Manufacturing India specific medical devices will increase cost to patient, deliberates MTaI board

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New Delhi: At a board meeting on 20th December 2016, the members of the Medical Technology Association of India (MTaI) discussed the forecast for 2017 for the medical devices industry in India. While the Government has made progress in many directions, the board thinks, logjams on some key issues pertaining to the industry at the policy level are likely to do irreparable damages that will ultimately create repercussions for patients.

Deliberations at meeting, underscored some key areas that need immediate attention from the Government. The viewpoints of its various prominent members on burning issues relevant to medical technology industry in India was highlighted during the course of discussions which was released to media by MTaI in a detailed press release.

Medical Devices Rules

Sushobhan Dasgupta, Managing Director, Johnson & Johnson Medical and MTaI founding member said, “The move towards creating a separate draft policy on medical devices, the fact that the Government has taken notice that devices are different from drugs, is a very welcome change and much appreciated by the industry. Having said that there are some rules that need further amendments. The first being the 5 year cap on shelf life of medical devices. Here we would like to highlight that devices unlike drugs (which are chemical entities) are more stable and hence restricting

the shelf life of devices to 5 years will not be suitable especially the devices made of stable metals. The reason given is that restriction of shelf life is required for 'Indian conditions', whereas even more underdeveloped continents like Africa, where the 'conditions' are similar or worse as compared to India do not have such a restriction. Since 2006 devices which are regulated are available in the country with a 10 year shelf life. Hence there is no scientific data to backup the 'Indian conditions' claim. However we manufacturers claim 10 years shelf life based on stability data. For those devices where a shelf life of 10 years is globally accepted, there is no reason to restrict shelf life to 5 years."

"The most important question to ask here is that – 'Whose responsibility is it to ensure that the right storage conditions and the right logistical facilities etc are maintained?' – It is the responsibility of the law enforcer, which is the Ministry of Health and its regulating agencies, which have done some path breaking work in the current regime. We request the regulator to keep its bar high for Medical Devices too by ensuring better compliance to storage norms and not penalize the medical devices industry for any short falls in their own work" said Pavan Choudary, Director General, MTaI.

"Second issue to be highlighted is labelling. We have been informed that the gazette notification 690E in 2014 (which was arrived at after a detailed and nuanced study done by the Government with the objective of maintaining uninterrupted supply of critical care products) all medical devices were allowed to label manufacturing date and physical manufacturer's address prior to distribution in India. To re-iterate the main observations which made the Government arrive at GSR 690E were that mandating pre-printing the country specific requirements and restrictions on shelf life, manufacturing date over and above globally established representations to this effect will lead to India specific production which will significantly increase the cost of the device, in turn cost to patient and most importantly will also lead to issues of availability of the products in Indian market, impacting the healthcare delivery in the country. We, as stakeholders, as an industry, are trying to be a part of the Government's vision of affordable, assessable healthcare for all and we are relieved that Government plans to abide by the sanctity of GSE 690E" added Sushobhan

"Another rule mentioned by CDSCO is the implementation of UDI (Unique Device Identifier) for medical devices, a regulation that is being rolled-out in a stage-wise process in both the US and EU as per the classification of the device. Hence, asking every medical device to have a UDI from 2017 in India is not feasible as the companies will not be in a position to do so only for India. It would force upon manufacturers to India specific line which will really take the cost of treatment high," said Probir Das, Managing Director, Terumo India and MTaI Founder Member.

Custom duty on medical devices

"The import duties on medical devices and equipments have been increased almost across the board by 7.3 percent. Since most of the items affected were falling in the 11.6 percent range which has gone to 18.9 percent now, it means an effective duty increase of 62.7 percent. We would like to highlight the fact that import duties could indeed have been moderately increased (if benchmarking studies or precedent analysis of other countries showed that such a move would further the Make in India program) only for those sub sectors or product categories where a high level of import substitution of an acceptable quality has been obtained or can be obtained quickly. However, this steep custom duty increase has been slapped on almost all sub-sectors/product categories of the medical technology sector irrespective of level or possibility of import substitution in the near term. We wish to underscore that this custom duty increase for most part are only increasing the burden on the patient," said Pavan Choudary, Director General, MTaI and Managing Director, Vygon India

Presented below are factors which have promoted indigenous manufacturing of medical devices through a cross study of many countries and these are:

- Taxation policy (Corporate Tax) e.g. Ireland, Switzerland, Puerto Rico. Please note that all the three countries have a nil duty on medical devices.
- Work Force e.g. Great Britain
- Large market size e.g. USA
- Market size (+ our accent Proximity to large markets & a heritage of well-developed technological eco systems) e.g. Germany
- Advantageous geographical locations (+ our accent – Highly developed Infrastructure and logistical capability) helping country emerge as distribution hub e.g. Singapore – Research and Development e.g. Israel
- Local low cost e.g. Mexico

Pavan added, “When we look at these factors above, one concludes that it will be a process of incentivization, R&D, Skill Development, better infrastructure, catalysed evolution of the technological eco systems, greater health expenditure or better insurance penetration, simplified regulatory regime, greater ease of doing business which will benefit the cause of Make in India rather than custom duty increase. Custom duties for most part are only increasing the burden on the patient. Moreover, since the custom duty regime in the neighbouring countries like (Nepal, Bangladesh, Sri Lanka, Bhutan, Pakistan & Maldives) is now much lower than in India, the differential in duties created is likely to lead to the smuggling of many of these low-bulk-high-value devices. If that happens not only will the Government lose revenue but also the patient will be beset with products without adequate legal & service guarantees.”

MTaI has a huge and wide spread manufacturing foot print in India as it has among its members companies like, Johnson & Johnson, B Braun, Smith & Nephew, Terumo just to name a few. It has a strong foot print in the R&D and in the Health Care worker training space too.

GST for medical devices

As mentioned above, the government significantly increased import duties on medical devices in 2016. With more than 70 percent of medical devices demand supported by imports, this move will only hike the healthcare cost in India. “In the larger interest of healthcare service, Government should keenly interact with all players (Hospitals, pharmaceutical medical device manufactures and importers etc.) in this sector and understand their views on GST such as not to lose sight of its mission of growing the depth, breadth and size of healthcare that will make this available to all at affordable cost,” said Sanjay Bhutani, Managing Director, Bausch & Lomb, India & SAARC and a MTaI founder member

“Currently, the healthcare services are exempt from service tax. In its objective to encourage coverage of medical services, these could be exempt from GST as well. However, it is recommended that these services are zero rated, i.e., the healthcare operators should be allowed to take credit of the GST paid on inputs and claim refund for the same, just like exporters. Otherwise, while the service is not taxed, the input cost for service provider is already high which would eventually result in increased prices. This change therefore will address any inflationary effect of GST on this priority sector. Medical devices, similarly, should have cost neutral effect post GST roll out (as noted before, the costs have already gone up for imports). Presently, there is a favourable low VAT regime of 5 percent. Considering that it is a preferred sector for Government where they are keen to invite private

investment to help bridge the gulf between demand and supply, so as to create a world class medical infrastructure that delivers at competitive cost. This would promote medical tourism and help to bring in precious foreign exchange. There is lot of ground to cover and the industry is at a nascent stage compared to the goalpost it purports to reach. It is therefore most important that during implementation of GST, interests of this sector are duly protected. The Government while fixing GST rates, should ensure lower rates for Medical Devices as this would help to keep the overall healthcare costs low. As per economic analysis there is a significant private spending on healthcare (>80%) and any increase in cascading effect of high GST would result making this dearer to the masses. It is recommended that this sector should be accorded status of essential goods and taxed if not ‘zero percent’, maximum at 5 percent,” added Sanjay.