# KHIDI – Jung Yun-Taek, Head Researcher, Pharma Division – South Korea



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*Dr.*

*Jung Yun-Taek, head researcher of the pharmaceutical division at the Korea Health Industry Development Institute (KHIDI), discusses the real potential that Korean pharmaceutical companies offer to the rest of the world for disruptive and incremental innovation.*

**What are the current trends in Korea's pharmaceutical industry?**

The global market size of the pharmaceutical industry of 2012 is about USD 959 billion and Korea's market share is about USD 19 billion, or about two percent. As such the pharmaceutical industry represents approximately 1.3 percent of Korea's GDP and 4.86 percent of manufacturing GDP. Growth in recent years has been stagnant compared to other industries; nevertheless the industry is poised for continual growth. There are 647 domestic pharmaceutical companies in total, and the top 20 cover 48 percent of total production in Korea. 26,425 items are manufactured here which is comparatively small but the average production per company amounts to USD 21.8 million. The number of wholesalers and distributors has also increased significantly with 23,991 companies. There are 285 manufacturers of finished products, many of which have achieved GMP standards. However only about three companies make more than USD 500 million.

Korean pharmaceutical companies are experiencing greater export with a balance of USD 2 billion as of 2012. APIs and finished products' annual growth rates in recent years and our exports to pharmerging markets are increasing in comparison to developed markets. Japan, Vietnam, China and USA are all among the top five for exports.

**Historically, what have been the milestone achievements of the Korean drug industry?**

Korea's drug industry started to develop in the 1890s with Dong-Wha, the first pharmaceutical company in Korea. Up until the 1970s, Korea was focused on finished products and raw materials. In the 1980s, Korea was invited to the product patent system. In the 1990s, early stages of new drug development were already underway, with the introduction and Korean approval of a new cancer drug by Sunpla in 1999. By the 2000s, full-scale new drug development was commonplace, particularly with incrementally modified drugs (IMD).

LG Life Science's Factive was approved by the US FDA in 2003 and Dong-A recently had an antibiotic approved by the US FDA. This product was licensed out to a company in the US. Korea ranks in the top ten for clinical trials worldwide, and Seoul was ranked as the number one city in 2012 for clinical trials. Korea is ranked the $14^{th}$ worldwide by the ethical and prescription market, and the domestic market was valued at USD 11.7 billion in 2011 according to IMS.

**Will Korea be known as a country for incremental or disruptive innovation?**

It will be a combination of both. The government aims for a pharmaceutical market ranking of seventh by 2020, and to do so the industry is try to implement three business models. The first is to develop at least two companies to the top 50 level of big pharma companies. The second is a focus on specialty pharma, and the third is the global generic pharma industry. KHIDI promotes all three business models in Korea. Generics and IMDs will generate the most sales, and the final goal is to focus on disruptively innovative medicine. Celtrion's *Remsima*, a monoclonal antibody, was the first biosimilar to be approved by the EMA in 2013, and Hanmi's *Esomezol*, originally an AstraZeneca drug, was incrementally modified and approved by the FDA last year, the first Korean IMD to be approved by the US regulatory agency.

Historically, Korea has had very good new drug release competency, and every year since 1999 has seen at least two or three new drug approvals, totaling 21 new drugs and 31 new IMDs since then. Pharmicell has also received approval for a stem cell therapy product, and Green Cross's Hunterase for Hunter syndrome. Anterogen's *Cupistem* for Crohn's disease also has great potential. These drugs are being engaged in clinical trials worldwide.

It is true that many companies used to focus on generics but now it is more about innovative pharmaceuticals, with a Korean investment of USD 8.9 billion between 2013 and 2017. 671 items are currently new drug development in the pipeline, and we expect 30 new drugs by 2020.

**Where does Korea fit worldwide in terms of clinical trials?**

Many other countries' companies are participating in Korean clinical trials. Likewise, Korea is cooperating with global pharmaceutical companies and has made contracts to export domestically developed drugs in overseas markets. Global clinical trials are being conducted to acquire overseas licensing. Exports will become very important as part of an aggressive growth strategy and raise exports from USD 2.3 billion to about USD 20 billion by 2020. Korea also aims to double its R&D investments. We have benchmarks for our three strategies of global generics, specialty pharma, and global pharma. Many of our universities are geared towards new drug development, and KHID has about 100 GPKOL (global pharma key opinion leader) members in other countries, ranging from R&D strategy, GMP, regulatory affairs, to product management, and clinical trials. We would like to see at least two Korean companies among the top 50$^{th}$ pharmaceutical companies worldwide, with three blockbusters approved by the FDA and EMA, I hope to see Korea as a top seven pharmaceutical powerful nation by 2020.

**Where does KHIDI fit into this boosting of R&D investments?**

Previously there were many government R&D programs, but nowadays things are changing. Open innovation is very important for creating new drugs, so global openness is very important. Singapore has the BioPolis, KHIDI and A$^{*}$STAR makes the contract of the MoU, Korean products are developed in Singapore, and the governments of Korea and Singapore are granting money with Korean products.

**KHIDI engages in a number of partnerships and MoUs in countries across the world. Which partnerships would you highlight for pharmaceuticals?**

Last year, we contracted an MoU with the National Institute of Health in the United States and with NICE in the United Kingdom. There are many government to government activities, especially in the Middle East and Latin America. Recently, Ecuador became the first country to have homologation for drugs approved in Korea. A Korean company recently signed an MoU with the Saudis, and we can support them in the manufacturing of drugs

**Do these partnerships come about from your active searching, or do people come to you?**

KHIDI and the Ministry of Health are actively supporting the contact of other countries, gathering information to provide to Korean pharmaceutical companies. Essentially, we're trying to make a fast track to approach drugs. Given the enrichment of many emerging markets, countries without local pharmaceutical flagship companies become a great opportunities for us. In general, Korean companies have rapidly accelerated since the Korean War, our universal healthcare system is good, and healthcare expenditure is very low, representing only 7.6 percent of GDP in 2012. Korea healthcare system can be a benchmark country; many government officers visit Korea and KHIDI is invited to explain on behalf of pharmaceutical companies regarding our good quality and good infrastructure of our ministries.

**What would you like to achieve in the coming years?**

Korea is creating a success story in this case. The typical Korean success stories usually point to Samsung or Hyundai. The pharmaceutical industry could join that global standard. To have one of the top 50 companies become a Korean business would be great. Foreign companies are investing in Korea, especially generic manufacturers like Alvogen, Teva and handok with joint ventures. Koreans are already in contract with the United States for free trade agreements; the main issue is with patent linkage. The Korean market and R&D is very nice and good offers many opportunities for multinational companies.

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