INSIDE CHINA: new policies to bolster tech transfer wave

Changes to China's regulatory pathways, as well as increased government investment, are just a couple of things that will cause technology transfer activity to swell in the Chinese medical device market, predicts Michael Alper of NeuvoMedica

Technology transfer has always been an important part of China's development. Though the Chinese medical device market is no stranger to technology transfer, recent and forthcoming policies are expected to accelerate the rate of technology transfer in this space.

The first of these policies is the Medical Device Technology Industry 12th Five-Year Special Plan issued by the Ministry of Science and Technology. This policy sets the development of the medical device sector in China as a key government initiative with aggressive goals and timelines. Following up with this policy, actual funds have been allocated with the medical device sector receiving RMB1.5bn ($250m) through the Ministry of Industry and Information's "Special Supporting Program" in which participating companies can receive over RMB10m each. The Chinese government also plans to invest an additional RMB10bn in the medical device industry by 2020.

From a regulatory aspect, a green channel policy for medical devices has been issued that provides expedited approval process for innovative medical devices developed in China. The China Food and Drug Administration has also declared that it is issuing a new policy before the end of this year that will "level the playing field" for locally made medical devices in terms of product registration.

Over the past few years, the regulatory requirements and timeline for locally made medical devices has increased significantly. Though not always true, the perception is that getting a local product registered is more expensive and time-consuming than an imported product. The forthcoming new policy is supposed to set the same requirements for imported products as for domestically made products. What this means is that many imported products will now require a clinical trial conducted in China before they can be approved. This will significantly increase the cost and timeline for getting approval for imported products into China. It is my belief that this policy specifically will be the major catalyst that creates a wave of technology transfer in the med device space.

Higher hurdles for imports

Up until a few years ago, most large medical device companies were importing their high value medical device products into China. It was relatively inexpensive and quick to get a new imported product approved (1-2 years) assuming it was already approved in the country of origin. On the other hand, new locally manufactured products, especially class 3 products, take significantly longer (3-5 years) and are more expensive to get approved mostly due to the local clinical trial requirement. However, locally manufactured products do not require previous approval from any other country or region before being approved by the CFDA.

With the new regulatory policy, instead of taking 1-2 years to get approval for imported class 3 medical devices, it will likely also take 3-5 years (post country of origin approval) and require a much higher investment than before. With all of the incentive policies and the better reimbursement policies for locally made products, it will be very hard to justify investing in bringing imported products as opposed to just transferring the technology to a company's China operation and manufacturing domestically. Moreover as China becomes an even more strategically important market, the opportunity cost in waiting to get new products to market will also increase quite significantly. Having to wait 3-5 years after getting approval in the US or Europe will not be a palatable alternative. I expect to see products registered in parallel in the US/Europe and China among the large multinational companies to speed access to market in China.

Indeed, the recent year have already seen large multinational medical device companies going down the local manufacturing path, either through acquisition (Medtronic/Kanghui, Stryker/Trauson, etc.), through greenfield investment (J&J, Covidien, etc.) or both.

Smaller US & Europe based medical device companies will face a slightly different problem. Many of these companies have limited resources with which to approach the Chinese market. The common solution up until now has been to partner with local distribution companies who would fund the commercialization of the products in China. However with the new regulatory changes, finding such arrangements will be difficult as there are few distributors willing to fund an expensive trial over a 3-5 year time period. Thus smaller companies will have to find other solutions to access the second largest medical device market in the world.

The new solution is likely going to be Chinese medical device manufacturers who are willing and able to invest in a longer time horizon and are looking for new technologies to enhance their product portfolio and their production capabilities.

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