Young Kim – Founder & CEO, Synex, South Korea

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Young Kim, founder and CEO of Synex Consulting Ltd., a consulting fi

rm assisting healthcare companies in introducing and marketing their products on the Korean market, discusses how Synex's ICC (In-Country Caretaker) service allows smaller firms to overcome regulatory barriers without having to set up an affiliate years prior to a product launch. Ms Kim also assesses the state of regulations affecting innovation in Korea, and how this will impact Korea's hopes of becoming a hub for the 4th industrial revolution.

Ms. Kim, as the founder of the company, what was the gap in the market that you recognised and believed Synex could occupy?

I founded the company 17 years ago. At that time Korea was overlooked by many of the global companies. Thus, I believed that there was a lack of diversity of healthcare technologies in the market and that Korea needed the same level of variety for healthcare technologies as other countries in the world, giving Korean patients more choice and a better quality of care. Therefore, I wanted to become a kind of hub to bring globally developed technologies into the local market.

What are the main services you offer?

Many pharma companies now have large operations in Korea, with a full set of representatives covering market access. Companies like Biogen have become substantial in the market only in recent years. Thus, they are still trying to enter into the market, but preparation for launching a first product usually takes 4-5 years: 2-3 years for registration and another 2 years for approval. By using the competencies and services of Synex, prospective companies do not have to set up their own legal entity. We call this our in-country caretaker service

Indeed, Biogen worked with us through our in-country caretaker service but are now in the process of transferring their license to their own local affiliate to begin launching their product. We anticipate the reimbursement of their first product in the near future. Nonetheless, not all of the customers leave our services once they become viable in the market. We have a number of customers that wish to continue using our in-country caretaker services; we import the product and supply to their distributors. Biogen is an exception, given that their product is a blockbuster. Smaller companies stay with us for a more significant period of time, until they reach a commercially viable size. We have 25 customers who continue to demand our market services from import services to distribution. In fact, we have one customer who have remained with us for 14 years because of their satisfaction with our operations, in particularly regarding regulatory support.

We also provide a clinical operation, but this is not yet as competitive as I would like. The global CROs bring global research into the Korean market. The Korean market is huge in terms of clinical operations sites, but we focus solely on development companies, helping them to develop their own technologies, rather than receiving clinical operations from global companies.

What are the main challenges for companies coming to Korea?

The greatest challenge for international companies entering Korea is establishing a working network of professionals within the industry and the regulatory agencies to enable the introduction and sale of a product. This year, the most successful new customer has been Dexcom, a US based company importing glucose monitors. The company first requested our services a year ago. Through working with us intensively, they have already launched a product and are in the process of finalising reimbursement. The Vice President of the company told me that when he came to Korea for the first time last year, he had no contacts locally – no doctor, distribution agency, or reimbursement official. His only contact was our company. Through Synex, we connected them to all the necessary contacts so that he could advance and introduce products. We were also able to

provide our opinion on potential new contacts that he required, be they doctors or distributors. Furthermore, Synex advised them when responding to government queries. Thus, it is safe to say that we help our companies navigate through a very volatile period.

Where are the best opportunities to bring innovation to Korea?

Pharmaceutical companies in Korea are in the stage of incremental development, rather than innovation. We assist them in the innovation for incremental improvement. We strive to contribute to developing the needed R&D competencies within Korea. These R&D competencies are hard to obtain within the industry as a whole. In my experience, this will take 30 years to develop and Korea is only ten years into the process. Consequently, there is more time needed before Korean companies have the infrastructure and know-how for real innovation. At the moment they are in a stage of trial and error, a learning stage. By trying incremental development, companies can learn how to innovate.

Korea has been successful with stem cells and biosimilars. How well adapted are the regulations for new innovative products if Korea is to embrace the 4th industrial revolution?

I believe Korea has a large potential to become the leading country in biotech, AI, or Nano-technology. The main issue is that we continue to wait for the government to take real action that is needed to capitalise on this potential. In my view, the government is holding them back by not implementing the appropriate regulatory system to encourage the innovation process.

Regarding biosimilars, these require large volume manufacturing. It is not really R&D. These are manufacturing and processing technologies which are easier to obtain. For other types of innovation, perhaps up to ten times more competencies are required to start from the beginning of the process and progress to the end. Companies like Celltrion or Samsung Biologics are basically manufacturers and have yet to be successful in real innovation.

The regulations that govern Korean companies in the early stages of stem cell development are different. The Korean regulatory framework is not as ambitious as the US FDA. Korean regulatory products have already approved seven stem cell products. However, the approval criteria were not to as high a standard as the US FDA’s. This is not necessarily a bad thing but depends on what the regulatory authority is looking for. In Korea, the regulatory authority prefers to approve the product

and allow the product to be tested by the patient, to receive feedback on the technologies. The US FDA is more risk-averse and requires a certain level of confidence in the product before allowing its use by patients. Korea is endeavouring to advance its regulatory system; many of the bills pending debate in the national assembly, such as the medical technology law, cutting edge pharmaceutical law, demonstrate an exerted effort by policymakers to expedite the innovation process and to prevent companies being bogged down by government regulation.

While I believe the government would like to achieve this, there remain too many stakeholders, all of whom have a different level of understanding, from individual patients to high-level scientists and doctors. Patients fear that deregulating the industry will expose patients to the risk of untested technologies. In contrast, scientists are pushing regulation change so that Korea can keep up with the USA, the EU, and Japan. Unfortunately, the government lacks the power and focus to consolidate all of these opinions into one policy direction.

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