

# Interview with Kang-Choo Lee, President, Korea Drug Research Association (KDRA)

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21.09.2009

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What was the vision behind the creation of the Korea Drug Research Association and its main role in the pharmaceutical sector?

Until the middle of the 1980s when Korea Drug Research Association (KDRA) was established, the Korean pharmaceutical industry did very little in terms of innovation activities in R&D. They focused on manufacturing of licensed drugs and marketing activities, like most of the multinational pharmaceutical companies did in their history of growth until they finally become knowledge-based global leaders. With the adoption of the substance patent system in 1987 and establishment of KDRA in 1986 representing the R&D-based Korean pharmaceutical companies, Korean pharmaceutical innovation activities started on a full scale to equip the industry with knowledge-based innovation for securing a competitive edge in the global market with its own new drugs. In 1986, KDRA was established by leading pharmaceutical companies, based on the law for upbringing industrial research to cope with global trends changing and challenges, such as the adoption of substance patent system focused on the inventors' right of intellectual properties, speed-up of knowledge-based economic & market system, the global call for free trade, economic & industrial needs for globalization, etc. Since its establishment, KDRA has been leading the R&D based Korean pharmaceutical industry, representing 57 R&D-based pharmaceutical companies leading the industry, facilitating innovation activities for new medicines, doing advocacy for governmental policies that encourage the research and development of life-saving and life-

enhancing new medicines for patients by R&D-based pharmaceutical companies in several areas. KDRA has also been involved in achieving R&D incentives for new medicines & pharmaceutical companies, efficient regulatory affairs system, governmental research funds able to make up for the shortage of R&D funds etc. KDRA's leadership is not restricted to these areas. KDRA has since its establishment been accelerating the R&D collaboration activities between R&D-based pharmaceutical companies and domestic & overseas partners, colleges & universities, start-ups, public & research institutes etc. For this purpose, KDRA has often been managing directly several industry-academic R&D consortiums for new medicines sponsored by the government and industry. At present there are 2 consortiums existing under the control of KDRA. Since 2000 when PTBC (Pharma Tech Business Center) was established as a KDRA subsidiary organization for promoting domestic & overseas technology transaction, technology transfer, licensing and R&D co-works, KDRA has also been devoting much attention to global R&D out-sourcing activities with KDRA member companies to improve R&D efficiency through the time & money-saving R&D and ultimately carrying out a global win-win strategy. Lastly, with aims of accelerating information exchange and sharing new business opportunities, KDRA organized and now manages several professional groups & committees in areas of technology, business, API, regulatory affairs and pharmaceutical research analysis with 400 experts from 300 associate member companies.

How would you rate the progress of the Korean pharmaceutical industry with regard to innovation over these last two decades?

During the past two decades the world has witnessed a lot of progress in R&D innovations from the labs of Korean pharmaceutical companies. Back when R&D-based Korean pharmaceutical companies began innovation activities, all they had was a lack resources and financial capacity for large-scale R&D investments, scarce R&D infrastructure, little R&D experience etc. But they did have talented manpower and passion. They really began innovation activities in full swing on the basis of their talented manpower and enthusiasm, annually investing 50-80 percent to their net sales profit. Although this was still very small when compared with the MNCs' R&D investment scale, the country is rising like a phoenix from the ashes just as it did after the Korean War in the 1950s. As a result of the innovation activities, the R&D-based Korean pharmaceutical companies have developed 15 new drugs in total, since the first Korean new drug received KFDA approval in 1999. Moreover, LG Life Science Inc. one of the R&D-based companies has succeeded in launching a powerful new drug FACTIVE, a powerful quinolone antibiotic, in the United States. There are currently several Korean candidates in clinical trials in the United States waiting for US FDA approvals. Many of the R&D-based Korean pharmaceutical companies have also successfully out-licensed several dozen promising technologies and new drug candidates to MNCs for commercial

research and R&D collaboration for local market launch. Furthermore, there are at present several hundreds new drug R&D pipelines being refined in labs. Until recently, the R&D-based Korean pharmaceutical companies have focused on in-house innovation from basic research to development. As for R&D collaborations and partners, they have also focused on domestic co-works with start-ups, academic and research sectors. But over the last several years they have been extending the scope of R&D collaboration to the global level in order to overcome the R&D limitations and cope actively with the changes and challenges in global circumstances. These include the Free Trade Agreements between nations, high cost & low efficiency in R&D, reinforcement of regulation, market needs for custom-made medicines & healthier life etc. Recently MNCs are increasingly interested in and aware of the potential in terms of resources and R&D abilities of Korean pharmaceutical companies. This may be the result of global trends changing, in which MNCs are facing a decline in their own R&D efficiency and gradual patent expiration of their major drugs. We, KDRA, also hope that in the near future there will be more and more collaborations and alliances for innovation in the pharmaceutical industry between R&D-based Korean pharmaceutical companies and global partners, including MNCs, to draw the resources for win-win outcomes and mutual development.

How does the pharmaceutical industry fit within the government's plans to transform South Korea into a knowledge-based economy for the 21st Century?

Like other countries around the globe, Korea is on a constant mission to grow and make improvements to its economy. Since we do not have an abundance of natural resources like some other places, Korea has focused on knowledge-based industries as the main motor to develop the economy towards the future. In this regard, the pharmaceutical industry is one of the most representative knowledge-based sectors that exist. South Korea counts with highly qualified human capital, which the government is supporting in their quest to develop new drugs. Both the public and the private sectors have committed to making big investments in the fields of pharmaceutical innovation and biotech to this end.

In your view, which are the key strengths of the pharmaceutical industry and market in South Korea vis-à-vis other emerging countries in the area?

South Korea's main strength within the Asia-Pacific region, and indeed the world, is its high level of education and the very well trained human capital that we have. Korean pharmaceutical industry technology is very appreciated abroad and being exported in significant amounts. Another of South Korea's advantages is the good level of collaboration between the industry and the research institutions. As for the market, it is one of the biggest in the world and keeps growing; with an

ageing population and a lot of disposable income. Korean society has evolved a lot over 20 years, creating a very broad market with a large diversity of distribution channels. In Korea everyone is a consumer and it is possible to monitor the scale and trends of the market, which is not the case in China, for example.

To what extent are multinational companies investing in R&D and clinical trials in South Korea today?

Until recently, multinational companies in Korea have mostly focused on localization of their own medicines, manufacturing and marketing their products. In the past, there were several manufacturing facilities owned by MNCs in Korea, but it is very regretful that most of them have withdrawn from Korea in recent years. And when it comes to the MNCs' R&D, it seems that most of them have not had any interest at all because there are no R&D facilities operated by any of them. Instead of R&D activities, they have been doing and investing in clinical trials of their own products to launch in the Korean market. Despite all this, most of the MNCs traditionally have good relationships with Korean pharmaceutical companies, especially in drug marketing, R&D alliances etc. And they have also long contributed to the improvement of healthcare in Korea. Personally I am very glad to hear that several MNCs have interest in Korean R&D abilities and recently they decided to invest in several R&D projects done by Korean companies and research institutions. We, KDRA, really hope for the strengthening of R&D collaboration & partnership between Korean R&D-based pharmaceutical companies and MNCs in the near future. And furthermore - of course this may be a personal expectation - I hope that they will do R&D projects in their own R&D centers in Korea in collaboration with KDRA members which are ready in terms of R&D abilities, experiences and passions for new medicines.

Which are the leading players among South Korea's pharmaceutical companies?

The first major milestone for a Korean pharmaceutical company was for SK Chemicals which was able to launch Sunpla on the market in 1999. Of the association's 57 members, most are involved in R&D projects at different stages, either independently or through collaborations. There are a dozen players with considerable success, but the biggest players in sales are Dong-A and Hanmi.

Looking towards the future, what are the main challenges and opportunities for the Korean pharmaceutical industry in the coming years?

The pharmaceutical sector has two main objectives to reach: to improve human health and to advance the industry's development. These goals have come into conflict since the government has issued a series of laws heavily regulating the sector with the aim to reduce healthcare

expenditure. This could hamper many companies' ability or willingness to invest in R&D, so it is an obstacle that for the benefit of all must be overcome. The FTAs with the USA and possibly with Europe bring a new set of challenges for the local pharmaceutical industry as well, but I am confident that as in the past we will find the way forward. Korean companies will have to cooperate more closely amongst each other and with multinationals. With a strong industry focus on R&D and contributions from the government and research community, we hope to create a global Korean pharmaceutical company.

What is your final message to the readers of Pharmaceutical Executive on behalf of KDRA?

It is very important for the world to realize South Korea's potential and to know the reality of what is happening in the country's pharmaceutical industry. We have already made great progress in areas like human resources and manufacturing standards, and continue striving to be globalized and at the same level of the most developed pharmaceutical markets in the world.

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