

6-4 Stable and Safe High-Quality Drugs

Ensure Safe, Stable and Timely Delivery of Medicines to Meet Patients' Needs

To ensure that patients can obtain safe and high-quality drugs on a timely basis, we inspect and consider all factors that may affect patients' accessibility to drugs in all management actions related to the right to the access of medicine, and draft solutions accordingly. By enforcing quality management before, during, and post- production and post-marketing, we provide a safe, stable, and timely delivery of drugs to patients so that the patients' needs can be met. As BESREMi[®] has obtained regulatory marketing approval from the U.S. FDA in November 2021, action plans that specifically address the U.S. market will also be described to provide American patients with access to medicine as well as to widen our impact to the overall medical and healthcare system and the external society. For a complete description of our quality and safety assurance at each stage of the product life cycle, please refer to [Chapter 3](#).

