Maximizing Product Value

ONO conducts R&D activities to maximize the product value of the anticancer drug OPDIVO, the biggest growth driver at ONO. It also works on exploiting the full potential of each of its products through marketing activities to shorten the time between product market launch to peak sales, and activities to ensure product quality and reliability.

Maximizing OPDIVO's product value

To maximize OPDIVO's product value, ONO works with its partner Bristol-Myers Squibb (U.S.A.) with focus on four perspectives.
We engage in adding indicated cancers. We work on development to obtain approval for adding more than 20 indications for carcinomas to the already approved indications: malignant melanoma, non-small cell lung cancer, renal cell cancer, Hodgkin's lymphoma, head and neck cancer, and gastric cancer.
For approved indications for cancers, the Clinical Development Division plays a leading role in efforts to enable OPDIVO as early as possible to be used at earlier stages from third- to second- to first-line treatment.
We also proceed with clinical trials in various combinations or dosages and dose regimens. OPDIVO may have more therapeutic effects in combination with another immune checkpoint inhibitor, chemotherapy with anticancer drugs with different mechanism of action, or radiotherapy, rather than alone.
Biomarkers, substances in a living organism, are indicative of any change in disease or reaction to therapy. Their measurements can be used as an indicator of presence or progress of disease or therapeutic effects. We advance the search for optimal biomarkers that will predict patients who are more likely to be expected to exhibit the therapeutic effects of OPDIVO.

Activities to maximize OPDIVO's product value

Adding indicated tumors	Working with corporate partners to progress clinical trials targeting various tumors
Adding treatment lines	Moving ahead with clinical trials to enable OPDIVO's use at earlier stages
Developing combination therapies	Searching for ways of boosting its therapeutic effects by combining OPDIVO with other drugs or treatments
Searching for biomarkers	Advancing the search for indicative biomarkers that will predict the effects of OPDIVO administration

Marketing (Scientific Information Dissemination) Enhancing Product Value Through Supply, Collection and Feedback of Proper Product Information

Drugs are of no value unless they can be used properly in those who are suffering from disease while undergoing medical treatment. Moreover, drugs could determine life or death. It is therefore of paramount importance that accurate information is supplied appropriately. Our medical representatives (MRs) shoulder this all-important role of communicating drug information. MRs meet with medical professionals to provide information on proper drug usage, as well as to provide and collect information on drug efficacy and safety.

Marketing Activities to Enhance Product Value

The Sales & Marketing Division develops a strategy formation that constantly ensures competitive advantage by adjusting with agility to environmental changes in each stage of the product life cycle to maximize the potential of every product we offer.
In addition, we make every effort to collect patient opinions through meetings with healthcare professionals to understand potential healthcare needs toward development of narrative-based medicine (NBM), which is based on actual clinical experiences for patients. We will make use of what has been obtained through these efforts in future information dissemination activities to enhance product value.

Maximizing Product Value

Information Sharing Framework Architecture

In addition to providing information, MRs uphold the importance of exchanging information with medical professionals to ascertain whether our drugs truly benefit each individual patient and their family throughout the course of the patient's treatment. Our information-sharing framework enables our MRs to share across the company the valuable information they gather from the frontline of healthcare. We also have a system in place that allows all the MRs to access the information at all times from their tablet devices. All the MRs are equipped with highly secure smartphones. The smartphones feature a sales force automation (SFA) system that makes the entire sales process more efficient, as well as functions for using the FAQ system.
Our framework promotes information sharing and enables rapid responses to healthcare providers' needs.

Relaying Up-To-Date Drug Information to Frontline of Healthcare

Pharmaceuticals and medical technology undergo daily advances. It is one of the roles of drug manufacturers to relay as quickly as possible up-to-date information about such drugs and technology to the frontline of healthcare and to provide opportunities for information exchange. ONO actively provides information by organizing symposiums and seminars in conjunction with academic conferences held in Japan and through workshops and lectures in regional areas.
In addition, we put effort into disseminating up-to-date drug information through operating several websites for medical professionals. In FY2017, we held more than 100 live webinars. We also provide small-scale area live webinars in line with community needs to relay up-to-date drug information to the frontline of healthcare.

Strengthening Community-Based Activities

With medical care zone initiatives for community areas proceeding toward the establishment of community-based integrated care systems, we propose possible improvements in the medical care systems through consultation with medical providers upon understanding of the characteristics of the healthcare provision system of each community area, so that our drugs will truly benefit each individual patient, to become a player who can carry out information dissemination activities to be appreciated by medical professionals.
As an activity that distinguishes ONO MRs from the rest, our MRs hold table discussion meetings (TDMs) in each area. TDMs are projects where lectures are organized based on themes proposed in line with the context of local healthcare issues, providing opportunities to solve questions in daily medical care through discussion with lecturers. TDMs are thoughtfully planned and orchestrated so as to contribute to local healthcare through responding to different needs of each area.

Manufacturing Enhancing Product Value Through Stable Supply of High-Quality Drugs

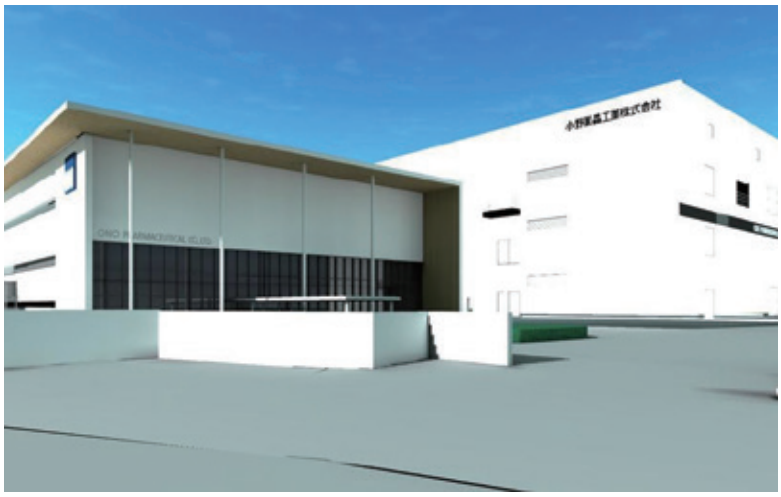
At ONO, all the divisions involved in manufacturing cooperate closely with each other and consistently maintain a strong sense of responsibility and ethics as they faithfully practice scientific evidence-based manufacturing operations according to the operating procedures and continuously make maximum efforts for the stable supply of high-quality drugs. We are committed to strengthening our capabilities in both hardware and software related to manufacturing activities for the stable supply of drugs.

Initiatives to Ensure Stable Supply of High-Quality Drugs

It is essential to improve productivity for stable product supply. We continually review production systems and invest appropriately in plant and equipment for further optimization of marketed products, while keeping in mind the timing of marketing, quantities and product features relevant to the production system structure for products destined for market launch. We are also consistently managing costs, from active pharmaceutical ingredient production to commercialization.
We ensure quality assurance and system reliability by monitoring efficacy and safety information, checking manufacturing and testing records for all products we manufacture, so as to deliver only products that have been ascertained to have assured quality.
We take various measures to stably supply high-quality drugs, including education and training of not only plant workers but also all other workers involved in production, and upgrading of risk management systems at our manufacturing centers.

Strengthening Production Systems

Our manufacturing centers in Shizuoka and Osaka are compliant with GMP (a set of standards relating to the manufacturing control and quality control of pharmaceuticals). The main Fujiyama Plant has continually improved and expanded its facilities since its establishment. In addition to strengthening our production capabilities aimed at future business expansion, a new plant is under construction in Yamaguchi to mitigate the risk of major disaster from the business continuity perspective. Equipped with a production line for highly active antibody drugs, this plant is scheduled to start operation in 2020 to serve as a manufacturing center that will support ONO's production capabilities together with the Fujiyama Plant.



As-built image of Yamaguchi Plant

Safety and Quality Assurance Enhancing Product Value Through Drug Reliability Assurance Activities

From a patient standpoint, ONO conducts drug reliability assurance activities with global perspective through drug life cycle to constantly check for drug quality assurance and reflect opinions from healthcare professionals and patients on further quality improvement. In addition, we analyze and assess, based on latest scientific evidence, drug quality and efficacy and safety (adverse reaction) information collected from, e.g., reports from patients and healthcare professionals, literature, and surveys, to constantly provide updates to the frontline of healthcare.

Quality Assurance Policy

We not only meet the legal requirements as a marketing authorization holder, but also set out our own quality manual to establish a drug quality system and work to continuously improve systems so as to provide high-quality drugs from the viewpoints of patients, caretakers and healthcare professionals. In addition, we contribute to society through stable supply of pharmaceuticals that are assured to a high-quality standard.

Initiatives for Proper Use of Pharmaceuticals

We develop a risk management plan and collect and manage safety (adverse reaction) information for each pharmaceutical. We assess collected data and information, and if necessary revise the cautions on package inserts and make announcements about proper use. As safety information drastically increases inside and outside Japan after market launch of antineoplastic drugs, we assess such information based on opinions from external medical experts to promote the proper use of the drugs, e.g., by disseminating it through promotional materials, conference presentations, and medical journals.

Maintenance of Product Recall System

We have a system in place to recall any products with efficacy, quality or safety problems and to promptly provide medical professionals with information on them. We also conduct periodical drills in preparation for product recall to check that they can be executed quickly even in unexpected circumstances.