ONLINE REGISTRATIONS AND LICENSE FOR IMPORT OF MEDICAL DEVICES WILL BE POSSIBLE

February 2016

We all know that registration certificates and import license for drugs can be procured by click of a mouse through SUGAM. However, there is no such facility for medical devices. With foreign players coming in the sector, the facility to get registration and licensing related paperwork of import of medical devices via an online system was much awaited. CDSCO is planning to launch a web portal for licensing the import of medical device from March, under SUGAM, an online solution for submission, application and grant of permission for the import of drugs, in compliance with Union health ministry's initiative of e-governance. Once a system is in place, the users such as, drug importers, Indian agents, corporates, foreign enterprises holding Indian subsidiaries and manufacturing units, will not only get to apply for licenses online, they will also get an option to track the status of their applications online through an application reference number provided by the system during the submission of application.

PSA view: Medical device industry has emerged leaps and bounds if we trace its evolution from the beginning of the 20th century. Seeing the growth in the sector, Ministry of Health and Family Welfare had some time back issued a list of medical devices that have been categorized as Drugs and precisely these devices need to be registered. As of date, registration, procuring license and getting them renewed after three years is a lengthy process. We are hoping for a user friendly portal.

Medical device testing labs to be set up for the first time in India

As on date, medical devices are usually sent to foreign countries for testing owing to lack of a reliable and advanced medical device testing facilities in India. Although there are a few testing labs in the country, however they are quite redundant and obsolete. With a view to ensure safety and efficacy of medical devices marketed in the country, the Union government plans to set up two medical device testing labs in the country at Vadodara and another at Noida. The medical device testing lab in Vadodara would be the first of its kind and the only dedicated biomaterials and implants testing lab in the country. The lab at Noida will be set up primarily to test electrical and electronic medical devices in the country. Testing labs will enable medical device manufacturers to overcome deficiencies in their products and consequently enhance product value in the market.

PSA view: While this move will complement government's Make in India' drive, what is to be seen is if the manufacturers would still feel the need to get the devices verified at foreign labs. The new law for regulating medical devices is in the pipeline. It would be good to see if lab testing is made mandatory. Further, this will

FSSAI relaxes approval norms for products for which standards have not been prescribed yet

In a bid to relax norms on regulation of products for which no standards have been specified under the Food Safety and Standards Act ("FSS Act"), the FSSAI has excluded certain products from the purview of product approval. Section 22 of the FSS Act deals with (i) genetically-modified articles of food, (ii) irradiated food, (iii) organic foods, (iv) foods for special dietary uses, (v) functional foods, (vi) nutraceuticals, (vii) health supplements, (viii) proprietary food and novel food. Till now, such foods were being manufactured and sold by virtue of Regulation 2.12 of the Food Products (Standards and Food Additives) Regulations ("Additives Regulations"), which described proprietary food as non-standardised food which needed to conform to certain requirements. Recently, the Additives Regulations have been amended to expressly exclude "any novel food, food for special dietary use, functional food, nutraceutical, and health supplement" from the definition of "proprietary foods". The amended Additive Regulations also state that proprietary foods need to comply with the prescribed food additives provisions and the microbiological specifications and all other regulations made under the FSS Act which will be the responsibility of food business operators.

PSA view: Through this change, FSSAI has now allowed manufacturing and sale of a vast majority of proprietary foods without the requirement of any approval. By virtue of these amended regulations, FBOs dealing with nutraceuticals, food and health supplements will now need no FSSAI approval, but may have to comply with Draft Food Safety and Standards (Food or Health Supplements, Nutraceuticals, Foods for Special Dietary uses, Foods for Special Medical Purposes, Functional Foods, and Novel Foods) Regulations, 2015 issued earlier in August, 2015. Moreover, FBOs now need to be careful to check whether their products fall under any of the excluded categories and accordingly, comply with the relevant standards prescribed for each such category. Nonetheless, easing the procedure for food approval would serve as a much needed impetus in the industry.

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