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# Drugs and cosmetics amendment bill must consider stakeholder views, urges medical device industry

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With the winter session of Parliament approaching, the Advance Medical technology Association (AdvaMed) along with other representatives of the medical device industry has urged the Parliamentary Standing Committee on Health and Family Welfare to consider their recommendations for the Drugs & Cosmetic (Amendment) Bill 2013 so that the benefits of the bill can result in faster and safer solutions for Indian patients and more investments for the country.Â

The various organisations and trade bodies in their submissions have made detailed recommendations which should be considered when the Bill is passed, which could otherwise pose the risk of shortchanging the potential benefits medical device industry can bring to the country.

India has traditionally had an overwhelming burden of communicable diseases, but non-communicable diseases (NCDs) are fast emerging to be the country's next public health challenge. The World Health Organization, NCD Country Profiles, 2011 states that more than 53% of total deaths every year in India are due to NCDs and by 2020, over 60 million Indians will succumb to them. Medical devices play an increasingly critical role in the diagnosis and management of NCDs. As India strives to provide universal health facilities to its citizens, medical technology will become an even more integral part of the country's public health system as these help in the diagnosis and management of complex non-communicable diseases, thereby alleviating pain, restoring health and extending life of the people. However, in its present form, there are some significant aspects of the Bill that could stifle this enthusiasm even before the potential and utility of medical technology can be fully realized.

AdvaMed in its submission has suggested that all the regulations for medical devices are harmonised with international best practices such as the International Organization for Standardization (ISO) and International Medical Device Regulators Forum (IMDRF), so that medical device manufacturers achieve the highest standards of safety and efficacy and also become globally competitive. The suggestions also highlight adoption of risk based approach to ensure timely access to medical technology and revision of provisions related to clinical trials to maintain highest ethical standards.

Ms. Abby Pratt, Associate Vice President, Global Strategy & Analysis at AdvaMed states, "The medical device industry is encouraged by the Bill for recognizing medical devices as a separate and critical element of the Indian healthcare delivery system, and believes that the Bill will improve the industry's ability to serve India's growing healthcare needs in a safe, effective and timely manner. We congratulate the government for introducing the bill and thank the Parliamentary Standing Committee for soliciting our suggestions. AdvaMed and its member companies stand ready to participate as full partners in India's effort to improve the quality of life for all its citizens".

Currently, the industry is concerned about the lack of standardisation in line with global best practices like the Global Harmonization Task Force (GHTF) and the IMDRF. Some of the penal provisions as defined in the Bill, where even minor violations attract severe penal action often disproportionate to the nature or severity of the crime, are not in line with international practices. The Bill also needs to clarify the terms 'manufacture' and 'manufacturer', as appropriate to medical

devices (Presently, the same definitions as applicable to drugs have been used for devices.)

At a broader level, the Bill recognizes the fact that medical devices are different from drugs, but the distinction needs to be carried to the last mile. In keeping with the proactive spirit of introducing the Bill, the industry is hopeful that adequate consideration and deliberation will take place ahead of the passing of the Bill, and that it can contribute meaningfully to the formulation of the Bill.