BioSpectrum the business of Bio & Health Sciences

AiMeD responds to the recent industry investigation

28 November 2018 | News

The number of cases of a medical device implant going wrong in a patient have increased from 40 in 2014 to 556 in 2018.

Rajiv Nath, Forum Coordinator of Association of Indian Medical Device Industry (AiMeD) responded on the recent investigation into the Indian medical devices industry which has revealed a number of serious problems, including companies lobbying and bribing doctors, and patients being duped into unnecessary operations. It has revealed some glaring loopholes in the regulatory framework that governs the medical devices industry.

Global majors Medtronic and Stryker, Abbott and Bayer, all operating in a regulatory regime where there is no oversight for medical devices — either for their quality, clinical testing, pricing or performance.

It has been found that from coronary stents and pacemakers to breast and knee implants, from pelvic meshes to intrauterine devices — almost every medical device is advertised, sold, surgically implanted in a regulatory system that, effectively, doesn't exist.

India's medical device industry is estimated to be worth $5.2 billion – the fourth largest in Asia. The market at retail and institutional level is estimated to be over Rs. 10000 Cr.

The number of cases of a medical device implant going wrong in a patient have increased from 40 in 2014 to 556 in 2018.

Rajiv Nath responded - "It was a big shocker. Even though we were expecting bad news but when I went through the story, even I was shocked by what has been happening internationally and also in India."

This year the government did introduce a separate medical device rulebook but it is still under the existing drug act which is a misfit, Nath said, adding that two years back we were promised that a separate act will be coming out but we have not seen any consultation with stakeholders on the draft that was created by the ministry of health.

Did u know it's challenging for a new start up / entrepreneur to get his medical devices used by a surgeon in India as

Surgeons if unsure of quality in absence of a Quality Certification or Regulatory Approval will not even try it - understandably so.

Only 23 out of over 5000 categories of devices are regulated and that also incorrectly as a Drug.

Government needs to regulate all kinds of devices at one go with a defined transition period. If Govt is reluctant that it's going to harm industry especially MSME and manufacturing may suffer then Govt needs to consider a phased in calibrated approach of initially incentivising Voluntary QA ICMED certification by QCI to enable capacity building of MSME and then in next phase pass Quality Control order under BIS Act to make certain provisions in the Medical Devices Rules mandatory for all medical devices manufacturers and imports .

As ICMED is voluntary it needs to be incentivized by giving preference in public health care procurement instead of seeking USFDA & CE Regulatory approvals which are beyond reach of a start up or most entrepreneurs.

Finally we do need a separate law for medical Devices and need to initiate that ASAP as the legislative process is lengthy.

Right now Govt. even does not know who makes what and how many manufacturers are there in India.

Ayushman Bharat will take care of the needy 1/3 of Indian population with nil or near nil income What about the middle class ? For them to afford healthcare at reasonable costs we need regulations of Healthcare & Medical Devices and caps on Trade Markups and a strong ethical marketing watchdog. No?

As an Association that encourages responsible manufactures we have consistently lobbied and requested GoI Dept for above with initial supportive response and then a confused stalemate as the Govt. conferred with the ones who are not interested in such regulations.

Does India need a calibrated approach to regulations to clean up the market and address the problem of over 1000-2000% mark up being charged on medical devices?

With elections coming, healthcare and affordable access is going to be a major issue and public will not be happy if the governments at Centre or at states continue to ignore the issue that's looting the common man and harming the ethical manufacturers and forcing them to market their products unethically.

Government listens to us and is supportive initially but consults importers who don't want loss of their share and end up confusing government into an inaction stalemate.