AdvaMed
Advanced Medical Technology Association

AMCHAM
INDIA

16 April 2015

Dr. V K Subburaj (IAS)
Secretary
Department of Pharmaceuticals
Ministry of Chemicals and Fertilizers
Shastri Bhawan, New Delhi

Dear Dr. Subburaj,

The medical device industry is encouraged by your recognising the sector as a crucial and distinct pillar of our healthcare system and your insights into the challenges faced by the industry in the report on *Recommendations of the Task force on the Medical Devices Sector in India – 2015.*

As you know, medical devices are currently regulated under the same statute as pharmaceuticals and this has stood in the way of the industry's ability to effectively address the needs of Indian patients. We are particularly grateful for the DoP taskforce's unequivocal recommendation that the Drugs & Cosmetics (Amendment) bill 2015 be passed. We appreciate your support of a globally harmonised set of regulations for the sake of high quality and patient safety and believe that your endorsement of a risk based classification will go a long way in ensuring that various categories of medical devices will be regulated appropriately. Several recommendations proposed – creation of medical device parks, a single window clearance system, R&D centres, minimum/zero import duty on import of raw materials and manufacturing equipment – will help foster the fledgling medical device sector.

However, we are also deeply concerned about some of the taskforce's proposed measures that stand in the way of the medical device industry's ability to achieve its full potential:

- **Price Control for medical devices:**
  We believe that at a time when medical devices are on the verge of being differentiated in the Drugs and Cosmetics (Amendment) Act, it is sub-optimal and confusing to subject them to drug pricing rules and regulations. As you are aware, medical devices are an extremely diverse and complex group of products and very different from drugs in many ways including their composition, innovation cycle and in the way they manage the disease. Using a one-size-fits-all approach is likely to be counter-productive and detrimental to the industry's ability to ensure access, affordability and availability to all.

- **Taxes proportionate to MRPs / Labelling on MRPs for imports:**
  While for pharmaceuticals, pricing is a function of the product supplied, for medical devices pricing is a function of both the product and the services provided. Contrary to popular belief, most medical devices do in fact, have an MRP. However, for those where service costs such as that of supporting accessories, instruments, capital equipment and professional services need to be factored in, using MRPs has no precedence or relevance. It is considered inappropriate because by their very nature, they do not lend themselves to sale over retail counters. Moreover, for the sake of the

patient, our regulators must evolve a system, which recognises value as a function of both quality and cost.

- **Preferential treatment in government procurement to medical devices that are "made in India":**
  It will be impossible for both domestic and foreign manufacturers to 'Make in India' if the economy is restricted and prices are controlled. Manufacturing high-quality medical devices requires large investments of capital, R&D, technology transfer and skill development with long gestation periods. Giving preferential treatment to devices made in India must go hand in hand with evolution of the domestic industry in terms of sophistication, scale and quality over time to manufacture high-quality medical devices. The medical device industry in India is still at a nascent stage and giving early preferential treatment to domestic manufacturers may compromise on quality of medical devices and patient safety.

Please find attached for your reference a research based white paper highlighting the need to separate pricing policy for medical devices from that for drugs with the purpose of creating a robust healthcare sector – which meets the needs of India's patients.

We request your support in:

(i) **Recommending that medical devices not be included in the Ministry of Health's Committee's review of the revised National List of Essential Medicines (NLEM)**

(ii) **Keeping the medical device sector out of the NPPA's purview**

AdvaMed looks forward to every opportunity you may provide us to discuss this, including delivering an oral representation. Our members stand ready to work with regulators, and participate as full partners in India's effort to provide accessible and quality healthcare to its citizens.

Sincerely,

Sanjay Banerjee
Chair – India Working Group
AdvaMed

Prabal Chakraborty
Chair: Medical Devices Committee
American Chamber of Commerce in India