

Material Issue 13

Stable Supply of Products

Management of Priority Issues

Reason for being a priority issue	The provision of a stable supply of our drugs to patients who need them is a basic duty of our business.
Vision over the medium to long term	Our products are supplied stably to patients throughout the world.
Indicators	<ul style="list-style-type: none"> • No out-of-stock incidences
Major activities	<ul style="list-style-type: none"> • Building a global product supply system • Implementing risk management for overall operations related to product supply, such as strengthening response to BCP, maintaining proper inventory, etc. • Examining mid- to long-term stable production systems, including increased production efficiency and the use of CMO, etc.

Management of the Supply Chain

In order to ensure a stable supply of high-quality medical products as a pharmaceutical company involved in health, ONO manufacturers all its drugs under an appropriate manufacturing and quality assurance system both in our plants and in outsourced companies. Although the manufacturing locations and suppliers of drug substances (APIs), raw materials, and formulations of pharmaceuticals are spread throughout the world and the supply chain has become increasingly complex, we are striving to supply pharmaceuticals that can be used safely by patients in compliance with the regulations and compliance requirements of each country and region.

In addition, we are working to further expand our supply chain for self-sales in Europe and the United States. We set appropriate inventory levels of APIs and products for each product according to the manufacturing lead time, delivery time, and number of manufacturing bases for APIs, raw materials, and formulations. By constantly monitoring and maintaining appropriate inventory levels, we strive to ensure a stable supply of products even when production is temporarily halted due to problems during manufacturing.

Initiatives to Keep Facilities Operating

To ensure stable production, we formulate and implement maintenance plans that combine preventive and post-maintenance for manufacturing equipment for oral and injectable drugs, air conditioning systems, pharmaceutical water systems, and analytical equipment used for various tests. Preventive maintenance involves replacing major parts of equipment and facilities and setting the frequency of periodic maintenance to avoid breakdowns due to age-related deterioration. In addition, to prepare for unexpected breakdowns, for parts that take a long time to be delivered, we keep spare parts in-house so we can quickly restore production and analytical equipment.

In addition, we have begun working on predictive maintenance of facilities, and have begun developing a system to prevent outages due to unexpected facility problems. This involves using AI to analyze the various types of electrical data, such as pressure and temperature measured during operation, and predicting failures.

If effective predictive maintenance can be established, it will lead to improved productivity by reducing the frequency of periodic inspections. We are also working to stabilize quality through the use of digital data, and are considering the use of digital data and AI in the visual inspection process of products, which requires the recruitment of a large number of inspectors.

Stable Supply of Products in Disasters

To ensure continuous supply of products even in the event of a large-scale disaster, we have formulated a crisis response and business continuity manual, and conduct periodic drills based on the manual.

From the viewpoint of stable supply, having multiple manufacturing bases is also important, and we have dispersed our own manufacturing bases to two locations: the Fujiyama Plant in Shizuoka Prefecture and the Yamaguchi Plant in Yamaguchi Prefecture. Furthermore, by actively outsourcing, we are diversifying risks in the event of a large-scale disaster. We have already established a system that enables us to produce Opdivo, our main product, at our two manufacturing bases, Fujiyama and Yamaguchi, and we are carrying out risk analysis for other products, and considering production at multiple manufacturing bases for other products as necessary.

In addition, we are working to secure multiple manufacturing bases for APIs because all APIs are outsourced. Risk assessments are also conducted for supply chains other than products and APIs, and efforts are being made to ensure a stable supply.



Fujiyama Plant



Yamaguchi Plant