Open innovation networks expanding in Japan – Bridging the innovative technology and investigators

Summary

The Japanese government is enhancing open innovation in healthcare by taking various measures on regulatory and systems, for innovative pharmaceuticals, medical devices and regenerative medicines. The data shows improvements in drug approval in speed for the practical application in 2014\(^1\). The collaborations of academia and industry in R&D, and the funded research from the private sectors to universities have been increasing for three consecutive years.\(^2\) The new life science cluster in Kawasaki-city, located southern part of Tokyo, is establishing presence as the international life science hub and promoting active collaborations for the open innovation. The cluster includes the new COINS (center for open innovation network for smart health) and iCONM (innovation center for nanomedicine) and provides opportunities for linking to the frontier of R&D in life sciences in Japan.

Funds increase for open innovation with universities in Japan

The Ministry of Education, Culture and Science published a report in November on “Open innovation at universities in Japan”. In 2014, the amount of collaborative research funds with private sectors was record high, JPY42 billion (Euro 321 million). The number of collaborative research cases also increased by 1,189 and total cases were 10,070. The funded research from companies to universities has been increasing for three consecutive years and the total number was about 7,000, increased by 276 cases compared to the previous year.\(^2\) The number of patent right cases was 10,802 in 2014 and collaborations of academia and industry have spread to various levels including local governments\(^2\). The government, the industry and academia are all enhancing the network and promoting more ‘open innovation’.

Early practical application for innovative or unmet medical needs of pharmaceuticals, devices and regenerative medicines – “SAKIGAKE” designation

The Government of Japan has been actively promoting the practical applications of pharmaceuticals, medical devices and regenerative medicines since 2013. Japan had relatively long regulatory approval time in the past. However, this is changing. Japan approved the highest number of New Active Substances (NAS) in the decade 2005-2014, leading the EU and the U.S. according to the report of the centre for innovation in regulatory science of 2014\(^1\). The Japanese government has been taking various measures to improve the regulatory environment including enhancing human resources at the approval authority, PMDA (Pharmaceutical, Medical Device Agency). Especially for early practical applications for innovative or high, unmet medical needs of pharmaceuticals, medical devices and regenerative medicines, the government started a fast track approval system called “SAKIGAKE” (meaning “to lead or to precursor”) designation\(^3\). The scope of the council on
unapproved innovative or unmet medical needs products is **now to include drugs of EU and U.S., using the data from overseas**, if they satisfy certain conditions. These innovative products will benefit from shortened lead time, prioritized consultation, review system, and premium pricing of the higher drug price for the National Health Insurance (NHI) drug list of the reimbursement to the hospitals/pharmacies.

**Drugs selected for the fast track approval system and international collaborations**

In October 2015, the Ministry of Health, Labor and Welfare (MHLW) announced six drugs out of fifty candidates, as the first batch of products designated under its fast track review system, “SAKIGAKE”. Among major pharmaceuticals such as Astellas, Shionogi and MSD, a product currently under development by a venture, "Nobel pharma" was selected for early launch. It is an orphan drug, "Sirolimus(NPC-12G)", an external preparation for the treatment of angiofibroma in tuberous sclerosis. Nobel Pharma focuses on rare diseases and unmet medical need diseases and was established with 8 employees in Tokyo in 2003. Most of their products are originated overseas, or drugs that had been unapproved for a long time in Japan. In 7 years, they launched 13 products and 10 of them are originated overseas. The president of Nobel pharma, Mr. Shiomura quotes “We make contracts with companies from overseas. Because of mergers in the Pharma industry, there are products that had stopped developing, or seeds in the universities that need collaborations in R&D. We now have over 200 experienced professionals and actively developing innovative products through collaborations, and co-investment to minimize the risk.” By receiving the SAKIGAKE strategic package, this drug is expected to shorten the review period by half to 6 months from normal 12 months.

**Network to enhance R&D, industrialization and entrepreneurship – “Innovation Hubs”**

There were significant advancements in biotechnology and nanotechnology over the years in Japan including advancements in human genome, and iPS cells were awarded the Nobel Prize. From the aspect of the international R&D comparison, Japan keeps a high level in all areas of basic research, but had showed low capability in applications in the field of healthcare. According to the World Economic Forum report in 2015, in the innovation category, Japan ranks 2nd for “Company spending on R&D”, but ranks 16th for “University-industry collaboration in R&D”. The ranks for the Netherlands are 18th and 9th respectively. Japan leads individual countries in numerous technological fields, but is lacking behind the ‘open innovation’ collaborative process, f.e. in the EU and US.

Barriers to entrepreneurship are another issue for Japan. It has been documented that traditional reasons for the small number of venture businesses in Japan are; low number of venture capitalists or business angels, weak globalisation, lower esteem for entrepreneurship, weak policy and support from the government. However, the corporate venture capital has been increasing steadily, from JPY18 billion to 46.3 billion (Euro 141 million to 363 million) from 2008 to 2014, and increasingly financial support is being provided for start-up companies by national and local governments. So, what are the key issues of Japan?
In fact, the common ground for those countries that have increased the number of venture business is they emphasize on the measures for partnerships with large companies, and have hubs for technology and industrialization with actively exchanging personnel.\(^8\) Earning entrepreneurship in the diverse environment setting is also important and these are the real challenges for growing innovative ventures in Japan.

**Open Innovation Network for Smart Health, “COINS” and the Innovation Center of Nanomedicine, “iCONM” in Kawasaki-city**

COINS (Center of Open Innovation Network for Smart Health)\(^9\) is an initiative under the Center of Innovation Science and Technology based program of the Ministry of Education, Culture, Sports, Science and Technology in Japan. It is a research center for developing "Products and services that changes the future". The government has designated the area in Kawasaki-city, southern part of Tokyo, as an international strategic zone for life science. It is recognized as one of the most promising life science cluster with open innovation. Tenants are able to benefit from preferential tax treatment, funding, as well as easing regulations. Major innovative companies such as Fujifilm, Johnson & Johnson, Cyberdyne, and research centers from the public and private sectors already started collaborations by mutually utilizing intellectual, human resources in Kawasaki.\(^10\) The government decided to build a bridge to connect this life science hub to Tokyo International Airport, “Haneda” that are 600 m apart for an easy access for visitors from overseas.

Promotion of open innovation has been penetrated among industries, academia and governments at various levels. At the recent COINS international symposium which was held at the University of Tokyo on 24 of November discussions focused on the Innovation Center of Nanomedicine (iCONM).\(^11\) This center started operation in April 2015 in Kawasaki to bridge cutting-edge technologies and investigators, human resources and ideas from universities and companies around the world. The project leader of iCONM, Dr. Hiromichi Kimura is a Professor of the Pharmaco-Business Innovation at the Pharmaceutical Sciences at University of Tokyo. He is also a CEO of management consulting and an investment firm for Life Science. The research leader of iCONM is Professor Kazunori Kataoka from University of Tokyo, the department of materials engineering and the center for disease biology and interactive medicine. The fields of his studies are biomaterials, DDS and Gene delivery system. He was awarded the 2015 Gutenberg Research Award at the University of Mainz (http://www.qfk.uni-mainz.de/eng/1090.php).

Professor Kataoka says: “The life science challenges cannot be solved solely through one technology. Biotechnology information, materials science and engineering have to tackle these issues together and collaborate in a diverse team environment. ” The new initiatives in Kawasaki stimulate precisely such crossover innovative collaborations.

**Growing open innovation opportunities for universities in Japan**

Globalisation and diversity are the key drivers for advancing technology. Increase of internationalization and competitiveness is the crucial issue in Japan. Unfortunately, according to the OECD reports in November 2015, the number of Japanese students studying abroad has its peak in 2004, and it has been decreasing rapidly and only 1% of students
were enrolled abroad in 2013\textsuperscript{(12)}. It is ranked 22\textsuperscript{nd} in the world, according to the Nikkei data in June 2014.

The inward-looking tendency among young generation is considered as a social problem and it is a hurdle for the globalization of research in Japan. With this trend in mind the universities in Japan are actively trying to stimulate the opportunities from globalization and entrepreneurship among their student base. For example, University of Tokyo, ranked 9\textsuperscript{th} in the World reputation ranking in 2013 and selected as one of the super global universities by the Japanese government, is actively establishing strategic partnerships worldwide\textsuperscript{(13)}, 19\% (2,873) of total graduate and undergraduate out of 28,000 students is from overseas. Especially, the ratio is high for engineering students and 32\% (921 students) is from overseas\textsuperscript{(12)}\textsuperscript{(13)}, Professor Kataoka from University of Tokyo and the Research leader of iCONM in Kawasaki project enhanced the importance of fostering innovative mind and leadership for researchers and encouraged to experience in the diverse team environment. Enhancing open innovation from research in global settings would expand more opportunities and accelerate the speed of development.

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