

US-Korea Free Trade Agreement Pharmaceuticals



New Opportunities

- Korea is a \$1 trillion economy and the 7th largest U.S. trading partner
- Korea has committed to transparency in pricing and reimbursement procedures
- Korea has a steady and diversified growth of 4.6%, with small and medium size businesses taking on stronger and more dynamic roles within the economy.

The agreement contains provisions on pharmaceutical market access issues that go far beyond those in other U.S. FTAs. The agreement includes commitments to improve access to innovative products and to ensure the transparent, predictable, and non-discriminatory pricing and reimbursement of innovative and generic pharmaceutical products and medical devices. In addition, the agreement contains provisions to enhance ethical business practices, improve the predictability and transparency of the pricing and reimbursement system, and to establish a Medicines and Medical Devices Committee to monitor implementation of commitments in this area. The agreement also requires Korea to create an independent mechanism to review pricing and reimbursement decisions.

Industry Trends

The Korean market, the 12th largest pharmaceutical market in the world, was valued at USD 7.7 billion in 2005. According to industry sources, Korean market demand for pharmaceuticals is estimated to have grown by 11 percent in 2006 to reach USD 8.5 billion and is forecast to grow at an average annual rate of 10 percent over the next few years since the need for medical treatment for senior citizens is rapidly increasing.

The Korean pharmaceutical market has continued to experience unprecedented restructuring since 1999, when the Korean government implemented significant reforms to improve transparency in the health care system. These reforms have helped increase transparency in the reimbursement system and have, to some degree, leveled the playing field for multinationals. There have also been positive changes in the regulatory climate that have allowed smoother and earlier market access for new, innovative drugs. Multinationals have expanded their

share of the total therapeutic (ethical and over-the-counter) pharmaceutical market in recent years.

Business Tools

The US Commercial Service is ready to help your company enter and expand in the dynamic Korean market.

We can help you:

- √ Research market potential
- ✓ Locate and arrange appointments with qualified buyers and distributors
- Advise on intellectual property rights, regulatory hurdles, and government contracts
- Provide you with essential company background information that will help you make more informed decisions
- ✓ Launch your product in Korea with a promotional or technical seminar

With the Korean government's encouragement, the Korean biotech pharmaceutical industry is striving to invest more in R&D (currently only 4-5 percent based on sales revenue) and diversify from the production of generics and antibiotics. This trend presents excellent opportunities for U.S. biotech firms to participate in Korea's strategic biotech sector. Although Korea's pharmaceutical industry is competitive in terms of chemical synthesizing technologies, it is much less competitive in drug screening, safety evaluation and clinical trials. Korean companies are pursuing strategic alliances with multinational firms to finance R&D for new products or for cross-licensing of existing technologies. Industry experts predict that the U.S. market share will increase as more U.S. biotechnology-based products become commercially available over the next few years.

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