

- Storage and shelf life

If any of the above information is written in a language other than Korean, the original foreign language document should be submitted along with a summary in Korean. If necessary, the KFDA may request that a full translation of the information be made. Generally, the application review process by the KFDA takes approximately 120 days to complete. In the case of imported drugs, the KFDA may call for an inspection of the foreign manufacturing site; the applicant is notified of an inspection 20 days prior to the inspection.

### **7.3 ORPHAN DRUGS IN KOREA**

#### **7.3.1 Orphan Drug Definition and Legislation**

In Korea, orphan drugs are supplied to patients by pharmaceutical companies or the Korea Orphan Drug Center, and as of 2008, 156 orphan drugs had been approved by the KFDA.

The requirements for orphan drug designation in Korea are as follows:

- Fewer than 20,000 people in Korea suffer from the disease/condition, or there is no available treatment for the disease/condition in Korea.
- If the product is manufactured in Korea, the total production should be less than 5 billion won (U.S. \$5 million). If the drug is manufactured outside of Korea and imported for sale, the total imports of the drug should be less than U.S. \$5 million.

The orphan drug application process takes around 6 to 9 months to complete. Approved orphan drugs are generally granted about 6 years of marketing exclusivity, at the government's discretion.

In general, Korea has reimbursed orphan drugs at about one-half to two-thirds of the actual cost of the drug and doctor visits. Patient and parent groups have also lobbied the Korean government with some success. In some cases, though, reimbursement levels are too low for drugmakers. Currently, Shire Human Genetic Therapies is negotiating with Korea's National Health Insurance Corporation for higher reimbursement before it will sell Elaprase, a treatment for Hunter syndrome, into Korea. The NHIC determines reimbursement for orphan drugs on a case-by-case basis and is strongly oriented toward keeping overall medical spending down.