



14th July 2015

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

Dear Dr. Subburaj,

The Advanced Medical Technology Association (AdvaMed) and the American Chamber of Commerce in India (AmCham) congratulates the Department of Pharmaceuticals and the Ministry of Chemicals and Fertilizers on the release of the draft *National Medical Device Policy 2015* and welcome the opportunity to submit our comments on the draft policy. Overall, we are delighted that the government is taking significant steps to make health a fundamental right in India.

This release is a revolutionary milestone for the Medical Device Industry in India. In the past, medical devices had been left out of policy and public health discourse and the industry is now encouraged that the Government is keenly promoting research and development, innovation and manufacturing of medical devices in India.

As you are well aware, select categories of high-risk medical devices are currently regulated under the same statute as pharmaceuticals in India. The inappropriate regulation has always stood in the way of the industry's ability to effectively address the needs of Indian patients. We are particularly grateful for the DoP's continuing support in ensuring that the Drugs & Cosmetics (Amendment) bill 2015 is tabled in the Parliament at the soonest.

This well-intentioned Policy requires the robust support of a globally harmonised set of regulations for ensuring access of safe, high quality medical devices to Indian patients and also facilitating international exports of medical devices manufactured locally in India. The essence of 'Make in India' is to 'Make in India, for the World' and implementation of globally established Quality Standards will increase the competitiveness of the Indian Medical Device Industry globally.

We believe that your vision of creating a National Medical Device Authority that will provide a 'single window' for promotion of the medical device industry, will go a long way in ensuring that India becomes the hub of production and innovation in medical devices.

Several of the Policy's salient features – minimum/zero import duty on import of raw materials and manufacturing equipment, 10 years window for 200% weighted tax deduction on approved R&D expenditure, creation of benchmarks as per international best practices,

knowledge networks with Industry, support in commercialization of innovations, medical device parks– will help nurture the fledgling medical device sector.

On the other hand, we are also deeply concerned about the narrow scope of the draft Policy's Objective and some of the Salient Features that we believe would be counter-productive to the overall goal and intention of the National Medical Device Policy of India.

Policy Objective focussed on Make in India:

We believe that a National Medical Device Policy should be a comprehensive document addressing all stages of the life cycle of medical devices. While the body of the draft policy includes several very positive proposals for promoting Research and Development, Innovation, Exports promotion and others, the entire policy 'Objective' seems to focus only on Make in India and reducing dependence on Imports.

We propose that the Objective of Policy be reinforced as:

The National Medical Device Policy, 2015 has the objective of strengthening and supporting the medical device sector in India by -

- implementing globally harmonized regulations for medical devices
- promoting innovation and research in the field of medical devices
- focusing on the Make In India drive and thereby gradually reducing the dependence on imported medical devices and promoting export from India, with critical focus on making safe, high-quality, affordable medical devices accessible to all Indian Citizens.

Price Control for medical devices:

We are cognizant of the Government's objective in establishing price control of critical medical devices to ensure access, affordability and availability to Indian Patients. However, we are concerned that applying price control to medical devices in a manner identical to pharmaceuticals will not only be counter-productive and detrimental to the medical device industry but may also defeat the very noble objective of the Government. This is because, unlike pharmaceuticals, critical medical devices are not sold by retail or purchased by the patient. The healthcare practitioners, hospitals and healthcare providers play a major role in controlling the cost of the device to the patient and a balanced approach involving multiple stakeholders needs to be implemented in order to make healthcare affordable.

Preference in government procurement to medical devices that are "Made in India":

We have great faith that the government is creating a conducive environment for both foreign and domestic manufacturers and believe that it will be impossible for the 'Make in India' initiative to be successful 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. In order to promote the deserved incentivization for the innovation, we propose the tiered pricing/reimbursement model, wherein incremental innovation and radical innovation are rewarded appropriately. Different stakeholders make significant investments in developing new technologies & improving patient access; evidence based reimbursement & pricing



policies will create enough opportunity to provide an appropriate return on investment for all stakeholders.

AdvaMed and AmCham respectfully submit the enclosed detailed comments on the proposed policy. Our inputs are guided by the global experience of our member companies, which range from the largest to the smallest medical technology innovators, producing over 40 per cent of the healthcare technology that is utilised annually across the world.

Sincerely,

A handwritten signature in blue ink, appearing to read "Sanjay Banerjee", written over a light blue grid background.

Sanjay Banerjee
Chair – India Working Group
AdvaMed

A handwritten signature in blue ink, appearing to read "Prabal Chakraborty", written over a light blue grid background.

Prabal Chakraborty
Chair-Medical Devices Committee
AmCham

Enclosed: Recommendations Matrix