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What's with the medtech registration scenario in Taiwan?

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Taiwan is a major economic player in the domain of electronics, information and communication technology, and is also considered a producer of intermediary and final products. Although its size and economy is not as robust as its neighbor, China, the island nation of 23 million inhabitants has a per capita gross domestic product (GDP) of $20,000 and spends around seven percent of its GDP on healthcare, which is higher than what is spent by most of its neighbors in Asia Pacific. Moreover, nearly 99 percent of its population is covered by the National Health Insurance Scheme.

The medical device market in Taiwan is valued at about $1.8 billion and is the fifth-largest medical device market in Asia. However, surprisingly Taiwan imports 75 percent of its medical devices from overseas. This shows that a considerable number of medical devices are used in Taiwan and this demand for medtech devices is only going to increase as the nation's 20 percent population become over 65 of age by 2025.

In Taiwan, all medical devices require registration with the Taiwan FDA (TFDA), regardless of the fact of whether they belong to Class I (pose the lowest risk) or Class III (pose the highest risk). For combination devices, classification depends on the product's primary function. There are two applications required for Class II and Class III medical device registration in Taiwan, the Quality System Documentation (QSD) and Product Registration.

Regulatory changes made in 2012-13

During late-2012, the Taiwan FDA announced that it would start using the Summary Technical Documentation (STED) format for medical device technical document submissions, joining regions such as Japan, Australia, Canada, the US, and the European Union. This change occurred to align the country with the Global Harmonization Task Force standards and to aid the goal of achieving uniformity between various countries' regulatory bodies.

STED is expected to fully be implemented for all Class II and III medical devices by July 2013. For product registration, foreign medical device companies have henceforth been advised to include device description and product specification (including variants, components and accessories), as well as an essential principles checklist (including risk analysis and control summary, design and manufacturing process).

Another recent change made by the Taiwan FDA was allowing sales of Class I medical devices through "virtual channels" beginning in July 2012. Virtual channels are those in which the product cannot be examined in person (including internet, radio, newspapers and television among others). Previously, no medical devices could be sold through virtual channels but now Class I medical device manufacturers can sell their devices this way if they fulfill several requirements: The criterias for sale through virtal channels is that the manufacturer must be registered with the Department of Health (DOH), the manufacturer must have a functioning physical sales channel in Taiwan, and every virtual sales channel must be registered with the DOH.

Problems faced during poduct registration

Although ammendments and changes have been made in regulatory processes in Taiwan, foreign and domestic firms often find it difficult to get their product registered in the island nation. One of the major issues that foreign companies face while trying to get their products registered with the Taiwan FDA is over the 'Country of Origin'.

Currently, TFDA recognizes only the 'actual manufacturer' (the factory that produces the product) rather than the 'legal manufacturer' (the organization to whom the product belongs). This issue usually crops up when components are outsourced and then they are assembled by different makers. This issues also pops up if the company is unable to obtain a Certificate of Manufacturing from the actual manufacturer.

Furthermore, since the Taiwan FDA accepts documentation only from the actual manufacturer, delays may be caused when promotional materials are in the name of the legal manufacturer. Although the Taiwan FDA has been continuously trying to reform its processes to resolve the problems, it has not met with much success yet.