

Medical devices parks get ready to race

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As three states - Andhra Pradesh, Maharashtra and Gujarat - are racing ahead to establish exclusive world class medical device manufacturing parks, Association of Indian Medical Device Industry (AIMED), the apex body of medical device manufactures in the country has recommended eight key policy measures which must be rolled out to ensure the financial viability of these parks as well as to make India a super international hub for medical device manufacturing.

AIMED recommendations range from tariff corrections to a new regulatory regime. Specifically AIMED has urged the government both at the Centre and states to ensure the following:

(i) A separate Medical Device Regulatory Act and separate Rules with IHPRA - Indian Healthcare Products Regulatory Authority rather than proposed ongoing amendment to D&C Act with compliance audits by 3rd party certification and have a mandatory compliance and regulatory framework built on soon to be launched QCI certification to ensure Patient Safety.

(ii) A medical device export promotion and India's first Import substitution council - MEDISEXPC

(iii) A dept for Medical Devices, a Separate Ministry for Healthcare products to act as facilitator and regulator and coordinated plan between Central Government and State Governments to aid existing manufacturing clusters and new medical device parks.

(iv) Continued tariff correction to enable business viability.

(v) MRP based tax as disincentive for high MRP to ensure consumer protection.

(vi) Launch of a voluntary ICMED 13485 certification by QCI for enabling doctors and procurement agencies to have

confidence in good quality medical devices.

(vii) A 'Buy Indian' preferred market access policy for those manufacturers who have ICMED certification.

(viii) A 15 percent preferential pricing online of World Bank and WHO tenders to support domestic manufacturers and counter 17 percent subsidy from China.

"These policy rollouts would reduce our humungous import dependency quickly, create vibrant manufacturing eco-system and generate lakhs of high-value jobs within the country, something which we all want," said Mr Rajiv Nath, forum coordinator of AIMED.

Mr Nath added that these policies are a must to make India a super global hub for medical device manufacturing and to boost up PM Modi's 'Make in India' vision.

It may be known that the country has been struggling to reduce its heavy import dependency in a sector which is a critical component of national healthcare security. Besides, the high import dependency in this sector has been a stress point on country's foreign exchange situation as well as depriving high-value employment creation within the country. Currently, the medical device industry is estimated to be of Rs 30000 crore size with over 70 percent import dependency and nearly 90 percent import dependency in high-end electronic medical devices.

The market at retail and institutional sale is expected to grow to over Rs 2,00,000 lakh crore by 2020. Thus if domestic manufacturing is not boosted, it will create multi-dimensional macro-economic and social security problems. Medical device was also among the top five priority sectors as part 'Make in India' roll out program.

The government at the Centre has taken some appreciable measures to rekindle domestic manufacturing but certain critical policy and regulatory support are still not in place to translate good intentions into ground reality. Accordign to AIMED, these 8-point recommendations will go a long way to fill the gaps and vitalize the medical device manufacturing.

AIMED has also submitted these recommendations to Shri Chandrababu Naidu, Chief Minister of Andhra Pradesh during their recent meeting with him in relation with the exclusive medical device park coming up in the state, with a request to use his good office and good relations with the Centre to work upon these recommendations to PM Modi.

"I am all thankful to Shri Chandrababu Naidu for not only taking the lead in setting up country's first medical device park but also for assuring us that he will utilize his good office to ensure the success of medical device manufacturing by taking up industry's concerns at the appropriate platform," said Mr Nath.

On behalf of industry, Mr Nath has also expressed his heartfelt thanks to Dr Jitendar Sharma, Advisor to AP Govt on Health & Medical Technology and also the head of Technology Division of NHSRC, Ministry of Health & Family Welfare, GOI for his proactive support for ensuring smooth setting of medical device park in the state having common manufacturing facilities to reduce capital expenditure for their project and offer low cost rentals and revenue support services to enable these units to be Competitive instead of the usual capital subsidy model .