Health

Under its corporate philosophy “Otsuka-people creating new products for better health worldwide,” the Otsuka group actively implements CSR initiatives based on the recognition that CSR is an integral part of our business. The desire to be healthy is universal. Every day, the Otsuka group carries out activities to prevent and treat diseases and to contribute to the maintenance and improvement of people’s health worldwide. The world continues to face a host of healthcare issues, such as the spread of infectious diseases, inadequate medical care facilities, and lack of effective therapies.

In aiming to solve these issues, we constantly ask ourselves if it is something that only Otsuka can do, and work to find solutions for unmet medical needs that the majority of other companies have yet to address. Moreover, issues such as medical cost inflation mean that maintaining and improving health is now an issue that society as a whole, not just individuals, must face head on. In addition to initiatives that raise awareness of health among individuals, the Otsuka group undertakes initiatives for maintaining and improving health in society at large, including through collaboration with local communities.

Pharmaceutical Business

The Challenge of Addressing Unmet Medical Needs

1. Psychiatry and Neurology

Japan’s Ministry of Health, Labour and Welfare has defined psychiatric disorders as one of the five major disease areas. The rising number of patients with such disorders poses a pressing global issue. However, while the list of psychiatric and neurological diseases is long, including schizophrenia, depression, bipolar disorder, and Alzheimer’s-related dementia, R&D in this area is challenging. The underlying causes of these diseases have yet to be precisely elucidated, and satisfaction with current treatment methods is low. However, patients and their families are in immediate need of new therapies. Psychiatry and neurology is a key area in which the Otsuka group has been making headway, namely with the development of antipsychotic drugs ABILIFY MAINTENA and REXULTI, as well as Selincro, a drug that helps in the reduction of alcohol consumption in patients with alcohol dependency. We are also taking on the challenge of developing therapeutic drugs for diseases with no effective medicines.

2. Oncology

As medical science advances, year by year progress is made toward the shift toward genomic medicine and personalized medicine tailored to the characteristics of the cancer in each individual patient. Going forward, we will continue to advance our R&D to deliver innovative therapeutic drugs to patients with greater speed.

3. Infectious Diseases

Tuberculosis is one of the world’s three major infectious diseases, the others being AIDS and malaria. It is the single infectious disease that accounts for the largest number of deaths. Multidrug-resistant tuberculosis is difficult to treat because it is resistant to a number of existing therapeutic drugs, and poses a serious public health hazard. Otsuka’s long period of research and development into a tuberculosis treatment culminated in the 2014 approval of tuberculosis drug DELTYBA. We are expanding access and bringing DELTYBA to more patients by obtaining regulatory approval in each country/region, and through programs developed by governments and international organizations, the Global Drug Facility launched by the Stop TB Partnership and by working with alliance partners. As of December 2019, DELTYBA is available in more than 100 countries/regions. Furthermore, we are responding to unmet medical needs by expanding indications for pediatric care and cooperating in a U.S. NIH-led trial for multidrug-resistant tuberculosis. Given this need, we are advancing R&D for OIC-167832, a new therapeutic drug to follow DELTYBA.

Partnerships

1. Eradicating Tuberculosis

The Global Health Innovative Technology Fund (GHIT Fund) is a public interest incorporated association and international public-private partnership involving the Japanese government, private corporations, the Bill & Melinda Gates Foundation, the Welcome Trust, and the United Nations Development Program (UNDP). It funds drugs, vaccine, diagnostic and other R&D in order to leverage Japan’s high level of technology and innovation in the fight against the world’s three major infectious diseases and neglected tropical diseases, which mainly affect developing countries. Since June 2016, Otsuka Pharmaceutical has contributed to the GHIT Fund as an associate partner.

2. Initiatives in Kidney Disease

Autosomal dominant polycystic kidney disease (ADPKD) is a hereditary, intractable orphan disease. It involves the progressive enlargement and enlargement of a large number of fluid-filled cysts in both kidneys due to gene mutations. The kidneys grow to many times their original size, resulting in the gradual deterioration of kidney function. Otsuka Pharmaceutical has signed a comprehensive partnership agreement on ADPKD with the Japan Kidney Association, and is working to raise awareness about ADPKD and improve the level of medical care. Otsuka Pharmaceutical has signed a collaborative agreement—also with the Japan Kidney Association—aimed at the practical application of basic research by young researchers in the kidney field. We are openly soliciting drug discovery research themes from academia through the Kidney Research Initiative-Japan (KRI-J)—a platform for collaboration between academia, industry and government established by the Japan Kidney Association. The signing of joint research agreements between the research institutions and Otsuka Pharmaceutical will enable us to carry out research on the selected themes.

Supplying Pharmaceuticals to More Patients

1. Fair Pricing and Improved Healthcare Infrastructure

With the aim of contributing to improved access to pharmaceuticals, the Otsuka group researches, develops and extends therapeutic drugs and IV solutions that address unmet medical needs. We also work to provide pharmaceuticals at fair prices to support improved healthcare infrastructure.

One example is Otsuka Pharmaceutical Factory’s approach to IV solutions, which are defined as basic drugs (a drug with high clinical necessity whose manufacturing and sales will continue to be required without interruption). * Group companies manufacture IV solutions locally, which contributes to local communities, such as through the supply of products at fair prices and the creation of employment opportunities.


2. Expanding Access to Medicine

There are patients who cannot expect satisfactory outcomes from existing treatments, and also are not eligible to participate in clinical trials with critical, life-threatening diseases. Such patients are unable to access investigational drugs that might be a potential treatment option. Through its Expanded Access Program, Otsuka group provides patients that are ineligible to participate in clinical trials with access to investigational drugs based on application by their physician and if they meet pre-specified conditions.

Nutraceutical Business

Initiatives for Yet-To-Be-Imagined Needs

To be healthy is a desire of people worldwide. Advances in medical technology and improvements in public health have extended life expectancy globally, but have also given rise to new health issues. The Otsuka group’s Nutraceutical Business is centered on functional beverages and functional foods that support the maintenance and improvement of day-to-day health. Our activities enable people worldwide to live healthy and independent lifestyles. Our contribution to health is not only helping to treat diseases, but also helping healthy people stay healthy through nutrition.

Current social issues include extending healthy life expectancy, responding to decreasing birthrates and aging populations, and controlling medical costs. We have set “the essence of life” as a theme for contributing to health. Under this theme, we are engaged in product development and information provision activities that are backed by scientific evidence based on applied expertise from the Pharmaceutical Business.

1. Health Maintenance and Improvement Initiatives in Coordination with All 47 Prefectures of Japan

The Otsuka group is promoting community-based health maintenance and improvement initiatives, as well as disaster prevention and relief activities. As an example, Otsuka Pharmaceutical has concluded health-related partnership agreements with all 47 prefectures of Japan. We are cooperating with local governments to find solutions to the health issues of people living in each region, which includes applying our knowledge and expertise on topics such as dietary education, prevention of lifestyle-related diseases, prevention of heat disorders, sports promotion, women’s health and disaster countermeasures.
2. Raising Awareness of Proper Hydration

Since the launch of POCARI SWEAT, Otsuka Pharmaceutical has been promoting the importance of hydration in various contexts. Surprised by the establishment of the Japan Amateur Sports Association (now Japan Sport Association) Study Group for Prevention of Heat Disorders in Sports Activities, our cooperation in efforts to prevent heat disorders through awareness activities began in 1992. Since then, we have provided information on such themes as children’s sports activities, occupational safety and hygiene, and hydration for the elderly. Otsuka Pharmaceutical’s website includes an information section titled Protect Yourself! From Heat Disorders and a section presenting content based on JSPSO’s A Guidebook for the Prevention of Heat Disorder During Sports Activities (First Edition). Another initiative is the Heat Disorders Prevention website, which was created in collaboration with weather forecasters. Through these and other activities, we are further raising awareness of the topic. In addition, Otsuka Pharmaceutical Factory, which sells OS-1, an oral hydration solution, provides operational support for Oshiete! “Kakure Dassui” linka, an organization that raises awareness of ways to prevent and treat dehydration before it becomes critical.

3. Raising Awareness of Women’s Health

The Japanese average life expectancy is over 80 years for both men and women. In 2015, average life expectancy was defined as the period in which a person can live without being bedridden and without limitation to daily activities due to health issues. The difference between average life expectancy and healthy life expectancy is about 9 years for men and 12 for women in Japan. Therefore, extending healthy life expectancy is a central issue under the Health Japan 21 (the second term) plan established by the Ministry of Health, Labour and Welfare. With greater participation in the workforce, women are faced with the issues of balancing work with childcare, nursing care, and personal health. The effects of rapid hormonal changes are felt by women in their 40s and 50s in particular, which can impact their everyday work and private lives. Furthermore, care taken during this period may impact their future healthy life expectancy. In response, Otsuka Pharmaceutical has developed a product containing equol, a soy-derived ingredient. It can help maintain and improve the health of women at a time when they are felt by women in their 40s and 50s in particular, which can impact their everyday work and private lives.

Group-wide Activities

1. 30 Years of the Otsuka Health Comic Library

We began publishing the Otsuka Health Comic Library in 1989 to promote sound growth and development of health habits among children of the next generation. Produced with editorial supervision from the Japan Medical Association and the Japan Society of School Health, and endorsed by the Japan Pediatric Society, the library seeks to convey basic health knowledge to children, covering topics such as the makeup of the human body and nutrition, in a broad, easy-to-understand manner through a medium of comic. Every year we choose a different theme and publish a new volume. The comics are donated to elementary schools, special needs schools, Japanese schools overseas, and public libraries.

Each year’s theme is decided based on requests from schools and the opinions of organizations involved in school health. With the cooperation of experts in various fields, we are finding ways to deliver factual, accurate health information to children in a fun way. We are also working to make the comics a more useful part of school health education. Since 2015, together with the Japan Society of School Health, we have sponsored lectures by health experts and usage demonstrations of the library at schools. We are continuing to evolve 30 years after the first volume, and deepening our ability to communicate the value of health.

2. Disaster Relief and Other Support

In light of our obligation as a company that handles items needed during emergencies, such as IV solutions, therapeutic drugs, foods and beverages, we actively engage in disaster relief activities and disaster victim assistance.

Our support for measures to counteract COVID-19 is one such example. In Japan, we supplied products such as beverages as well as masks and protective clothing for medical use. Overseas, we donated group products such as beverages and medical products to local healthcare facilities and chapters of the Red Cross Society, in addition to making monetary donations to such organizations.

Our activities are aimed at all generations. For children, our app SketchCook helps teach proper dietary habits and knowledge of nutrition in a world where such information can be difficult to acquire. For busy modern adults, we provide, in Japan, the Nature Made Supplement Check, an app that allows users to easily analyze the nutritional content of a meal by taking a smartphone picture.

Development of Human Resources

Basic Policy

Throughout history, innovation has always been generated by people. At the Otsuka group, we strive to attract talented personnel, develop their individual abilities on an ongoing basis, and enable them to fulfill their potential. This enables us to continuously generate innovation.

Approach

In addition to medium-to-long-term business investments, the development of next-generation executive human resources is essential if we are to constantly achieve creative, innovative, and sustained growth in the medium and long term, as well as significant growth in corporate value.

In 2016, we launched the Otsuka Global Academy (OGA), human resource development program, with the aim of identifying and nurturing talented personnel that will underpin the development of the next generation. Executive human resource development programs are produced and run in-house across the Otsuka group, while also aiming to realize effective HR development through collaboration with external agencies. The programs emphasize the handing down of corporate culture and seek to identify the kind of candidates required to lead the Otsuka group in the future. As of December 31, 2019, a total of 141 employees from across the group had participated in the programs. In April 2020, we launched the Global E-Learning Platform in cooperation with Harvard Business School Publishing. Approximately 1,000 Otsuka group employees in Japan and overseas use this global platform to improve their business literacy and skills.

In addition, individual group companies are vigorously promoting human resource development. For instance, Otsuka Pharmaceutical has operated WING, a voluntary leadership study group, since 2009. Participants identify internal and external issues, and work in teams to discuss potential solutions before formulating a proposal for consideration. Takih Pharmaceutical established “Global One Academy,” a corporate university. In 2016, in the one-year program, selected participants learn about the corporate DNA, and acquire leadership, task-setting and problem-solving skills. Recognizing that good input produces good output, Otsuka Warehouse conducts various programs intended to inspire participants to generate unique new ideas. Programs offer ambitious employees a variety of opportunities, including the opportunity to attend business school courses, or to go on overseas tours of cutting-edge technology facilities in order to improve their IT literacy.

The Otsuka group is building an educational framework that enables each member company to continue developing and displaying his or her individual potential and reflects the characteristics of each group company’s business.

We have also established an open recruitment system1 and self-assessment system2 for the purpose of enhancing the capabilities of employees at each company. At Otsuka Pharmaceutical, the Human Resources Department holds individual interviews with every employee, and follows up on the issues they raise. Interviews are conducted with more than 1,500 employees every year.

1. Under this system, the Otsuka group internally discloses requirements of a certain position or job and then five to six people apply who satisfy the requirements can apply directly to the company offering the position and be transferred if expectations of both parties are in agreement. The open recruitment system can be utilized by employees working in group companies in Japan, and is aimed at boosting employee capability and motivation, as well as integrating exchange within the group.

2. Under this system, employees can submit opinions and suggestions regarding their current work styles and workflows, as well as career plans aspirations, to the Human Resources Department. The self-assessment system is implemented on a once yearly cycle, with the goal of further developing employee potential, choosing assignment to appropriate jobs, and improving the workplace environment.
Diversity & Inclusion

Female manager ratio: 10.3%

Employees taking parental leave (of whom male employees): 513 (210)

Basic Policy
The Otsuka group actively promotes diversity based on the belief that active participation by a wide range of employees further advances innovation and globalization. Accordingly, as a corporate group constantly in pursuit of innovation, we are endeavoring to establish a richly diverse workplace environment.

Approach
Since the 1980s, a time when the concept of diversity had yet to gain wide acceptance, our top management has actively promoted diversity in the belief that active contributions from personnel with diverse nationalities, races, ages, genders, disabilities, and other characteristics are essential in creating innovative products and ideas that drive corporate growth.

The Otsuka group has stated its commitment to promoting diversity in the Otsuka Group Global Code of Business Ethics. Furthermore, in 2017 the group became a signatory to the Women’s Empowerment Principles (WEPs), a set of corporate principles jointly developed by the United Nations Global Compact (UNGC) and UN Women that offers guidance on how to empower women in the workplace.

To demonstrate our commitment as a signatory to the WEPs, we have introduced a number of systems that meet WEPs at group companies in Japan. Notable examples are the Work Interval System, which mandates minimum rest periods for workers, and the Family Smile Support System, which encourages employees to work from home if necessary to deal with childbirth, childcare, and nursing care, thus achieving better work efficiency, productivity, and work-life balance. We also regularly hold group-wide training on women’s empowerment. In order to support our diverse employees in pursuing career continuity, we have enhanced childcare, nursing care, and other systems at each group company and have opened daycare centers at three of our business premises (in Tokushima, Osaka, and Tsukuba) to help employees balance childcare and work.

Moreover, we are actively conducting diversity promotion initiatives such as group-wide seminars with the theme of LGBT, with the aim of achieving a more inclusive workplace. As a company developing and supplying anti-cancer agents, Taiho Pharmaceutical has a team to realize “Workplace support for employees with cancer.” This team, mainly composed of the Human Resources Department and occupational nursing staff, aims to create a workplace where employees with cancer or other diseases can receive treatment while continuing to work. Taiho Pharmaceutical has been recognized with an Excellence Award from the Tokyo Metropolitan Government for its outstanding initiatives under this support framework that helps cancer patients balance treatment and work.

Furthermore, Otsuka Pharmaceutical established Heartful Kawauchi in Tokushima City in 2011 as a special purpose subsidiary. This subsidiary enables people with disabilities to fully realize their potential.

Additional Commitments: Women’s Empowerment Principles

1. Scope: Figures for 2019 at nine companies (Otsuka Pharmaceutical, Otsuka Pharmavite)
2. United Nations Entity for Gender Equality and the Empowerment of Women (UNGWA)
3. Revised telework system for increased flexibility

Health & Safety

Participants in Health Seminars held by the group for employees and family members: 1,050 (Cumulative)

Participants in Anzen Dojo programs (Otsuka Chemical): 658 (Fiscal 2019)

Basic Policy
The Otsuka group recognizes that the mental and physical well-being of each and every employee is indispensable to realizing the group’s shared corporate philosophy. To this end, we are committed to creating a safe workplace environment and are continuously implementing initiatives to help employees maintain and improve their health.

Approach
The major Otsuka group companies have issued a declaration on health under which they strive to create a workplace environment conducive to employee health maintenance and improvement. As part of efforts led by Otsuka Holdings, officers in charge of health management at each group company cooperate with the Otsuka Pharmaceutical Health Insurance Association and medical professionals in activities aimed at improving the health of employees. One such activity is the hosting of Health Seminars for group employees and their families. Held in major cities across Japan, these seminars are aimed at communicating the group’s initiatives on health, introducing the Otsuka Pharmaceutical Health Insurance Association, and disseminating information relevant to improving the health of employees and their families. Another activity is the workplace-wide Tokushima Health Project, known as TOK-L, launched in 2017 under the theme of creating lively and cheerful workplaces by lowering the risk of lifestyle diseases. This project targets the Tokushima region—where the greatest concentration of group employees live and work—and focuses on raising awareness of health issues in the region as a whole. The project promotes walking, exercise, and a healthy diet.

Improving Workplace Health and Safety

For the purpose of creating a safe and secure workplace, at factories and other business sites of each group company in Japan we have established safety and health committees, as defined in the Industrial Safety and Health Act. We actively carry out workplace health and safety inspections, as well as the necessary measures to ensure appropriate management of health, operations, and the workplace environment, in addition to relevant education and training. These activities are reported at health and safety committee meetings and form the basis for improvements to the workplace environment. Furthermore, major group companies hold a joint meeting every year to share reports on workplace accidents and recurrence prevention measures.

Otsuka Chemical, which handles chemical substances, conducts various workplace safety initiatives. Major initiatives include a system for swift information sharing on issues related to factory operations among all domestic and overseas locations, as well as regular reporting of group safety at Board of Directors meetings. Another key initiative is Anzen Dojo, an experience-based safety training center which opened in 2012 as part of measures to prevent occupational accidents. The center runs training programs aimed at improving safety awareness for group employees, employees of overseas affiliates, and third parties. Through classroom instruction and simulations of past accidents, the center reinforces lessons from failures and safety knowledge, sharpens awareness of danger, and develops the ability to identify potential risks. In recognition of its activities to improve health and safety education and establish a safety culture through Anzen Dojo, Otsuka Chemical received an RC Outstanding Award from the Japan Chemical Industry Association at the 8th Annual Responsible Care Awards in 2014.

External Recognition

Nadeshiko Brand
System for selecting companies that actively promote the employment and advancement of women.

Platinum Kurumin and Kurumin
Certification system based on the Act on Advancement of Measures to Support Raising Next-Generation Children. Platinum Kurumin is a certification for Kurumin-certified companies that have carried out high-.csv agenda invitations.

Platinum Kurumin: Otsuka Pharmaceutical Factory, Taiho Pharmaceutical
Kurumin: Otsuka Pharmaceutical, and others

Eruboshi
Certification system based on the Act on Promotion of Women’s Participation and Advancement in the Workplace. Companies are recognized for excellent efforts to empower women in the workplace.

Kurumin (highest grade): Otsuka Chemical

Diversity Management Selection 100
System recognizing companies that have improved corporate value through diversity management.

Otsuka Pharmaceutical
2014 Award: Otsuka Pharmaceutical

Health & Productivity Management Outstanding Organization* (White 500) (large enterprise category)

Otsuka Holdings, Otsuka Pharmaceutical, Taiho Pharmaceutical Factory

Health & Productivity Management Outstanding Organization* (SMC category)

Otsuka Electronics, JIMRO, Otsuka Wellness Vending

* The Health & Productivity Management Outstanding Organization Recognition Program recognizes organizations working to overcome health-related challenges in local communities or to promote health-conscious activities led by the Nippon Kenko Kaigi, and recognizes organizations for outstanding efforts in health and productivity management.
Quality in All We Do

To help build a sustainable society, the Otsuka group seeks to achieve sustainability by addressing environmental and social issues and by establishing a quality assurance structure that ensures safety and reliability at every stage of the value chain.

R&D

1. Ethical Considerations Concerning Appropriate R&D

The use of experimental animals to verify efficacy and safety in R&D is at times necessary. The Otsuka group complies with all related laws, ordinances, and guidelines while striving to uphold scientifically valid methodologies and ethical considerations from the viewpoints of animal protection and welfare, including the lives of the animals; preservation of the environment; and the safety of experimenters.

As an in-house management system, we have developed and implemented rules on experiments that involve animals, have established an Animal Experiment Committee, and properly carry out animal experiments and breeding.

The Animal Experiment Committee evaluates whether each proposed animal experiment plan is appropriate based on the 3Rs principles. These are Replacement/avoidance or substitution, Reduction in the number of animals used, and Refinement to improve the quality of animal suffering. Based on these, we conduct researcher education and internal inspections and evaluations of the implementation of experiments involving animals.

2. Ethics in Development

In the development of pharmaceuticals, we confirm the safety and effectiveness of candidate compounds by conducting clinical trials with the cooperation of healthy individuals and patients.

Recognizing the importance of ethical considerations regarding human rights and personal information, the Otsuka group implements clinical trials in compliance with ethical principles and standards, including ICH-GCP, an international standard for the implementation of clinical trials for pharmaceutical products.

Procurement

Basic Policy

The Otsuka group, together with its business partners, aims to contribute to building the sustainable society by promoting CSR procurement that takes into consideration factors such as legal and regulatory compliance, the environment, and the protection of human rights.

Approach

Across the entire value chain, the Otsuka group engages in business activities that are safe, reliable, socially acceptable, and in compliance with laws and regulations. When commencing transactions with a supplier, we perform screening and checks to ensure the quality of raw materials and to guarantee stable procurement. We also conclude a basic transaction agreement. In the case of a new supplier, transactions are determined only after we have carried out due diligence.

We aim for mutually sustainable development through fair, equitable and transparent procurement and the establishment of healthy relationships with business partners. To achieve this, we have formulated and share with all business partners the Otsuka Group Sourcing/Procurement Vision & Policy, which we have formulated and share with all business partners the Otsuka Group Sourcing/Procurement Vision & Policy. We also make sure to assess our business partners not only with respect to the Basic Policy but also on the basis of the provisions of the above vision and policy. In order to ensure a stable supply of products, we perform advance risk assessments on key raw materials to identify potential risks so that we can take countermeasures. We also make sure to source raw materials from multiple companies, in principle. For products that use palm oil, for example, Otsuka Pharmaceutical confirms that its business partners are RSPO* members before purchasing raw materials.

1. Collaboration with Business Partners

We conduct surveys of business partners using the CSR procurement self-assessment questionnaire* published by UN Global Compact Japan. In 2018, we asked 26 companies to complete the survey, and received responses from 25. In 2019, nine companies were selected, all of whom responded.

We assess our business partners not only with respect to legal and regulatory compliance but also with respect to their activities regarding human rights, labor, and anti-corruption measures.

We have also formulated the Otsuka Group Sourcing/Procurement Vision & Policy, which we have formulated and share with all business partners the Otsuka Group Sourcing/Procurement Vision & Policy. We also make sure to assess our business partners not only with respect to the Basic Policy but also on the basis of the provisions of the above vision and policy. In order to ensure a stable supply of products, we perform advance risk assessments on key raw materials to identify potential risks so that we can take countermeasures. We also make sure to source raw materials from multiple companies, in principle. For products that use palm oil, for example, Otsuka Pharmaceutical confirms that its business partners are RSPO* members before purchasing raw materials.

Guidelines to provide more specific descriptions of the provisions of the above vision and policy. In order to ensure a stable supply of products, we perform advance risk assessments on key raw materials to identify potential risks so that we can take countermeasures. We also make sure to source raw materials from multiple companies, in principle. For products that use palm oil, for example, Otsuka Pharmaceutical confirms that its business partners are RSPO* members before purchasing raw materials.

Production, Quality Control and Patient/Customer Safety

1. Production

Production departments at the Otsuka group employ a traceability system covering all stages of the value chain, from raw material procurement to production, distribution, and sales, thereby enabling thorough management throughout the entire value chain.

Moreover, for over 30 years, production departments have held a global production meeting aimed at group-wide improvements by sharing techniques and information.

In 2019, the meeting was attended by approximately 100 employees involved in production at group companies in 13 countries/regions. In addition, failure case study meetings and environmental management information exchange meetings began in 2017 and 2018, respectively. At these meetings, participants share presentations and opinions on case studies of collaborative measures and technological development to address quality, safety, cost and environmental issues, the future outlook, and overseas development.

At the global production meeting, we also present awards to employees who have made significant contributions to production activities, lay the foundations for further improvements in productivity, and conduct personnel training.

2. Joint Business Partner Audit by Pharmaceutical Companies

In the Otsuka group, four pharmaceutical companies conduct joint business partner audits for shared suppliers of raw materials. We began these audits in 2016, applying proprietary methodologies and including an auditor skills training program.

3. Global Product Quality Team Activities for the Pharmaceutical Business

Since 2016, Otsuka Pharmaceutical and its group companies have conducted activities to enhance compliance with GxPs* for a range of processes from development through to the finished product. Among initiatives to improve quality control systems, we hold annual meetings attended by management personnel, as well as group-wide meetings.

The Pharmaceutical Business established global product quality policies in 2017. Activities are carried out globally, and include ensuring the reliability of quality data and compliance with relevant regulations.

4. Quality Control Activities for the Nutraceutical Business

In 2018, Otsuka Pharmaceutical established the Quality Division for the purpose of further facilitating quality improvement and safety control for products in the Nutraceutical Business. Furthermore, with the establishment of the Quality Assurance Office, we have implemented a system based on GMP for pharmaceuticals. The system enables central management of all processes from identifying and verifying risks arising from changes, to investigating causes and taking remedial action when risks manifest. As of May 2020, all of our factories in Japan that manufacture nutraceuticals are certified for the FSSC 22000 food safety standard.
5. Collaboration between Pharmaceutical and Nutraceutical Departments

Product quality departments of the Pharmaceutical Business and Nutraceutical Business jointly hold an annual global product quality meeting. The 2019 meeting was attended by around 100 managers and quality supervisors for pharmaceuticals and nutraceuticals from 22 companies in nine countries.

The meeting is an opportunity for participants to review the preceding year’s quality control performance and to work on improving quality control and developing personnel by sharing reports that illustrate the need for predictive risk management in production activities, based on the importance of learning from examples of issues as well as successes.

Promotion of Customer-centric Management

Basic Policy

In October 2018, the Otsuka group announced its Declaration of Customer-centric Commitment, as a way of putting the corporate philosophy into practice. Promotion of customer-centric management has been targeted in activities for material issues. In conducting business, we recognize that respecting consumer rights is an important human rights issue. Our Declaration of Customer-centric Commitment establishes basic policies stating our commitment to our social responsibilities as a corporation, which we fulfill by pursuing customer-centric management and making appropriate decisions that are based on dialogue with all stakeholders.

1. Inculcating a Customer-centric Mindset in Employees

Customer-facing employees from group companies in Japan meet twice yearly to share best practices for customer service and product improvements. This helps foster a customer-centric corporate culture.

2. Enhancing Information Exchange with Customers and Mechanisms for Reflecting Customer Feedback

Each group company establishes dedicated customer contact points for patients, healthcare professionals and general consumers, and provides appropriate training for the employees who work there. For example, the assignment of specially trained female operators enables us to better answer inquiries about products designed for women. This approach helps us deepen communication with customers, provide appropriate information and reflect customer requests and suggestions in product improvements.

One such product improvement was for OS-1*1 Jelly, produced by Otsuka Pharmaceutical Factory. These products are foods for persons with medical conditions. We received feedback from elderly individuals, customers receiving treatment, those in need of nursing care and others who said that they had difficulty opening the cap because of muscular strength issues. Based on this feedback, we redesigned the container to be easier to open. We have also created websites that provide product information in Japanese, English, Chinese and Spanish, and added QR codes to product labelling that link with these websites.

Example of Improved Product: OS-1 Jelly

For packaging produced by group companies in Japan, with the exception of certain products such as those with space limitations, we ensure the understandability of labelling. In addition to information required by law, the following information is presented: instructions for storage after opening, precautions for use, an easy-to-read list of allergens contained (mandatory and recommended items), and a clear indication of packaging materials. Based on customer feedback, we continue to make further improvements. For example, Otsuka Foods has redesigned allergen labelling by adding a list of allergens on the package in a separate location from the comprehensive list of instructions and precautions. For Bon Curry for Children, illustrations have been added to make the informations easier to understand, so that consumers can purchase it with peace of mind.

Sales and Marketing

Basic Policy

The Otsuka group believes that it has a responsibility to deliver higher-value products and services to customers. To do so, we will engage in suitable promotion and advertising activities to ensure the practice of ethical, patient-oriented medical care.

The Otsuka group delivers products throughout Japan, mainly via group company Otsuka Warehouse. To ensure the control and maintenance of product quality, Otsuka Warehouse has set up the GDP*2 Promotion Office to facilitate appropriate logistics in accordance with the GDP guidelines for pharmaceuticals.

Logistics

Basic Policy

The Otsuka group handles products that relate directly to human life, including pharmaceuticals, foods and beverages. As such, we ensure the rigorous control and maintenance of product quality throughout distribution, and actively take measures to ensure stable supply in the event of a natural disaster or other emergency situation. The group also promotes environmentally friendly logistics operations through measures such as reducing CO₂ emissions.

Approach

The Otsuka group delivers products throughout Japan, mainly via group company Otsuka Warehouse. Otsuka Warehouse has set up the GDP*2 Promotion Office to facilitate appropriate logistics in accordance with the GDP guidelines for pharmaceuticals. We disseminate the principles of the GDP guidelines among personnel engaged in each aspect of the distribution of pharmaceuticals through training and drills on quality management systems, document control, administration of outsourced processes, facility and equipment maintenance, storage and transport operations, assessment of supplier and customer eligibility, among others. In addition, we conduct regular training to ensure compliance with internal standards and procedures.

We also strive to standardize data management system specifications in order to facilitate collaboration and cooperation between shippers and logistics operators.

Specifically, we are improving logistics quality by introducing IT systems for truck dispatch and vehicle monitoring, which enable better tracking of transport and delivery status. Other initiatives include computerizing warehouse operations to reduce incorrect shipments and mispicks, thereby helping quality improvement through higher efficiency.

The diverse assortment of shipping forms has been standardized and digitalized, with benefits that include lower mishandling rates when orders are changed.

Otsuka Warehouse is working to ensure stable supply by establishing distributed storage facilities across Japan to maintain adequate product stocks that reflect product characteristics. Furthermore, for pharmaceuticals, a framework for business continuity planning (BCP) has been established that ensures essential products can be delivered to where they are needed. In addition to securing stock, measures include developing an emergency response system for transporting products, for example registering vehicles for authorized access to restricted areas and exchanging MOUs with shippers, warehouse owners and other partners for cooperation in the transport of emergency relief supplies.

Sales and Marketing

Basic Policy

The Otsuka group believes that it has a responsibility to deliver higher-value products and services to customers. To do so, we will engage in suitable promotion and advertising activities that comply with laws and regulations, and communicate with customers in an appropriate manner.

Approach

The Otsuka group has expanded on the JPMA Promotion Code for Prescription Drugs—a code of behavior for healthcare professionals issued by the Japan Pharmaceutical Manufacturers Association (JPMA)—to formulate its own Code of Practice co-authored by group company in an effort to engage in appropriate collaboration based on relationships of trust with all stakeholders, including medical practitioners.

The Otsuka group has expanded on the JPMA Promotion Code for Prescription Drugs—a code of behavior for healthcare professionals issued by the Japan Pharmaceutical Manufacturers Association (JPMA)—to formulate its own Code of Practice co-authored by group company in an effort to engage in appropriate collaboration based on relationships of trust with all stakeholders, including medical practitioners.

Otsuka Holdings Co., Ltd. INTEGRATED REPORT 2019

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* GDP: Good Distribution Practice

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