Medical Devices and Systems: ICT and the Future of Healthcare

Japan’s Market Environment

An ageing society and rapidly developing technology are pushing the need to control healthcare costs. This is a common challenge for medical devices industries and R&D for the foreseeable future. The latest available figure states that national healthcare costs total JPY 40 trillion (EUR 325 billion), but it is showing a rising trend. The market size of the medical devices industry is JPY 2.7 trillion (EUR 22 billion) and 53 percent consist of therapeutics devices (Catheter, pace-maker et cetera) and 26 percent consists of diagnostic devices (endoscope, CT/MRI) (latest available data, 2013). (Source 1) Recent trend is to develop devices using tablets and mobile phones for medical use, and new business models are emerging.

Japan is of course well-known for its cutting edge manufacturing technologies, and is also strong in the diagnostic devices market and products for niche market. Devices for treatment are mainly imported from overseas. Overall, 46 percent of medical devices are imported in 2012, mainly from the United States and European Union. (Source 1) Prevention, homecare and \textit{minimally invasive surgery} are prioritized areas in the field of medical devices, because they may help to stabilize healthcare costs. Japanese companies will increase partnerships and collaborations to speed up research and development.

Key players and Strategic Alliances

The top 3 Japanese players in the medical device industry are Olympus (22 percent domestic marketshare), Terumo (21 percent) and Nipro (16 percent). The major areas of Olympus are early diagnosis, particularly in gastrointestinal endoscopes, and minimally invasive therapy with emphasis on surgical devices, video endoscopy systems. Terumo has a large share of cardiovascular and vessel systems. Terumo invested in, and obtained exclusive global distribution rights for, the Dutch company Quirem Medical B.V., which was originally developed by UMC Utrecht and focuses on radioembolization treatment. Toshiba medical and Hitachi medico are positioned within top 5 in the CT/MRI/US field. (Source 2)

Terumo and Quirem B.V. Press release


The government’s Growth Strategy

The Japanese government positioned the medical device as one of the strategic areas to boost industrial growth and has eased regulations and systems to encourage newcomers to enter the market. A prioritized approval system will apply for selected projects of innovative pharmaceuticals, medical devices and regenerative medicine. Already, Japan is strong in
areas such as healthcare robots and diagnostic medical devices, where engineering and healthcare meet. Several selected open innovation projects are funded by the governments and fringe organizations.

**ICT projects and AMED**

The Japan Agency for Medical Research and Development (AMED) was established in April 2015 and consolidates the R&D budgets for three ministries, the Ministry of Education, Culture, Sports, Science & Technology (MEXT), the Ministry of Health, Labour & Welfare (MHLW) and the Ministry of Economy, Trade & Industry (METI), to direct integrated research and development projects. The areas for funding include research and development projects for future medicine, medical-engineering collaboration promotion and development of robots for care, as well as establishing regenerative medicine industrialization pathways. AMED selected three *medical assistance technology research projects using ICT* in August 2015. They are: (1) Cardiovascular diagnosis technology by wearable monitors (Omron Healthcare and Kyushu University etc), (2) Real-time assessment of psychological symptom by expression, voice and daily activity of patients (Nihon Microsoft, Softbank, Keio University, etc), (3) Diagnostic devices for developmental disabilities (JVC Kenwood, Osaka University and 7 universities). These projects are funded for four years and expected to create new healthcare technologies and develop innovative devices to contribute for health care cost, quality and new business creation. (Source 3) [http://www.amed.go.jp/news/program/020120150520_kettei.html](http://www.amed.go.jp/news/program/020120150520_kettei.html)

AMED actively promotes open innovation. In September 2015, out of 109 projects, 10 were chosen as "The innovative business-academia collaboration healthcare program". There are four pharmaceutical and six medical device/technology projects, and three were using ICT and imaging. They are spin-off ventures from universities and large technology based companies (Chart I).

Chart I: Open innovation programs by AMED (Source 3)

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<tr>
<th>R&amp;D projects</th>
<th>Leader</th>
<th>Co-development</th>
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<tr>
<td>1. Surgery system for real-time navigation by near infrared imaging using projection mapping</td>
<td>Panasonic, AVC Networks Company</td>
<td>Kyoto Univ., Yamada Shadowless Lamp</td>
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<td>2. [*¹⁸⁷F]*DiFA Imaging system for oncology PET low oxygen diagnosis</td>
<td>Univ. of Hokkaido</td>
<td>Nihon medi-physics</td>
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<tr>
<td>3. Photodynamic athermal arrhythmia therapy device</td>
<td>Keio Univ.</td>
<td>Arai medphoton research laboratories, Nippon medical school, Tokyo medical Univ.</td>
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<tr>
<td>4. Inhaled gas therapy for ischemic reperfusion</td>
<td>Sumitomo seika chemicals</td>
<td>Kitasato Univ.</td>
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<td></td>
<td>Cochlear implant (artificial hearing epithelium) for elderly</td>
<td>Shiga medical center research institute</td>
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<td>5</td>
<td>Diabetes therapy device by artificial pancreas</td>
<td>Tokyo medical and dental Univ.</td>
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**Innovation Leaders**

The Ministry of Health, Labour & Welfare approved HAL, a robot suit for medical use (Lower limb type) for patients with neuromuscular difficulties in November 2015. HAL obtained the insurance reimbursement for category C2, a new technical fee. HAL has already sold 428 units in 2015, in Japan and expected to grow further based on market demand, aided by this new insurance coverage. The application was also submitted to include the treatment by HAL for medical use in Germany in October 2015. HAL also filed for FDA in the U.S. in 2015. (Source 4)

Cyberdyne was founded by Professor Yoshiyuki Sankai of University of Tsukuba. HAL robot suit helps the disabled and elderly to walk, and is being used in hospitals and care facilities. Sankai started growing the idea of powered suits when he earned his doctorate in engineering and studied artificial organs in 1987. (Source 5) The brain sends bioelectric signals through the spinal cord to the specific muscles. When a limb moves, HAL functions by detecting and interpreting the signals. Motors can assist the wearer in making the desired motions and makes actions possible for those with compromised mobility. The brain, nerves and muscles exchange the signals through a network consisting of motor and sensory neurons. The robot steps in between the cerebral nerve system and the muscles to help reconstruct a network loop (for the signals). This technology can be used for various areas such as medical, rehabilitation/care supports in rescue efforts, or as heavy labor support systems (e.g. in homecare facilities).

The possibility of combined therapy of Robot Suit HAL and regenerative medicine is in the study. At the Japan Medical Association meeting in April 2015, Professor Sankai explained the study of technology promoting growth of nerve cells without using stem cells. After these basic researches, he plans to collaborate with the group of Professor Shinya Yamanaka of University of Kyoto, a Nobel prize winner, on combined therapy of using stem cells and Robot Suit HAL for the patients of spinal cord injuries. (Source 6)

The integrated innovative technologies are valuable to solve changing social issues. Cyberdyne proactively partners with companies like Omron for sales distribution and in an effort to penetrate its experimental technologies quickly to the society, and to create a new industry for further innovation.
Putting healthcare online: e-Health

The Japanese market is not closed to outsiders. Having enhanced the home care business and enriched the pipeline as early as in 2000, Philips for example is expanding its market share of the patient care and monitoring solution business in Japan. The company expects to innovate the Japanese healthcare system with its technology for respiratory and pathology for sleep therapy. This year, Philips announced it is collaborating with Hitachi Data Systems for a new Vendor-Neutral Archive (VNA). Clinicians can access this to gain multi-disciplinary medical imaging information in less than three seconds. With such e-Health initiatives, this ‘outsider’ technology company is pushing innovation throughout the Japanese healthcare system. (Source 7)

New entrants, partnerships and open innovation

The medical field has seen increasingly business cross-overs/fusion of different fields. Among Japan’s 20 main digital device companies, 90 percent have or are developing medical related products and 50 percent out of 99 Japanese major material/chemical companies already have medical related products. Mitsubishi heavy industries, Pioneer, and other electronics, digital or machine parts companies have joined the industry. Newcomers with new materials and new technologies will develop products for unmet medical needs and added value in the medical device industry. (Source 8)

A legal revision in 2013 for pharmaceutical and medical equipment, made it easier to enter the medical devices market. Authorities for approval are strengthened so that approval periods can be shortened. More initiatives for open innovation, partnerships, collaborations and acquisitions of technologies are expected to develop innovative technologies. The trend in medical device R&D in Japan for the coming years will be focused on integrating needs and technologies, and promoting collaboration of companies with manufacturing technology and universities and hospitals.

Sources:

(1) Mizuho Bank “Trend of Japanese industry” Seot.2015
(2) Mitsubishi Tokyo UFJ Bank “Expanding the market in medical device” Oct.2013
(3) AMED in Japanese
(4) Cyberdyne
   Annual report 2014 “Interview with Professor Sankai”
(5) Nikkei technology online, May 2013
   http://techon.nikkeibp.co.jp/article/COLUMN/20130422/278232/
(6) Nikkei Digital Health, April 2015
"Robot suits x iPS cells Regenerative medicine"
http://techon.nikkeibp.co.jp/article/EVENT/20150427/416294/?ST=ndh

(7) Philips
http://www.philips.com/a-w/about-philips/company-profile.html

(8) Nikkei digital health Sept. 2014
http://techon.nikkeibp.co.jp/article/FEATURE/20140910/375660/?ST=ndh

Links: Companies for Chart I:
Nihon medi-physics
http://www.nmp.co.jp/eng/business/reseach_development/achievements/index.html
Yamada Shadowless Lamp Co., Ltd.
http://www.skylux.co.jp/english/medical-lighting-lab/
Arai medphoton research laboratories
http://www.arai-medphoton.com/index.html
Sumitomo Seika Chemical
http://www.sumitomoseika.co.jp/english/index.html

Noriko Ogawa, Innovatie Attaché Tokio, 14 March 2016

‘Het IA-Netwerk verbindt in opdracht van het ministerie van Economische Zaken kennis over internationale innovatieve ontwikkelingen en daaraan gerelateerde trends aan Nederlandse bedrijven, kennisinstituten en overheden.’