

## Kyung Kook Lee - Chairman, KMDIA, South Korea

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*Kyung Kook Lee, chairman of KMDIA, explains the association's role in working with the medical devices industry to boost both the local market and to raise Korea's profile as a global hub for medical devices. Lee concludes with his assessment of Korea's potential in the medical devices industry, especially with the rise of fast-moving new players such as China.*

### **Can you introduce our international readers to KMDIA and the role you play in leading the organisation?**

KMDIA is composed of 13 teams from 6 departments and 10 committees (legal, reimbursement, ethics compliance, public relations, international affairs, IVD, industry development, education, membership, and the 4th industrial revolution medical devices special committee). Each team executes its duties through collaboration. Every committee is comprised of members that chose an issue of their choice and volunteer accordingly for communal development.

I was approved by the members to be the eighth chairman of KMDIA on February 28, 2018. My duty is to try and ensure that the organisation continues to fulfil its objectives, of which there are five key elements. Firstly, we seek to establish the order of supply locally and internationally. Secondly, we endeavour to ensure that high quality medical devices are produced locally in Korea. Thirdly, KMDIA seeks to contribute to the growth of the industry. In addition, we protect the rights and welfare of our associate members. Finally, through creating innovative medical devices and

providing them to patients globally, we aspire to enhance health and welfare for those in Korea and abroad.

In order to accomplish these goals, I meet with key stakeholders in various positions, such as practitioners, policy makers, decision makers both locally and internationally, the national assembly, health regulatory agencies, as well as with patients and academia. In meetings, I explain our positions as well as any issues we are facing. We offer solutions by suggesting adequate policy changes from regulators.

### **Can you provide us with an overview of the medical devices market in Korea?**

The companies in the domestic medical devices market can be categorized as either domestic manufacturers or multinational corporations and importers with a Korean branch who import. As of 2017, the number of manufacturers has doubled compared with 2007, from 1,662 to 3,283. Multinational corporations and importers have increased by 60 percent from 1,381 to 2,257. Consequently, the medical devices industry has a bright prospect as more and more start-ups basing their technology on the fourth industrial revolution are being created.

The industry is growing steadily for a number of reasons. First, the current president has a strong will on policy enforcement and on R&D support, which is encouraging the industry to flourish. Moreover, over time the industry has matured developing impressive technology and an abundance of talent spanning production, ICT, and medicine. Thirdly, we are observing an increased interest in health care and beauty, partially as a result of the rapidly ageing population and increasing rate of diseases.

These main driving forces are complexly intertwined to lead to the development of the market's demands and service accordingly, and the government is promoting the growth of the industry by implementing policy and injecting public funds. The current government is striving to lead the growth of the industry in terms of 'strengthening the protection of health insurance' and 'reforming MD regulations and fostering industry.'

The MD industry requires constant clinical trials and accumulated data to guarantee safety. The Korean MD market consists only 1.8 percent of the industry worldwide as of now, but one needs to take note of the size and speed in growth. Korean medical devices are also gaining credibility by meeting the regulations of large MD markets of the US, Europe, China and diving into their market.

## **What are the main regulations governing pricing and approval of medical devices into the Korean health system?**

A medical device authorized by the Food and Drug Administration goes on sale through notification from the Ministry of Health and Welfare after having been registered for insurance and its price set by the HIRA. The insurance policy regarding health care (practice of medicine, drugs, medical devices) is applied to diagnosis-related groups (ophthalmology, otorhinolaryngology, general surgery, gynaecology). This group is expected to be expanded in the future.

There are plans to implement '*The Advanced Medical Technology Rapid Access Evaluation Track*' to speed up access to the latest medical treatment market in the fields of AI, 3D printing, and robotics. The pre-existent track evaluates the safety and validity of newly developed medical treatment based on clinical literature before allowing a device to enter the market. However, this method has been criticised for being too restrictive for promising upcoming technology or newly developed technology. The technology that has entered the market after evaluation gets re-evaluated based on 3-5 years of performance at clinical trials.

## **Which companies are the main drivers of the new technologies in medical devices?**

As of now, there are no companies capable of generating revenues of over 1 trillion won in forward linkage effects (car, shipbuilding) through the promotion of the medical devices industry. It is mostly small, medium-sized companies and start-ups, and the product credibility and brand power remain weak. With an active encouragement of start-ups, we are striving to produce more innovative and marketable products, but it still remains difficult to produce a product with 'the world's first' technology because of the disadvantageous insurance system for small companies, obstacles passing the new evaluation track, and a high cost of clinical trials.

Viewing the growth of medical devices industry as an opportunity, the investment from venture capital, angel fund, start-up loan is on the rise and the information regarding investments is becoming more readily available. Even then, the association is proposing to further expand investment regarding government-funded R&D, launching, and exporting.

## **How easily can new companies enter the medical devices market based on current regulations?**

Entering the medical devices market is getting easier for new companies with the modification of policy and regulations. Of course, there still may be some difficulties for inexperienced companies due to heavy regulations, but there have also been more consulting companies aiding them with research and assistance into entering global markets.

In addition, the Ministry of Health and Welfare and the KHIDI established the Medical Device Industry Comprehensive Support Centre and 'Health Industry Innovation Business Centre' to consult and resolve the issues that tend to arise during the start-up phase. KMDIA is also helping with modification of policy to overcome the start-up "death-valley", where so many promising startups fail to get off the ground.

To illustrate my point with an example, we have assisted a promising domestic medical device get tested in large hospitals to improve quality and secure credibility. We have also been successful in providing opportunities for collaboration with international institutions and pioneers of the market to a company possessing promising new technology but struggling to penetrate the global marketplace.

### **How does Korea compare with other regional competitors such as China and Japan in its endeavour to become a global exporter of medical devices?**

In March 2014, former president Park presented a mid/ long- term development plan for growth of the medical devices industry to foster the industry inspire a new growth engine, with a view to Korea becoming one of the seven strongest MD industry in the world by 2020. In 2014, the domestic medical devices industry amounted up to USD \$4.76 billion. In 2017, the market grew to USD \$5.8 billion, making Korea the 9th largest in the world. Commensurately, the annual growth rate for Korea's medical device industry is 7.6 percent, three times the average global growth of 2.6 percent. Consequently, breaking to be the 7th largest industry by 2020 remains a possibility.

Revenues from the export of medical devices by country are USD \$512 million to the USA, \$618 million to the EU, \$198 million to Japan, \$509 million to China. This is an annual 14.4 percent increase in medical device exports to China, a 3.9 percent increase to the EU, 2.2 percent increase to the US, and a 1.0 percent decrease in exports to Japan.

As far as innovative products go, Korean medical devices equal those of the US and Japan in quality and will be superior to Chinese products for at least the next 3-4 years. Korea is both competitive in quality and in price. Moreover, we have a similar starting point to the US and Japan regarding the embracement of medical devices in the context of the 4th industrial revolution. Hence, Korea's

industry has gained momentum. Nevertheless, we cannot rest on our laurels as China is rapidly becoming a strong competitor thanks to intense government policy and support.

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