



2016 Top Markets Report **Pharmaceuticals** Country Case Study

South Korea

South Korea's rapid economic growth has fostered the development of a robust healthcare sector in a relatively short period. Rising incomes, a growing elderly population and increased health insurance coverage are catalyzing pharmaceutical sales. While the country has a sophisticated domestic pharmaceutical manufacturing industry, imports from the United States and Japan remain a significant part of the market. An uncertain and difficult pricing and reimbursement environment, however, may affect the export outlook for U.S.-based pharmaceutical companies going forward.

Overall
Rank

19

South Korea is the 13th largest pharmaceutical market in the world and the third largest in Asia.¹ Sales are forecast to grow from \$15.1 billion in 2015 to \$18.3 billion by 2020, representing a strong annual growth rate of 3.9 percent. Current spending on healthcare reached \$101 billion, or around 7.4 percent of GDP, which is very low for a developed country.² Still, South Korea boasts a world-class health system in terms of access and quality and is one of the few Asian countries whose population is able to afford innovative treatments.

Like other developed countries with growing public healthcare burdens, budgetary constraints are leading to cost containment measures. In recent years, the South Korean government has slowed pharmaceutical market growth through aggressive price cuts and tightening reimbursement criteria for both innovative and generic medicines. Reimbursement prices of generics are already approximately half the average for OECD countries.

Due to a large domestic generics industry and government policies to encourage usage, generics make up a comparatively large portion of the total market at 47 percent. Further government price cuts,

Figure 1: Korea Snapshot

Population: 50 million
Population over 65: 6.6 million (13%)
Total healthcare expenditure: \$101 billion (7.4% of GDP)
Government healthcare expenditure: \$52 billion (51% of total)
Private healthcare expenditure: \$49 billion (49% of total)
Total pharmaceutical sales: \$15.1 billion (1.12% of GDP; 15% of total healthcare exp.)
Per capita pharmaceutical sales: \$301
Generic sales: \$7.1 billion (47% of total sales)
Patented sales: \$5 billion (33% of total sales)
OTC sales: \$3 billion (19% of total sales)
U.S. pharmaceutical exports: \$934 million

stricter regulations on sales and rebates and intensified competition, however, are creating a difficult environment for generics companies moving forward.

The patented drug sector has seen steady growth above the global average, growing at an average annual rate of 4.1 percent over the last five years. Innovative treatments are introduced swiftly following approval, and the United

States-Korea Free Trade Agreement (KORUS) contains provisions that, if adhered to, will strengthen the IP climate. Significant government subsidies and incentives are also being directed towards innovative companies investing in R&D. As with generics, however, government price cutting is dampening potential market growth.

U.S. exports

The United States exported \$934 million of pharmaceuticals in 2015, representing around 21 percent of South Korea's total pharmaceutical imports. Over the last five years, U.S. pharmaceutical exports have grown at an annual rate of 7.7 percent. With the KORUS deepening South Korea's reliance on U.S. medicine, the country will remain attractive to U.S. companies looking to pursue innovation and partnerships with local manufacturers in various parts of the supply chain. Low pricing and reimbursement levels, as well as the lack of predictability and due process in reimbursement decisions, still remain the primary concerns for U.S. companies.

Competitive environment

South Korea's domestic pharmaceutical industry is relatively advanced and dominated by large generics firms. In recent years, the government has used subsidies, tax breaks, reimbursement policies and IP laws to promote R&D investment by both domestic and multinational firms.³ The country now boasts a robust and growing R&D sector, particularly in biotech, with several locally-developed innovative drugs receiving approval in recent years.⁴ With the establishment of an approval pathway for biosimilars in 2009, South Korea aims to become a global leader in biosimilar development and stem cell research. The country has a booming clinical trials industry, bolstered by a streamlined regulatory process and world-class medical facilities. Seoul is now one of the world's largest clinical research centers by trial numbers.⁵

Demographics and disease burden

Due to a low fertility rate, South Korea's population over 65 is expected to increase from 13.1 percent of the total in 2015 to 15.8 percent by 2020. This aging population will sustain demand for pharmaceuticals given its high burden of non-communicable diseases, such as heart disease, obesity, cancer and diabetes. In 2012, South Korea recorded 220,000 new cancer cases,

which is the leading cause of death.⁶ An estimated 8.7 percent of the adult population has diabetes, and 22 percent of all deaths are caused by heart disease.⁷

Healthcare, reimbursement and pricing

South Korea provides compulsory, universal healthcare to all residents, regardless of citizenship, through the National Health Insurance (NHI) and Medical Aid Program. The NHI covers 97 percent of all residents and is funded by employers, employees and government subsidies. The Medical Aid Program is strictly government funded. The system is efficient in terms of providing high quality care with low administrative costs. It also relies on high co-payments from patients, set at 35 to 40 percent for drugs, and it is increasing reimbursement restrictions. Many individuals who require expensive treatments must therefore purchase additional private insurance.

Getting products listed on the NHI's reimbursable list is crucial for success in this market. As the only public insurer, NHI has an advantageous position in price negotiations, and the review process is complex. Drugs are assessed by two organizations, the Health Insurance Review & Assessment Service (HIRA) and the National Health Insurance Service (NHIS). HIRA first reviews a pharmacoeconomic analysis of a new medicine and sets a maximum price. NHIS then tries to negotiate down the maximum price with the manufacturer, taking into account projected sales volumes. The final price cannot exceed a basket of reference countries. The process takes about a year to 18 months before final ratification by the Ministry of Health and Welfare (MoHW). U.S. industry has raised a number of concerns about the predictability, methodology and transparency of this process, claiming that final price decisions often lack supporting data and scientific justification.

Once listed, drugs are subject to multiple price cuts for various reasons, such as punishment for illegal rebates, exceeding expected volume sales, fluctuations in reference country prices and automatic price reductions when drugs go off patent. The latter is of particular concern. Following patent expiry, the price of a generic drug is capped at 59.50 percent of the original drug's price. After a year, the cap is lowered again to 53.55 percent. But because new drugs are originally priced against a weighted average in a therapeutic category that includes generics, the patent-expiry price cuts cause a downward spiral in prices across the board.

The result is that prices for new drugs are set lower than those of existing drugs.⁸ Not only does this limit revenues for innovative manufacturers; it also depresses reference prices around the world.⁹

The government's cost containment efforts also include cracking down on illegal rebates and promotional practices. South Korea has had a history of overpricing scandals and pharmaceutical firms providing kickbacks to boost drug sales.¹⁰ In 2010, the government enacted legislation to regulate such behavior, which mostly targeted the business practices of domestic generics firms. Still, U.S. companies have noted that the regulatory language could be better clarified and more consistently enforced.

KORUS

KORUS entered into force on March 15, 2012 and contains provisions on facilitating high-quality health care and improving access to safe and effective innovative and generic pharmaceutical products. KORUS requires the United States and South Korea to ensure fair, reasonable and non-discriminatory treatment and to provide predictability and transparency in the pricing and reimbursement process for pharmaceutical products. Importantly, it also strengthens patent protection, such as regulatory data protection and IP enforcement. Since KORUS has been implemented, South Korea has reduced tariffs, enhanced its regulatory transparency and attracted further investment from multinationals.¹¹

Challenges and Barriers for U.S. Exports

Pricing and reimbursement

U.S. companies continue to raise concerns that, contrary to KORUS obligations, South Korean regulations relating to pricing and reimbursement of pharmaceutical products - such as continued price cuts on innovative drugs - do not appropriately recognize the value of innovation and lack transparency.

Under KORUS, any new regulations affecting pricing and reimbursement of pharmaceuticals are to be published in advance for comment, and the South Korean government is to address significant, substantive public comments received and explain any

substantive revisions made to proposed regulations in writing. The Ministry of Health and Welfare (MoHW), however, continues to make pricing and reimbursement policies with little transparency and opportunity for stakeholder input. Concerns remain that South Korea is, in practice, still not living up to its KORUS obligation to make available an independent review mechanism (IRM) for stakeholders directly affected by pricing and reimbursement decisions. Although the South Korean government argues it has already adopted an IRM for stakeholders, U.S. industry stakeholders argue that the system now in place does not function in the intended manner.

In addition, there are concerns regarding recent policies that allow pharmaceutical companies with drugs first approved in South Korea to negotiate prices confidentially through a rebate system. Such loopholes tend to discriminate in practice against foreign companies. Additional pricing incentives for locally developed drugs are likely in the works and should be monitored carefully.

Patent enforcement

As part of KORUS, in March 2015, South Korea instituted a pharmaceutical patent linkage system. Known as the "Green List", the system is designed to meet base requirements for deterring patent infringement prior to obtaining marketing approval for generic drugs. Its effectiveness remains to be seen, as the provision only provides for a nine-month sales stay, which may not be sufficient time to resolve a dispute, and sales stays are not automatic and could be denied.

Data submissions

U.S. companies remain concerned with South Korea's continued resistance to align its domestic patent rules fully with international standards. In particular, the Korean Intellectual Property Office (KIPO) requires onerous data submissions for pharmaceuticals at the time of filing and does not allow supplemental data to be submitted during patent challenges. The result is that some products that are patentable in other countries cannot be patented in South Korea.

¹ Figure 1: Korea Snapshot:

Pharmaceutical sales, Pharmaceutical sales per capita, Generic drug sales, Patented drug sales, OTC sales: Korea Pharmaceutical Manufacturers Association (KPMA), Korea Health Industry Statistics System, (KHISS) BMI Health spending, Govt. health spend, Private health spend: World Health Organization (WHO), BMI Population, Population over 65: World Bank/UN/BMI

See also: BMI, *South Korea Pharmaceuticals & Healthcare Report*, November 2015 (referenced throughout)

² Government healthcare expenditure as a percentage of total healthcare spending is far lower than the OECD average of 72.3 percent in 2012. Only three other countries - the United States, Chile and Mexico - had a lower percentage.

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⁵ PMLive, Catarina Féria Walsh, *Country report: The healthcare market in South Korea*, May 2012,

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⁶ International Agency for Research on Cancer/World Health Organization, *Globocan 2012: Estimated Cancer Incidence, Mortality and Prevalence Worldwide in 2012*, "Population Fact Sheets,"

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⁷ International Diabetes Federation, *Republic of Korea*, <http://www.idf.org/membership/wp/korea>

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⁸ The Pharma Letter, *South Korea's Pharma price setting system under criticism*, February 2016,

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⁹ The average price for a new drug in South Korea is 44.4 percent of the average for OECD members, and 73 percent of new drugs are priced the lowest among OECD members.

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¹⁰ BMI, *South Korea Pharmaceuticals & Healthcare Report*, "Regulatory Development," November 2015

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¹¹ BioPharm International, Jill Sackman, *Navigating Emerging Markets: South Korea*, August 2013,

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