AdvaMed
Advanced Medical Technology Association

AMCHAM INDIA

12th February, 2016

Sh. R. G Singh
Under Secretary
Ministry of Health & Family Welfare
Government of India
Nirman Bhawan

Dear Sir,

**Subject: Feedback on draft Gazette notification G.S.R.1011(E) and request for a meeting**

The Advanced Medical Technology Association (AdvaMed) and the American Chamber of Commerce in India (AmCham India) would like to thank the Government of India for the opportunity to comment on draft notification G.S.R 1011(E) published by the Ministry of Health & Family Welfare on the Central Drugs Standard Control Organization's (CDSCO) website.

On behalf of members of AdvaMed and AmCham, we wish to point out serious concerns with the government's proposal to increase the registration fees for critical lifesaving products. We feel that this move could have serious implications for a sector that is at a nascent stage and poised to grow at a CAGR of 10-15% over the next several years. In addition, there has been a 50% increase in the cost of product registrations from 2003 rates due to exchange rate fluctuations. Given this situation, AmCham and AdvaMed strongly urge the government to reconsider its proposal and maintain the current level of registration fees for medical devices. We appreciate the consultative approach that the government has taken in the past and involving all stakeholders and therefore, request for an opportunity to discuss this fee increase proposal with relevant officials in the Ministry before any decision is finalized.

Based on our industry's experience with fee systems all over the world, we would like to share best practices in which, fee increases are linked to improvements in regulator capacity. On behalf of both organizations, we request the government to kindly consider the following specific recommendations:

- Based on global experiences, an effective fee structure must include (1) a clear methodology for determining fees that is fully transparent and non-discriminatory; (2) assurances that revenue from fees should be applied directly to increasing regulatory capacity; and (3) assurances that increases in fees should will be commensurate with commitments to make tangible improvements in the regulatory process (e.g., reduced regulatory review timeframes, increased opportunities for industry consultation with regulators, etc.)

- If the government seeks additional resources to enhance regulatory capacity and expedite approval times, we recommend that the government develop a framework that gradually increases fees over several years in a transparent and predictable manner.

- Further, once India adopts a distinct regulatory framework for medical devices, fees should be applied based on the risk classification of a particular device. For example, the registration fee for a low risk device which would understandably take less time to review should cost less than that of medium or high risk device. Currently the registration cost of a simple Urinary Catheter is the same as that of a cardiac stents or other high-end high risk device. Globally, product registration costs are based on a product's risk category because as the risk classification increases, so too does the requirements for conformity assessment.

- We recommend that CDSCO extend the validity of registration certificates and import licenses from 3 years to 5 years.

- Any fees should be in the national currency; therefore, in this case we recommend all fees be in Indian Rupees.

- Lastly, in order to give medical device manufacturers time to adjust to the new fee structure, we suggest a minimum 6-month transition period.

We urge the Government of India to consider the potential impact of such a substantial hike in registration fee towards delivering high-quality medical devices to Indian patients in a cost-efficient manner in one of the most competitive markets of the world. We request the government to defer this steep increase in the registration fees as such fees would inhibit the growth of the medical devices sector which is at early stages of growth.

In summary, we request an opportunity to discuss on the above subject with appropriate Government officials in a meeting and present industry's views to the government. We take this opportunity to once again assure you that both AdvaMed and AmCham members are committed to the cause of widespread reach and access to high quality healthcare in India and assure you our fullest cooperation by actions contemplated to meet this objective.

Thanking You
Yours Sincerely

Varun Khanna
India Working Group Chair
AdvaMed

Prabal Chakraborty
Medical Devices Committee Chair
AmCham