

State and subject of health and sports medical devices industry at oversea*

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Abstract

Most of people do not remind of 'Who is domestic medical device business?' A lot of people that Johnson and Johnson, GE and Philips and other foreign companies belong to medical device company. In fact, local enterprises small place based on world market. Local medical device industry's production has grown up rapidly last 10 years. Sales increased nearly 3 times from trillion and 500 billion KRW in 2004 to 4 trillion and 600 billion KRW in 2014. The production record constantly increased owing to safety and good quality of domestic medical devices. As many as 59% of medical devices made in Korea is exported to 198 countries in the world. Currently, medical device industry in the world has been given considerable attention. Cognition and awareness are very much low. Medical device industry, high income creating industry, is said to next generation industry to increase scale, and Korea does not follow world flow. The industry is given support from the government that is not enough. Korean enterprises have small scale among a lot of global enterprises. Being interested in development of medical devices, the author selected department of IT at college.

Keywords: State, Subject, Medical Devices Industry, Overseas

1. Medical device industry at home and abroad

Most of people do not remind of 'Who is domestic medical device business?' A lot of people that Johnson and Johnson, GE and Philips and other foreign companies belong to medical device company. In fact, local enterprises small place based on world market. Local medical device industry's production has grown up rapidly last 10 years(Song & Kim, 2016). It will triple from KRW 1.5 trillion in 2004 to KRW 4.6 trillion in 2014, and it is expected to grow to about US \$ 454.6 billion by 2018. The production record constantly increased owing to safety and good quality of domestic medical devices(Lee & Jeong, 2015).

As many as 59% of medical devices made in Korea is exported to 198 countries in the world. In 2014, export of medical devices accounted for 2.4 billion dollars 4% up than 2.3 billion dollars in 2013 to grow up 14% a year on average. Samsung Medison exported 220 million dollars to be the highest, followed by Korea GE Ultrasonic and SD. Ultrasound imaging system, dental implant and soft contact lens ranked high ranking export product(Yim, Seo, & kim, 2013).

Sonic computed tomography X-ray photographer amounting 18 million dollars was exported to China

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590% up than previous year to admit of good quality of Korean medical device(Ko & Park, 2016). High ranking export country of Korean made medical device was USA, China, Japan, Russia and Germany in order, and high ranking export region was Asia, Western Europe, Eastern Europe, Central and South America, middle east and Africa in order.

2. Overseas market development of local medical device business

View Works Co., Ltd develops and produces and sells medical and industrial use imaging equipment. DR type flat board X-ray portable director converts X-ray into visible ray to produce digital imaging when taking X-ray photograph. View Works export ratio occupies very much at medical device to export 84% based on money value in 2014. View Works supplies important parts of imaging equipment and/or upgrade that are used at hospitals in the world.

Export was done owing to technical innovation and investigation into trends in the market. Technical innovation includes AED and AP that View Works developed for the first time in the world to introduce to the market: AED detects X-ray to produce image, and AP transmits image data to tablet and/or lap top computer by radio communication. The function is thought to be important and to meet development flow of X-ray photographing unit. X-ray photographing unit has been developed from film system to CR and from CR to DR and to be upgraded by View Works. Upon demand of the market, View Works replaced X-ray generator from analog to digital. Since start of X-ray business in 2012, Samsung Electronics has grown up at 160% on average to supply premium class new product to UK outpatient diagnose department in the United States.



Source: Viewworks (2017).

Figure 1. Multi-purpose Portable Flat Panel Detector for Digital Radiography

The product can be exported owing to differentiation from existing digital X-ray, Detector technology has been differentiated from digital X-ray, and image processing algorithm gives good quality image, and soft handling allows user to manipulate easily and to alleviate patient's rejection. The product increases user's satisfaction by technical innovation. Production based on the technical development could forecast flow of medical device market to read consumer's demand.

3. Government support for export of medical device

The government announced mid to long term medical device industry development plan to be 7 power of medical device industry to set goal of 130,000 employees, 3.8% market share of world market and 13.5 trillion KRW of export.

The government's policy for high added value medical device industry and high demand on medical device could develop medical device industry, and small business oriented cooking device industry shall overcome difficulty. Enterprises shall strengthen capacity and political environment of industrial development shall be used to make base of the growth.

This Association of Medical Device Industry investigated state of healthcare industry to promote projects for quality improvement of local medical device enterprises and to promote export.

Not only National Tax Service but also Small Business Administration shall support small businesses. The purpose small business support is to give cost saving effect and to support export business of medical device to the United States. Small business' sales does not exceed 100 million dollars, and when obtaining FDA small business license, burden of application to export of medical device shall be deducted 50% to 75% from standard expense. Participation in the exhibition can produce effect with small expense. And, small business may be given great burden by booth rental, transportation of exhibition and equipment, application to the service, labor employment cost, advertising and sales promotion production, and business trip expense and others(Ahn, Kim, & Lee, 2010; Govindan, Jha, & Garg, 2016).

Since 1999, the government has supported exhibition having great influence to promote national economy, and local businesses have participated in exhibition in foreign countries.

The Association of Medical Device Industry of Korea supported participating business to alleviate burden when medical device manufacturers participate in overseas exhibition for the purpose of foreign market development. The Association of Medical Device Industry of Korea was nominated to open the exhibition and to lessen expenses of the businesses and to provide booth for public relations and administration of the government exhibition hall and to let businesses concentrate on marketing.

4. Problems of R&D investment of medical device businesses

R&S expenses of enterprises having high global R&D expense were 4.9% up than previous year based on 2013 to increase more than increase of sales during same period. R&D investment was thought to be important at keen competition and uncertain economy. '2014 EU industrial R&D scoreboard' of the Committee of European Executive in December 2014 said 5.45 billion Euro of R&D expense of top 10 companies in 2013 to occupy 3.4% of R&D expense of the sales. Annual growth rate of R&D investment of the three years (2011-2013) was Carl Sexism(13.7%), Striker(10.8%) and Baxter international(10.0%) to be higher than 10% of annual average.

Ratio of R&D expense of the sales of medical device production was: 13.0% of electric diagnose and therapy device production (13.0%) to be the highest, followed by production of body correction tool for orthopedics (10.5%) and production of radiation device (9.9%) (Yim, Seo, & kim, 2013).

KISTEP said medical device enterprise R&D expense (455 companies) was 357.6 billion KRW 2.3% up than previous year (349.4 billion KRW, 409 companies), and ratio of the sales was 12.36% in 2010 to be the highest to decrease continuously, and 9.07% to be 0.1% up than previous year in 2013.

Local enterprise's R&D ratio was high comparing with global enterprise to decrease after 2010. Domestic medical device industry grew up rapidly, and global enterprises also took quick action to invest R&D expense and to expand new market. Local enterprise's R&D investment accounted for one 5 hundredth of global enterprise to have much difference. Local medical device enterprise was short of R&D workers than global enterprise was, and local medical device enterprises were small. Counteraction based on international standard was insufficient and weak(La, 2015).

Table 1. Local medical device R&D enterprise investment

	R&D expense (100 million KRW)		Sales (100 million KRW)		Ratio of R&D expense of the sales
	R&D expense	R&D expense on average of each enterprise	Sales	Sales on average of each enterprise	
2009(259 companies)	2,118	8.2	22,887	88	9.26
2010(287 companies)	2,786	9.5	22,143	77	12.36
2011(386 companies)	3,178	8.2	31,260	81	10.17
2012(409 companies)	3,494	8.5	38,931	95	8.97
2013(455 companies)	3,576	7.9	39,442	87	9.07

Source: MFDS (2017).

Medical device industry in Korea has much low technology than the one in advanced countries has. No more than 38 enterprises of more than 3,000 medical device enterprises have been listed to have 16 employees and 4.5 products and about 1.7 billion KRW of the production on average. 54% of the enterprises do not reach 100 million KRW of production(Suh et al., 2007). Difference of technical power with the United States is about 13 years, and that of image diagnosis device is 2.3 years, living body phenomenon tester 1.4 years, device control and medical information 1.6 years, and medical treatment device 2 years. R&D investment is needed. Nonetheless, R&D workers are in short supply, and training system of practical workers is not enough. It takes long time to introduce local medical devices to the market than global enterprises do. Ultrasonic image diagnosis system, dental use implant, and IT convergence product are said to have technology of advanced countries, and medical image storing and transmitting system has made use of 90% of Korean made medical device.

In Korea, system support is not enough because of short history of medical device industry. When entering medical market, new medical evaluation system requires KFSA's permit of safety and effectiveness. Even medical device permitted has no system limitation when entering market. Limited medical technology rating that was put into practice from 2014 has been used at medical technology having no alternative treatment and requiring prompt clinical experiment: No more than 5 technologies applied have been selected. Local manufacturers had great barriers. New medical technology has uncertain definition to be inconsistent and to be difficult to judge.

5. Solutions

Such problems occurred because of insufficient source technology at short history of medical device industry, low brand cognition and intellectual properties and difficulties at entry into global market. Fusion and complex medical devices shall be developed based on ICT fusion industry to create new growth power.

Inspect trends of world medical device market by referring to success case of trend of world medical device market. Customized medical device market for the aged shall be developed in future medical device market to support R&D and business foundation of good medical workers.

It takes long time for local medical devices to enter market: Test and certification and permit of medical devices shall be given support to make system. Legal system of IT medical device shall be reformed to

train and to build up industrial environment.

Unique strategy shall be used at competition with global enterprises to discover and develop new fusion medical devices. The aged friendly medical devices shall be developed in accordance with social environment to give services. People shall pay attention to medical devices at hospital to expand joint buying and to recommend use of local products. R&D shall be done to localize parts producing high income.

Problems of medical device industry of small enterprises shall be solved. Joint cooperation and development with small businesses shall get source technology to do merge and acquisition with enterprises shall make global medical industry based on small business.

6. Summary

These days, medical device industry producing high income has been given attention. Local medical device industry having short history is short of government support and social cognition. Some of local enterprises made technologies in global market to have uncertain future. Enterprises shall be given systematic support at government level. R&D investment is needed to strengthen capability of enterprises. Domestic market shall be developed to lessen gap with global enterprises and Korean made medical device shall be made to develop small enterprises.

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