Young-jin Kim – Chairman & CEO, Handok, South Korea

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Historically, Handok has been the entry point of multinational companies to Korea. Now Handok is reinventing itself as a total healthcare company with global ambitions. Its chairman and CEO, Young-jin Kim, explains how he has continued his father's legacy while also driving the transition to new

product development by following an open innovation model and diversifying the company's portfolio into OTC drugs, medical devices and health functional foods through partnerships and acquisitions.

Since the foundation of Handok in 1954, Handok has shaped the Korean pharmaceutical landscape by establishing manufacturing, technology, and distribution collaborations with international companies. How have you leveraged your experience to continue this legacy?

Founded in 1954, Handok has grown through strategic partnerships with global leaders in healthcare and has contributed to the Korean market by bringing high-quality medicine. In 1959, we built our first factory with licensed technology from Hoechst. We have always been regarded as the benchmark for manufacturing quality among other Korean companies. In my early years at Handok, I had the chance to observe the manufacturing practices at Hoechst. The factory built in 1959 was located in the outskirts of Seoul at the time but due to city's expansion it found itself in

the middle of a residential area, so we decided to move the facilities in 1995. We invested substantial resources in building a new state-of-the-art factory that could become a tactical manufacturing site for Asia. Still to this day, it is considered as the best GMP certified factory in Korea. In the beginning, we exported products to more than 20 countries from Hoechst then Aventis. Today, we still continue this collaboration with Sanofi as we have developed Amaryl (combination therapy of sulfonylurea and metformin) and export to all the countries where Sanofi distributes these products.

Handok also manufactures products for MNCs for the Korean market. Before the late 1980s, the local regulation required international companies to produce their drugs locally. After the regulation changed, many international companies stopped producing locally and looked for partners to provide toll manufacturing services. As a result, in 1989 Handok started providing toll manufacturing for many international companies such as Roche, Pfizer, Bayer, GSK, Eisai and Janssen.

Moreover, according to the Korean regulation, if companies stop local production and start importing finished products, they must first repeat quality testing. Multinational companies asked us whether we can provide this service. In the beginning, I was somewhat hesitant to engage in this new business as I was not sure if it would be sustainable. At any moment, the regulation could change and Handok would lose part of its business. Moreover, I was worried if we could keep our price competitive advantage. Luckily, my worries did not materialize and Handok has gained unique expertise in terms of quality control.

Under my leadership, Handok also pioneered medical marketing in Korea. In fact, we were the first Korean company to establish a medical affairs department. At the time, my peers were critical of Handok for recruiting medical doctors. We recruited a doctor and sent him to the US to be trained in pharmacology. Through the years, Handok has built one of the strongest expertise in clinical development and regulatory affairs in Korea.

Handok distributes an extensive portfolio of ETC and OTC drugs, medical devices and health functional foods. Why did Handok decide to diversify its portfolio in these different business areas?

Until 2005, we had a limited portfolio. 80 percent of our business was prescription drugs, mainly Aventis products, less than 10 percent in diagnostics and the rest in OTC. We went through a difficult period after the hostile takeover of Aventis by Sanofi. All of a sudden, our partner changed

from Aventis to Sanofi. After tough negotiations, both parties agreed on the value of continuing working together but to split into two separate entities without changing the shareholding structure. Sanofi kept its 50 percent ownership stake in Handok while Handok owns shares in Sanofi. By becoming an independent entity, Handok lost the opportunity to bring the future pipeline of Sanofi to Korea. As a result, we had to start looking for new products. We strengthened our business development team and were able to quickly sign new partnerships with MNCs. For instance, Handok and Novartis established a co-promotion partnership for Galvus. We also formed partnerships with Actelion, which is still going strong despite the takeover by J&J in 2017.

Even though we were able to establish these partnerships, it became clear that Handok could no longer solely rely on the small Korean market for growth. Since 2007, the pricing regulation started becoming increasingly tougher which has deteriorated the profitability of the pharmaceutical industry, especially for established medicine, while Handok relied heavily on off-patent drugs. To face this business challenge, Handok adopted a two-pronged strategy. On the one hand, we started our own research programs. On the other hand, in order to survive in the Korean market, we expanded our portfolio of OTC and medical devices as well as health functional foods, under the condition that we only select quality products. As part of this strategy, we acquired Amore’s pharmaceutical division, Pacific Pharma, in 2013. The main target was Ketotop, a topical pain relief patch, their leading product with USD 20 million in sales. Now five years later, sales have doubled, and we have built a plaster factory to produce Ketotop. We are now expanding international sales, predominantly in Asian countries such as Singapore, Malaysia, Vietnam and Uzbekistan, and more recently in Algeria.

Handok is now foraging into new drug development in various treatment areas. What is your R&D strategy?

Handok is a late-comer when it comes to R&D because we did not do any basic research as a joint-venture, whereas other traditional pharma companies in Korea had been doing basic research for many years. As a result, the challenge for Handok was how to catch up to them in a short amount of time. Fortunately, I had experience in big pharma companies. For ten years I acted as Country Manager and General Manager for Hoechst and Aventis where I learned a lot about basic research. My main takeaway from this experience is that basic research is like a black box where you put a lot of things but never know what will come out. If you are lucky you might get one promising compound. Most of the time you get nothing. As a result, I decided to follow an open innovation. Fortunately, we identified promising opportunities at that time. In particular, we started

collaborating with Genexine, a Korean biotech, on three projects. While two of them failed, one of them, our biological drug for growth hormone deficiency, has proven successful and is now entering Phase III in the US and Europe. In order to strengthen our relationship with Genexine, we acquired a 30% majority stake in the company for USD 30 million, which has now been diluted to about 18%. When we invested in Genexine, I made it clear that we did not want to interfere in its operations and follow a model similar to the one established between Roche and Genentech. In the meantime, Genexine has made a lot of progress. Genexine still does not have a product on the market but we do hope some of the projects in their pipeline eventually reach patients.

What is your strategy to bring the products in your pipeline such as your growth hormone to the global market?

We cannot market the growth hormone product by ourselves and are actively looking to form partnerships with global companies. Moreover, in order to establish a presence in the US market, Handok, together with Genexine, acquired Rezolute, an American biopharmaceutical company. Rezolute spent more than USD 60 million to develop a long-acting insulin that only reached Phase I. As a result, the company was running out of cash. Luckily, it was able to license-in two compounds including an orphan drug for diabetes already in Phase IIB. As a strong player in the diabetes field, we were interested in acquiring this drug candidate. In addition, they have a very strong clinical team experiences in growth hormone development that can help us perform Phase III trials for our growth hormone in the US.

Although Handok’s ambition is to go global, I think it remains important for us to strengthen our position in Korea by securing products for the local market. We agreed with ABL Bio to receive exclusive rights in Korea for seven compounds. This deal also strengthens our position in oncology In oncology, we are still behind but have secured promising anticancer biologic drugs from ABL Bio, as well as a chemical drug, that are entering Phase I in Korea. I really wish to go further in this area.

The Korean government is pushing Korean companies to globalize but many of them struggle. In your opinion, what model should Korean companies follow to go global?

Celltrion is trying to establish subsidiaries globally to market their own products instead of partnering in order to retain more margin. I am not sure of this model can be successful as Celltrion

is competing with big pharma companies who already possess such a strong marketing power and established relationships with stakeholders around the world.

In my opinion, if we are lucky, a handful of Korean companies will succeed in developing two or three blockbuster drugs. It took Japanese companies more than 20 years to find global success, and they also started by licensing out.

At Handok we pursue a philosophy of “open innovation” to build our internal pipeline through external collaboration. Through this, the company is strengthening its product pipeline and raising its R&D capabilities in a short period of time, while laying the foundation for securing global competitiveness. In recent years, Handok has invested in US-based bio-ventures, such as Rezolute and TRIGR Therapeutics, based on an expanded open innovation strategy.

The vice president of KPBMA called for the support to Moon government to the pharmaceutical sector saying that viewing the pharmaceutical sector as a thing to regulate, it should evenly promote it as it did for the semiconductor industry. What is your assessment of the government’s role in developing the pharmaceutical industry?

The pharmaceutical industry is under the Ministry of Health and Welfare. The primary concern of the Ministry of Health and Welfare is to regulate the industry and manage the health insurance fund. We have been asking the government for many years for the pharmaceutical industry to be transferred under the supervision of the Ministry of Science and Technology, but to no avail. Moreover, the government is mainly focused on helping the biopharmaceutical sector due to the success of biosimilars and have somewhat neglected traditional pharmaceutical companies. We are not a bio-venture. For bio ventures, funding is much easier to come by and if they fail, that is it. However, for a company like Handok that has been traded on the stock market for decades, failing is not an option. This is the reason why we believe open innovation is the way forward for Handok.

What are next milestones for Handok to achieve your ambition of becoming a global total healthcare company?

I think we still have a long way to go to become a truly global company. That being said, we now have a solid foundation to achieve this goal in the next five to ten years with our diversified pipeline, in particular, our growth hormone product. However, Handok is well on its way to becoming a total healthcare company in the next three years. In the OTC business, as I mentioned,

we are globalizing our sales of Ketotop. In the field of medical devices, we have invested in Venture Companies. One of them is developing an ultrasensitive diagnostic chip which we plan to commercialize internationally in two years. Another is Handok Kalos Medical which is developing a non-invasive therapy device for resistant hypertension that has already received CE certification, and is patented in the US, Korea, and Japan. My ambition is to develop this product globally. Finally, in the functional food area, we acquired Theravalues Corporation, a company in Japan that has developed Theracurmin, the most advanced version of curcumin that dramatically increases the bioavailability and is patented in many countries including the US, Europe, Japan China and Korea. We are already selling in Korea, Japan, the US and China and are now entering Europe. We wish to grow this brand. To conclude, we now have a diversified product portfolio to globalize and have established the grounds for success.

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