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# AdvaMed welcomes health ministry's desire to treat medical devices differently

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The Advanced Medical Technology Association (AdvaMed), along with other representatives of the global medical device industry, urged India's Parliamentary Standing Committee on Health and Family Welfare to consider important modifications to the country's Drugs & Cosmetics (Amendment) Bill 2013 to help ensure important benefits of the legislation, including more timely patient access to safe and effective medical treatments and cures for India's patients, and greater access to needed capital for the country's medical technology entrepreneurs and innovators.

The Committee's recommendations, which were tabled in Parliament in December 2013, are currently being examined by the Ministry of Health and Family Welfare. On Feb. 9, Abu Hasem Khan Choudhury, Minister of State for Health and Family Welfare, emphasised the need to ensure that there is sufficient dialogue with stakeholders before submission of the revised bill. AdvaMed welcomes the Ministry's resolve on this issue.

Referring to the concerns of the medical device industry, Choudhury said, "Medical devices and drugs are very different and we want to ensure that the distinction in their regulation is taken to the last mile." He also added, "For the bill to have maximum impact, it is important for us to consider the views of other ministries, the industry and the civil society. We do not wish to hastily push forward a draft Bill without listening to the views of all stakeholders." The minister stated that, once finalised, the Bill would ensure the highest standards of safety and efficacy.

"The medical device industry welcomes the ministry's recognition of the critical need to differentiate medical devices from pharmaceutical products in the regulatory structure, and as a vital element of the Indian health care delivery system," said Ralph Ives, Executive Vice President, Global Strategy and Analysis at AdvaMed. "We believe the revised Bill will improve industry's ability to serve India's growing health care needs in a safe, effective and timely manner. We commend and appreciate the government's willingness to consult with all stakeholders on this very important legislation," Ives said.

The Drugs and Cosmetics (Amendment) Bill 2013 proposes changes in the regulation of the import, export, manufacture, distribution and sale of drugs, cosmetics and medical devices, including measures to ensure product safety, efficacy and quality in clinical trials. Introduced in the Rajya Sabha in August last year, the Bill was later referred to the Standing Committee. The Bill is significant because it recognises medical devices as distinct from pharmaceuticals for the first time and brings needed clarity to device regulation. Consideration of concerns from all stakeholders will help address India's health care challenges while ensuring maximum benefit for patients and the healthcare system.