Interview with Bup Wan Kim, President, Korea Health Industry Development Institute

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What is KHIDI’s role in supporting the development of the Korean health industry?

KHIDI performs three major roles in supporting the Korean health industry, which includes pharmaceuticals, medical devices, cosmetics, functional food and medical care. First role is developing the health system and policies. The next role is funding R&D and supporting technology commercialization. And lastly, we play a role in strengthening healthcare infrastructure. For the system improvement, we constantly do research on advancing the system in order to strengthen international competitiveness and to revitalize the industry. We support research programs, including translational research, preclinical research, pre-clinical trial infrastructure, and consider the value of new medicine, medical devices and medical information. In 2008, KHIDI funded $152.7 million dollars in total. In order to strengthen industry infrastructure, we train experts and have newly established the Center for health industry statistics. In the beginning of this year, KHIDI has been authorized as a government statistical institute. In addition, we support patent, authorization, overseas marketing and quality evaluation.

What is the importance of the health industry within the Korean government’s focus on building a knowledge economy for the 21st century?

As a high value-added knowledge-based industry, the health industry is known as a key driving factor in the Korean economy. The Government has a strong willingness to expand the health

industry, including medical tourism, in order to make the industry lucrative. The health industry is likely to face new challenges and opportunities, along with several transformations. The medical service paradigm will change due to the aging, demand in well-being and increase in income. The population over the age of 65 is expected to increase from 8% (2004) to 20% (2020). In consequence, the demand for advanced medical care and e-health will increase. In addition, the WTO and FTA agreements are opening the markets and increasing competition among nations. Multinational companies are likely to lead the global market with rich in information and capital. Health industry will develop through innovations in BT and the acceleration of BT•IT•NT converging technology. The era of personalized medicine will arrive, using new technology such as gene, protein substance and bioinformatics. There will be also a worldwide health technology network and expansion of international co-research.

What is the scope of KHIDI's international activities and overseas promotion of Korea's health and pharmaceutical industry?

KHIDI's international activities mainly focus on helping the domestic pharmaceutical industry expand the business abroad by harmonization of international standards. To achieve our goal, we work along with international organizations. International organizations including ICH, PIC/S, APEC, WHO, play an important role in establishing and expanding global standards, and assist the policy determination of each country. KHIDI actively participates in such activities and strives to harmonize with international standards. This year in particular, APEC has endorsed the establishment of Harmonization Center in Korea, and we are trying to make the most of this opportunity to enhance Korea's pharmaceutical industry and to expand international harmonization. Furthermore, KHIDI has concluded MOUs with 10 institutions in Germany, the U.S., and many more. Our goal is to enhance Korean companies' opportunities to enter the business abroad and to build infrastructure for overseas expansion. In terms of overseas promotion, we do the overseas promotion of domestic products, and the overseas promotion of domestic technologies. In order to effectively achieve overseas promotion, we operate KHIDI overseas offices and conduct activities such as approval and authorization, and consulting buyers. Currently we have offices in New York, Beijing and Singapore, and expect to open a new site in Frankfurt at the early of 2009.

Which are the main trends currently driving the health industry in South Korea?

Due to the technology development and increase in demand, the health industry has been constantly growing. As BT, IT, NT are being integrated into the existing health industry, new sectors including personalized medicine, preventive medicine, biopharmaceuticals and biochip are being

created. Moreover, due to the rapid increase of senior population, the senior-friendly industry has become one of the promising sectors. In 2008, the population over 60 years old is above 10% of the total population, and in July this year the senior long-term insurance system was enacted. In addition, as a result of the increase in income and change in traditional values, interest in beauty has also grown, so related industries like cosmetics have expanded enormously.

What is Korea’s track record, potential and ambition in the strategic biotechnology sector?

The Korean government initiated to develop the bio-sector in the mid-1980s. When the Plan for Biotech 2000 was established in 1994, the government harmonized national policy and began to expand investment in R&D at a great level. Through the years, the competitiveness in Korean life science has been improving. Based on that, we now produce productive results for the industry and economy. Koreans have published many distinguished research papers in leading scientific journals, and the number of publication in the three big journals, namely Nature, Science and Cell, has been increasing constantly. In total, 71 papers have been published in last 6 years. Furthermore, 6 new drugs which were developed by Korean pharmaceutical companies (LG Life Sciences, SK and DongA), are in the process of getting approval from the USFDA. Since the launch of Sunpla by SK pharmaceuticals in 1999(07), Korean companies have developed 14 new drugs (up to 2008).

What are South Korea’s primary strengths in terms of human capital, technology and niche expertise in relation to the health industry?

Korea has excellent human resources in sectors of medical and life science. In particular, Korea has strength in the following areas: ○ Gene-based personalized medicine: Although there is still a significant gap in gene sequence determination technology related to human disease between developed countries, we are on the same level regarding information on human body origin resources bank sector and gene, and on clinical bio-dynamics. In the areas of personalized prevention and treatment program on diseases, Korea can lead the world market in the coming years thanks to its IT facilities. ○ Regenerative medicine using the stem cell: The number of Korean research papers on embryo stem cell ranked fourth in the world (Cell Stem Cell, 2007) and 5 Cell therapy theories using adult stem cell are in the process of clinical trials. ○ Clinical Trials: In Korea, many hospitals are acknowledged for their advanced medical technology and excellent human resources. Recently, Korea’s clinical trial infrastructure has improved rapidly, and leading global pharmaceutical companies have shown great interest in Korea’s pharmaceutical sector. In 2006, about 100 multinational clinical trials were performed in the country. ○ Imaging and living body diagnosis devices: 5 products including ultrasonic image diagnosis device and PACS, are in a sector

which Korea has technical expertise in and the potential world market leader based on the world's best IT. ○ U-Health: the domestic market share of home mobile healthcare in 2012 is estimated 1,200 to 2,000 billion won. And there is potential for growth by using domestic cutting-edge IT thanks to having a public patent rate of 41.5% (U.S: 29.8%, Japan: 22.4%, Europe: 6.3% (2006). ○ Biogeneric (biosimilar): Korea's biogeneric development capacity is as high as developed countries in that interferon and EPO were introduced into the market from 1990s. As worldwide blockbuster pharmaceuticals' patent expires, there is a prospect for generic market of 67 billon dollars from 2007 to 2012. ○ Development of Incrementally Modified Drug: Korea's technology in IMD equals the level of advanced countries. Hypertension drug Amlodipine was developed in 2004 and sold 0.1 billion won in 2005 and 2006.

What is your assessment of the impact that cost containment measures such as the Drug Expense Rationalization Program (DERP) are having on South Korea's pharmaceutical industry performance and ability to invest in innovation?

In 2006, Korea enforced the DERP in order to stabilize the finances of National Health Insurance. The DERP has positive effects on customer welfare, but it is likely to bring difficulties in terms of actual sales, results and R&D of pharmaceutical companies. To solve this problem, the government has improved predictability through prior consultation, promoting market progress through a reduction of the insurance benefit registration period. In addition, the government tries to implement systematic complements such as limiting economic efficiency evaluation from the new medicine as a whole to a part. However, even before enforcing DERP, the R&D portion of Korean pharmaceutical companies was only 4~6% of the sales compared to 15~20% in developed countries. This is very low in order to achieve the potential value. These days, the Korean government and companies are trying hard to secure transparency in business, which will allow the industry to transfer past investments in rebates towards R&D.

How would you rate the level of public-private partnerships (PPP) in South Korea bringing together government, research institutions and the industry for increased R&D and new drug development?

The Korean pharmaceutical industry is promoting public-private partnerships (PPP) in order to have greater capital and technical strength. The government actively invests and supports the pharmaceutical industry to develop new drugs and export technologies. Furthermore, we expect consistent expansion of the research capacity. In particular, there have been active exchange and cooperation among global pharmaceutical companies in the clinical R&D sector. In April 2004, KHIDI, KPMA (Korean Pharmaceutical Manufacturers Association) and SDI (Scottish Development International) collaborated to conduct research development. In June 2007, Pfizer concluded the

MOU with the Ministry for Health, Welfare and Family Affairs to invest 300 billion won until 2010 for global clinical training, strategic approach, producing R&D experts, technology transfer and information sharing. In January 2008, CCCP (Core Centers for Clinical Pharmacology: Seoul National University Hospital, Severance Hospital, Asan Medical Center, Busan Paik hospital) and J-CLIPNET (6 hospitals in Japan, leading clinical pharmacology) also reached a cooperation agreement to develop new drugs. In October 2008, KHIDI, Novartis and KOTRA chose Korean venture company PharmAbcine to invest in as a part of the GATE (Get Armed to Explore Global Market) project. We plan to further continue to invest in bio-venture companies.

How does South Korea’s health industry competitiveness compare with regional Asian players and global leaders in terms of health industry education, R&D, infrastructure, technology and regulatory framework?

In general, the Korean pharmaceutical industry has a high educational standard. Compared to other Asian countries, our price competitiveness is not the strongest asset, but in terms of technology alone, we have greater competitiveness. In addition, the Korean pharmaceutical industry has secure political and economic stability. On the other hand, compared to developed countries in Europe, the U.S. and Japan, we have relatively high educational standard but have lower technical expertise. In terms of price competitiveness, it is understood as a fairly good level. In particular, in terms of cost, multinational pharmaceutical companies facilitate CMO (Contract Manufacturing Organization) with intermediate components and API (Active Pharmaceutical Ingredients) in countries such as India and China, who have superior price competitiveness than Korea. Because of that, the countries like India and China are becoming Asia production base. However, there are still some manufacturing examples such as BMS which has chosen Celltrion in Korea for biological medicine production in volume. Korea also performs latter intermediate or API commission for a Japanese pharmaceutical company. Korea’s patent technology competitiveness has grown increasingly: ranking 20th place (from 1994 to 1997) to 17th place (1998 to 2001) to 15th place (2002 to 2005). In Korea, the capacity of global clinical trials has also been growing. For example, the number of multinational clinical trials by multinational pharmaceutical companies has increased, from 33 approvals in 2000 to 146 in 2005.

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