Industry

Optimistic Diagnosis for Korea’s Medical Devices

Korea is making strides to become a leader in the global medical device market.

Medical devices involve the combination and convergence of engineering technologies such as electronic engineering, information technology (IT), mechanical engineering, bioengineering and medical technologies. For that reason, they experience a short product life span that is associated with their sensitivity changes and rapid improvements in technology. Korea boasts strengths not only in IT, but also in medical technology, offering prospects for great success in the medical device industry.

The global markets of the medical device industry are forecast to grow from USD 382.8 billion in 2013 to USD 546 billion in 2020, making the industry a high-growth sector. Korea aims to export USD 13 billion worth of medical devices and produce 130,000 employees in the industry by 2020 (exports worth USD 2.5 billion and 37,000 employees for 2013). In 2009, Korea designated the medical device industry a future new-growth engine sector, and in March 2014, its incumbent government prepared a mid- and long-term plan on the industry’s development, and has been extensively fostering the medical device industry accordingly.

Medical Devices

Medical devices include not only contact lenses, eyeglasses and hearing aids, but also stents, artificial bones, joints, heart pacemakers, dentures and metal dental crowns, which are embedded in the human body through an operational procedure. The wide variety of home medical devices includes thermometers and blood pressure gauges; diagnostic devices, including X-ray equipment; ultrasonic diagnostic equipment; blood-extraction syringes and needles; blood and urine examination equipment; and endoscopes. Medical devices for serious treatments and operations include laser equipment, cyber knives, thermotherapy devices, artificial pump-oxygenators and anesthetic machines.

Unlike other industrial products, medical devices have to do with human life and thereby require a high level of safety and reliability. Only products with proven safety and performance should be manufactured, imported and sold under the Medical Devices Act.

Market Trends

Global population aging is accelerating, and concern for well-being is growing. Medical costs for the elderly and costs for managing chronic diseases are ever-rising, and the quality of life in newly industrialized nations is improving. Thus, the global medical device market in 2013 grew, coming in at an estimated USD 382.4 billion based on production and CIF price, and the markets have continued to grow 5.0 percent annually since 2008.

According to global data (2013), the size of the U.S. market was USD 145.7 billion, which accounted for 38.1 percent of the global market, followed by Japan with USD 45.2 billion (11.8 percent), China with USD 24.2 billion (6.3 percent), Germany with USD 23.6 billion (6.2 percent) and France with USD 15.5 billion (4.0 percent). In terms of the 2013 global market size, Korea ranked No. 13 (USD 4.8 billion), accounting for 1.3 percent of the global market. China and India led the market growth with the rates of 11.6 percent and 10.0 percent, respectively. As such, new emerging nations, along with leading nations, will rapidly expand their medical device markets.

In 2013, Korean medical devices, while growing in competitiveness, increased their exports, posting KRW 4.2 trillion (USD 4.1 billion), up 8.9 percent from 2012 (KRW 3.9 trillion). Their industrial size (production and import) was KRW 7.2 trillion, up 5.9 percent from 2012, and the trade deficit stood at KRW 407.4 billion, down 43 percent from 2012, thanks to expanded exports.

Last year’s top-ranking production items, in order of ranking, are dental implants, ultrasonic imaging diagnostic devices, dental noble metal alloys, soft contact lenses, vision-correction eyeglass lenses and medical imaging processing device software.

According to the Korea Medical Devices Industry Association’s handout on medical device manufacturers, importers and exporters, the number of market leaders with a production amount exceeding KRW 10 billion in 2013 increased 36.7 percent, from 62 in 2011 to 86 in 2013. In 2013, there were 2,009 importers.

The current medical device market trend is of higher demand for early diagnosis and prevention rather than for treatment, in light of enhanced living standards and improved quality of life. Therefore, the healthcare industry, with devices involving the combination and convergence of IT technology, is growing significantly.

U-healthcare services, which involve information and communication technology and medical services, are designed to monitor patients by wireless communications. With the growing use of smart devices, smart health and wearable devices and mobile devices that can, for example, measure an individual’s physical activity and calories, they have also become used as healthcare devices, thereby prompting the rapid emergence of the digital healthcare era, in which the individual’s health and disease are managed via mobile health.

Yet another trend is apparent in the high growth of the dental medical device market. The number of dental implants, operable in a wide age range, has been increasing significantly each year in their market size. The growth is now enabling dental shape manufacturing work—which was previously manually performed—to be conducted with CAD and Cam technology, and consequently shortening work time drastically while speeding up treatment.

With the rapid development of combined and convergence technology, which is, in turn, breaking down barriers between medical devices, demand is ever rising for devices that are capable of conducting diverse examinations simultaneously, and for devices that conduct imaging diagnoses and treatment. Developed nations are developing ultrasonic / MRI combined devices, PET / MRI combined devices, endoscopic ultrasonic technology and fluorescent endoscopes. Korea needs to create new markets for CT and MRIs, in addition to ultrasonic devices, and develop innovative technology to resolve the technical divide.

Government Policies

In March, the Korean government announced a mid- and long-term development plan for the medical device market with the goal of joining the ranks of the world’s top seven leaders in medical devices by 2020. In the plan, to facilitate the successful entry of Korean products in global markets, business-hospital systems will be implemented across the entire research and development (R&D) process through the support of areas where Korean strengths are high, or where medical expenditures are high. Furthermore, to construct the infrastructures for high-value-added industries, increased efforts will be made to use the funds to develop a world-class pharmaceutical industry, invest in ventures and small- and medium-sized medical devices and support the commercialization of products with the mindset of promoting healthcare and exploring new markets.

There is a need for industry-university collaboration to develop and transfer technology through intensive investment in R&D for promising technologies—which will boost the nation’s future competitiveness—and to develop practical products. In addition, if innovative products are evaluated at proper prices under a healthcare insurance system, and an environment in which corresponding proceeds are reinvested in new products is firmly established, then Korea’s medical device industry will enter the ranks of the top seven medical device leaders by 2020.

By Chang, Jung Yan
Director of Industry Development Headquarters
Korea Medical Devices Industry Association
changy@imdias.or.kr

Korea’s Yearly Medical Device Markets

<table>
<thead>
<tr>
<th>Category</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
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<tbody>
<tr>
<td>Production</td>
<td>2,764,261</td>
<td>2,964,445</td>
<td>3,366,342</td>
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<td>Export</td>
<td>1,519,072</td>
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<td>Import</td>
<td>2,398,814</td>
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<td>Trade balance</td>
<td>-879,787</td>
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<td>Export surplus</td>
<td>-1,214,597</td>
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<td>Import surplus</td>
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<td>693,274</td>
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<td>Import share</td>
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<td>67.1%</td>
<td>64.9%</td>
<td>63.8%</td>
<td>64.5%</td>
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* [ ] denotes USD 1,000