Kim Ribbink

Ahn-Nyeong SOUTH KOREA

Emerges

With a sophisticated and highly evolved healthcare market, South Korea is a world-class destination for clinical trials and innovation.

In just three years, South Korea has been reclassified from an emerging market to a developed market by IMS. This is based on South Korea's GDP level, as well as a well-established and growing economy, rising income levels, better living conditions, and an improved healthcare system that has led to general improvements in public health. For example, infant mortality has decreased and life expectancy has increased, according to a report from Fast Market Research.

"South Korea still has some characteristics of an emerging market, but combined sales of prescription drugs and OTC medicines are forecast to post high single-digit compound annual growth rates over the next five years," says Jamie Davies, head of pharmaceuticals and healthcare analysis at Business Monitor International (BMI). "The operating environment is similar to that of traditional markets."

South Korea's pharmaceutical market is valued at $17 billion, says Jong Ran Kim, senior director for Asia clinical operations, Icon Clinical Research.

"South Korea is the third-largest pharmaceutical market after Japan and China in the region and the country's economy has continued to grow in double digits since 2002," Ms. Kim says.

Consumer spending in the nation's drug market is expected to top $16.8 billion by 2014, with an estimated CAGR of 7.1% in local currency terms, according to BMI. An aging population and the impact that has on drug demand and the planned liberalization of the country's health insurance industry are predicted to increase pharmaceutical expenditures to $23.42 billion by 2019.

"South Korea's developed and high-growth economy, an aging population, a talented workforce, a robust infrastructure, as well as governmental support in promoting biopharmaceutical innovation make the country attractive for multinational biopharmaceutical companies looking to develop, manufacture, and market their products," says Michael Klein, head of sites Asia, Quintiles.

The Pharmaceutical Landscape

Recently, large foreign companies dominated the South Korea marketplace, but they are now suffering the fallout from the loss of patent protection on their best-selling products.

"A number of the top 100 drugs are licensed to and marketed by South Korean drug

FAST FACT

THE BIOLOGIC SECTOR IN SOUTH KOREA IS EXPERIENCING RAPID GROWTH AND MANY DOMESTIC COMPANIES EXPANDED THEIR OPERATIONS IN 2010.

Source: The Pharmaceutical Market: South Korea, Espicom

manufacturers, but October 2008 statistics from South Korea's Health Insurance Review Agency (HIRA) revealed that only 14 of the country's 100 best-selling prescription drugs were developed by local companies," Mr. Davies says.

South Korea's strengthened position in the Asia-Pacific region are due to its support of innovation and intellectual property protection.

"South Korea rewards innovative patent-protected medicines at international price levels," says Jan Willem Eleveld, VP, management consulting, IMS, Asia Pacific.

"In addition, there is a developing local R&D environment that is likely to generate more innovative medicines."

Mr. Davies notes that 15 new molecular entities discovered by South Korean pharmaceutical companies have been approved by the Korea Food and Drug Administration (KFDA) since 1999. To put this achievement in context, India and China, with much larger economies, have yet to introduce any internationally recognized innovative medicine, he says.

Among the government's initiatives aimed at stimulating innovation is Bio-Vision 2016, a national plan to promote biotechnology aimed at strengthening the core infrastructure necessary to develop and commercialize original biotechnologies, Mr. Klein says. "Supported by the country's strong R&D infrastructure, the local pharmaceutical industry players, whose traditional focus has been on the generic business, have in recent years turned their attention to the discovery and development of novel, originator drugs," he says.

Aside from governmental support of life sciences, factors such as strong ties to the United States and an export strategy focused on high-margin, easily transportable goods, such as medicine, are major drivers, Mr. Davies notes.

Won-Jung Choi, CEO of DreamCIS, says Korean pharmaceutical companies realize the importance of R&D investment in new drugs, and are seeking to compete at a global level.

For example, Hanmi Pharmaceuticals' invested 15.4% of its revenue in R&D in 2010, an increase of 39.2% compared with 2009; Green Cross invested 5.56%, a 96.3% increase; and Dong-A Pharmaceuticals invested 7.64%, a 26.7% increase, Mr. Choi notes.

For international companies, Korea's intellectual property protection improved significantly with the April 2007 signing of the US-South Korea (KORUS) FTA, which ensures transparent, predictable, and nondiscriminatory pricing and reimbursement of innovative and generic pharmaceutical products, medical devices, and biologics, Mr. Davies notes.

"In 2009 as well as 2010, however, PhRMA recommended in its version of the Special 301 Submission that South Korea be placed on the Priority Watch List for countries with the most serious free trade and intellectual property protection failings," he says.

The Connected Physician

The Internet is a critical component of physicians' work and learning in South Korea. Online journals, news, medical references, conferences, peer-contributed information, and other digital content have become integrated into the physician resource mix and almost all of the physicians online for professional purposes say the Internet is essential to their practice.

Here are a few key trends about how online physicians in South Korea use professional information and services:

- Search engines are integral in day-to-day info seeking for physicians surveyed in South Korea, with about three-quarters of physicians using search engines weekly or more often.
- Medigate and KIMSonline are the most popular professional websites among physicians surveyed.
- More than half of physicians surveyed expressed interest in being able to access medical images through pharmaceutical websites.
- Although the Internet is an important part of the physician resource mix, recommending websites to patients is not a common practice in South Korea, with only one-third of physicians surveyed doing so.

Source: Manhattan Research, Taking the Pulse Asia v10.0 (2010)
For more information, visit manhattanresearch.com.

"High-growth areas are related to key unmet medical needs, such as hepatitis, oncology, and cardiovascular."

JAN WILLEM ELEVELD / IMS

"Reimbursement procedures are improving and more innovative products are making the list of applicable medicines."

JAMIE DAVIES / BMI

Clinical Attractions

In 2002, the South Korean government implemented its IND policy, marking a turning point in the clinical research industry.

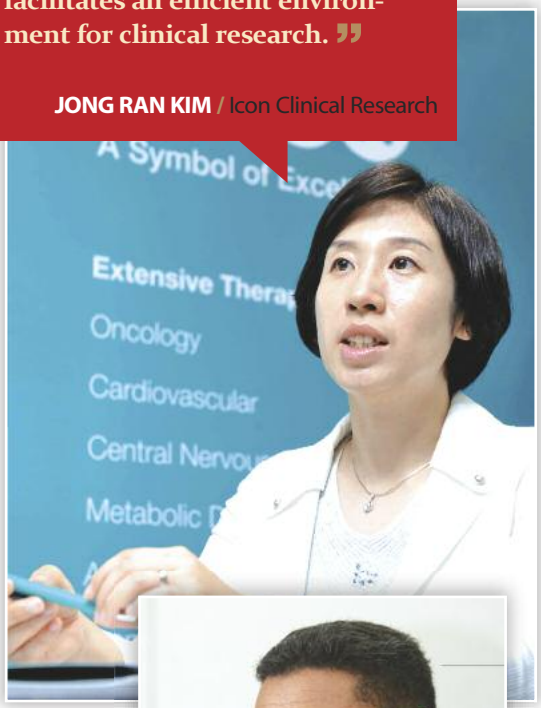
"The policy meant that multinational pharmaceutical companies were allowed to practice clinical research in Korea for the early stages of developing new drugs," Mr. Choi says.

Mr. Choi adds that 438 INDs were approved in 2010, a significant increase from 202 in 2009. There also has been a growth in early-phase clinical trials, he adds, noting that in 2010 preclinical and Phase I trials accounted for 22.6% of the total number of approved trials (99 out of 438).

Oncology, cardiology, CNS, endocrinology, infectious, and respiratory are the six leading therapeutic areas based on investigator sites involved in registered industry-sponsored clinical trials, Ms. Kim says.

There are a number of reasons why South

> "South Korea's regulatory system protects new drug patents and facilitates an efficient environment for clinical research."
>
> **JONG RAN KIM** / Icon Clinical Research



> "The rapid growth of South Korea's biopharmaceutical industry is due in no small part to local government support."
>
> **MICHAEL KLEIN** / Quintiles

Korea is considered an attractive market for clinical trials, including the ability to recruit patients, the fact that hospitals designated as clinical research centers are located in major cities, and medical services meet global standards, Mr. Choi explains.

"Many hospitals have clinical trial centers — one-stop, dedicated centers to support clinical trials, including study coordinators, continuous training for investigators, dedicated pharmacy and pharmacists, archiving facilities, dedicated monitoring rooms, and so on," Icon's Ms. Kim says.

In addition, the government has invested $60 million to establish nine regional clinical trial centers by 2011 that are designed as support centers in certain regions, she says.

These advantages prompted Quintiles to extend its global prime site program to South Korea last year by partnering with Seoul National University Hospital (SNUH).

The rapidly evolving clinical research industry has led to the need for more experienced CRAs, and it can be challenging to recruit the required level of staff, Ms. Kim adds.

In addition Ms. Kim says, the KFDA requires extensive documents as a part of its IND submission packages; CMC data, preclinical data and clinical data are required.

"These complicated data need to be summarized into a KFDA-specific format translated into Korean," she says. "Because of the large volumes of documents that need to be translated and the extensive data requirements, there can be a delay in the preparation of the IND submission package."

South Korea: Market Facts

- Population: 48.4 million
- Population growth: 0.27%
- GDP (PPP): $1.2 trillion
- Per Capita Income (PPP): $24,800

Source: 2010 CMR International Asia Pacific Pharmaceutical Factbook, October 2010.
For more information, visit cmr.thomsonreuters.com.

Reimbursement

Government assistance with medical fees also encourages companies to invest in R&D.

"When a Korean pharmaceutical company receives regulatory approval for a product approved by the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), or Japan's Pharmaceuticals and Medical Devices Agency (PMDA), the maximum cost covered by national health insurance will be ensured for five years," Mr. Choi says. "When launching generic drugs or biosimilar products that involve R&D investment at some level, the cost covered by insurance will be 80% to 90% of that new drug."

"Reimbursement procedures are improving and more innovative products are making the list of applicable medicines, although more can be achieved," Mr. Davies says.

South Korea has a well-functioning reimbursement system, where all Koreans have access to healthcare, Mr. Eleveld says.

"The focus for companies is to get their product approved for reimbursement," he says "This is a two-step process and can take considerable time. Engagement with key stakeholders as well as a transparent negotiation process are keys to a successful and speedy outcome."

> "Easy Internet access, active discussions among patients, and the prevalence of smartphones contribute to the changes in the medical sector."
>
> **JUNGHWA LEE** / Kantar Health

The Health Insurance Review & Assessment Service (HIRA) is responsible for reviewing medical fees, assessing quality of healthcare institutions, and evaluating whether healthcare services are medically necessary and delivered to beneficiaries at an appropriate level and cost. Participation in the program is mandatory for all Koreans except for low-income citizens.

To curtail the overuse of healthcare services and lessen the burden on medical services in large urban hospitals, copayments have been set according to the level and type of medical institution.

For example, major general hospitals, including sanitarium and university hospitals, would incur a 60% copayment for convalescence and examination costs, says DonKi Kim, an expert with GLG. A clinic, being a smaller center, would incur a copayment of 30%.

There is a ceiling on copayment to prevent financial burdens on citizens who experience a catastrophic or high-cost illness.

Mr. Kim says the burden on national medical expenses is rapidly increasing, causing the national insurance scheme's financial status to deteriorate.

"The expense this year is assumed to be 3,8139.4 million KRW ($34 million) but income is assumed at 3,7626.4 million KRW ($33.5 million), he says. "With health insurance at risk of financial depletion, an increase in fees is likely."

The insurance fee for salaried employees already has increased from 5.33% to 5.64%, and this will keep increasing constantly and more rapidly, Mr. Kim adds.

At the end of 2006, the Korean government implemented the National Health In-

> "There is a need for the government to strictly manage medicines that are competitive in the domestic market."
>
> **DONKI KIM** / GLG

> "It is very likely that South Korea will function as a global hub for clinical trials for the next four to five years."
>
> **WON-JUNG CHOI** / DreamCIS

surance (NHI) Drug Expenditure Rationalization Plan (DERP). Key to this was a change in the NHI drug management system from a Negative List System, in which all medicines were covered by insurance, to a Positive List System, in which explicit item-by-item approval is needed for reimbursement.

The financial burden is growing and it will be important to find ways to reduce costs, both through the Positive List System and by paying close attention to pharmacoeconomic data.

According to Mr. Kim, it will be harder to reduce medical costs due to development of new medicines.

"This means competitive medicines should be compared with existing medicines and the price should be based on pharmacoeconomic data as a way to reduce costs," he says.

The DERP allows for a number of ways to cut costs and Mr. Kim says more can be done, including decreasing the price of the first generic after the original drug's patent expires, continuously evaluating prices against those of the advanced seven (A7) countries, and conducting follow up analysis to adjust the price to match those of other markets.

On the Market

Recently, there has been a crackdown on promotional activities in the country. A new regulation from the Korean Research-based Pharmaceutical Industry Association (KRPIA) introduced in 2010 prohibits companies from offering rebates to physicians to prescribe medications.

"The purpose of the regulation is to root out the cause of high drug prices and improve transparency," says Junghwa Lee, general manager, Korea, Kantar Health. "This policy has limited the marketing/promotional activities of companies to some extent."

This is because of the limits placed on consulting and market research activities by KRPIA's Mutual Fair Trade Regulations

"On the other hand, a variety of patient-support programs and community-service activities are being developed," Ms. Lee says.

For example, pharmaceutical companies have been monitoring patients' influence on prescriptions and promoting patient-support programs to accommodate their needs and improve the system so that their opinions are reflected in the prescribing process, she says.

"Companies will need to thoroughly evaluate and understand their served markets in South Korea as well as the latent and expressed needs of these market segments to successfully shape the positioning of their brands and go-to-market strategies," Mr. Klein says.

The biggest therapeutic areas by sales volume in South Korea include cardiovascular (hypertension and thrombosis), endocrine (diabetes and hyperlipidemia), and cancer (specifically targeted cancers) drugs, according to IMS data. Studies about biosimilar products and compound products for treating hypertension, hyperlidemia, and diabetes are actively ongoing at the moment.

"Also, the entry of antithrombotic and anticoagulant drugs into the market is being evaluated" Ms. Lee says. PV

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EXPERTS

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Biosimilars and Generics Gather STEAM

Kim Ribbink

South Korea is embracing the biosimilar industry after the government pledged to provide support.

In an effort to make South Korea a market leader in biosimilars and generics, the government has pledged to provide both financial and institutional support and is aiming to capture 22% of the global market by 2020.

In a meeting with leaders of local pharmaceutical firms, the Minister of Knowledge Economy Choi Kyung-hwan said: "The local generic pharmaceutical industry failed to advance to the global market because it just settled for the domestic market. We need to make this an opportunity for South Korea to become a leader in the global bio and pharmaceutical industry."

In 2009, South Korea released a draft guidance on biosimilars, in line with the European Medicine Agency's (EMA) biosimilar regulatory framework.

"There is no harmonized worldwide regulatory framework for biosimilars, but South Korea is one of the countries in the Asia-Pacific region with specific guidelines," says Jong Ran Kim, senior director for Asia clinical operations, Icon Clinical Research.

Ever since the South Korean government officially announced biosimilars as a new engine of the country's economic growth, South Korean pharmaceutical companies have been eager to participate in the market, says Junghwa Lee, general manager, Korea, Kantar Health.

"So far, five clinical trials have been approved, subsequently followed by the recent approval of Samsung Electronics' IND for MabThera," Ms. Lee says.

In March 2011, Korea FDA approved Samsung Electronics' IND to commence Phase I clinical trials of a biosimilar of Roche's MabThera (rituximab), marking the first step of the electronics and semiconductor giant's ambition to enter the healthcare sector.

> "Since the government announced biosimilars could be a new engine of the country's economic growth, South Korean pharmaceutical companies are eager to participate."
>
> **JUNGHWA LEE** / Kantar Health

MabThera is the first and only selective B cell therapy for rheumatoid arthritis (RA).

In February, Samsung announced plans to invest $264 million in a joint venture with Quintiles in Incheon, South Korea, to pursue biosimilars.

The venture will build a new plant that the partners expect to be able to bring into production by 2013.

Ms. Lee notes that Celltrion, LG Life Sciences, and Dream Pharma also will be competing in the biosimilars industry.

"Because biosimilar development can be advanced to Phase III immediately after Phase I, the biosimilar product can be released before the biopharmaceutical product's patent expires," Ms. Lee notes.

In March 2011, the state of Incheon announced plans to promote Song-do as the new hub of the bioindustry in South Korea, says Won-Jung Choi, CEO of DreamCIS.

> "South Korea is one of the few countries in the Asia-Pacific region with specific guidelines on biosimilars."
>
> **JONG RAN KIM** / Icon Clinical Research

> "As patents on blockbuster biomedicines near expiration, the Korean pharmaceutical industry is paying attention to biosimilar products."
>
> **WON-JUNG CHOI** / DreamCIS

"The plan includes balanced development in manufacturing, research, hospital, and academic facilities," Mr. Choi says. "By 2012, the University of Biotechnology will be established and by 2015 biotech laboratories and postgraduate schools will be completed."

To support the biopharmaceutical industry, Incheon plans to set up an international hospital in Song-do, and in 2009 took its first step by signing a memorandum of understanding with Johns Hopkins Hospital.

Apart from biosimilars, drugs derived from natural products is another focus for the Korean pharmaceutical market, Mr. Choi says.

"Chronic diseases that existing synthetic, chemical drugs cannot treat require a new breakthrough, and substances extracted from natural products are one possibility," he says.

The Price of Medicine

National health insurance is well entrenched in South Korea. Industrial workers in large corporations have had mandatory health insurance since 1977, and this was extended in stages until by 1989 the entire population was covered. The Ministry of Health & Welfare provides general supervision over the operation. The National Health Insurance Corporation (NHIC) is in charge of administering the national health insurance program, including the management of the enrollment of the insured and their dependents, the collection of contributions, the setting of medical fee schedules, and the provision of health insurance benefits, and so on. PV

EXPERTS

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