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11th Feb, 2016

Shri K.L. Sharma
Joint Secretary (Regulation)
Ministry of Health and Family Welfare
Nirman Bhavan
New Delhi

Dear Sir,

Sub: Gazette Notification No.S.O.237(E) dated 25/1/2016 bringing 'ablation devices' under notified category

This is in the reference to the Gazette notification issued by the Ministry of Health notifying Ablation Devices as regulated Device with immediate effect under the category of Drug (Section 3b(iv)). In this connection we would like to bring to your kind notice the following facts:

- Ablation devices are broad category of devices under Dermatology, Urology, Endometrial, Electrophysiology/ cardiac etc. various therapeutic areas. The DTAB and DCC minutes were categorically discussed for "Endometrial Ablation Devices". The draft Gazette notification/ order immediately implements listing of "all Ablation devices" under Drug Category (Section 3b (iv)).
- Ablation devices constitute of capital parts (RF generator, electrical parts/console/wires/foot switches, etc.) and the consumables like electrodes, cannulas, probes, catheters etc. We request more clarity on what is going to be regulated under Ablation devices, as currently we only register the consumables that fall under the notified device category and none of the capital equipment are registered.
- The Ablation devices are available to Indian Patients since more than a decade without any restriction/ approval/ licence requirement since past more than a decade in India. Post the above mentioned Gazette notification all ablation devices must be registered / licensed prior to market.
- Usually it takes 4-6 months by the Indian Agent / companies / firms to arrange for the documents/ dossier/ submission package/ data for the purpose of application for registration / manufacturing licence. Further 9-12 months are taken by CDSCO to register a product as per the standard timelines and the manufacturing licence timelines vary from state to state. Thus, approximately 15 to 18 months' time is required by the importer / Indian agent/ Indian manufacturer or companies to register / obtain licence.

- As the current Gazette order is made applicable with immediate effect, the ablation devices might not be available to the needy patients for 15-18 months due to above listed reasons. Example Annually 10,000 to 12000 patients in India need cardiac ablation. Hence, in the interest of patients, it is requested to provide the transition time of atleast 18 months so that all importers / manufacturers of the Ablation devices shall obtain the necessary licenses from CDSCO / State Drug Authorities.

In light of above facts, we request Ministry of Health to:

1. Provide clarity on what part is going to be regulated under Ablation devices, as currently ablation catheters fall under the notified device category and none of the capital equipment are registered.
2. Allow the registration under scope of grandfathering category, instead of New Medical Device Registration category.
3. Allow the transition time of atleast 18 months so that all importers / manufacturers of the Ablation devices shall obtain the necessary licenses from CDSCO / State Drug Authorities.

With best regards,
Yours Sincerely,

Ajay Singha
Executive Director
AmCham India