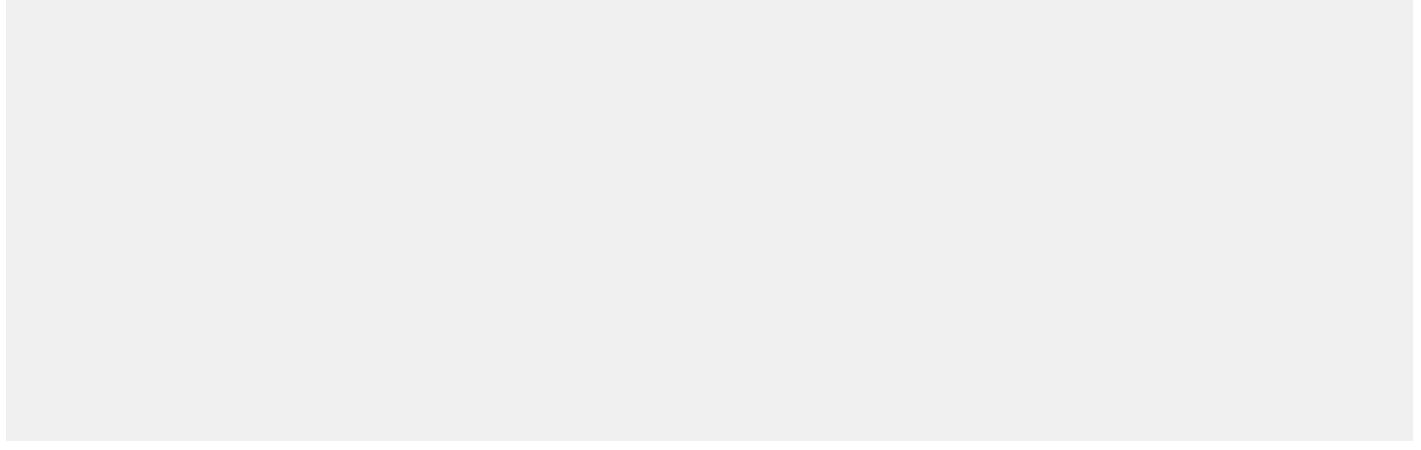


# Interview with Kyu-Hwang Lee, Executive Director, Korea Research based Pharmaceutical Industry Association

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Since KRPIA's creation in 1999, what would you say have been its main achievements in the South Korean pharmaceutical landscape?

KRPIA's foremost achievement during its existence has been its contribution to bringing the focus on R&D to the pharmaceutical industry in South Korea. Our member companies spend between 17% and 20% of their sales on R&D activities globally. These global research-based companies based in Korea spend 5~7% of their local sales in R&D, a figure that is expected to grow significantly as Korea is gaining importance amongst advanced nations. As the pharmaceutical industry in Korea moves forward, we play a key role in highlighting the importance of innovation. Healthier people are also more productive, so there is a significant contribution to the country's development as well. Likewise, the pharmaceutical industry has been supporting economic growth through increased employment. Lastly, KRPIA has established valuable communication channels between the industry and the government, particularly in terms of discussing global issues and policies regarding the pharmaceutical and healthcare industries. In a globalized economy, research based companies are agents for introducing new concepts in key areas like management and technologies.

What is your assessment of the South Korean government's intentions of supporting the development of the BT industries so as to match the success of other areas like IT and automobile?

As an economy reaches a certain level of development, the industrial structure starts focusing on the services sector as an added-value source of further growth. In this regard, the biotechnology (BT) industry has been identified by the government as one of the key priorities for the future development of South Korea. The BT sector in the country encompasses several different businesses within the healthcare industry, but the drug discovery industry is certainly one of the key areas. The government has plans announcing their intention to support the development of the BT industry in the long term, but we would like to see more in terms of specific initiatives in this regard.

After two years of the Drug Expense Rationalization Plan (DERP) was established by the government to contain healthcare expenditures, what is your assessment of its success in reaching its objectives and of its impact on the pharmaceutical industry?

Since it is the South Korean government which pays the bills of the country's universal healthcare system, they are understandably focusing on cost containment measures in order to make it more sustainable. However, KRPIA considers that some aspects of this policy are counterproductive for one of the government's other stated priorities which is to develop the health industries. In particular, we have pointed out many areas of disagreements and made recommendations in reference to the Drug Expenditure Rationalization Plan (DERP) which came into effect in late 2006. Although the plan has had a certain degree of success in stabilizing public healthcare spending, its negative impact on the pharmaceutical industry is far greater. DERP is further contributing to distortions in a market which is already affected by asymmetric information and a government monopoly on insurance reimbursements and price. We understand that this is a market which requires regulation, but DERP has gone too far. There are specific effects such as lack of clarity and transparency stemming from those measures, which give the impression of arbitrary decisions by the government in terms of reimbursement and pricing policies. The criteria for these fundamental decisions are expressed too broadly and with a lack of scientific definitions and, moreover, there are inconsistencies between the HIRA and NHIC. In sum, over-regulation is hurting both the competitiveness of the pharmaceutical industry and companies' willingness to invest in R&D activities for new technologies and drug discovery.

How comfortable are global research-based companies in South Korea with regard to intellectual property protection and the question of aggressive generics competition on the market?

South Korea has made significant progress in terms of intellectual property protection, so the members of KRPIA consider that this is not a matter of concern. Indeed, once the FTA with the United States is ratified a new system linking patent protection and the Korean FDA approval process will come into effect. Nonetheless, we believe that current regulations offer generic manufacturers excessively high prices for their products, illustrated by the low price differential between original and generic drugs on the market when compared to international standards. This ensures generic players high margins, contributing to maintain a fragmented pharmaceutical market and to discourage investments in R&D. Indeed, the situation is particularly unfair regarding the introduction of innovative drugs on the market, for which the price is now determined based on a basket of many other drugs with over 80% of the market share. Having this imprecise system in which ultimately the price is based on a quantitative measure of other drugs (mostly generics) places South Korea far from international standards on the matter. Generics, unlike new drugs, do not require intensive R&D investments, so clearly this is an unbalanced system. It also fails to value all the additional effects and benefits of innovation to patients.

To what extent are the global research-based companies operating in South Korea also investing in terms of R&D and manufacturing?

Global research-based companies based in South Korea are making great contributions to clinical trial activity in the country. It is true that in the pharmaceutical industry there is not yet a large amount of investments in R&D in the early phases, but that also has to do with a lack of existing infrastructure and of trained human resources for that purpose. But the investments by global research-based companies based in Korea in clinical trials are quite significant, expected to exceed \$1 billion between 2006 and 2012, and as the capabilities develop they are likely to be more active in pre-clinical stages as well. I believe that this is an area in which there can be more cooperation between global research-based companies, local companies and the government. There is a lot of talk about supporting the BT industry, so we should be seeing more concrete incentives for conducting R&D in South Korea. In terms of manufacturing, many global research-based companies have decided to withdraw from South Korea in recent years, for several reasons. Primarily this has been a result of a lost in cost competitiveness, since both labor and land in South Korea are considerably more expensive than other regional manufacturing hubs like China. Likewise, the recurring difficulties between management and the strong labor unions are also mentioned as a key factor which led to the closing of production sites in Korea.

South Korea's pharmaceutical market has been growing strongly for many years, but to what extent is this sustainable as the government gets tougher on prices and reimbursements?

The expectations are for the Korean pharmaceutical market to grow at a rate of 10% on top of GDP evolution over the next several years. This will be supported by a growing economy, greater disposable income among the middle class, as well as an ageing population, which will call for more quality healthcare systems and medicines. Additionally, new diseases related to increased life expectancy and changing lifestyles will continue gaining ground. In consequence, there is reason to believe that there will be a growing need for the kinds of new drugs that research-based companies including KRPIA members can provide. And despite all the reservations we may have about some industry policies, there are certainly many opportunities for global research-based companies to grow in the Korean market towards the future.

Which do you consider to be the main highlights of the Free Trade Agreement (FTA) signed in 2007 between South Korea and the United States for the pharmaceutical industry?

The Korea-US FTA will provide a framework which will facilitate access to innovative medicines for Koreans, and allow the local pharmaceutical industry to export more easily to the world's largest market. Hopefully the FTA with Europe will also succeed along similar lines and create further opportunities to increase pharmaceutical industry trade.

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

KRPIA members hold regular board of director meetings and teleconferences in order to keep up to date and discuss the main issues affecting the global research-based companies operating in South Korea. As KRPIA's member companies have expertise and know-how on R&D, we can play a significant role for the development of R&D in Korean Pharmaceutical industry in cooperation with KPMA which is mainly composed of local companies. Therefore, we will work to increase predictability and improve irrationality of current policies which have some obstacles of R&D development in Korea. We will contribute to achieve two goals together; one is contribution to the health of people in Korea and the other is the development of the industry.

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