

7. KOREA

7.1 OVERVIEW

The Korean pharmaceutical market is currently valued at around \$8 billion, the fourth largest in Asia behind those of Japan, China, and India. While the market has been growing steadily at 7-9% per year for the past several years, the Korea Food and Drug Administration (KFDA) continues to work on the internationalization and improvement of the country's pharmaceutical regulations. In May 2005, the KFDA entered into a Memorandum of Understanding with the World Health Organization to participate in an International Program on Chemical Safety for pharmaceuticals and other medical products. Some of the departments under the KFDA and their respective duties include the following.

- Pharmaceutical Safety Bureau
 - Develops safety plans for drugs, cosmetics and medical devices
- Safety Evaluation Office
 - Controls the safety standards for drugs, devices and foods
- National Institute of Toxicological Research
 - Reviews safety and efficacy data submitted by drug registration applicants
- Regional Agencies
 - Agencies that conduct drug/food laboratory inspections and surveillance

7.2 DRUG REGISTRATION OVERVIEW

The *Guideline to Registration of Drug Substances* (KFDA Notification No. 2002-20) became effective March 25, 2004. This guideline outlines the drug registration process, including data preparation, the scope of the data required and possible exemptions from submission.

The registration of new chemical entities in Korea requires the completion of the *Application Form for Registration of Drug Substances*. The required items are as follows.

- Name, address and contact information of manufacturer
- Manufacturer's registration number
- Information on manufacturer's representative, including email address
- Conformity with Korea Good Manufacturing Practice, or other recognized GMP standards (i.e. US FDA GMP)
- Product trade name and generic name
- Product appearance, physical and chemical properties, and route of administration
- Manufacturing process and quality control measures
- Stability information
- Packaging, containers and product handling information
- Batch analysis, analytical procedures and solvents used