices Laboratory, which is recommended for specific medical device testing and analysis competency. We request that the Government set up Central Medical Device Laboratory and the same be defined in the Act.
    - **Medical Device Consultative Committee:** The proposed Bill defines a Drugs Consultative Committee that will also carry out the functions for Medical Devices. We request that a separate Medical Device Consultative Committee be created and defined in the Act. The composition and functions of this Medical Device Consultative Committee should also be defined.
    - **Medical Device Technical Advisory Board and the proposed Medical Device Consultative Committee:** Given the important role that manufacturers of imported medical devices play in supplying India patients with lifesaving medical technologies, we recommend that the Medical Devices Technical Advisory Board include several representatives of the imported medical device industry.
    - **Drugs, Cosmetics and Medical Devices Consultative Committee**: The stated composition of the Committee specifies that there should be two representatives of the Central Government and one of the State Government, without mandating the inclusion of experts from each field, for example, medical devices. Since the regulation of drugs and medical devices is highly technical and involves human life, the government should constitute three independent consultative committees with experts from the relevant areas.

- We recommend that the devices already approved by the CLA and currently marketed in India should be grandfathered once this Act is implemented and it should be understood that notified medical devices which are construed as drugs currently will be treated as registered medical devices in India.

- **Distinct recognition for In-Vitro Diagnostics:** Following adequate stakeholder consultation, the government should cover the IVD industry under a separate chapter in the Bill. IVDs being in-vitro, are very different from most drugs and devices which are in-vivo. Bringing the IVDs under the same stringent regulation as drugs and medical devices, would limit the industry's potential to grow.

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