



Otsuka Group

Sustainability Report 2022



Sustainability Report 2022

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Sustainability Report 2022

■ Content

Otsuka Holdings Co., Ltd. publishes an integrated report and an environmental report each year to provide stakeholders with a better understanding of the Otsuka group's efforts as a global healthcare enterprise seeking to become an indispensable contributor to people's health. Meanwhile, the company provides more detailed updates on sustainability via its website. In 2022, however, the company decided to enhance transparency even further by publishing a sustainability report in PDF format on its website, and that report will be available in the archives there as well, going forward. This report is a PDF version of the sustainability information posted on the Otsuka Holdings website and is current as of September 2023. Please check the website for the most up-to-date information.

■ Reporting Period

Fiscal 2022 (January 1, 2022 to December 31, 2022); Note that certain information from January 2023 onward is also included.

■ Scope of Reporting

In principle, this report covers Otsuka Holdings Co., Ltd. and its subsidiaries. Where the scope of activities or data is narrower, details are noted.

■ Precautions Regarding Forward-Looking Statements

This integrated report summarizes the operating and financial results of the Otsuka group (Otsuka Holdings Co., Ltd. and its subsidiaries) for fiscal 2022 (January 1, 2022 to December 31, 2022). The report contains forward-looking statements and forecast pertaining to plans, projections, strategies, and performance for the Otsuka group of companies. These statements are based upon current analysis and beliefs in light of the information available on the issuing date of the report. Actual results may therefore differ due to the risks and uncertainties that may affect Otsuka group operations.

■ Medical Information

In this integrated report, for the sake of readability a unified brand name is used when a product has different brand names in different countries or regions. Therefore, these products may not be available in all countries, or may be available under different brand names, for different indications, in different dosages and strengths. Please note that the information regarding pharmaceutical products (including products under development) is not intended for advertising or promotional purposes, or as medical advice.

Our Approach to Sustainability

HOME > Sustainability > Our Approach to Sustainability

Guided by its corporate philosophy, the Otsuka group strives to address social issues.

Corporate Philosophy

Otsuka-people creating new products for better health worldwide

Otsuka's Goal

To become an indispensable contributor to people's health worldwide

Sustainability Mission

Address social issues such as the evolution toward a healthier and more sustainable society, while simultaneously achieving growth. These activities are all supported by a comprehensive governance system.

Contribution to a More Sustainable Society



Message from the Director in Charge of Sustainability

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Resolving Social Issues through Our Business

The Otsuka group of companies, in accordance with its corporate philosophy, "Otsuka-people creating new products for better health worldwide," seeks to be an indispensable contributor to people's health worldwide through a wide range of innovative and creative products including pharmaceuticals, functional beverages, and foods. We believe that by making our philosophy a reality we will effectively achieve sustainability.

As such, our basic stance is to grow sustainably and help resolve social issues through our business, in accordance with that philosophy.

In 2019, when we unveiled the Third Medium-Term Management Plan, we also announced our Sustainability Mission and Materiality (the initiatives that Otsuka is focused on) to further clarify the group's commitment to sustainable growth. The material issues were selected with consideration of social issues and based on the characteristics and strengths of the Otsuka group in conducting broad-ranging businesses, and we are working together to achieve the goals we have set for each material issue.

In Search of Solutions for Unmet Needs

One of the Otsuka group's important missions is to contribute to the resolution of unmet needs. We work every day to help in the prevention and treatment of illness around the world, and to maintain and improve peoples' health. Daunting challenges remain, including the threat of prolonged pandemics, insufficient medical infrastructure, lack of effective treatments for some conditions, and undernutrition. We approach these issues by considering what only Otsuka can do and setting about addressing the related unmet medical needs.

For example, in the Pharmaceutical Business, we seek to eradicate tuberculosis—one of the “big three” infectious diseases. Tuberculosis is a serious public health challenge, and like COVID-19, accounts for a high number of deaths every year. In fact, tuberculosis kills 1.5 million people annually,^{1,2} and is particularly prevalent in the developing world. We continue to work with various partners around the world to deliver drugs and address the disparity in access to medicines due to economic factors.

In the Nutraceutical Business, we develop innovative science-based products that leverage the know-how that the Pharmaceutical Business has accumulated over many years, and conduct ongoing health education programs aimed at tackling challenges involved in access to nutrition.

1: Global Tuberculosis Report 2021, World Health Organization

2: WHO Coronavirus (COVID-19) Dashboard, World Health Organization

People and Quality in All We Do Are Essential for Sustained Corporate Growth

Nurturing successive generations of talent is essential for the sustainable growth of a company. At the Otsuka group, we know that the diversity of our people is key to innovation, globalization, and the development of revolutionary products. That is why we always seek to hire a broad range of people, encourage effective personnel exchanges within the group, and conduct training that further invigorates and develops our workforce. The Otsuka Group Global Code of Business Ethics, a code of conduct for business activities in global markets, includes topics on human rights and diversity. Furthermore, we are signatories to the United Nations Global Compact (as of 2016), which stipulates ten principles on human rights, labor, the environment, and anti-corruption, as well as to the Women's Empowerment Principles (as of 2017), thus further underlining our commitment to social responsibility. In addition, we released the Otsuka Group Human Rights Policy in 2021, and are engaged in group-wide initiatives to ensure respect for human rights.

Commitment to quality has been an important part of the Otsuka spirit since the company's inception. “Quality in all we do” signifies not only our product quality, but quality at all stages of the value chain, from R&D and production through to distribution and accountability to customers, as well as quality in management. We will continue with our group-wide efforts to achieve higher levels of quality.

Our 2050 Environmental Vision, “Net Zero”

The Otsuka group aims to help resolve social issues through its business activities. In 2021, amid the increasing seriousness of climate change and various other environmental issues, we adopted the 2050 Environmental Vision, “Net Zero,” which calls for us to reduce the total environmental impacts of our business activities to zero. Under this vision, we identified three environmental material issues: *carbon neutrality*, *circular economy*, and *water neutrality*; set new medium-term targets that include reducing 50% in CO₂ emissions compared to 2017 levels by 2028; and raised the target of the Otsuka Group Plastic Policy to 100% use of recycled and plant-derived raw materials in our PET bottles by 2030. The group will work as one to achieve its 2050 Environmental Vision, “Net Zero,” by pursuing unique initiatives to realize a sustainable society that can be passed on to future generations.

Further Strengthening Group Corporate Governance

For the Otsuka group to remain relevant to all stakeholders, a strong governance structure is necessary. Based on realizing its corporate philosophy, Otsuka Holdings is committed to maximizing corporate value sustainably over the medium to long term. To meet this commitment, its basic policy is to make transparent, fair, and timely decisions, and to fulfil its corporate social responsibility by living up to the expectations of all stakeholders and engaging in ongoing dialogue. Governance has been a key focus since the establishment of Otsuka Holdings. We continue working to strengthen governance, as illustrated by the introduction of Enterprise Risk Management (ERM) in July 2020.

Sustainability Management Structure

We believe that sustainability initiatives are an integral part of our business and should be undertaken by each and every employee. To this end, the Otsuka group has established the Otsuka Group Sustainability Promotion Committee.

The committee was formed in 2018 to discuss and determine the direction and plans for the group's sustainability efforts. Committee members comprise managers of departments related to sustainability-relevant areas such as the supply chain, the environment, human resources, general affairs, compliance and risk management, public relations, and, from 2021, production and quality.

For those in charge of the supply chain, the environment, human rights, and other relevant areas, the committee provides a forum for sharing their initiatives and progress on sustainability issues. Amid rapid day-to-day change in the external environment and societal demands related to sustainability, opportunities to participate in lectures and discussions by outside experts on the latest trends are also provided.

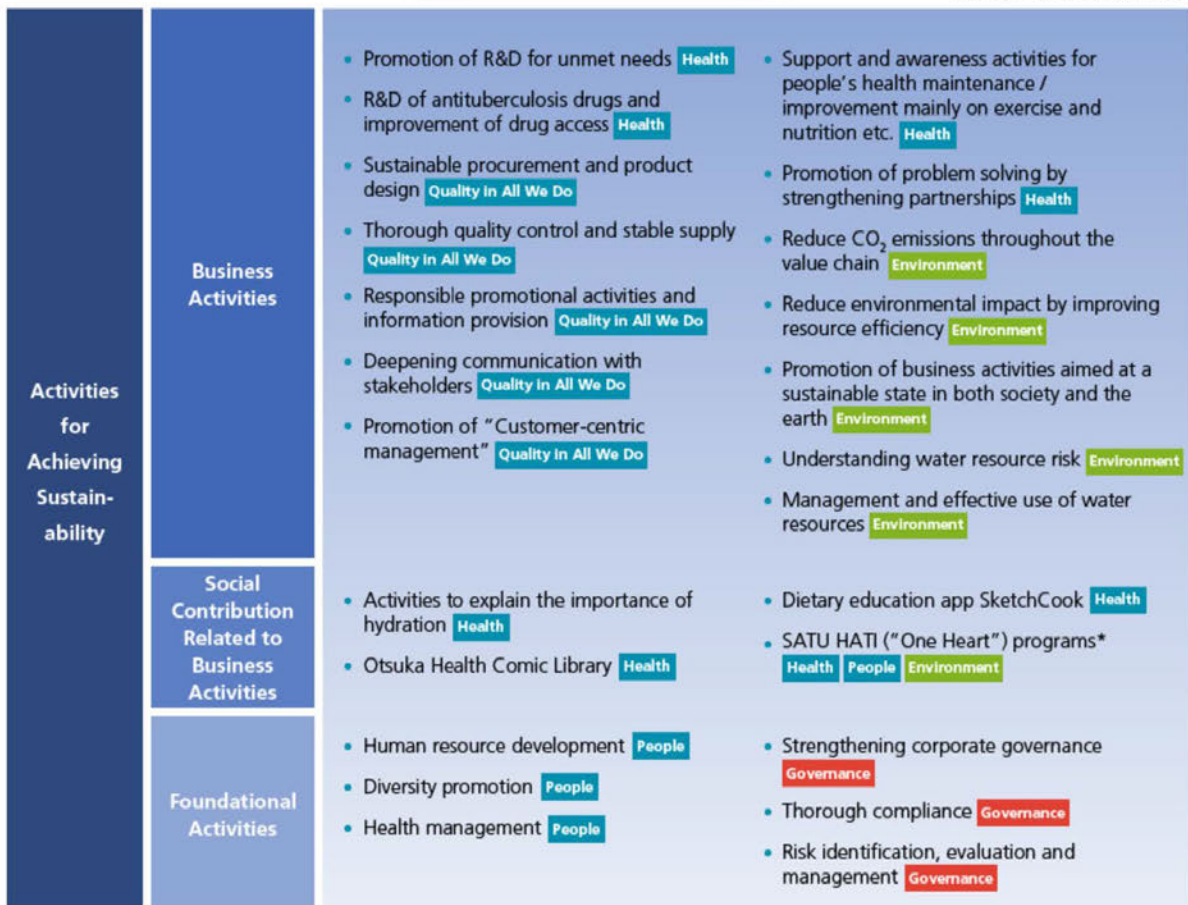
We at the Otsuka group are committed to growing sustainably in accordance with our corporate philosophy and resolving social issues through our business.

The Otsuka Group's Approach to Sustainability

Guided by its corporate philosophy, the Otsuka group works to solve social issues through its businesses and aims to grow while contributing to the creation of a healthy and sustainable society. We define “business activities,” “social contribution related to business activities,” and “foundational activities” as three core areas to achieve sustainability, and are proactively advancing these initiatives.

Contribution to a More Sustainable Society

Examples of Our Activities



* To give back to the local community in Indonesia, POCARI SWEAT manufacturer and distributor P.T. Amerta Indah Otsuka has implemented a social action program based on three core pillars: SATU HATI Cerdaskan Bangsa (“One Heart for Education”), SATU HATI Peduli Lingkungan (“One Heart for Environment”), and SATU HATI Sehatkan Bangsa (“One Heart for Health”).

Process for Determining Materiality (Material Issues)

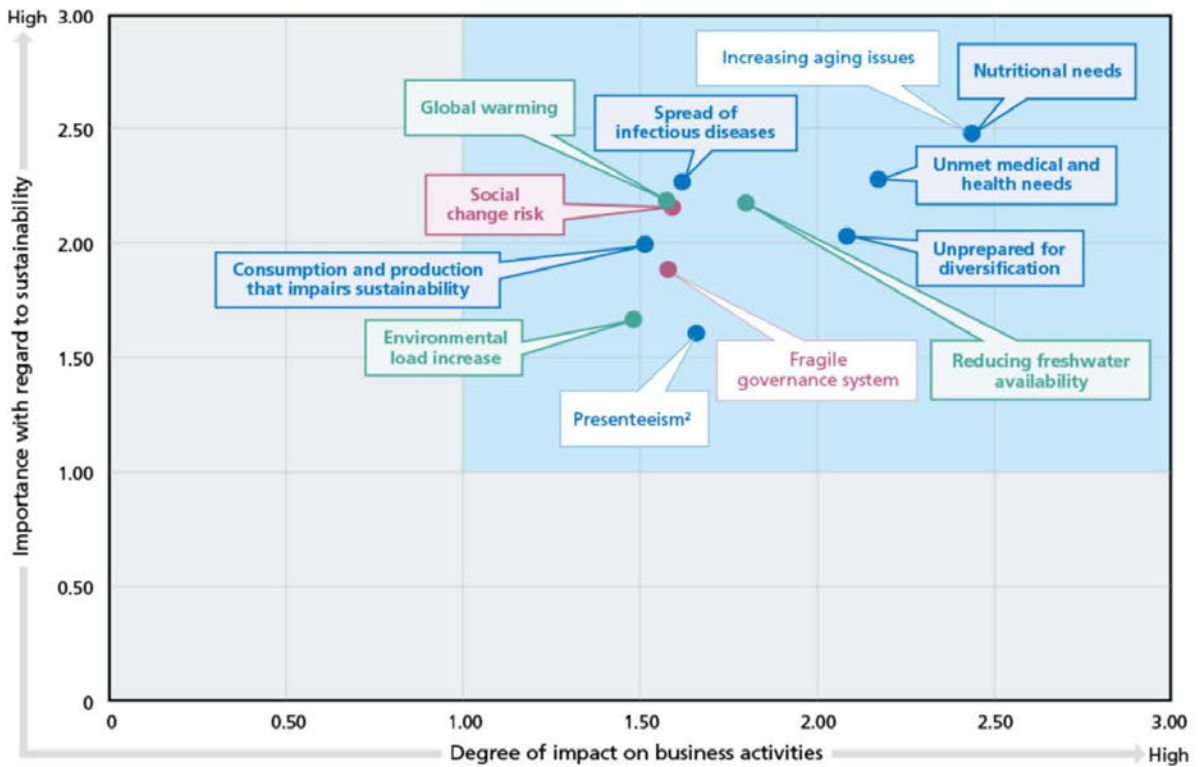
Materiality is initiatives that Otsuka is focused on. To determine the Otsuka group's material issues, we first compiled a list of social issues, referencing a range of international guidelines and frameworks, including ISO 26000, GRI, and the U.N. SDGs. We narrowed down the list of issues by evaluating them in terms of their importance, taking into account our ability to contribute to a solution, their impact on business, and our strengths. Issues were then discussed by the Sustainability Promotion Committee¹ and approved at the Otsuka Holdings Board of Directors meeting. As a result, the material issues of the Otsuka group were determined to be: *society (health, people, quality in all we do)*, *environment (Carbon Neutrality, Circular Economy, Water Neutrality)*, and *governance*.

*1 The Sustainability Promotion Committee promotes sustainability throughout the Otsuka group. The committee's responsibilities include discussing and deciding on the direction and plans for sustainability activities. The Otsuka Holdings director in charge of sustainability promotion serves as the committee chair. Committee members comprise group managers of departments relating to sustainability and the sustainability officers of each company.




Map of Social Issues

We compiled a list of the social issues relevant to the Otsuka group's businesses, and created a map of social issues considering their importance in terms of sustainability and their degree of impact on business activities.



*2 The situation where productivity does not go up due to the poor condition of the mind and body despite coming to work

The Otsuka Group's Materiality (Material Issues) and Related SDGs

Materiality	Social Issues	Our Goals	Our Activities	Related SDGs	
Society (Healthier Society)	Health	<ul style="list-style-type: none"> Unmet medical and health needs Spread of infectious diseases Nutritional needs Increasing aging issues 	<ul style="list-style-type: none"> Contribute to unmet needs solutions Eradication of tuberculosis Creation of a system for the realization of healthy lifestyles Healthy life extension 	<ul style="list-style-type: none"> Promotion of R&D for unmet needs R&D of antituberculosis drugs and improvement of drug access Support and awareness activities for people's health maintenance/improvement mainly on exercise and nutrition etc. Promotion of problem solving by strengthening partnerships 	
	People	<ul style="list-style-type: none"> Presenteeism Unprepared for diversification 	<ul style="list-style-type: none"> Creation of a corporate culture that stimulates creativity Enhance employee engagement 	<ul style="list-style-type: none"> Human resource development Diversity promotion Health and productivity management 	
	Quality in All We Do	<ul style="list-style-type: none"> Consumption and production that impairs sustainability 	<ul style="list-style-type: none"> Gaining stakeholder trust Pursuing sustainability at all levels of the value chain Establishing a quality assurance system for safety and security 	<ul style="list-style-type: none"> Sustainable procurement and product design Thorough quality control and stable supply Responsible promotional activities and information provision Deepening communication with stakeholders Promotion of "consumer-oriented management" 	
Environment (Healthier Planet)	Carbon Neutrality※1	<ul style="list-style-type: none"> Global warming 	<ul style="list-style-type: none"> 2028 targets : Reduce 50% in CO₂ emissions compared to 2017 	<ul style="list-style-type: none"> Reduce CO₂ emissions throughout the value chain 	
	Circular Economy※2	<ul style="list-style-type: none"> Environmental load increase 	<ul style="list-style-type: none"> 2028 targets : Reduce 50% in simple incineration and landfill disposal compared to 2019 2030 targets : 100% content of recycled and plant-based materials in our PET bottles 	<ul style="list-style-type: none"> Reduce environmental impact by improving resource efficiency Promotion of business activities aimed at sustainability for both society and the earth 	
	Water Neutrality※3	<ul style="list-style-type: none"> Reducing freshwater availability 	<ul style="list-style-type: none"> 2028 targets: Expand the plant water management program to all locations globally 2028 targets: Develop a water use strategy for business locations in water-stressed areas 	<ul style="list-style-type: none"> Understanding water resources risk Management and effective use of water resources 	
Governance	<ul style="list-style-type: none"> Fragile governance system Social change risk 	<ul style="list-style-type: none"> Long-term improvement of corporate value 	<ul style="list-style-type: none"> Strengthening corporate governance Thorough compliance Risk identification, evaluation and management 		

※1 Sustainable energy use, ※2 Sustainable use of raw materials, ※3 Sustainable use of water resources

Stakeholder Engagement

The Otsuka group has been, and continues to be, supported by many stakeholders, including consumers, patients, healthcare professionals, business collaborators, and local communities.

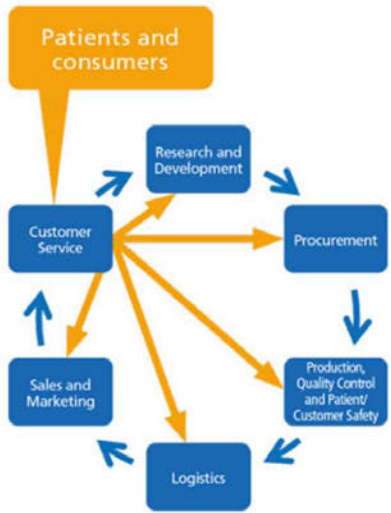
Based on the understanding that collaboration with stakeholders is essential to fulfilling our corporate social responsibility, we aim to build relationships of trust with our stakeholders by enhancing various channels of communication.

Stakeholders	Approach	Main Responsibilities and Issues
Patients, Consumers, and Healthcare Professionals	<ul style="list-style-type: none"> • Providing information on pharmaceutical products through medical representatives and collecting safety information • Conducting awareness-raising activities related to health • Paying attention to and acting on customer feedback • Holding seminars for healthcare professionals and events to support patient associations 	<ul style="list-style-type: none"> • R&D of products that address unmet medical needs • Support for disease prevention, treatment, health maintenance while helping to extend healthy lifespans and quality of life (QOL)
Employees	<ul style="list-style-type: none"> • Conducting human resource development programs and training sessions • Implementing a self-assessment system • Conducting human resource interviews, questionnaires, etc. • Operating helplines for whistleblowing and harassment complaints, etc. 	<ul style="list-style-type: none"> • Development of human resources • Respect for diversity • Work-life balance initiatives • Childcare and nursing care support • Occupational safety and health
Collaborators	<ul style="list-style-type: none"> • Holding company information sessions, facility tours, and factory visits • Meeting and exchanging opinions with partners • Collaborating with suppliers to implement social sustainability measures • Conducting joint R&D of products, technologies, and systems and cooperation through co-promotion and co-marketing 	<ul style="list-style-type: none"> • Quality assurance and stable product supply • Better provision of product information • Consideration for human rights, environmental, social, and other issues throughout the supply chain • Fair and honest business dealings • Sustainable growth and development with collaborators
Investors and Shareholders	<ul style="list-style-type: none"> • Drawing up and disclosing medium-term management plans • Engaging in investor relations activities, such as regular company information sessions for analysts and institutional investors • Expanding information disclosure in English for international institutional investors and holding shareholder meetings that are easy to understand for individual shareholders 	<ul style="list-style-type: none"> • Sustainable growth and improvement of corporate value • Returns on dividends • Timely and appropriate information disclosure • Measures to attract socially responsible investment
Local Communities and Society	<ul style="list-style-type: none"> • Operating factories in harmony with the environment and the community • Developing and launching eco-friendly products • Interacting and collaborating with local communities • Engaging in disaster relief • Conducting educational support activities 	<ul style="list-style-type: none"> • Environmental conservation • Contribution to local communities • Support for the next generation

Examples of Engagement

Reflecting Stakeholders' Views in Company Activities

Customer-facing departments of Otsuka group companies receive a broad variety of feedback from patients, healthcare professionals, and consumers, and we make sure that feedback is shared appropriately with the relevant departments. We also strive to share this feedback throughout the value chain with the right executives and departments, so that it can be properly reflected in our company activities.



Value Chain	Communication with Stakeholders
Procurement	The cross-group Otsuka Sustainable Procurement Task Force communicates closely with suppliers to promote sustainable procurement.
Production	Otsuka Pharmaceutical's Tokushima Itano Factory and Human Resource Development Institute, and Otsuka Foods' Tokushima Factory hold online factory tours as part of community outreach.
Quality Control and Patient/Customer Safety	In addition to collecting feedback through the Consumer-Relations Office, Otsuka Pharmaceutical collects and analyzes consumer comments from social media, and incorporates these comments in product improvements.
Logistics	Otsuka Warehouse, which handles the Otsuka group's logistics operations, holds meetings with transport partners as necessary to share policies and initiatives, and also engages in mutual employee exchanges aimed at promoting digital transformation and operational improvements.
Sales and Marketing	Swift dissemination of information using online tools enabled us to provide information about pharmaceuticals and nutritional products without compromising strict COVID-19 countermeasures.

Key Initiatives and Organizations

WE SUPPORT



[Read more](#)

[— close](#)

The United Nations Global Compact (UNGC) is a voluntary initiative in which signatory companies and organizations commit to a global framework embodying 10 principles on the protection of human rights, humane and non-discriminatory labour practices, environmentally sound practices, and prevention of corruption. Otsuka Holdings became a signatory to the UNGC in 2016.

In support of

WOMEN'S EMPOWERMENT PRINCIPLES

Established by UN Women and the UN Global Compact Office

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[— close](#)

The Women's Empowerment Principles (WEPs) are a set of voluntary principles offering guidance for corporate practices to promote equality and women's empowerment. Otsuka Holdings became a signatory to the WEPs in 2017.

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The Task Force on Climate-related Financial Disclosure (TCFD) created by the Financial Stability Board encourages recognition and disclosure of climate-related financial risks and opportunities. In 2017, the TCFD released climate-related financial disclosure recommendations to help companies provide better information for informed capital allocation. The Otsuka group announced its support for recommendations issued by the TCFD in 2021.

[Read more](#) — [close](#)

The international RE100 initiative asks companies to commit to using 100% renewable energy in their business activities. The Otsuka group joined the initiative in 2022.

JAPAN CLIMATE INITIATIVE

[Read more](#) — [close](#)

The Japan Climate Initiative is a network of companies, local governments, NGOs, and other groups engaged in climate action that work to strengthen information distribution and exchange opinions on this important topic.

Also, to work for the development of the various group industries and to solve common issues, Otsuka group companies are affiliated with several organizations such as the Japan Pharmaceutical Manufacturers Association, The Intravenous Solutions Society, and the Japan Soft Drink Association.

Declaration on Health

The major Otsuka group companies have issued a declaration on health to advance a variety of initiatives related to employee health. The goal is to create comfortable workplace environments where each and every employee can enjoy physical and mental health.

Declaration of Consumer-oriented Commitment

The Otsuka group established its Declaration of Consumer-oriented Commitment to further promote business activities focused on customers.

Otsuka Group Procurement Policy

With the goal of achieving mutually sustainable development through fair, equitable, and transparent procurement and the establishment of healthy relationships, we have formulated and share with our business collaborators the Otsuka Group Procurement Policy.

We have also formulated the Otsuka Group Sustainable Procurement Guidelines that expand on the Otsuka Group Procurement Policy in more practical detail, which makes them more directly applicable to our business collaborators.

Otsuka Group Intellectual Property Statement

The statement outlines Otsuka group's basic policy in regard to intellectual property.

Otsuka Group Environmental Policy

The Otsuka group established the Otsuka Group Environmental Policy to ensure that its business activities take the global environment into account throughout the value chain.

Otsuka Group Plastic Policy

The Otsuka group formulated the Otsuka Group Plastic Policy as an initiative to help resolve the issue of plastic waste and contribute to the sustainable recycling of resources.

Support Recommendations of the Task Force on Climate-related Financial Disclosure (TCFD)

The Otsuka group is actively engaged in analysis of climate-related business risks and opportunities and development of appropriate responses.

Otsuka Group Global Anti-Corruption Policy

The Otsuka Group Global Anti-Corruption Policy embodies and reiterates our steadfast commitment to conducting business with integrity and in compliance with all relevant anti-corruption laws. This Policy outlines how to prevent, detect and deter violations of anti-corruption laws.

Otsuka Group Global Conflict of Interest Policy

The Otsuka group considers conflicts of interest between the company and individual employees to be relevant to organizational integrity, and that addressing such conflicts is of particular importance for the group's future growth. Based on that thinking, the Otsuka group established this policy, and is working to promote it globally.

Otsuka Group Global Privacy Policy

In recent years, numerous countries have been establishing privacy protection laws, such as the EU's General Data Protection Regulation (GDPR) enacted in May 2018. The Otsuka group is also working to strengthen privacy protection. In addition to formulating the Otsuka Group Global Privacy Policy to define our stance and guiding principles on privacy protection, we establish related rules and review management systems in accordance with the laws and regulations related to privacy protection in each country.

Otsuka Group Global Speak-Up Policy

The Otsuka group has established the Otsuka Group Global Speak-Up Policy with the aim of clarifying the basic principles of the internal reporting system and enhancing its effectiveness so that employees can speak up when they become aware of fraud, inappropriate behavior, or any other action that goes against the group's values, policies or processes, or any other suspect behavior.

Sustainability Management Structure

The Otsuka Group Sustainability Promotion Committee was established in 2018 and is chaired by the director in charge of sustainability promotion at Otsuka Holdings. The committee promotes sustainability for the entire Otsuka Group, acting as an engine for discussions and decision-making regarding the direction of sustainability-related activities, plans, and other measures. Committee meetings are held regularly to discuss direction and evaluate activities, develop systems in each area of sustainability promotion, and update promotion plans, as necessary. Committee members comprise group officers in charge of areas relating to sustainability, such as supply chain, environment, human resources, corporate governance, compliance risk management, and public relations, with the Sustainability Promotion, IR and Corporate Planning Departments of Otsuka Holdings functioning as the secretariat.

Sustainability Management Structure



1. Activities are promoted through various conference bodies, WGs, TFs, and others (including time-limited PJ)
2. Consumer Relations: Activities to build trust between companies and consumers

Socially Responsible Investment (SRI) Indices

MSCI Japan Empowering Women (WIN) Select Index

An index developed by MSCI of the U.S. Companies are selected based on their promotion of women's empowerment and high scores for gender diversity, from among companies in the MSCI Japan IMI Top 500 Index. Otsuka Holdings has been included since 2018.

FTSE Blossom Japan Sector Relative Index

An index constructed by global index provider FTSE Russell is designed to be sector-neutral, reflecting the performance of Japanese companies with relatively superior environmental, social, and governance (ESG) practices. Otsuka Holdings has been included since 2022.

S&P/JPX Carbon Efficient Index

An index for ESG investment drawn from TOPIX-listed stocks, with portfolio weight determined by the disclosure status of environmental data and level of carbon efficiency (carbon emissions per unit of revenue). Japan's Government Pension Investment Fund (GPIF)—one of the world's largest pension funds—has selected this index for investment. Otsuka Holdings has been included since 2018.

External Recognition

CDP

An international NGO based in the U.K. that works on climate change and other environmental issues. It asks the world's major companies and cities to disclose information on how they address issues such as climate change and water management, and conducts surveys and evaluations. In 2022, Otsuka Holdings received an evaluation of A for climate change, and B for water resources.

Nadeshiko Brand

A selection jointly determined by Japan's Ministry of Economy, Trade and Industry and the Tokyo Stock Exchange of listed companies with an outstanding record in empowering women in the workplace. Otsuka Holdings was selected as a Semi-Nadeshiko Brand in 2019 and as a Nadeshiko Brand in 2020 and 2023.*



* Scope of survey: Otsuka Holdings and Otsuka Pharmaceutical

Platinum Kurumin and Kurumin

A certification system based on Japan's Act on Advancement of Measures to Support Raising Next-Generation Children, operated by the Ministry of Health, Labour and Welfare. Platinum Kurumin is a certification for Kurumin-certified companies that have carried out higher-level initiatives. Among group companies, Otsuka Pharmaceutical Factory, Taiho Pharmaceutical and Otsuka Chemical are certified as Platinum Kurumin, and Otsuka Pharmaceutical, Otsuka Foods and Otsuka Warehouse are certified as Kurumin.



Eruboshi

A certification system based on Japan's Act on Promotion of Women's Participation and Advancement in the Workplace, under which the Ministry of Health, Labour and Welfare certifies companies that meet certain criteria and are recognized for excellence in empowering women in the workplace. Among group companies, Otsuka Chemical is certified as Eruboshi (Level 3).



MONISU Certification

The Monisu Certification System is a system in which the Minister of Health, Labour and Welfare certifies small- and medium-sized enterprises that excel in their efforts to hire more people with disabilities and provide them with stable employment. Among group companies, Heartful Kawauchi was certified in 2020, as one of the first companies to be certified under the program.



Health & Productivity Management Outstanding Organization

A program, led by the Nippon Kenko Kaigi, that examines organizations such as large corporations as well as small- and medium-sized enterprises working to overcome health-related challenges in local communities or to promote health-conscious activities. The program recognizes organizations that make outstanding efforts in health and productivity management. Among group companies, Otsuka Pharmaceutical and Taiho Pharmaceutical were certified as among the "White 500" enterprises.

Sports Yell Company

Program recognizing companies that actively support and promote measures to improve employees' health through sports. (Japan Sports Agency) Otsuka Pharmaceutical and Taiho Pharmaceutical were selected as a Sports Yell Company in 2023.

Tokyo Metropolitan Government Sports Promotion Model Company(Practical Division)

The Tokyo Metropolitan Government Sports Promotion Company certification program recognizes companies that implement quality initiatives to encourage and support employee participation in sports. Otsuka Pharmaceutical was selected as a Tokyo Metropolitan Government Sports Promotion Model Company (Practical Division) in 2021.



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Policy

Seek to resolve global health issues from a total healthcare perspective.

Do away with deep-seated preconceptions and promote the development of creative human resources.

Pursue product quality and reliability from the viewpoint of consumers.

Otsuka Group's Materiality and Related SDGs

Materiality	Social Issues	Our Goals	Our Activities	Related SDGs	
Society (Healthier Society)	Health	<ul style="list-style-type: none"> Unmet medical and health needs Spread of infectious diseases Nutritional needs Increasing aging issues 	<ul style="list-style-type: none"> Contribute to unmet needs solutions Eradication of tuberculosis Creation of a system for the realization of healthy lifestyles Healthy life extension 	<ul style="list-style-type: none"> Promotion of R&D for unmet needs R&D of antituberculosis drugs and improvement of drug access Support and awareness activities for people's health maintenance/improvement mainly on exercise and nutrition etc. Promotion of problem solving by strengthening partnerships 	
	People	<ul style="list-style-type: none"> Presenteeism* Unprepared for diversification 	<ul style="list-style-type: none"> Creation of a corporate culture that stimulates creativity Enhance employee engagement 	<ul style="list-style-type: none"> Human resource development Diversity promotion Health and productivity management 	
	Quality in All We Do	<ul style="list-style-type: none"> Consumption and production that impairs sustainability 	<ul style="list-style-type: none"> Gaining stakeholder trust Pursuing sustainability at all levels of the value chain Establishing a quality assurance system for safety and security 	<ul style="list-style-type: none"> Sustainable procurement and product design Thorough quality control and stable supply Responsible promotional activities and information provision Deepening communication with stakeholders Promotion of "consumer-oriented management" 	

* Absenteeism is a phenomenon where employees are absent from work frequently due to illness or poor health, or without permission. The term "presenteeism" was coined by combining "absenteeism" with the word "present." For a long time, the lost productivity due to absenteeism has traditionally been regarded as a problem in corporate labor management. Recently, however, it has been found that presenteeism, in which an employee is physically present but cannot concentrate fully on work, causes greater loss for the organization as a whole.



Under its corporate philosophy “Otsuka-people creating new products for better health worldwide,” the Otsuka group actively works to solve social issues through its businesses. 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 undertaking initiatives that raise awareness of health among individuals, the Otsuka group contributes to initiatives for maintaining and improving health in society at large, including through collaboration with local communities.

The Challenge of Addressing Unmet Medical Needs

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, R&D in this area is challenging, and the underlying causes of these diseases have yet to be precisely elucidated. In recent years, there has been a particularly sharp rise in patients with depression or dementia. Satisfaction with current treatment methods is low, and patients and their families are in immediate need of new therapeutics. Psychiatry and neurology is a key focus area in which the Otsuka group has been making headway, namely with the development of antipsychotic drugs *REXULTI* and *ABILIFY MAINTENA*, as well as *Selincro*, a drug that helps in the reduction of alcohol consumption in patients with alcohol dependency. We are also proactively developing therapeutic drugs for diseases with no effective medicines. Behavioral disorders (agitation) associated with Alzheimer's disease are an issue of particular social concern. It is thought that a large number of Alzheimer's patients exhibit some form of agitation, such as excessive motor activity, and verbal or physical aggression. This kind of disorder places a burden on patients and caregivers, impacting quality of life. Moreover, agitation is associated with an increased likelihood of having to move into nursing facilities and the progression of dementia, so the Otsuka group is working to develop effective treatments.

Oncology

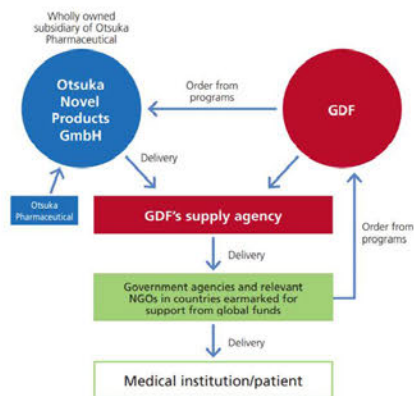
As medical science advances, year by year progress is being made in the diagnosis and treatment of cancer, which is the number one cause of death in Japan. Nevertheless, there are still many forms of cancer that lack effective treatments and from which it is difficult to make a complete recovery. The oncology area, where there are still many unmet medical needs, is another of the Otsuka group's key focus areas. This stems from our track record since the 1970s as a pioneer in developing oral anti-cancer agents, which at that time were not widely used anywhere in the world. In addition to conventional chemotherapy and molecular targeting drugs used to treat specific organs, we are taking on challenges in the new fields of gene therapy and cell therapy in order to keep pace with 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.

Infectious Diseases

Tuberculosis is one of the world's three major infectious diseases, the others being AIDS and malaria. It is an infectious disease with a high number of deaths as well as COVID-19. It has also been designated as a disease to be eradicated by 2030 as part of the Sustainable Development Goals (SDGs). Each year, tuberculosis affects more than 9.9 million people and causes 1.5 million deaths worldwide. Furthermore, according to a modelling analysis by the Stop TB Partnership, the tuberculosis mortality rate has increased because of reduced diagnosis and reporting due to lockdowns and other movement restrictions related to the COVID-19 pandemic, and is becoming a significant problem. After more than 30 years of research and development, Otsuka Pharmaceutical successfully created *DELTYBA*, a new tuberculosis drug. It is one of the world's first new tuberculosis drugs in nearly 40 years, and is recommended in WHO's treatment guidelines. Given the current situation, in which *DELTYBA* needs to be made available as quickly as possible as a new option for multidrug-resistant tuberculosis, Otsuka Pharmaceutical entered into a public-private partnership with Stop TB Partnership's Global Drug Facility (GDF) in 2016. We have obtained regulatory approval in various countries, and as a result of increased access through alliance partners and through access programs operated by governments and public international organizations, the use of *DELTYBA* is now being promoted in more than 120 countries and regions as of December 2021.

In addition, the Otsuka group is conducting research and development of a new multidrug-resistant tuberculosis agent (development code: OPC-167832), and will continue working toward the eradication of tuberculosis.

■ *DELTYBA*: Supply route via StopTB/GDF



Partnerships

Eradicating Tuberculosis

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

Also, in line with the goal of eradicating tuberculosis, we have participated in the planning of the Project to Accelerate New Treatments for Tuberculosis (PAN-TB collaboration) since February 2020. This world-first global cross-industry collaboration between charitable and non-profit organizations and the drug industry aims to satisfy the Target Regimen Profiles (TRP) proposed by the World Health Organization (WHO) for tuberculosis by speeding up the development of a new pan-TB regimen suitable for all tuberculosis patients.

Initiatives in Kidney Disease

Autosomal dominant polycystic kidney disease (ADPKD) is a hereditary, intractable orphan disease. It involves the progressive development 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 (Access to Medicine)

Expanding Access to Medicine

The Otsuka group is committed to improving access to medicines not only through research and development of pharmaceuticals and IV solutions that address unmet needs, but also by supporting those with limited access to medicines due to financial or other reasons.

Otsuka Pharmaceutical has implemented the Otsuka Global Patient Access Support Policy to improve patient access to medical care. This includes the introduction of the Otsuka Patient Assistance Program using Iclusig tablets for patients with certain types of leukemia in Asian countries and regions. The program provides financial support for pharmaceuticals and in other ways to patients who cannot afford medical care due to insufficient insurance reimbursement or other financial reasons.

Initiatives to Expand Access to Tuberculosis Drug *DELTYBA*

Eradicating tuberculosis is still a major challenge worldwide. In support of that effort, Otsuka has been working to expand access to *DELTYBA*, and since 2016 has shipped enough doses to treat more than 40,000 cases.

- Access programs implemented by countries and public international organizations
 - endTB project conducted by Unitaid (a global health agency)
 - Access programs implemented by the governments of South Africa and India
- Access through compassionate use programs¹
 - Supplied to more than 200 patients in 19 countries (ERJ, 2020²)
- Supply from Stop TB Partnership's GDF (since February 2016)
- Access through alliance partners
 - Alliance with R-Pharm JSC (Russia, CIS, etc.)
 - Alliance with Mylan N.V. (India, South Africa, other TB high-burden countries)

1 Public programs that provide access to yet-to-be-approved drugs on an exceptional basis to patients with serious or life-threatening diseases

2 Ghosh S et al., *Eur Respir J*. 2020 Nov 26; 2002483.

Expanding Access to Medicine

There are patients who cannot expect satisfactory outcomes from existing treatments, or whose conditions render them ineligible to participate in clinical trials. Such patients are unable to access investigational drugs that might be a potential treatment option. Through its Expanded Access Program, the 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.

Initiatives of Otsuka Pharmaceutical Development & Commercialization (OPDC)

While it is preferable for patients to participate in clinical trials, it is not always possible for them to do so. In such cases, OPDC may enable patient access to investigational drugs. This method, also known as compassionate use, provides patients with drugs that are not yet approved by the FDA for use outside of clinical trials. OPDC accepts requests for Expanded Access Program from doctors treating patients who have no other effective treatment options.

Initiatives of Taiho Oncology

Taiho Oncology, Inc. ("Taiho") is committed to helping patients with cancer obtain access to new treatments. While we believe this is best accomplished through participation in clinical trials, we recognize that this is not always possible for every cancer patient. In such situations, Taiho may be able to provide pre-approval access to an investigational drug through our Expanded Access Program. Expanded Access, also known as Compassionate Use, is the use of an investigational medical product intended to diagnose, monitor or treat a patient's disease or condition, prior to FDA approval and outside of use in a clinical trial. Taiho accepts requests for pre-approval access to investigational cancer medicines from physicians only.

Patient Support Programs

In some countries and regions, the Otsuka group offers a variety of programs that provide support to patients and caregivers when patients purchase certain Otsuka group products.

Initiatives of the Otsuka Patient Assistance Foundation (OPAF)

OPAF is a nonprofit organization providing Otsuka's pharmaceuticals free of charge to patients who are not insured or whose treatment costs are not fully covered by insurance.



Initiatives of the Otsuka Patient Assistance Foundation (OPAF)

OPAF's Otsuka Patient Support™ combines resources, tools, and support teams to help patients, caregivers, and healthcare professionals.



Initiatives of Taiho Oncology

Taiho Oncology runs the Taiho Oncology Patient Support™ program to provide patients, caregivers, and healthcare professionals with services such as insurance confirmation, treatment cost assistance, and treatment planning support when starting treatment with *Lonsurf*.



Initiatives of the Taiho Pharma Canada, Inc. (TCAN)

Taiho Pharma Canada (TCAN) has a personalized patient support program (Conexus Patient Support Program™) in Canada that provides services, including reimbursement information, one-on-one support from a dedicated nurse, specialized pharmacy services and home delivery, and educational services for patients, caregivers and healthcare workers when starting treatment with the anticancer drug *Lonsurf*.



Fair Pricing of Pharmaceuticals 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. Not many of Japan's pharmaceutical companies supply locally manufactured pharmaceuticals in other countries, due to the risks involved and differences in technical capabilities. However, we insist on manufacturing IV solutions in the country in which they are sold because we believe in supplying pharmaceuticals at fair prices for each country or region so that all people can receive medical treatment equally, whether rich or poor. The Otsuka Global Quality Standards have been set to maintain high quality in every country that manufactures our products, aiming to further improve quality.

*Vision for the Pharmaceutical Industry 2013, Ministry of Health, Labour and Welfare

Providing Information to Patients, Their Families and Caregivers

Across its product portfolio, the Otsuka group provides patients, their families, and caregivers with a variety of materials and information to help foster their understanding of disease and assist patients in their medical care.

Initiatives of Otsuka America Pharmaceutical, Inc. (OAPI)

This company provides educational materials online for patients, their families, and caregivers to better understand disease.



Initiatives of Taiho Pharmaceutical

Taiho Pharmaceutical creates and provides a variety of materials that healthcare professionals can use to assist in patient care. Since 2016, it has distributed its 20–TWENTY– booklet for cancer patients in the AYA generation (adolescents and young adults), their families, friends, and others close to them. The booklet does more than just focus on issues of physical appearance; it also addresses topics related to overcoming obstacles in daily life, dealing with negative emotions, and developing a positive attitude. The company distributes these materials to healthcare professionals in the hope that they will help patients undergoing cancer treatment deal with the issues they face



20–TWENTY–

In 2017, Taiho Pharmaceutical published a booklet entitled *Thinking about Having Children: Handbook for Cancer Patients to Preserve Fertility*. Recent advances in medical care have ushered in an era in which cancer can often be brought into remission, and even when it cannot, patient life expectancy is still longer. At the same time, fertility preservation technology has also improved. This booklet is designed to give patients more knowledge about fertility preservation before cancer treatment, so they can understand the possibility, for those who wish, of having children in the future. The company hopes that, armed with a full understanding of the situation based on this new knowledge, patients can then move forward with treatment.



Thinking about Having Children:
Handbook for Cancer Patients to Preserve Fertility

Initiatives of the Sozosei Foundation

Otsuka America Pharmaceutical, a U.S.-based group company, established the Sozosei* Foundation in 2019. The purpose of the foundation is to spread awareness of medical issues in the U.S., disseminate information and promote education about medical care and health-related issues, and contribute to related organizations. The foundation mainly provides support in the psychiatry and neurology area, and the renal area, and contributes to disaster relief activities and local communities. In 2021, the foundation made donations to support patients affected by COVID-19 as well as their families and healthcare providers.

* Sozosei (creativity) is one of the Otsuka values.

Global public health improved thanks to anti-tuberculosis drug, delamanid

Tuberculosis (TB) has been the scourge of humankind for millenia. There's evidence that it existed in ancient Egypt.^{*1} It is the world's second leading infectious killer after COVID-19.^{*2,3} Drug-resistant strains proliferating in recent decades have rendered TB even more lethal.

TB is, however, curable and preventable. By deploying its anti-tuberculosis drug, delamanid, the Otsuka group is seeking to go even further and eliminate TB.

^{*1} Thomas M. Daniel (2006)

^{*2} World Health Organization. Global tuberculosis report 2020

^{*3} World Health Organization. Coronavirus disease (COVID-19) dashboard

What is tuberculosis?

TB is one of the most serious infectious diseases in the world, where *Mycobacterium tuberculosis* (M.tb) enters the body and multiplies, mainly in the lungs, resulting in symptoms such as coughing and production of sputum. In serious cases, the infection can cause breathing difficulties and affect other organs, potentially resulting in death. While highly contagious, about 5-10% of infected people will develop the disease at some time in their lives. Some of them may develop the disease several years after infection due to declining physical strength or aging.

Multidrug-Resistant and Extensively Drug-Resistant TB

Since the 1990s, M.tb bacteria have emerged which have acquired widespread resistance to anti-tuberculosis drugs.

Discontinuation of medication for any reason, such as irregular doses or tolerability, gives rise to bacteria that are resistant to the drugs that have been taken. Among these are multidrug-resistant TB (MDR-TB) bacteria that have become resistant to rifampicin and isoniazid, the two most potent first-line therapeutic agents. Extensively drug-resistant TB (XDR-TB) is resistant to an even greater number of drugs, representing a major global challenge to efforts to control the disease.

SDGs target 3.3

In 2015, the United Nations set out its Sustainable Development Goals. SDG 3 addressed public health. SDG 3.3 set the year 2030 as the target to end the epidemics of AIDS, TB, malaria and neglected tropical diseases, as well as to combat hepatitis, waterborne infections and other communicable diseases. However, modeling from the Stop TB Partnership on COVID-19 disruptions to TB services in countries with a high burden of the disease, indicates that the 2030 target may be set back at least five years.^{*4}

^{*4} "TB and COVID-19" Stop TB Partnership website, available at: <http://www.stoptb.org/covid19.asp>

Number of individuals infected with Mycobacterium tuberculosis: approx. 1.7 billion

Annual deaths from tuberculosis: approx. 1.5 million

TB still spreading worldwide

TB is highly contagious. About 1.7 billion people are said to be infected with M.tb bacteria in the world. An estimated 9.9 million people develop TB in 2020, of whom about 1.5 million die.⁵

TB is prevalent in many low- and middle-income countries. Because TB requires long-term treatment, it represents a major economic challenge in high burden countries.

⁵ World Health Organization. Global Tuberculosis Report 2021

Limitations of conventional medicinal treatment

M.tb, which may develop into active TB disease, is a very “stubborn bacterium.” Currently, treatment usually involves administering three to four drugs, to suppress the risk of the patient developing resistance to any one of them. In most cases, drug-sensitive TB can be successfully treated with what are known as “first-line drugs” and proper case management. However, for the more dangerous MDR- and XDR-TB strains, doctors turn to “second-line” drugs, and those combinations can include delamanid.

Delamanid is improving global health One of the first new drugs in 40 years

Birth of delamanid

“If nobody does it, Otsuka must do it.”

Delamanid first received approval in 2014 in the European Union for the treatment of adult, pulmonary MDR-TB. It has a completely different mechanism of action compared with previous therapeutic agents, and is also effective against TB bacteria that have become resistant to existing drugs. Since 2015, delamanid has been included in the WHO Model List of Essential Medicines (list of priority drugs in any country).

Delamanid is one of the newest anti-tuberculosis drugs approved in the world in the past 40 years. Although MDR-TB is currently gaining prominent attention, it had been thought that TB had become a disease that humankind has already overcome since rifampicin, currently used as one of the first-line drugs, was discovered in 1964. In the 1970s, when many researchers and research institutes around the world stopped development, Otsuka Pharmaceutical continued research, based on the belief that “TB is a serious global health problem, and we must continue our research if nobody else does it.” Delamanid was created after more than 30 years. Otsuka Pharmaceutical remains actively engaged in Research & Development on new anti-tuberculosis drugs. For more than a decade, the company has consistently ranked among the top funders of TB R&D worldwide.



TABLE 1

Top 15 Funders of TB Research, 2019

Rank	Funder	Funder Type	2019 Funding	2018 Funding
1	U.S. National Institutes of Health, National Institute of Allergy and Infectious Diseases (NIAID)	P	\$286,972,907	\$253,434,034
2	Bill & Melinda Gates Foundation	F	\$117,557,700	\$141,115,233
3	U.S. National Institutes of Health, Other Institutes and Centers (NIH Other ICs)	P	\$44,949,029	\$43,946,795
4	U.S. Agency for International Development (USAID)	P	\$37,139,231	\$36,735,190
5	Unitaid	M	\$35,800,429	\$26,193,134
6	Company X	C	\$32,183,188	\$30,319,517
7	U.K. Department for International Development (DFID)	P	\$25,022,125	\$24,677,306
8	European and Developing Countries Clinical Trials Partnership (EDCTP)	P	\$24,591,735	\$24,491,122
9	German Federal Ministry of Education and Research (BMBF)	P	\$23,543,671	\$16,351,364
10	Indian Council of Medical Research (ICMR)	P	\$19,070,083	\$24,243,814
11	Otsuka Pharmaceutical	C	\$15,435,292	\$28,405,543
12	U.S. Centers for Disease Control and Prevention (CDC)	P	\$15,432,560	\$17,619,008
13	U.K. Medical Research Council (U.K. MRC)	P	\$15,384,488	\$16,395,195
14	European Commission	P	\$14,252,272	\$18,527,670
15	Global Affairs Canada	P	\$12,965,569	\$12,949,750

C = Corporation/Private Sector; F = Foundation/Philanthropy; M = Multilateral; P = Public-Sector R&D Agency



Tuberculosis Research Funding Trends 2005 – 2019, Stop TB Partnership and Treatment Action Group

A brief history of Otsuka Pharmaceutical's Global TB Programme

1971	TB selected as one of the company's earliest research priorities
2002	Otsuka Pharmaceutical researchers find a new anti-TB drug candidate compound
2004	Phase I clinical trial of OPC-67683, (later named delamanid) starts
2008	Phase II clinical trial for MDR-TB patients starts
2011	Phase III clinical trial for MDR-TB patients starts
2013	Clinical trials for paediatric patients with MDR-TB start
2014	Approval granted in the European Union and Japan for treatment of pulmonary MDR-TB in adult patients
2016	Phase I of OPC-167832, a second new anti-TB compound starts
2018	Phase I/II of OPC-167832 starts
2020	Participate in the world's first-of-its kind collaboration, the PAN-TB Consortium, that transcends industry boundaries

Delamanid for children

Between 25,000 and 32,000 children develop MDR-TB each year.⁶ Of these, only 3 - 4 per cent are diagnosed and treated and consequently approximately 21 per cent of children with MDR-TB are likely to die.⁷

The treatment for MDR-TB is arduous and particularly so for children.

Otsuka Pharmaceutical has developed a novel paediatric formulation of delamanid. In 2021, it was approved by the European Medicines' Agency (EMA) for use in children weighing at least 10 kgs.⁶ Access to Medicine Foundation report "Tuberculosis in Children: Underdiagnosed and Undertreated" (2020)

⁷ Helen E Jenkins and Courtney M Yuen (2018)

External Collaborations

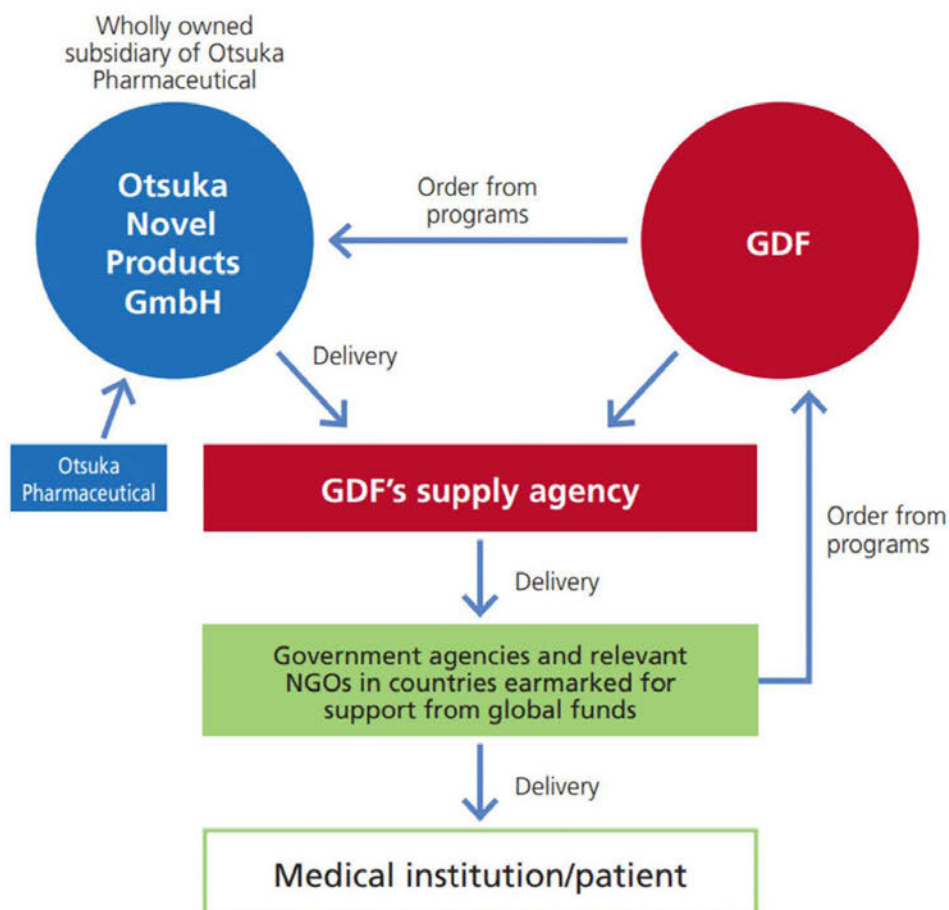
Expanding access to tuberculosis drugs in low-income countries in collaboration with the Stop TB Partnership's Global Drug Facility ⁸

Delamanid is one of the first new anti-tuberculosis drugs approved in the past 40 years, but this is meaningless if the drug is not accessible to patients. That said, there are many TB patients in developing countries of Africa, Asia, and other regions where the Otsuka Group does not have a business base. For this reason, we work with the Stop TB Partnership's Global Drug Facility (GDF), an organization dedicated to expanding access to quality-assured anti-tuberculosis drugs and diagnostic agents, and ensuring the sustainable procurement of those drugs in developing countries. GDF now supplies delamanid to more than 80 countries, and the majority of patients currently taking this drug receive their medicines through GDF, highlighting the organization's excellent contribution to expanding access.

⁸ Founded in 2001, the Stop TB Partnership has a mission to serve every person who is vulnerable to TB and to ensure that high-quality diagnosis, treatment and care are available to all who need it. GDF is the largest global provider of quality-assured anti-tuberculosis medicines, diagnostics, and laboratory supplies to the public sector while also providing technical assistance to TB programs and supporting wide use of innovative tools.



■ DELTYBA : Supply route via StopTB/GDF

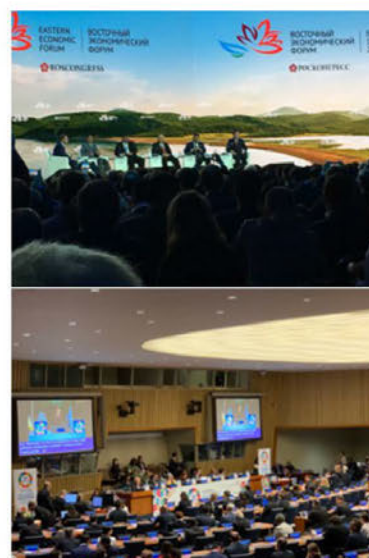


Cooperation with Japanese government on delamanid

We also cooperate with, and receive support from, the Japanese government in various ways. These include support for access initiatives overseas and sharing educational information at international conferences and events.

One of the eight points in the economic cooperation plan agreed by Japanese and Russian leaders is to improve medical care and promote healthy life spans. At the Eastern Economic Forum in Vladivostok on September 7, 2017, Japan's Prime Minister, Shinzo Abe, spoke of mutual cooperation, aimed at getting swift approval for delamanid in Russia. In that speech, he said, "In the fight against TB, Japan and Russia have joined hands." Delamanid received regulatory approval in the Russian Federation in 2020.

At the United Nations General Assembly High-Level Meeting on Tuberculosis in New York City on September 26, 2018, Katsunobu Kato, Minister of Health, Labour and Welfare, gave a speech on developing treatments for MDR-TB in Japan and contributing to eradication of the disease worldwide, and at the same time adopted the political declaration toward eliminating TB.



Establishing a supply network which will save patients around the world

Expanding access to patients worldwide

Numerous collaborations have been formed to combat TB and other diseases that threaten global health, for example with the WHO, United Nations and national governments who provide active support. In addition to its cooperation with GDF, Otsuka Pharmaceutical contributes to the health of people around the world through collaborative initiatives with its many stakeholders. These include: our participation in the Global Health Innovative Technology Fund (GHIT); a Japanese public-private partnership established to address infectious diseases worldwide; and cooperation with programs spearheaded by Médecins Sans Frontières/Doctors Without Borders (MSF). We have also received grants from the Bill & Melinda Gates Foundation to support clinical developments for a novel regimen of TB treatment. As for global access, we have built alliances with international companies which have strengths in public health or in areas where the Otsuka group does not have business bases, such as Viatriis in India, South Africa and other countries with a high burden of TB and R-Pharm in Russia/CIS region.



Initiatives in which Otsuka Pharmaceutical participates

Rome 5

a Vatican initiative historically focused on children living with HIV & now including TB.

Ending Workplace TB

a collaboration of the World Economic Forum, the Global Fund and private sector companies to end TB in the workplace. Through internal and external communication drives, Otsuka Pharmaceutical has pledged to raise awareness of the disease with the public and its own employees in countries with a high burden of TB.

Otsuka Pharmaceutical and Viatriis are completing technology transfer aiming for production in India in order to ensure affordable access to delamanid in high-burden countries.

In March 2017, we launched a delamanid clinical access program (DCAP) in cooperation with the South African government. The aim of the national program was to give patients with MDR-TB swift access to delamanid before regulatory approval. Delamanid is now approved and widely available in South Africa.

In other initiatives, Otsuka Pharmaceutical is working to establish sustainable drug delivery systems at affordable prices, so that patients around the world who need delamanid can be treated regardless of socioeconomic status or income level. As of 2021, more than 110 countries are expanding use of delamanid based on this multifaceted approach.

Next-generation tuberculosis drug candidate, OPC-167832

Otsuka Pharmaceutical is conducting research into anti-tuberculosis drugs that will follow delamanid. The latest development is a compound called OPC-167832, which as of 2021 is undergoing initial trials in South Africa to confirm its safety and efficacy.

OPC-167832 kills TB bacteria through a mechanism that inhibits the activity of enzymes that are essential for synthesizing mycobacterium tuberculosis cell walls. Because its mechanism of action differs completely from those of existing anti-tuberculosis drugs, including delamanid, it is expected to be effective as a treatment for various strains of TB. In developing the drug, we received grants from the Bill & Melinda Gates Foundation, which has cited elimination of TB worldwide as one of its top priorities, to advance clinical trials. We will continue engaging in TB R&D with the aim of establishing innovative treatment methods.

Initiatives in which Otsuka Pharmaceutical participates

The Project to Accelerate New Treatments for Tuberculosis (PAN-TB)

the first collaboration among philanthropic, non-profit and private sector organizations, led by the Bill & Melinda Gates Foundation. It aims to accelerate the development of an investigational drug regimen capable of treating all forms of TB (a pan-TB regimen).

Unite4TB

another public-private collaboration supported by the European Innovative Medicines Initiative (IMI) to accelerate development of novel TB combinations.

EU-Pearl

which aims to make drug trials more efficient and patient-friendly.

Fighting Antimicrobial Resistance (AMR)

The Economist Intelligence Unit, in its 2019 report "It's Time to End Drug-Resistant Tuberculosis, 11 asserts that, by the year 2050, drug-resistant TB could account for 2.5 million deaths annually⁹.

Otsuka Pharmaceutical has been implementing the Responsible Access Program to prevent the outbreak of delamanid-resistant TB and to promote proper use of the drug.

Our stewardship achievements, including efforts to educate about proper use, increase global access to delamanid as well as continuous research and development into drug-resistant TB, are acknowledged in the AMR Benchmark, a survey of 17 global pharmaceutical companies.¹⁰ The Benchmark is compiled by the Access to Medicine Foundation, and is funded by the UK and Dutch governments.

⁹ The Review on Antimicrobial Resistance. Tackling drug-resistant infections globally: Final report and recommendations. London: Wellcome Trust and HM Government, 2016.

Initiatives for Yet-To-Be-Imagined Needs

The term “nutraceuticals” was created by combining the words “nutrition” and “pharmaceuticals.” It was coined in 1989 in the U.S. by Dr. Stephen L. DeFelice and refers to foods and beverages with benefits that have a scientific basis, and which contribute to the maintenance of everyday health. Our range of nutritional products fit this definition well, which led us to adopt the term to describe our science-based foods and beverages that help maintain and promote day-to-day health. To be healthy is a universal desire of people worldwide. While advances in medical technology and improvements in public health have extended life expectancy globally, new health issues such as population aging and lifestyle diseases have also arisen. 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. Utilizing expertise honed in our Pharmaceutical Business, the innovative, science-based products we develop enable people worldwide to live healthier, more active lives. Furthermore, we engage in health awareness activities as part of our initiatives to expand access to nutrition.

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

Amid trends including medical cost inflation and the aging of Japan's population, the Otsuka group is promoting community-based health maintenance and improvement initiatives, as well as disaster prevention and relief activities. 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.

Raising Awareness of Proper Hydration

Since the launch of *POCARI SWEAT*, Otsuka Pharmaceutical has been promoting the importance of hydration in various contexts. Spurred by the establishment of the Japan Amateur Sports Association (now Japan Sport Association (JSPO)) Study Group for Prevention of Heat Disorders in Sports Activities in 1991, we began cooperating in efforts to prevent heat disorders through awareness activities 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 JSPO'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.



Lecture by Otsuka Pharmaceutical employees

Raising Awareness of Women's Health

The average life expectancy in Japan is over 80 years for both men and women. Healthy life expectancy is 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. In response, the Otsuka group developed a product containing equol, a soy-derived ingredient that functions in a similar way to the female hormone estrogen. It can help maintain and improve the health of women at a time when they can experience a range of mental and physical changes. Based on expertise obtained during the R&D process, we conduct activities to spread accurate understanding of the mental and physical changes experienced by women and related health issues, as well as solutions to those issues and evidence for the efficacy of equol. A wide range of other information on nutrition in relation to women's health and other topics can be found on the Otsuka Pharmaceutical website.

Nutritional Support and Helping Families Fill Nutrition Gaps

Pharmavite, which is based in the U.S. and handles the development and sales of Nature Made products, has partnered with the non-profit organization Feed the Children to provide products and support for health over three years. Through this partnership, the company has donated approximately 15 million children's chewable multivitamins. Each family received a two-year supply of children's vitamins, reaching 8,800 families in total.

In addition, Nature Made registered dietitians provided on-site nutritional education to families on how to compensate for nutritional deficiencies.



Conveying the Importance of Nutrition

We continue to conduct dietary education activities that explain the importance of nutrition, based on expertise gained through product development of nutritional products. 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, Nature Made Supplement Check, an app that allows users to easily analyze the nutritional content of a meal by taking a smartphone picture.



Dietary education app
SketchCook

Learning the SDGs through Plant-Based Foods

The Otsuka group has released plant-based soy meat products that are free of ingredients derived from animals. Plant-based foods have been gaining attention as sustainable products with less environmental impact than animal products. We have co-produced teaching materials titled "Learning the SDGs through Plant-Based Foods" with Gakken Plus Co., Ltd. to support education on the United Nations' Sustainable Development Goals (SDGs) for elementary school children, who will be the leaders of the next generation. In addition, the Daizu Meat Lab provides information on the appeal of soy meat through columns, recipes, and news.

A 40-Year History and the Future of POCARI SWEAT

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Raising Awareness of Heat Disorders and the Importance of Replenishing Fluids and Electrolytes

Founded as a chemical raw material manufacturer in 1921, the Otsuka group launched its intravenous solutions business in 1946. Leveraging expertise cultivated in the intravenous solutions business, we developed *POCARI SWEAT* as a beverage that replenishes the body's fluids and electrolytes, which are important for maintaining and improving day-to-day physical health. Later, in 1992, we participated in the Japan Amateur Sports Association (now Japan Sport Association (JSPO)) Study Group for Prevention of Heat Disorders in Sports Activities, and began full-fledged activities to raise awareness of heat disorders and their prevention. Since then, we have used scientific evidence to raise awareness of the importance of fluid and electrolyte replenishment in various aspects of life.

This brings us to the present day. The pathology of heat disorders, which was not well known in those early days, and the concept of supplying electrolytes together with fluids as a countermeasure, are now widely understood and recognized throughout society. *POCARI SWEAT* has become a popular staple in all kinds of situations where people sweat, including sports, commuting, outdoor work, and after a bath or waking up. Today, we continue to promote awareness of the importance of replenishing fluids and electrolytes in various contexts, including children's sports activities, occupational safety and hygiene, and hydration for the elderly.



POCARI SWEAT is a health beverage that easily replenishes the body with fluids and electrolytes lost due to perspiration. When people sweat to regulate their body temperature, they lose electrolytes along with fluids. Just drinking water may upset the balance between fluids and electrolytes, which can negatively affect physical condition and performance. Proper hydration is necessary. As a beverage that is similar to fluids already present in the human body, *POCARI SWEAT* enables efficient fluid replenishment.

1980
Launched in
Japan



1987
Cumulative
units sold:
3 billion¹

1. One unit equals 340 ml;
units sold includes overseas sales

1982
First overseas
market entry

1992

Began cooperation with Japan Amateur Sports Association² Study Group for Prevention of Heat Disorders in Sports Activities

2. Now Japan Sport Association (JSPO)

1993

Began cosponsoring JSPO heat disorder prevention awareness activities and cosponsored production of *A Guidebook for the Prevention of Heat Disorder in Sports Activities (First Edition)*



1993
Cumulative
units sold:
10 billion¹

1998
Cumulative
units sold:
20 billion¹

2007

Conducted lectures on hydration for 500,000 members of junior sports clubs nationwide as part of the Sports Activities Campaign

2007

Began cosponsoring production of a guidebook on heat disorder prevention, based on the *Guidelines for Prevention of Heat Disorders in Everyday Life (Ver. 1)* published by the Japan Society of Biometeorology



2008
Cumulative
units sold:
30 billion¹

2012

Co-sponsored production of the Heat Disorders Prevention website (NPO Weather Caster Network)



2016

Received Best Communicator and Top Runner Award at the Heatstroke Prevention Award at the Heatstroke Prevention Communication Project Hitosuzumi Awards 2016

2020
40th
anniversary

2010

Commenced activities at public and other health centers across Japan to raise heat disorder awareness among seniors

2012

Began Live On Seminar as a lecture for industrial physicians and public health nurses, nurses, nutritionists, and health and safety staff working at business offices in Japan



2017

Participated in the reprinting of the Ministry of the Environment's *Environmental Health Manual on Heat Disorders*

Supplying quality fluids and electrolytes
to people all around the world

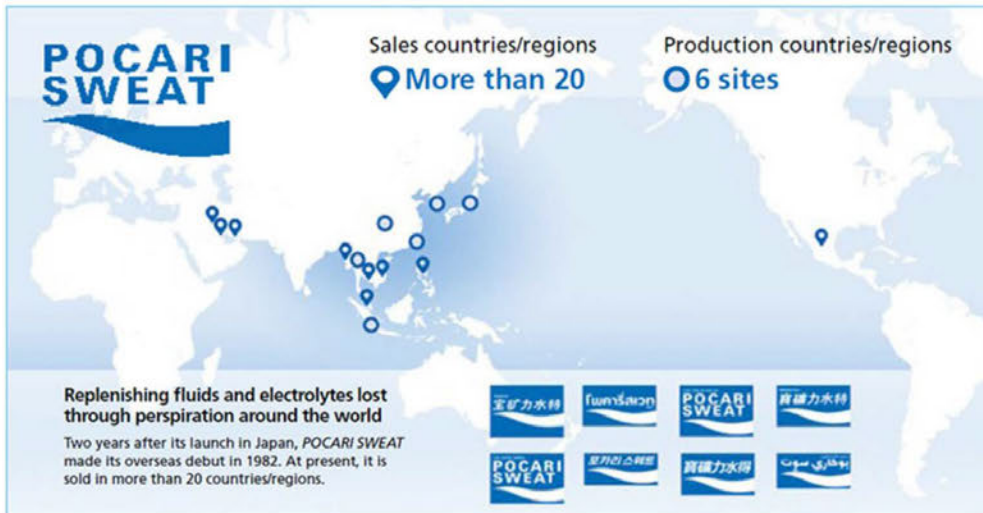


Why *POCARI SWEAT* Continues to Create New Value

Situations in which the body becomes dehydrated are various, and are not limited to any particular time or place.

Otsuka Pharmaceutical's marketing of *POCARI SWEAT* includes activities to raise awareness of the importance of hydration in more than 20 countries/regions around the world.

POCARI SWEAT continues to create new value—meeting the challenge of changes in the environment and people's values, and social diversification. This is because *POCARI SWEAT* continues to be closely intertwined with people's lives, and to uncover and address underlying issues. As a science-based solution for universal needs, it generates value that leads to better health and better lifestyles.



The World *POCARI SWEAT* Aims to Create

Global warming is having a major worldwide impact on climate and the natural environment, as well as people's lives. Should global warming continue, as many as 1.2 billion people could be at risk of heat disorders every year by the year 2100. Also, it is estimated that due to the expansion of habitats conducive to the propagation of organisms that carry tropical diseases, including Zika fever and dengue fever, the number of people at risk of infection could increase by 383–725 million by 2050.* Meanwhile, the importance of and proper methods for fluid and electrolyte replenishment as “first aid” for heat disorders and tropical disease infection have not yet become globally recognized.

We explore and identify underlying issues in each country, consider solutions, convey the scientific grounds and encourage consumers to try *POCARI SWEAT*. Through simple measures such as these, we contribute to the health of people worldwide.

Fluids and electrolytes are essential to life. Our vision is to use our enduring spirit of inquiry and our ability to flexibly address the needs of a diversifying society to make *POCARI SWEAT* a health beverage like no other.



Around the world, there are many people who have difficulty maintaining their health because they lack access to a quality source of hydration. *POCARI SWEAT* aims to change the world by being an industry leader and contributing to solving social issues.

* Daniel Li et al., *Environ Res Lett* 2020

Otsuka Pharmaceutical's Saga Nutraceuticals Research Institute gathers various kinds of evidence through clinical trials on the replenishment of fluids and electrolytes under various conditions.

In 2018, leveraging our expertise from research into heat disorders, we launched *POCARI SWEAT ICE SLURRY*. We developed this product using proprietary technology for creating a formulation that freezes in the form of ice slurry (in which solid particles are dispersed in a liquid), which is known for its high cooling properties. This “drinkable ice” efficiently cools the body from its core, and offers people a new option for combating heat disorders when active in hot environments.



*This page is reprinted from Otsuka Holdings Integrated Report 2019.

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 the medium of comics. 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 cosponsored 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.



* Approx. 23,000 books each year

Support in Disasters and Emergencies

HOME > Sustainability > Society > Health > Support in Disasters and Emergencies

In light of our obligation as a group of companies 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. In addition, Otsuka group companies are providing humanitarian assistance to the Ukrainian people whose lives have been severely affected and those who have been evacuated to neighboring countries.

[|◀ Back to TOC](#)



The Otsuka group believes that the active participation of a diverse range of employees in a free and open-minded workplace environment generates innovation and sustainable corporate growth. To this end, we aim to foster a corporate culture that encourages creativity, invest in the development of human resources, and actively promote diversity among our personnel. We have a safe workplace environment and strive for fair hiring, evaluation, and promotion processes that respect human rights.

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.

In addition, we intend to continually drive innovation by actively promoting communication and engagement both inside and outside the group and by building networks that transcend job category and field that are not bound by a stereotype.

Approach

Upholding Our Corporate Culture and Developing Global Leaders

In 2016, Otsuka Holdings established the Otsuka Global Academy with the aim of ongoing identification and development of the global human resources needed for sustained growth. The academy's programs, which target Otsuka group employees worldwide, are designed and run in-house, but we also partner with outside institutions in some areas for more effective human resource development.

Guided by the commitment of Otsuka Holdings' executives and rooted in the leadership of the Otsuka group's founding figures and the group's unique approach to business, participants learn about and discuss the kinds of people the Otsuka group needs for its next generation of leaders and the skills they are expected to possess, and are cultivated as future leadership candidates.



Meanwhile, since 2021 Taiho Pharmaceutical has partnered with outside institutions to provide training that emphasizes dialogue on upholding the company's longstanding corporate culture and mindset. Inspired by the company's slogan "Acting on what should be done," training currently targets company executives, but the company intends to broaden coverage going forward.

A System That Generates Innovation

Human Resource Development through Collaboration Inside and Outside the Group

The Otsuka group views partnerships and collaborative efforts inside and outside the group as opportunities to help address the unmet medical needs of patients worldwide. By sharing expertise and state-of-the-art technologies, we are boosting our drug discovery capabilities, further improving our development capabilities, and stepping up our global expansion. For example, Taiho Pharmaceutical established its own corporate venture capital (CVC) subsidiary in the U.S. in 2016, and is using it to forge a network with promising biotech start-ups and the academic community in the U.S. and elsewhere with a view to generating innovation. The company also seconded employees from Japan to the CVC subsidiary for a few years to gain overseas experience as part of their professional development.

Open Recruitment System/Self-assessment System

We have also established an open recruitment system¹ and self-assessment system² for the purpose of enhancing the capabilities of employees at each company.

- 1: Under this system, the Otsuka group internally discloses requirements of a certain position or job and then fills it from among those who apply. Employees that satisfy the requirements can apply directly to the company offering the position and be transferred if the expectations of both parties are in agreement. The open recruitment system can be utilized by employees working at group companies in Japan, and is aimed at boosting employee capabilities and motivation, as well as invigorating exchange within the group.
- 2: Under this system, employees can submit opinions and suggestions regarding their current work duties and workplace, as well as career plan aspirations, to the Human Resources Department. The self-assessment system is implemented on a once yearly cycle, with the goals of further developing employee potential, ensuring assignment to appropriate jobs, and improving the workplace environment.

Fostering Human Resources Adept in the Digital Era

Otsuka Holdings is conducting a variety of initiatives to speed up digital transformation throughout the group. One example is the Otsuka Group AI Forum, which is used to share case studies of group companies' successes and generally promote the spread and understanding of artificial intelligence mainly among group company managements and directors. Training in a wide spectrum of technologies such as data science is also provided in order to help boost employees' IT capabilities. In addition, a group-wide portal site was launched in 2021 to disseminate and share in-house and external information relating to digitalization.

Otsuka Medical Devices hosted a training session at which university professors shared examples of how to employ artificial intelligence in the field of medicine.

Meanwhile Otsuka Warehouse, knowing that IT is vital for overcoming the challenges faced by the logistics industry, is seeking to improve the IT literacy of its employees through encouraging employees to take the Japanese government's IT Passport exam by holding in-house study workshops and subsidizing examination fees. The company's commitment to building IT competency also includes ongoing year-round IT skills training for those who pass the exam.



Human Resource Development Institute Encourages People to Turn Ideas on Their Head

“Our mission is the development of human resources who can break the mold.”

In March 1988, the Otsuka group established the Human Resource Development Institute, an employee training center in Tokushima City, the birthplace of the Otsuka group of companies. The institute's mission is to foster the development of creative human resources who can break the mold of conventional thinking and contribute to Otsuka's ongoing success as a “big venture” company. The institute has three monuments that embody the Otsuka values of actualization and creativity, including the Giant Tomato Plant Tree, which symbolizes the theme of the institute: “turning ideas on their head.” New employees are trained in these ways every year at the institute.



Support of Career Independence

HR Interviews and Communication between Supervisors and Staff

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.

At Taiho Pharmaceutical, approximately one-third of personnel in the Human Resources Department have obtained career consultant* qualifications, and the company actively supports career development that accommodates the aims of each employee. In 2014, the company opened a career counseling office staffed with both industrial counselors and career consultants. In addition, since 2021 Taiho Pharmaceutical has distributed a handbook on career counselling for managers, and have started a system that allows supervisors and subordinates to openly discuss their careers using a career design sheet (developed inhouse) as a tool for employees to think deeply about their own careers.



* In April 2016, “career consultant” was defined in Japan’s Human Resources Development Promotion Act and became a national qualification. Career consultants are professionals who provide consultation and advice on job selection and skill development to students, job seekers, people currently working, and others.

Learning Support

At Otsuka group companies, we have introduced support for self-study using e-learning run by external organizations, in this way providing opportunities for employees to achieve personal growth and self-fulfillment.

In April 2020, we launched the Global E-Learning (GEL) Platform employing the Harvard ManageMentor program provided by Harvard Business School Publishing Corporate Learning. A first for the Otsuka group, it is a shared learning platform for group employees worldwide. So far, a total of 2,400 employees from 75 group companies in 29 countries/regions have participated. In addition to cultivating business literacy and skills, the program features messages from top Otsuka group executives, as well as training initiatives unique to Otsuka that group employees around the globe can take part in together, including a learning “café” and webinars.



Otsuka Chemical assists employees in improving their skills and knowledge under our qualification acquisition support system, which provides examination fees and incentives for getting qualifications in a variety of fields. Otsuka Warehouse also has a system in place for employees who raise their hands and wish to take on a challenge to attend business school, based on the belief that good input produces good output.

Employee Evaluation and Feedback Process

At Otsuka group companies, individual sets goals that are rooted in organizational objectives. Employees sit down and talk with their supervisors to help with goal setting. Every six months the supervisors evaluate and provide feedback on employees' self-assessments regarding progress to aid with their development. Also, a system was introduced in 2020 to enable the integrated management of personal information in such areas as goals, evaluation, training, and the selection, promotion and nurturing of exceptional human resources. As of June 2022, more than 10,000 group employees have been entered into the system, helping to maximize human resource development and organizational strengths.

Basic Policy

At the Otsuka group, we know that the contributions of a diverse array of people is conducive to innovation and globalization, and to the development of innovative products. That is why we embrace and promote diversity. As a group of companies driven to innovate, we are committed to ensuring our workplaces are welcoming to all people.

Promotion System

Since 2008, the Diversity and Inclusion Promotion Team at each group company has led efforts for greater diversity and inclusion through individual company and coordinated group initiatives. These initiatives include planning group-wide systems, conducting seminars, and holding regular meetings to share each company's effective examples of diversity and inclusion.

Approach

Initiatives to Promote Diversity

Implement group-wide training and seminars on women's empowerment Ikuboss Corporate Alliance

We hold regular group-wide diversity seminars. A total of 2,770 people attended the seven seminars held from fiscal 2019 through fiscal 2021. We know that it is not enough for only employees to be aware of the issues—their bosses must broaden their awareness too. That is why we* established the Ikuboss (managers supportive of work-life balance) declaration

	Theme
2019	<ul style="list-style-type: none"> • Enhance performance and a sense of joy through Ikuboss system • Translate diverse human resources into a strength for the company
2020	<ul style="list-style-type: none"> • Consider new ways of working for the future • LGBT seminar
2021	<ul style="list-style-type: none"> • Unconscious bias • Learning from gold medal Olympic athletes about diversity (multiple viewpoints and flexible thinking) • Promoting active participation of diverse human resources

* Nine group companies: Otsuka Pharmaceutical, Otsuka Pharmaceutical Factory, Taiho Pharmaceutical, Otsuka Warehouse, Otsuka Chemical, Otsuka Foods, Otsuka Medical Devices, Otsuka Techno, and Otsuka Electronics

Promotion of Women’s Participation and Advancement in the Workplace

Women's Empowerment Principles signed (WEPs)

The Otsuka Group Global Code of Business Ethics states our commitment is to promoting diversity . Further, in 2017 the group became a signatory to the Women's Empowerment Principles (WEPs)¹, a set of corporate principles jointly developed by the United Nations Global Compact (UNGC) and UN Women² that offers guidance on how to empower women in the workplace.

1 Women's Empowerment Principles

2 United Nations Entity for Gender Equality and the Empowerment of Women



Development of Female Leaders and Managers

Taiho Pharmaceutical believes that having women in management roles leads to more diverse views being reflected in management decisions. For this reason, the company began new initiatives in 2020 for female managers. Based on the results of an independent assessment, women reexamine their skills, abilities, and personality traits to create their own career plans, and are linking those plans to professional development through their work. Also, based on the independent assessment results, the company began individual training for women in management who want to move up to top-level positions. In 2021, to strengthen the development of female managers, we started new initiatives that include management training, dialogue with management, and mentoring.

Increase in Motivation

To further empower female employees, Otsuka Pharmaceutical started the Otsuka Women's Workshop as a forum for women to share information about marriage and childcare, in this way contributing to continued career development following marriage, childbirth, and childcare. WING was established in 2009 as a voluntary study group that identifies issues and discusses solutions in teams, which are then proposed to the company for making improvements. Participants are recruited throughout Japan regardless of gender or position to take part in cross-organizational activities under the theme, "When we change, we change the company." In addition, Otsuka Pharmaceutical Factory has been providing training on career design since 2017 to foster individual growth and strengthen our organization. In 2021, we conducted training that provided opportunities for development through mutual understanding between managers and mid-career employees with a view to developing leaders who can take full advantage of diversity.



Otsuka America Pharmaceutical among Recipients of HBA's ACE Award*

Otsuka Pharmaceutical in the U.S. established Otsuka's Network of Otsuka Women (NOW) in 2019 to drive efforts toward diversity, equity, and inclusion as key parts of its our global business strategy. With a membership of more than 500 employees, NOW connects women with opportunities to consider how to succeed and grow in the workplace, and NOW members have had higher promotion rates. In recognition of this and other initiatives, Otsuka America Pharmaceutical received the 2021 Advancement. Commitment. Engagement. (ACE) award^{*} from the Healthcare Businesswomen's Association (HBA).



* This award honors companies committed to ensuring gender diversity and leadership opportunities for women as part of their organizational DNA.

➤ About the female manager ratio, please refer [Key Sustainability Data](#)

Support of Diverse Work Styles

Introduction of the Work Interval System and the Family Smile Support System

In Japan, we have introduced the Family Smile Support System^{*}, which encourages employees to work from home before/after parental leave, or when taking on childcare/child-rearing and nursing care obligations. This system has led to improvements in work efficiency, productivity, and work-life balance. We have also introduced the Work Interval System, which mandates minimum rest periods for shift workers.

* Revised telework system for increased flexibility

Opened daycare centers at our business premises

We have opened daycare centers at three of our business premises (in Tokushima, Osaka, and Tsukuba) to help employees balance childcare and work. Since its establishment in Tokushima in 2011, it is now one of the few large-scale nurseries in Japan in terms of on-site childcare facilities.




Creating a Workplace Where Employees Can Receive Treatment While Continuing to Work

As a company developing and supplying anticancer 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. Going further, in 2019 the company launched C-Guide Portal, a portal site about cancer for employees. The site provides information on systems and consultation desks that employees and their families can use if someone develops cancer or another disease, and highlights the importance of cancer prevention and screening. It also has a page where users share experiences. Here, employees share information about the reality of treatment, learned through family members' or their own experiences fighting cancer. This helps employees deepen their understanding of and recognize issues in cancer treatment. Meanwhile, it enhances their appreciation of the role they play as employees of Taiho Pharmaceutical, an anticancer drug manufacturer.

While lectures and briefings are provided to other companies, including those in other industries, lectures are held not only at the company but also throughout the Otsuka group to continue spreading awareness throughout society.

Won an Award of Excellence under the Tokyo Work Circle Project in 2016 (organized by the Tokyo Metropolitan Government), which recognizes companies as having outstanding initiatives that help cancer patients balance treatment and work.

Won a gold prize for three consecutive years (2019–2021) at the Cancer Ally Awards organized by Gan Ally Club, a private-sector project addressing the issue of cancer and employment

* For details, please refer to the following URL.
[Human Resources Support for Balancing Work and Medical Treatment \(Taiho Pharmaceutical WEB site, Japanese\)](#) 



➤ About the trends of the numbers of employees taking parental leave, please refer [Key Sustainability Data](#)

Promoting the Active Participation of the LGBTQ community, People with Disabilities, and Senior Citizens

Initiatives for the LGBTQ Community

LGBTQ-related training is provided throughout the group, including for human resource departments and other sections, in order to promote understanding. Also, from 2020, Taiho Pharmaceutical has conducted training for the human resources (HR) department, the management tier, as well as other divisions and departments to introduce basic understanding on this topic and to convey the current thinking in Japanese society, with examples of initiatives by other companies. The training also covers specific examples of what can be done today. Approximately 1,700 employees have taken the course to date. In 2021, 230 employees took part in an Otsuka Chemical webinar for all employees entitled "Companies and LGBTQ: Considering Diversity in the Workplace." Otsuka Pharmaceutical also conducts training for all personnel, while Otsuka Warehouse is striving to create a more comfortable work environment, for example by removing the terms male and female from work regulations.

Initiatives for the Employment of People with Disabilities

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

- About the ration of employees with disabilities Please refer [Key Sustainability Data](#)



Encouraging Active Roles for Senior Employees




At Otsuka Pharmaceutical Factory and Taiho Pharmaceutical, older employees who have been recently recruited are an important force for the company, and a system has been established to recognize those who have contributed to corporate earnings and the development of human resources.



Diversity & Inclusion-related Systems

Please refer to the website of each company.

External Recognition

	Content	Company
	<p>Nadeshiko Brand System for selecting companies that actively promote the employment and advancement of women. (Ministry of Economy, Trade and Industry; Tokyo Stock Exchange)</p>	<p>Selected in 2020: Otsuka Holdings* * Scope of survey: Otsuka Holdings and Otsuka Pharmaceutical</p>
	<p>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 higher-level initiatives. (Ministry of Health, Labour and Welfare)</p>	<ul style="list-style-type: none"> Platinum Kurumin: Otsuka Pharmaceutical Factory, Taiho Pharmaceutical, and Otsuka Chemical Kurumin: Otsuka Pharmaceutical, Otsuka Foods, and others
	<p>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. (Ministry of Health, Labour and Welfare)</p>	<p>Eruboshi (Level 3): Otsuka Chemical (from 2019)</p>
	<p>MONISU Certification Certification system recognizing small- and medium-sized enterprises that excel in their efforts to provide employment to people with disabilities. (Ministry of Health, Labour and Welfare)</p>	<p>2020 certification: Heartful Kawauchi</p>
	<p>Acquired Tomonin Mark Certifies companies that strive to create a work environment that allows employees to balance work and caregiving. (Ministry of Health, Labour and Welfare)</p>	<p>Acquired by Otsuka Pharmaceutical</p>



Certified as a Great Place to Work[®]
Certifies companies that create an outstanding employee experience according to Great Place to Work[®], a global leader in workplace culture and employee awareness surveys

Selected in 2021: Otsuka America Pharmaceutical, Inc. (OAPI) and Otsuka Pharmaceutical Development & Commercialization, Inc. (OPDC)

Second place among large pharmaceutical and biotech companies in the Best Workplaces for Millennials category

Third place among large pharmaceutical and biotech companies in the Best Workplaces in New York category

Seventh place among biotech companies in the Best Workplaces in Health Care and Biopharma category

Basic Policy

At the Otsuka group, we believe that maintaining workplaces that enable each employee to work in good health and spirits is vital for making our shared corporate philosophy a reality. This was also the thinking behind the declarations on health made by major Otsuka group companies.

Health and Productivity Management



Otsuka-people creating new products for better health worldwide

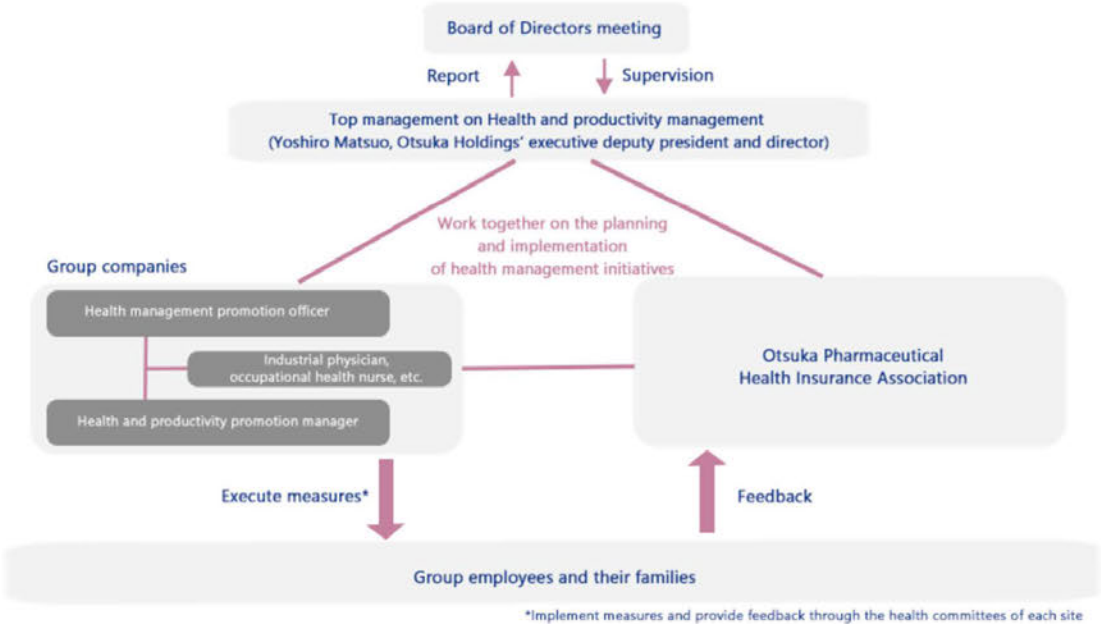
We believe that the physical and mental health of every employee is essential for us to live up to our corporate philosophy. We will strive for a working environment that supports employees in maintaining and improving their health, enabling them to play active roles while fully demonstrating their abilities and individuality.

Tatsuo Higuchi
President and Representative Director, CEO
Otsuka Holdings Co., Ltd
April 1, 2017

Promotion System for Health and Productivity Management

The mental and physical wellbeing of every employee is essential for the pursuit of the group's shared corporate philosophy. Therefore, Otsuka Holdings' executive deputy president and director is in charge of health and productivity management, and under his supervision the Otsuka Pharmaceutical health insurance association, each group company's health and productivity promotion manager, and specialist staff such as industrial physicians and nurses work collaboratively across the entire organization to help maintain and enhance the health of employees and their families. The Board of Directors also monitors issues related to maintaining and improving health as well as the goals and progress of health management initiatives.

Promotion System (Japan)



In addition, employees' health-related information is integrated into the health management system* so that medical staff, health officers, and supervisors at all business sites can share information that is required at any time. Based on this information, the health of each group company is analyzed so that group initiatives can be formulated.

* A system for managing health information from regular medical examinations and interviews with employees by industrial health staff, etc.

Health Management Action Plan Goals and Progress

Goals

Health checkup rate 90% (2023 target)

Implementation of specified healthcare guidance 55% (2023 target)

Progress

Health checkup rate 80.0% (2021)

Implementation of specified healthcare guidance 72.8% (2021)

* Insured persons and their dependents who are members of the Otsuka Pharmaceutical Health Insurance Association (for Otsuka group companies in Japan)

Health Promotion Activities

Health Seminars: Ensuring the Good Health of Employees and their Families

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 that started in 2015 is hosting 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. The seminars consist of information that draws on knowledge gained in the group's businesses, and encourage employees and their families to reexamine their ideas about health. In 2021, approximately 1,300 people participated in online seminars on women's health and cancer. In addition, in 2022 we started providing health consultations by a gynecologist under an initiative of the Otsuka Pharmaceutical Health Insurance Association with the aims of helping women live their lives the way they want and supporting the creation of a comfortable work environment. They are free to seek consultations on issues unique to women depending on their age and life stage, such as menstrual symptoms and diseases, PMS, and menopause.



Health Seminars

Group-wide Initiatives (Japan, 2021)

Otsuka Pharmaceutical Health Insurance Association conducts an annual health promotion program for all Group employees.

No	Initiatives	Objective/Outline	Number of times implemented / duration
1	Prevent of serious illness (letter recommending medical exam)	Prevent lifestyle-related diseases from becoming serious by recommending medical examinations when necessary for those who have not yet received treatment, providing effective treatments, and making improvements in their lifestyles.	Twice
2	Online health seminar	Intended to reduce presenteeism. Practice simple exercises or yoga at lunchtime, since many people suffer from stiff shoulders and back pain when working from home or at a desk.	Twice
3	KENPOWALK	Smartphone walk rally with pedometer app to develop healthy habits	Three-month period
4	30-day oral care challenge	Conduct jointly with Earth Corporation so that people can perform daily oral care correctly and effectively.	30-day period
5	Online stop-smoking clinic	Provide support for those who want to quit smoking.	December 2021 to March 2022

Other Group Company Initiatives

Initiatives to Promote Exercise, including POCARI/fresh [Otsuka Pharmaceutical, Taiho Pharmaceutical]



Otsuka Pharmaceutical conducts 8-minute “refresh calisthenics” (POCARI/fresh) once a week with different exercises each time at offices and factories under the supervision of an instructor. These exercises changed to online only in fiscal 2020 so that employees working remotely could also take part in POCARI/fresh. Taiho Pharmaceutical introduced an exercise app company-wide with the aim of providing the opportunity to exercise and improve communications related to exercises, in this way supporting good exercise habits for individual needs. This company also holds company-wide inhouse sports days using the same exercise app.

Zero Smoking Rate Initiatives (Taiho Pharmaceutical, Otsuka Foods)

As a health-related company that has made oncology a core business area, Taiho Pharmaceutical has set the goal of realizing a zero-employee smoking rate by 2023, and began, in 2020, new initiatives for reaching that goal. For example, we made systemic changes, such as subsidizing the cost of outpatient smoking cessation treatments and making nonsmoking a consideration when appointing people to management positions. In addition, we provide information, such as sharing tips on the company intranet from employees who successfully “kicked” the habit., Otsuka Foods also implements other initiatives, including a stop smoking support program (assistance with cost) and the removal of indoor and outdoor smoking areas.

Offering a Wellness Program for Employees (Pharmavite)

As a company that provides nutritional products, Pharmavite, a supplement company in the U.S., offers employees a wellness program called PharmaFit. Nutritionists visit the company to provide nutrition-related information and consultations, and the company provides incentives for employees to participate in exercise programs.

Boosting mental and physical health with a virtual run.

In conjunction with World Mental Health Day, the POCARI SWET RUN charity event took place between October 1 and November 14, 2021, in collaboration with Silver Ribbon-a mental health awareness NPO based in Singapore. The event is a virtual running race utilizing a smartphone app. Participants choose their distance and donate to the NPO based on how far they manage to run. Around 4,000 runners, including Otsuka group employees from Japan and Indonesia, laced up their running shoes and took part in the event.

Before the race, participants could join online seminars to hear psychiatrists and athletes talk about mental health, focusing on mental welling, exercise, and hydration. Events of this kind highlight how Otsuka can work closely with and support consumers' mental and physical health by utilizing the synergy of its two core businesses.



Mental Health Care Initiatives

We conduct stress tests once a year, as required by law. Also, Taiho Pharmaceutical's detailed initiatives include individual interviews and emails by nurses and public health officials to all employees who have posted away from their families or who are experiencing high stress based on their stress test results. Otsuka Pharmaceutical Factory established a new external consultation desk in 2020.

Infection Control and Prevention of Health Hazards

The Otsuka group has adopted new work practices to ensure that employees can work safely during the COVID-19 pandemic, including the introduction of a work-from-home system and the shift of documentation and approval processes to electronic formats.

Overtime Reduction Policy

The Otsuka group believes that reducing long work hours is critical to maintaining the physical and mental health of every employee. Guided by this policy, each operating company undertakes its own initiatives for shortened work hours following the laws and regulations of each country and region.



Initiatives to Reduce Overtime Hours

The Otsuka group is working to visualize overtime hours as part of the attendance system to reduce overtime hours. Initiatives designed to prevent long work hours include displaying on individual computer screens a warning regarding Article 36 of the Labor Standards Act and unregistered attendance. We have also introduced a system where personnel departments can check when individuals log on and off their computer to maintain the physical and mental wellbeing of employees. In order to reduce and shorten overtime, Otsuka Pharmaceutical requires employees to submit notifications before working overtime so that their supervisors can appropriately manage work hours. The company also mandates a minimum interval between shifts to foster an environment where employees can work in good health. Specifically, when an employee unavoidably works until late at night, a certain amount of rest time before the start of the next shift is guaranteed. In addition, at Otsuka Warehouse, the time that the last person leaves every head office department and branch office is posted on the intranet each day to make the work situation visible. The aim of this effort is to raise employees' awareness of productivity per hour. The company has also adopted a system to solve challenges in a company-wide effort rather than within each department alone.

In addition to the initiatives for its employees, Otsuka Warehouse have established a new truck reservation system to help solve the issues of long working hours for truck driver and the shortage of drivers and vehicles, which have become a challenge for the entire logistics industry. It is now possible to make online reservations for unloading times, in this way significantly reducing wait times for drivers and increasing the efficiency of transportation.

External Recognition

		
<p>Health & Productivity Management Outstanding Organization (White 500) (large enterprise category)</p>	<p>Health & Productivity Management Outstanding Organization (large enterprise category)</p>	<p>Health & Productivity Management Outstanding Organization (SME category)</p>
<p>Otsuka Holdings, Otsuka Pharmaceutical, Taiho Pharmaceutical</p>	<p>Otsuka Pharmaceutical Factory, Otsuka Foods, Otsuka Warehouse</p>	<p>Otsuka Medical Devices, Otsuka Pharmaceutical Health Insurance Association, Otsuka Wellness Vending, Otsuka Electronics, Otsuka Techno, JIMRO</p>

	Description	Company
 <p>SPORTS YELL COMPANY 2022</p>	<p>Sports Yell Company 2022 Program recognizing companies that actively support and promote measures to improve employees' health through sports. (Japan Sports Agency)</p>	<p>2022 selection: Otsuka Pharmaceutical (Bronze prize, selected for five consecutive years, since 2017), Taiho Pharmaceutical</p>
 <p>TOKYO 東京都スポーツ推進企業 2021 認定</p>	<p>Tokyo Metropolitan Government Sports Promotion Model Company The Tokyo Metropolitan Government Sports Promotion Company certification program recognizes companies that implement quality initiatives to encourage and support employee participation in sports.</p>	<p>2021 selection: Otsuka Pharmaceutical Note: Certified for seven consecutive years since 2015</p>

Basic Policy

The Otsuka group recognizes that ensuring safety and health across all of its business activities is an important element of the management. This recognition is based on our corporate philosophy of "Otsuka-people creating new products for better health worldwide." Accordingly, we strive to ensure all workplaces are safe and healthy, including by offering education and training for all concerned.

Otsuka Group Health and Safety Policy

1. Based on our recognition that ensuring safety and health is an important element of the management, we are committed to ensuring that each and every one of us proactively engages in safety and health activities, and we work together to create safe, healthy, and comfortable workplaces across the entire group.
2. We comply with the relevant laws and regulations of each country and region, as well as the voluntary management standards of each company and site.
3. We strive to prevent the expansion of damage and/or recurrence of accidents by practicing ongoing risk reduction activities such as forecasting, ascertaining, and periodically reviewing dangerous and hazardous factors, responding promptly and appropriately in the event of an emergency such as an industrial accident, and subsequently sharing lessons learned within the organization.
4. We request an understanding of our Policy and the promotion of health and safety awareness by all the business partners of the Otsuka group (including contractors, and suppliers, etc.)

Group-wide targets

■Goals of health and safety action plan

- Zero occupational accidents
- > Please refer to [Health and Productivity Management](#) for comprehensive goals regarding health management.

■Progress

- Rate of occupational accidents: 0.70 (2021 result)
- Severity of occupational accidents: 0.02 (2021 result)
- > Refer to [Key Sustainability Data](#) for details.

Promotion System for Health and Safety

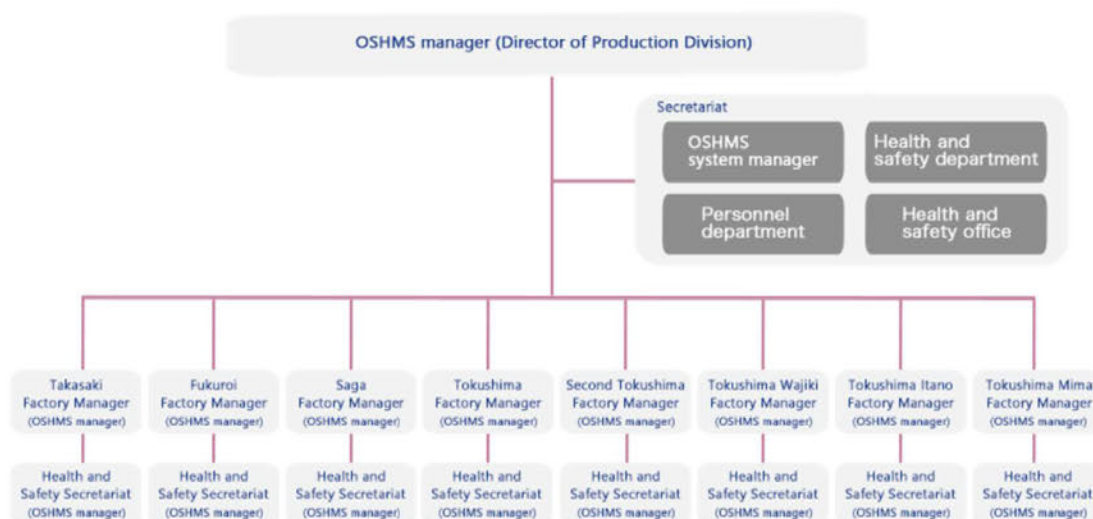
To help create safe, secure workplaces at factories and other business sites at every group company in Japan, we have established safety and health committees, as defined in the Industrial Safety and Health Act. We carry out workplace health and safety inspections, as well as other necessary activities to ensure effective management of health, operations, and the workplace environment, in addition to related education and training. These activities are reported at health and safety committee meetings and form the basis for improvements to the workplace environment.

Further, major group companies hold a joint group health and safety meeting every year to share reports on workplace accidents and recurrence prevention measures. Moreover, for over 30 years, the Global Production Meeting has been held with the aim of improving production technologies and sharing information group-wide. In fiscal 2021, this meeting was held online after a two-year absence due to the COVID-19 pandemic. The meeting had approximately 148 participants including management executives from 14 countries and regions for discussion on new models of production.

➤ Refer to [Production](#) for details of the Global Production Meeting.

Since each group company employs a different promotion system, the one for Otsuka Pharmaceutical is shown here.

Otsuka Pharmaceutical's Promotion System for Health and Safety (Production Division)



Otsuka Pharmaceutical has established an OSHMS* and will continue to improve the workplace environment based on company-wide policies.

* OSHMS (Occupational Safety and Health Management System) is a set of measures for safety and health management aimed at preventing occupational accidents, promoting the health of workers, creating a comfortable work environment and improving the safety and health standards of workplaces. These objectives are achieved by establishing a series of procedures and voluntarily conducting ongoing safety and health management based on a PDCA (plan-do-check-act) cycle implemented by a business with the cooperation of employees.

Evaluating and Addressing Risk

Safety and health committees have been established at locations where they are legally required. These committees meet regularly to discuss safety and health and how to maintain a safe work environment. In addition, information is shared on risk assessments at regular meetings to identify sources of risk.

For example, Otsuka Pharmaceutical conducts annual risk assessments to identify occupational health and safety issues at business sites. Risk assessments are used to find potential dangers or hazards in the workplace and to eliminate or reduce them. For each issue identified, we provide a written follow-up on the measures we implemented. We confirm that the risk has been mitigated in the risk assessment in the following fiscal year. In addition, we are working to reduce occupational health risks and improve the workplace environment by sharing information on social demands and onsite problem awareness, led by the person in charge of health and safety.

Status of Occupational Accidents

	2020		2021	
	Rate of occupational accidents	Severity of occupational accidents	Rate of occupational accidents	Severity of occupational accidents
Otsuka group	1.11	0.00	0.70	0.02
Industry-wide	1.95	0.09	2.09	0.09

The Otsuka group shares examples of occupational accidents that have occurred at group companies (production and research departments) through meetings held to exchange information on safety and health.

Communication Beyond the Company

Otsuka Pharmaceutical conducts a range of programs both inside and outside the Company to promote workplace health and safety. One example is an annual meeting to share workplace health and safety information with partner companies.

Occupational Health and Safety Information Exchange Meeting

*Not held in 2020 due to the COVID-19 pandemic.

	Topic
2019	15th "Safety and health activities in the first year of work style reform: Contributing to productivity improvement and health management"
2020	16th "Stress countermeasures amid new lifestyles: How to cope (Webinar)"

Supplier Occupational Safety and Health

The Otsuka group recognizes the importance of ensuring occupational safety and health at suppliers in the Otsuka Group Sustainable Procurement Guidelines. Specifically, we request that they respect human rights, ensure a safe, hygienic and comfortable work environment, and consider the health of employees. We hold briefings every year to help our suppliers understand the detailed content of the guidelines and have received written consent from all suppliers stating agreement with their objectives. The Otsuka group will continue to work together with suppliers to ensure occupational safety and health.

> Refer to [Procurement](#) for more details.

Company Involvement in Commitments to Labor Standard Initiatives or Frameworks

Example: Tokushima

- Tokushima Labor Standards Association (Otsuka Pharmaceutical, Taiho Pharmaceutical, Otsuka Warehouse, Otsuka Chemical, Otsuka Foods, etc.)

Regional association: [Tokushima Labor Standards Association Union Meeting](#) [↗](#)

- Naruto Labor Standards Association [Otsuka Pharmaceutical, Otsuka Pharmaceutical Factory, etc.]

- Anan Labor Standards Association [Otsuka Pharmaceutical, Otsuka Techno]

- Miyoshi Labor Standards Association [Otsuka Pharmaceutical]

Improvement Case Study

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.



Anzen Dojo, an experience-based safety training center

Basic Policy

At the Otsuka group, all activities relating to employment, such as recruiting, staffing allocations, performance evaluations, promotions, and transfers, are carried out under a fair employment policy based on the Otsuka Group Global Code of Business Ethics, and in accordance with laws and regulations related to human rights and labor. We do not evaluate employees unfairly based on race, skin color, nationality, heritage, gender, gender identity, religion, age, marital status, pregnancy, disability, or other attributes, but instead aim to empower every individual to realize their full potential by maintaining a fair, open, and equal workplace. We ensure that nobody is forced to work against their will by implementing self-assessments, interviews with employees, and an internal reporting system and also have committed to preventing child labor by confirming age during the hiring process. For compensation, we pay above the minimum wage prescribed by law in every country and region and set compensation at a fair level that references roles at the same level in each region. We promote equal pay for equal work. For example, in Japan, part-time workers are treated based on the Act on Improvement etc. of Employment Measures for Part-time and Fixed Term Workers to make sure there is no unreasonable disparity between full-time employees and regular as well as non-regular workers who work shorter hours when determining the nature of work and work reassignments.

Approach

Engagement with employees

Employee Representation System

The Otsuka group has introduced an employee representation system in where the opinions of employee representatives are sought when drafting and revising labor-management agreements and work regulations. At each workplace, employees either put their hand up as candidates or are recommended as representatives. These employee representatives are asked for their opinions on such matters as labor-management agreements and work regulations.

*Labor unions

Otsuka group employees in some regions are members of labor unions.

Employee Satisfaction Surveys

Otsuka group companies provide internal training on bullying and harassment for all employees, including managers. Further, Taiho Pharmaceutical conducts an annual survey on harassment for all employees and proactively work to prevent harassment through the creation of a system where harassment can be reported not only by someone experiencing harassment, but by anyone witnessing it. In addition, some group companies including Otsuka Pharmaceutical and Taiho Pharmaceutical conducts annual employee satisfaction surveys and share its results inside the company. Otsuka Pharmaceutical Factory holds interviews with employees as well as regular meetings of the Human Resources Department in order to raise engagement scores, and otherwise work to improve employee satisfaction.

Local Employment

As the Otsuka group expands business globally, we are promoting activities unique to Otsuka that respect local cultures and customs. For this reason, we believe it is important to strengthen local management, and our basic policy is to employ people from that country or region. In addition, we are committed to appointing people from the local area to important positions that drive the corporate management and business.

Basic Policy

The Otsuka group contributes to the health of people around the world by continuously creating new value, and recognizes that in order to continue sustainable growth, all business activities must be founded on respect for human rights. Based on this principle, we promote human rights initiatives across the group and work hard to consistently meet those responsibilities.

Approach

The Otsuka group joined the United Nations Global Compact (UNGC) in 2016, and the next year signed the Women's Empowerment Principles (WEPs), which were jointly formulated by the UNGC and UN Women as a set of principles based on which companies should voluntarily promote the active participation of women. In addition to declaring our support for these initiatives, we will pursue the fulfillment of our corporate philosophy with an awareness of how social responsibility, including consideration for society and the environment, is integral to our businesses. In 2020, we formulated the Otsuka Group Human Rights Policy in accordance with the United Nations Guiding Principles on Business and Human Rights. Based on this policy, we are promoting human rights initiatives across the Otsuka group.



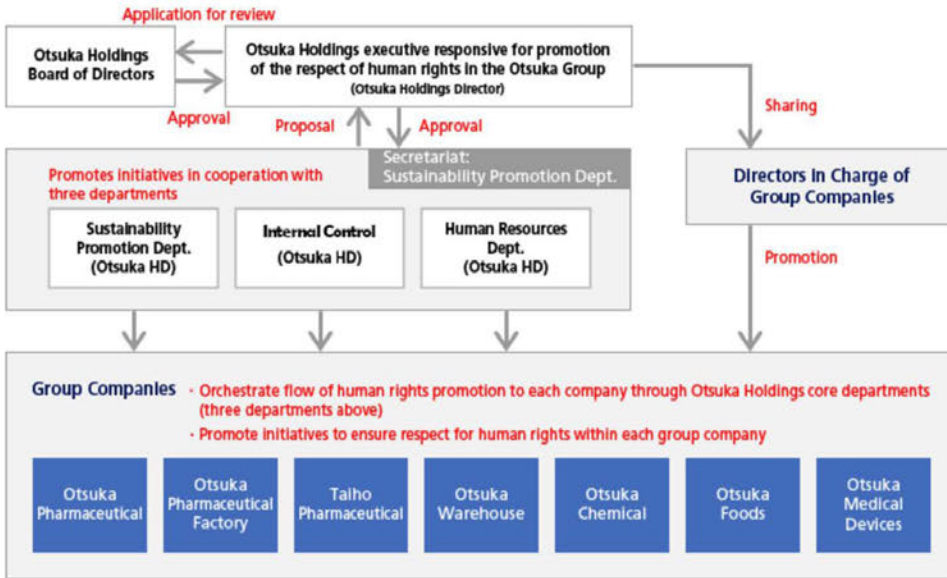
Formulation of Human Rights Policy

The Otsuka group of companies recognizes that respect for human rights in every aspect of our business activities must be the premise upon which we build to meet the expectations of our stakeholders, create new value, and contribute to the health and wellbeing of people all over the world as we continue to grow sustainably. The Otsuka group supports and respects international covenants governing human rights as set forth by the United Nations International Bill of Human Rights (the Universal Declaration of Human Rights; the International Covenant on Civil and Political Rights; the International Covenant of Economic, Social, and Cultural Rights) and the standards established by the International Labor Organization (ILO) in the Declaration on Fundamental Principles and Rights at Work. We also support and respect the United Nations Guiding Principles on Business and Human Rights. As a signatory of the United Nations Global Compact, we support and respect the Ten Principles. Considering the content of these principles, we formulated the Otsuka Group Human Rights Policy in December 2020, and enacted it in March 2021. In formulating the policy, we conducted a human rights risk assessment* of Otsuka Holdings and the seven main operating companies. In the assessment, we organized, analyzed and identified the human rights risks that we should address throughout the value chain, taking into consideration the human rights issues specific to the Otsuka group, including those in the pharmaceutical and food industries, cases of risks that materialized in regions globally, and the group's business characteristics. Based on that assessment, we identified the salient human rights issues in the Otsuka group. We plan to continuously disclose our concrete initiatives for these issues on the Otsuka Holdings website.

* Risk assessment: Identification and assessment of adverse impacts (i.e., risks); the first step in due diligence.

Promotion Framework

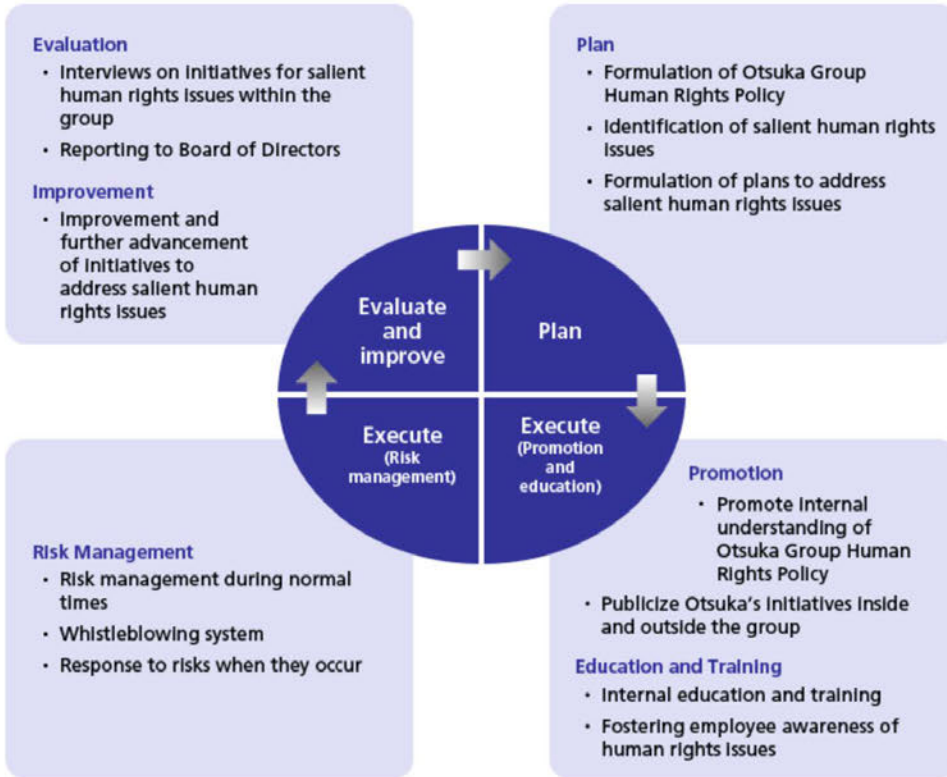
Human rights initiatives are necessary in various areas. In the Otsuka group, three departments—the Internal Control, Human Resources and Sustainability Promotion departments—cooperate to promote initiatives for respecting human rights, under the Otsuka Group Human Rights Promotion Leader (an Otsuka Holdings director).



The Otsuka group also regularly conducts interviews at group companies on human rights risks, and has a system to continuously monitor and address human rights risks group-wide. By practicing the PDCA cycle outlined below, we make ongoing efforts to resolve the Otsuka group's salient human rights issues.

Human Rights Due Diligence

To fulfill our responsibility regarding respect for human rights, the Otsuka group identifies human rights issues related to our business operations, and we continually perform due diligence to prevent and mitigate any impact, as outlined in the United Nations Guiding Principles on Business and Human Rights. Human rights due diligence in the Otsuka group refers to the entire process of the PDCA (plan-check-do-act) cycle outlined below, which is repeated as part of this ongoing process to resolve salient human rights issues for the Otsuka group. The PDCA (plan-check-do-act) cycle outlined below is repeated as part of this ongoing process to resolve key human rights issues for the Otsuka group. Moreover, we hold regular internal interviews to determine risks to human rights and have established a framework enabling a continuing response to these risks throughout the group.



Salient Human Rights Issues in the Otsuka Group

As part of our human rights due diligence in the Otsuka group, human rights assessments of Otsuka Holdings and the seven main operating companies* were conducted from 2019 through 2020. Based on the results, we identified the Otsuka group's salient human rights issues described below, which express our commitment to stakeholders.

* Otsuka Pharmaceutical, Otsuka Pharmaceutical Factory, Taiho Pharmaceutical, Otsuka Warehouse, Otsuka Chemical, Otsuka Foods, and Otsuka Medical Devices

1) Related to Our Patients and Consumers

Otsuka Group contributes to the health and wellbeing of people throughout the world, through the creation of innovative products and services. As a total healthcare company seeking solutions for health-related issues, we recognize our responsibility to patients and consumers, always prioritizing the quality and safety of our products, and reinforcing our supply chain. When issues regarding our products or services become apparent, we will collaborate with relevant departments to collect and analyze information and develop appropriate responses, enabling us to continue to provide our valued customers with better products and services.

2) Related to Management and Employees

As a signatory of the United Nations Global Compact, we are committed to the elimination of forced labor and the abolition of child labor, as we aim to create comfortable work environments in which human rights are fully respected. To maintain fair and open workplaces, we strictly prohibit discrimination and harassment. As a total healthcare company, we strive to provide workplace environments in keeping with the principles of health and productivity management, in which management and employees are encouraged to take the initiative in developing and maintaining their own health.

3) Related to Our Business Collaborators

In keeping with the principles of the United Nations Global Compact, we share our concerns for human rights, labor, environment and anti-corruption with our business collaborators and engage in ongoing dialogue and consultation to ensure respect for human rights across our entire supply chain.

4) Related to Society

We believe that efforts to reduce environmental issues are closely related to the issues surrounding human rights, and we will proactively and continuously engage in initiatives that benefit local communities and general society.

5) Related to Our Stakeholders

To fulfill our responsibility to respect human rights, we recognize the importance of ongoing dialogue and will proactively seek opportunities to engage with diverse stakeholders. We are also working to establish contacts and grievance mechanisms to address any human rights issues that may come to light.

Initiatives Regarding Respect of Human Rights

The Otsuka group implements an array of initiatives to ensure that employees and other stakeholders have respect for human rights.

Education and Awareness-Raising for Management and Employees

We are working to raise awareness of human rights among management and employees through a variety of initiatives.

- Provide annual education for all employees of group subsidiaries based on the Otsuka Group Code of Business Ethics.
- Provide annual education for all employees of group subsidiaries guided by the Otsuka Group Human Rights Policy.
- Conduct internal training on bullying and harassment (including how to respond when there has been a report of harassment) for management and employees at each group company.
- Conduct training that incorporates units on human rights as part of personnel training.
- Raise awareness within the group using in-house newsletters and other educational materials.
- Create training materials on human rights issues in promotional materials and advertising expressions to be checked by an organization that reviews these items, and distribute them as needed.
- Every year Taiho Pharmaceutical conducts a survey on harassment for all employees.
Create a system allowing employees to report harassment not only when it affects them personally but also when they see it in the workplace.

Initiatives related to Human Rights Risks—Supply Chain Transparency

We recognize that supply chain transparency is a particularly high-priority risk as a manufacturer whose operations extend from research and development to production and marketing. Therefore, we share with our business partners our consideration for human rights, labor, the environment and anticorruption measures, as we strengthen our sustainable procurement to further promote respect for human rights.

- Revised Otsuka Group Procurement Policy in 2020
- Established Otsuka Group Sustainable Procurement Guidelines in 2020
- As of 2021, 126 suppliers have been briefed on sustainable procurement practices. People attending these briefings learn about the Otsuka Group Procurement Policy and the Otsuka Group Sustainable Procurement Guidelines and our expectations for compliance. These events are also opportunities to stay up to date on human rights and environmental issues and to hear about the group's initiatives.
- As of 2021, 136 companies, including some overseas, have been provided with common SAQs (self-assessment questionnaires) published by Global Compact Network Japan. We have been conducting a survey of our suppliers since 2020 that combines the human rights SAQs and environmental SAQs that we created independently based on the Otsuka group's business activities. In 2021, we also conducted interviews with suppliers based on the results of all SAQs.

Whistleblowing

Whistleblowing

Internal Whistleblowing System

The Otsuka group has established internal whistleblowing systems at each group company to ensure that any illegal acts, including bribery, as well as violations of policies, laws and regulations, can be quickly uncovered and corrected. Rules for accepting reports extend beyond fulltime employees to include contract, dispatched, and parttime employees. In addition to the internal reporting systems, we have established a reporting system at the offices of an attorney and other external locations that can be accessed safely and anonymously and so that whistleblowers do not need to fear reprisals. Information about whistleblowers and their reports is strictly managed, and to prevent any repercussions, information is only shared with those who must know in order to conduct investigations and take correction action. Information on the operation the internal reporting systems at group companies is regularly reported at meetings of the Board of Directors of Otsuka Holdings.

Formulation of Otsuka Group Global Speak-Up Policy

The Otsuka group has established the Otsuka Group Global Speak-Up Policy with the aim of clarifying the basic principles of the internal reporting system and enhancing its effectiveness so that employees can speak up when they become aware of fraud, inappropriate behavior, or any action that goes against the group's values, policies, or processes, or any other suspect behavior.

Basic Principles

- Employees have the right and obligation to report in good faith
- Information will be strictly handled
- Anonymous reports will be accepted
- Reprisals against anyone making a report are strictly prohibited
- Investigations, corrective action, and preventive measures will always be carried out for a reported violation

External Inquiries and External Whistleblowing Hotline

Otsuka Holdings and major group companies have established a whistleblowing hotline that accepts inquiries and opinions from external stakeholders and general customers. Further, certain channels of the hotline also accept anonymous consulting and reports.

Dialog and Collaboration

External Collaboration



The Otsuka group, as a signatory company of the UN Global Compact, is part of the Human Rights Due Diligence Working Group¹, Human Rights Education Working Group², Supply Chain Working Group, and WEPs Working Group³ of Global Compact Network Japan (GCNJ), and together with other participating companies and organizations, obtains knowledge that can be used in the Otsuka group's initiatives.

1. Participating companies engage in activities and share information useful in their own concrete initiatives, using as reference the seven WEPs principles, which contribute to enhancing the international competitiveness of GCNJ signatory companies and improving gender equality in Japanese society.
2. Deepening the understanding of human rights education and creating educational tools that can be used internally by all employees through teaching basic knowledge of the United Nations Guiding Principles on Business and Human Rights, lectures by experts, case studies from other companies, and interaction between participants.
3. Promotes the efforts of each company through lectures by experts, progress assessments of company initiatives, workshops, group work and other activities to learn together about human rights due diligence initiatives based on the United Nations Guiding Principles on Business and Human Rights.

Commitment to Children's Rights

The Otsuka group does more than work to eliminate child labor in Japan and overseas by also respecting children's right to live, be protected, grow, and participate in society. The healthy upbringing of children as the leaders of the next generation is exactly what we have included in our corporate philosophy and business since our earliest days. We are making every effort to support the human rights of children in our business activities and social contribution activities.

Examples of Business Activities/Social Contribution Activities

- [OTSUKA Health Comic Library \(Otsuka Holdings\)](#)
- [Visiting lectures to teach the information related to health to children and students in an easy-to-understand way \(Otsuka Pharmaceutical\)](#) 
- [Initiatives for sports instructors \(Otsuka Pharmaceutical\)](#) 
- [Dietary education from the Deliciously Illustrated SketchCook education app \(Otsuka Pharmaceutical\)](#)
- [Teaching materials "Learning the SDGs through Plant-Based Foods" supporting the learning of elementary school students on the SDGs \(Otsuka Foods\)](#)







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Quality in All We Do

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To help build a sustainable society, the Otsuka group, guided by an enduring philosophy of “Customers First” and “Quality First,” pursues quality at all stages of the value chain, and promotes initiatives taking into account the environment, society and human rights.

Fields		Field-Specific <i>Quality in All We Do</i> Challenges
	Research and Development	<p>Ethical Considerations in Accordance with Laws and Guidelines We comply with all relevant laws and guidelines while striving to uphold bioethics and scientifically valid methodologies from the viewpoints of preservation of the environment and safety management.</p>
	Procurement	<p>Sustainable Procurement in Cooperation with Suppliers We share the Otsuka Group Procurement Policy and Otsuka Group Sustainable Procurement Guidelines with suppliers. We carry out robust due diligence when selecting new suppliers, and work with suppliers to promote sustainable procurement with regard to legal compliance, consideration for the environment, human rights, and other issues.</p>
	Production, Quality Control and Patient/ Customer Safety	<p>Group-wide Teamwork to Ensure Stable Supply of High-Quality Products We comply with relevant laws and regulations, administrative instructions, and industrial standards, and have also been working to obtain international certification for quality and food safety management standards. In addition, we observe the laws and regulations of each country in which we do business and, based on GxP,* perform quality control, quality assurance and utilize our global safety surveillance system to implement post-marketing safety measures, including the collection and monitoring of safety information concerning adverse events.</p> <p>* GxP (Good x Practice): A general term for "Good Practice" standards (ministerial ordinances, regulations, and guidelines) established by governments and other public institutions for ensuring safety and reliability</p>
	Logistics	<p>Building a Logistics Foundation with the Ultimate Mission of Ensuring Supply Stability We rigorously control and maintain product quality throughout pharmaceutical, food product, and beverage distribution. Furthermore, we have incorporated transportation into our business continuity planning, including registration of vehicles for authorized access to restricted areas in an emergency.</p>
	Sales and Marketing	<p>Appropriate Promotion and Enhanced Information Access We have established a Code of Practice that builds on the International Federation of Pharmaceutical Manufacturers & Associations' Code of Practice and the Japan Pharmaceutical Manufacturers Association's Promotion Code for Prescription Drugs. In addition to complying with that code, Otsuka group companies also observe industry rules such as the "Guidelines for Provision of Sales information on Prescription Drugs" and conduct sales and marketing activities responsibly and with a high level of ethics. We have also established an expert panel, comprising members drawn from multiple departments, to perform reviews of marketing plans and sales promotion materials.</p>
	Customer Service	<p>Sincere Response to Inquiries and Reflection in Company Activities We have established dedicated customer contact points (staffed by specially trained personnel) that field inquiries and are tailored to the characteristics of particular drugs, quasi-drugs, food products, and other respective products. Opinions and suggestions regarding products and services are proactively shared within the group for the purpose of product development and improvement.</p>



Ethical Considerations in Accordance with Laws and Guidelines

Basic Policy

The Otsuka group's multifaceted research and development—intended to discover highly innovative drugs for unmet medical needs—is guided by our corporate philosophy: “Otsuka-people creating new products for better health worldwide.” We also follow high ethical standards, including those covering bioethics.

Promotion System

The Otsuka group has established a promotion system for basic research and clinical trials based on compliance with all laws as well as a high level of ethics. For example, Otsuka Pharmaceutical has committees for research ethics, animal experimentation, genetic modification safety and biosafety under the guidance of the executive director in charge of research. The goal of our committees is to ensure the suitability of our research. We also held discussions on clinical trials from safety, medical and scientific perspectives under the executive director in charge of development to ensure that appropriate clinical trials are conducted.

Compliance in Basic Research

Research Involving Animals

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, and adopts experimental methodologies that respect animal life and are appropriate from the perspective of animal welfare. 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 replacement of animal use, Reduction/minimization in the number of animals used, and Refinement/minimization of animal suffering. Based on these principles, we conduct researcher education and internal inspections and evaluations of the implementation of experiments involving animals.

Research Involving Human-Derived Specimens

When conducting research using information or specimens collected from the human body, such as tissues or blood, the Otsuka group complies with all laws, ordinances, and guidelines and conducts scientifically and medically appropriate research that upholds ethical considerations. In addition, we establish committees that include outside members to ensure the appropriateness and credibility of research. The committees do so by examining research plans, the significance and goals of research, personal information management systems, research progress status, and research outcomes from the standpoints of ethical and scientific validity and of protection of personal information.

Research on Pathogenic Microorganisms (Pathogens)

In using pathogenic microorganisms (pathogens) or research samples that may contain these pathogens, the Otsuka group complies with all relevant laws and ordinances, including the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (the "Infectious Diseases Control Act"). We have also established internal regulations regarding the safe management (handling and storage) of such pathogens and for environmental security, and work to prevent experiment-related accidents through employee education.

Research on Genetically Modified Organisms

In experiments involving genetically modified organisms, we comply with all laws and regulations, including the Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (the "Cartagena Act"). We also have an internal review committee and to prevent environmental damage from the spread or leak of genetically modified organisms.

[Compliance in R&D by Otsuka Group Companies]

➤ [Otsuka Pharmaceutical \(Japanese\)](#) 

➤ [Otsuka Pharmaceutical Factory \(Japanese\)](#) 

➤ [Taiho Pharmaceutical \(Japanese\)](#) 

Ethics in Clinical trials

When developing pharmaceuticals, we confirm the safety and effectiveness of candidate compounds by conducting clinical trials with the cooperation of healthy individuals and patients. To protect the human rights, safety, and welfare of clinical subjects, discussions are held within the Otsuka group on safety, as well as the medical/scientific aspects of clinical research. For multinational as well as domestic clinical trials, we conduct reviews from the ethical and scientific standpoints in addition to ensuring their compliance with ethical principles and standards, including ICH-GCP and JGCP (Good Clinical Practice), an international standard for clinical trials of pharmaceutical products. When conducting clinical trials, we follow internal regulations, standardized procedures, and so on. As well, free and informed consent must be obtained in writing from each person cooperating on the clinical trial. We handle personal information in the course of conducting clinical trials following our Basic Rules for the Protection of Personal Information and other related rules.

[Compliance in R&D by Otsuka Group Companies]

> [Otsuka Pharmaceutical \(Japanese\)](#) 

> [Otsuka Pharmaceutical Factory \(Japanese\)](#) 

> [Taiho Pharmaceutical \(Japanese\)](#) 

[Click here](#) for details on post-sales safety measures

Management of Public Research Funds

The Otsuka group has formulated rules for management and control of public research funds and for prevention of research misconduct, based on the Guidelines for Managing and Auditing Public Research Funds at Research Institutions and the Guidelines for Responding to Misconduct in Research established by the Ministry of Education, Culture, Sports, Science and Technology, the Ministry of Health, Labour and Welfare, and the Ministry of Economy, Trade and Industry.

[Management of Public Research Funds at Group Companies]

> [Otsuka Pharmaceutical \(Japanese\)](#) 

> [Otsuka Pharmaceutical Factory \(Japanese\)](#) 

> [Taiho Pharmaceutical \(Japanese\)](#) 



Sustainable Procurement in Cooperation with Suppliers

Basic Policy

The Otsuka group is a signatory to the 2016 United Nations Global Compact (UNGC), and considers the compact's positions on human rights, labor, the environment, and anti-corruption to be universal values. Our procurement is guided by the Otsuka Group Procurement Policy, which sets out the direction for consistently upholding the UNGC's values, maintaining sustainable procurement practices in accordance with our corporate philosophy, "Otsuka-people creating new products for better health worldwide," and improving corporate value while making a contribution to society.

To promote sustainable procurement, we established the Otsuka Group Procurement Policy across the Group and the Otsuka Group Sustainable Procurement Guidelines in September 2020, which we expect our suppliers to follow. These guidelines are formed from six items: Quality, Safety, and Stable Supply; Human Rights and Labor Standards; Environment; Anti-Corruption; Intellectual Property and Information Security; Business and Development Proposals; throughout the supply chain involved in procurement.

Otsuka Group Procurement Policy

The Otsuka group of companies, in accordance with our corporate vision, "Otsuka-people creating new products for better health worldwide", and international norms, conducts procurement activities in a responsible way. Otsuka delivers innovative, safe, secure, and high-quality products in order to contribute to the construction and maintenance of a sustainable society, as well as to the health of people around the world.

1. Relationships with suppliers

As a collaborator with many suppliers, the Otsuka group aims to build good relationships for mutual sustainable development through shared understanding, based on a fair exchange of appropriate information and opinions.

2. Supplier selection

The Otsuka group selects suppliers in a fair, and transparent manner based on comprehensive assessments of supplier quality, costs, quantity, delivery terms, compliance with laws and regulations, promotion of environment preservation, etc..

3. Responsibilities toward society

For the realization of sustainable society, the Otsuka group strives to maintain procurement activities that reflect consideration for human rights, labor, the environment, and non-tolerance of corruption.

4. Compliance

The Otsuka group of companies observes all applicable laws and rules, and all Otsuka employees and supplier employees must act at all times with the highest level of ethics, consistent with social norms.

Otsuka Holdings Co., Ltd.
September, 2020

➤ [Otsuka Group Sustainable Procurement Guidelines \(for suppliers\)](#)  97KB

Promotion System

The Otsuka Sustainable Procurement Task Force, which is supervised by Otsuka Holdings' directors and comprises Otsuka Holdings and eight group companies,* was formed in 2020. The task force meets once every two months to share sustainable procurement issues views on challenges, exchange information, and engaged in various initiatives to promote sustainable procurement internally and externally.

* Otsuka Pharmaceutical, Otsuka Pharmaceutical Factory, Taiho Pharmaceutical, Otsuka Chemical, Otsuka Foods, Otsuka Packaging Industries, Otsuka Techno, and EN Otsuka Pharmaceutical.

Embedding Sustainable Procurement through Training

We provide sustainable procurement-related training that takes into consideration human rights, the environment, and other issues, in order to further embed the Otsuka Group Procurement Policy and Otsuka Group Sustainable Procurement Guidelines throughout the group. Moreover, specific task forces work to improve the skills of procurement staff, providing them with opportunities to learn about sustainable procurement issues and other topics.

Implementation of Briefings on Sustainable Procurement Practices

We hold briefings for suppliers on sustainable procurement practices. Attendees learn about the Otsuka Group Procurement Policy and the Otsuka Group Sustainable Procurement Guidelines, and our expectations regarding compliance. These events are also opportunities for all parties to stay up-to-date on human rights and environmental issues and hear about examples of the group's initiatives in action. Suppliers that agree to uphold our policies sign a pledge affirming their intention to cooperate in achieving sustainable procurement as business partners.



Implementation of Self-Assessment Questionnaire (SAQ) on Sustainable Procurement

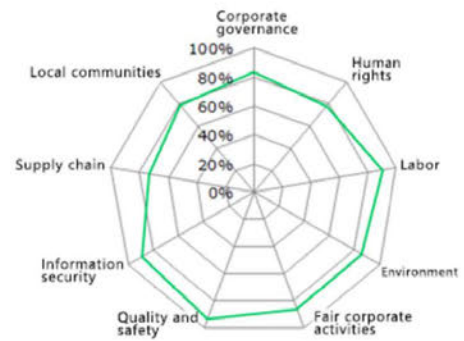
Suppliers that sign the pledge conduct a self-assessment, which consists of the common SAQ published by Global Compact Network Japan, and the Human Rights SAQ and Environmental SAQ that we have developed taking into account characteristics of the Otsuka group business activities. Based on the results, we then conduct interviews with suppliers. Seven companies were interviewed in fiscal 2021, with the interviews conducted remotely as a pandemic measure. The sharing of examples of sustainable procurement practices are opportunities to learn from successful case studies, and cooperating to address specific concerns ensures that we and our suppliers can make tangible progress toward sustainable procurement.



Sustainable Procurement Survey Results (2021)

SAQ Scoring Category	No. of Companies	Feedback and Actions for Improvement
Level A (70% or above)	43	<ul style="list-style-type: none"> Documented feedback on the chart of responding companies versus the average of companies that implemented the program. Conduct interviews as necessary
Level B (40 to 69%)	13	<ul style="list-style-type: none"> Documented feedback on the chart of responding companies versus the average of companies that implemented the program. Conduct interviews as necessary
Level C (39% or below)	1	<ul style="list-style-type: none"> Documented feedback on the chart of responding companies versus the average of companies that implemented the program. Conduct visits or interviews
Total responses (FY2021)		57

Average Score of 136 Companies



Environment Self-Assessment (Environment SAQ) Implementation Status

The Otsuka group administers the Otsuka Group Environment Self-Assessment Questionnaire (SAQ) in conjunction with the common Global Compact Network Japan SAQ based on a recognition of the importance of building better communication with suppliers and other business partners and working together to reduce environmental burden throughout the supply chain. We are increasing opportunities for dialog with suppliers and striving to further improve our efforts to resolve issues caused by climate change.

Human Rights Self-Assessment (Human Rights SAQ) Implementation Status

We formulated the Otsuka Group Human Rights Policy in 2021, and based on a human rights risk assessment conducted at Otsuka Holdings and the seven main operating companies, we identified the prominent human rights issues in the Otsuka group and created the Otsuka Group Human Rights Self-Assessment Questionnaire (SAQ). We asked the same companies that filled out the Global Compact Network Japan SAQ to cooperate with our SAQ to identify, mitigate, and prevent adverse effects on human rights by reviewing the results and specifying risks.



Naoyuki Miyashita

Section Leader, Purchasing
Department

Otsuka Pharmaceutical Co., Ltd.

Activities of the Otsuka Group Sustainable Procurement Task Force

The Otsuka Group Sustainable Procurement Task Force devises ways to effectively communicate with suppliers through discussions with members. In addition to briefings and SAQs, direct communication through interviews allows us to gain a deeper understanding of the approach of and issues facing each supplier, providing us with the opportunity to learn best practices. We are making steady progress in addressing supply chain issues and will continue promoting sustainable procurement throughout the Otsuka group.

Establishment of the Group Meeting on Sustainable Procurement

Group meetings on sustainable procurement were launched in 2022 under top management for sustainable procurement at Otsuka Holdings aimed at promoting activities as well as stable procurement, related to the four areas defined by the United Nations Global Compact: human rights, labor, the environment, and anticorruption.



Group meeting on sustainable procurement:
Attendees include directors, executive officers and staff members from Otsuka Holdings, Otsuka Pharmaceutical, Otsuka Pharmaceutical Factory, Taiho Pharmaceutical, Otsuka Chemical, and Otsuka Foods who are in charge of purchasing, sustainability promotion, and IT.

Robust Global Network for Stable Supply of Prescription Drugs

Otsuka Pharmaceutical established the Global Supply Chain Committee (GSCC) in 2017 to make decisions on important production and supply-related issues for anticancer drugs, orphan drugs, tuberculosis drugs and others to ensure a stable supply of pharmaceuticals in the global market. Otsuka Pharmaceutical and our overseas subsidiaries are cooperating to strengthen the supply chain. This includes the addition of manufacturing bases in 2022 to bolster the supply chain in the global market for core products.

Joint Business Partner Audits 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 that include an auditor skills training program.



Yasumasa Omote
Director, Quality Assurance
Department, Headquarters for
Product Safety and Product
Assurance
Otsuka Pharmaceutical Co., Ltd.

Joint Business Partner Audits

Through joint efforts by the Otsuka group's pharmaceutical-related companies, we standardized business partner audits and improved the skills of our auditors. This helps us respond to misconduct in the area of quality, which leads to more trusting relationships with raw material suppliers.



Group-wide Cooperation to Ensure Stable Supply of High-Quality Products

Basic Policy

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

Promotion System

At the Otsuka group, we aim to maintain a stable supply of high-quality products. To that end, our production departments practice stringent production management that facilitates the tracing of products throughout the entire supply chain, from the procurement of raw materials through production and distribution to sale.

To share information, hold discussions, and implement technical improvements groupwide, managers and staff from Otsuka group factories around the world come together for the Global Production Meeting, which has been held for over 30 years. This meeting leads to new activities that leverage the strengths of the Otsuka group in conducting broad-ranging business activities, including promoting information exchanges among companies.

For day-to-day production, we know the importance of reflecting on and learning from past performance, and for that reason we have held "Manufacturing Errors" Workshops twice a year since 2017. These meetings bring together representatives of group company production departments from Japan and around the world, and are an ideal opportunity to share and learn from case studies on manufacturing errors from each company.



Global Production Meeting



Ryo Harima
Vice President
Deputy General Manager,
Production Headquarters,
Otsuka Pharmaceutical Co., Ltd.

Over 30 Years of Technical Exchange at the Global Production Meeting

The Global Production Meeting returned in fiscal 2021 after a gap of two years due to the COVID-19 pandemic. The 2021 meeting was held online under the theme “New Forms of Production,” and 148 employees and executives from 14 countries/regions participated. Case studies were presented, including reports on remote support for the launch of a new overseas plant and the use of an analysis system for big data used in production. The participants exchanged views, and joined the ceremony for the 2021 Production Awards, which recognize outstanding production achievements.

Education system

At the Otsuka group, production departments formulate an annual education plan for each production site, provide training on health and safety and good manufacturing practices, as well as regular training on business continuity planning (BCP) and compliance.

Employee proposals for improvement

Every company in the Otsuka group works hard to make unique proposals for improvement. As an example, for 40 years Otsuka Pharmaceutical Factory has invited employees to submit proposals related to creativity, with the most useful proposals being adopted and implemented. This system leads to company improvements and raises employees' awareness of creativity. The event continues to spark interest even today. This fiscal year, three employees received the Award for Creativity* for 2022 given by the Minister of Education, Culture, Sports, Science and Technology (MEXT).



Kazuma Miyamoto
PG Department, Naruto Factory,
Manufacturing Division
Otsuka Pharmaceutical Factory



Junya Masamori
MP-V Department, Matsushige Factory,
Manufacturing Division
Otsuka Pharmaceutical Factory



Shuto Sekimukai
Engineering Department, Kushiro
Factory, Manufacturing Division
Otsuka Pharmaceutical Factory

* This award from MEXT recognizes the achievement of remarkable results in R&D as well as promoting the understanding of science and technology. The Award for Creativity is given to those who have contributed to technology improvements with outstanding creativity in their field. Employees at Otsuka Pharmaceutical Factory have received these awards for 13 consecutive years.

Also, this year marked the tenth anniversary of Otsuka Chemical's Kaizen Activities, in which employees submit proposals for improvements with the goal of creating a pleasant work environment through safety and security. The company was also awarded the 7th Tokushima Prefecture Science and Technology Award in the creativity category for significant cost reductions by proposing and implementing business improvements. Examples of improvements are given awards and this information is shared online.



Yasufumi Takebayashi
Tokushima Factory, Production HQ
Otsuka Chemical Co., Ltd.

Quality Control and Patient/Customer Safety

HOME > Sustainability > Society > Quality in All We Do > Quality Control and Patient/Customer Safety



Group-wide Cooperation to Ensure Stable Supply of High-Quality Products

Basic Policy

At the Otsuka group, we believe that providing a stable supply of high-quality products is part of our contribution to a sustainable society. Accordingly, we make the most effective use of the characteristics of our businesses, which include pharmaceuticals, foods, chemical products, and cosmetics, in the quest for a level of quality that justifies customers' faith in us. To that end, we believe it is vital to pursue talent development across departmental borders, to maintain a reliable quality assurance system spanning all relevant companies (which also has the advantage of enabling us to stay up to date with changes in the operating environment), to minimize quality risks, and to undertake dynamic initiatives that contribute to supply chain stability.

An Enduring Philosophy of “Customers First” and “Quality First”



Quality is vital in a factory and so is packaging. We have to manufacture and market, putting ourselves in the consumer's position.

Otsuka's founder, Busaburo Otsuka, is still referred to with fondness by employees as “Oyaji-san” (an informal term of address often used to mean “old man” or “father”). In 1946, when the Company began the manufacture and sale of injection drugs, Busaburo wrote the above guiding principles to clarify what his employees should do to ensure proper manufacturing, transportation, and sales. Today still, these principles are on display at the Company's manufacturing sites and other facilities, conveying our philosophy of “Customers First” and “Quality First.”

All employees of the Otsuka group will remain true to this philosophy, and now as in the past, our responsibility as a health-related company will always be to think of customers and quality first.

The Otsuka group's systems for production, quality, and safety management follow all laws and regulations, administrative instructions, and industry standards (including those prescribed by the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices and the Food Sanitation Act). Furthermore, we aim not only to obtain appropriate standards certification (ISO 9001 for quality, ISO 22000, and FSSC 22000 for food safety), but also to foster a "quality culture" that goes beyond the minimum obligations required by law. In order to ensure the stable supply of safe and secure products to patients and customers, we have formulated quality policies for each group company, and under the leadership of top management, we are continually working to enhance the quality of our products and services.

Promotion System for Pharmaceutical Business

The Otsuka group aims to both improve and maintain product quality guided by international standards in response to requirements in laws and regulations as well as look to improve the functionality of products and ensure a stable supply. For example, Otsuka Pharmaceutical has formulated the Policy for Pharmaceutical Quality Assurance, seeking to establish a high-level quality assurance system where all activities in all processes are based on this policy, including those undertaken by external contracted manufacturers. The Pharmaceutical Business established global product quality policy in 2017. Activities are carried out globally, and include ensuring the reliability of quality data and compiling procedural manuals.

Promotion System

The pharmaceutical segment of the Otsuka group complies with the Act on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices, and we observe the laws and regulations of the countries where we operate, performing quality control based on Good Quality Practice¹ and Good Vigilance Practice² in manufacturing and sales, and implementing post-marketing safety measures. Moreover, we submit all necessary reports, including those on adverse events, to regulatory authorities, and update and maintain all required documentation (Pharmacovigilance³). In addition, we ensure that all pharmaceuticals are manufactured under a quality assurance system to enable the stable supply of high-quality pharmaceuticals. We have established a quality assurance system that complies with international standards, such as GMP⁴ in each country and PIC/S⁵ GMP. We are also strengthening the quality control system based on the ICH Q10 Pharmaceutical Quality System Guidelines.

- 1: Standards for quality assurance in production and sales (GQP). In Japan, GQP is defined in a ministerial ordinance issued by the Ministry of Health, Labour and Welfare based on the Pharmaceutical and Medical Devices Act. The official name is the Ministerial Ordinance on Standards of Quality Assurance for Drugs, Quasi-drugs, Cosmetics and Medical Devices.
- 2: Standards for post-marketing safety management (GVP). Good post-marketing study practice (GPSP) and GVP are elements of post-marketing surveillance. GVP mandates the establishment of rules for the collection and monitoring of safety information, and the implementation of necessary safety measures after pharmaceuticals and medical devices are launched in the market. In Japan, GVP is defined in a ministerial ordinance issued by the Ministry of Health, Labour and Welfare based on the Pharmaceutical and Medical Devices Act. Its official name is the Ministerial Ordinance on Standards for Post-Marketing Safety Control of Drugs, Quasi-drugs, Cosmetics, Medical Devices, and Regenerative Medicine Products.
- 3: Pharmacovigilance refers to monitoring of drug safety information. It helps to promote appropriate use of drugs and protect patient safety by detecting, evaluating and preventing adverse reactions.
- 4: Standards designed to ensure proper manufacturing control and quality control in all processes from the receiving of raw materials to the shipment of final products. In Japan, GMP is defined in a ministerial ordinance issued by the Ministry of Health, Labour and Welfare based on the Pharmaceutical and Medical Devices Act. Its official name is the Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Drugs and Quasi-drugs.
- 5: Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) is the informal cooperative arrangement between regulatory authorities aimed at the international development, implementation and maintenance of harmonized GMP standards and quality systems for inspecting in the field of medicinal products.

Safety Management

The Otsuka group has established a safety management system that consists of the Quality Assurance Manager, who is responsible for the quality control of pharmaceuticals as required by the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices. Under this system, the Safety Control Manager responsible for post-marketing safety management and the General Marketing Compliance Officer oversees compliance. This ensures that actions taken for quality and safety are performed accurately. We also hold monthly debriefings for everyone from the General Marketing Compliance Officer to management.

The Triumvirate Structure in the Manufacture and Sale of Pharmaceuticals



Since 2016, Otsuka Pharmaceutical and group companies have enhanced compliance for a range of processes from development through to the finished product. Monthly debriefings are held with the director in charge of quality in addition to management reviews three times a year. The Nutraceutical Business holds monthly debriefings and quality assurance meetings with the director in charge of quality as part of a thorough quality management system.

Participation in Activities to Raise Awareness of and Eradicate Counterfeit Medicines

Annual worldwide sales of falsified (counterfeit) medicines¹ are estimated at more than \$75 billion.² In developing countries, where these medicines reportedly account for 10–30% of drug distribution, the safety of patients is seriously threatened. Otsuka Pharmaceutical participates in raising awareness of and eradicating falsified medicines in collaboration with the Pharmaceutical Security Institute (PSI).³ Otsuka Pharmaceutical and subsidiaries outside of Japan have formed a global product security team that practices market surveillance and cooperation with industry and government so that medicines reach patients through the correct distribution channels. This structure was strengthened in January 2021, and members with expertise from production, quality, procurement, and logistics departments are participating in cross-organizational activities.

1: The definition of falsified medicines was discussed at the 2017 WHO World Health Assembly. WHO defined falsified (counterfeit) medicines as "medical products that deliberately/fraudulently misrepresent their identity, composition or source."

2: Growing threat from counterfeit medicines" (Bulletin of the World Health Organization, Volume 88, Number 4, April 2010, 241–320)

3: Forty pharmaceutical companies from around the world fund the Pharmaceutical Security Institute's (PSI) anti-counterfeit medicine efforts (information gathering, collaboration with law enforcement, and awareness-raising activities).

Global Quality Assurance Officers' Meeting

Otsuka Pharmaceutical Factory insists on manufacturing IV solutions in the country where they are sold because we believe in supplying pharmaceuticals at fair prices for every country or region so that all people can receive medical treatment equally, whether they are rich or poor. The Otsuka Global Quality Standards have been set to maintain high quality in every country that manufactures our products, aiming to further improve quality. We send young engineers to other countries to oversee production, which also presents a huge opportunity for personal growth for those employees. The Global Quality Assurance Officers' Meeting is held every year for 15 group companies across 10 countries engaged in the IV solutions business. IV solutions require stricter quality control than other pharmaceuticals, since they are administered directly into the body.

While establishing a framework for exchanging safety data throughout the group, we are working as one to unify our approach to quality assurance and steadily maintain and improve product quality.

Promotion System for the Nutraceutical Business

In 2018, Otsuka Pharmaceutical established the Quality Division for making possible quality improvements and safety control for products in the Nutraceutical Business. The Global Product Quality Team consisting of members from 15 Otsuka group companies has begun formulating a common philosophy on quality and the NC Global Quality Policy was established in 2021.



Ken Konagai
Director
Office of Nutraceuticals
Quality Assurance
Quality Headquarters
Otsuka Pharmaceutical

Commitment to the NC Global Quality Policy

In 2018, Otsuka Pharmaceutical's Quality Assurance Office of the Quality Headquarters inaugurated a Global Product Quality Team, with members from 14 Otsuka group companies from around the world involved in the Nutraceutical Business. Otsuka Pharmaceutical's approach to quality is rooted in, and remains faithful to, founder Busaburo Otsuka's words: "Quality is vital in a factory and so is packaging. We have to manufacture and market, putting ourselves in the consumer's position."

The key message of the NC Global Quality Policy is "Customer delight through Quality," which expresses the founder's sentiment in our own words and declares our common global commitment.

Promotion System

Otsuka Pharmaceutical established a Quality Assurance Office. Based on the concept of good manufacturing practice for pharmaceuticals, the Global Product Quality Team, consisting of members from 15 group companies, built an integrated management system that ranges from identifying and investigating risk to examining the cause of issues that arise and taking effective countermeasures. As an example, in December 2020 Otsuka Pharmaceutical formulated rules for evaluating the quality of nutraceutical products from development to marketing to prevent risks to quality in all aspects of the value chain. In addition, we are promoting more quality improvements, such as acquiring international certifications at production bases to ensure global quality assurance.

Acquisition of International Certification (Nutraceutical and Consumer Products)

Company name	Certificate factory	ISO 9001 quality management system	Food safety management system	Others
			FSSC22000	
Otsuka Pharmaceutical	Second Tokushima Factory		○	
Otsuka Pharmaceutical	Tokushima Itano Factory		○	
Otsuka Pharmaceutical	Tokushima Wajiki Factory		○	
Otsuka Pharmaceutical	Saga Factory		○	
Otsuka Pharmaceutical	Takasaki Factory		○	
Otsuka Pharmaceutical	Fukuroi Factory		○	
Otsuka Foods	Tokushima Factory	○		HACCP
Otsuka Foods	Shiga Factory	○		HACCP (Beverage manufacturing line)
Otsuka Foods	Kushiro Factory	○		HACCP
Otsuka Foods	Gunma Factory	○		HACCP
Amerta Indah Otsuka (AIO)	Sukabumi	○	○	cGMP (IndonesianFDA)
Amerta Indah Otsuka (AIO)	Kejayan	○	○	
Otsuka Sims (Guangdong) Beverage (OSGB)	First Factory, Second Factory	○	○	
Tianjin Otsuka Beverage (TOB)	Tianjin Factory	○	○	HACCP
Pharmavite	San Fernando			FDA, USP-QSGMP-DSVP
Pharmavite	Opelika			FDA, USP-QSGMP-DSVP
N&S	REVEL1			IFS
Crystal Geyser Water	Bakersfield		○	
Crystal Geyser Water	Calistoga		○	
Daiya Foods	Burnaby			SQF

* FSSC22000: Food safety management system standard

* HACCP: Hygiene management system

* c-GMP (Current Good Manufacturing Practice): One of the food and drug quality control programs established by the U.S. Food and Drug Administration (FDA)

* USP (United States Pharmacopeia): Quality standard for U.S. pharmaceuticals (including supplements)

* BRC Global Standard: Food safety standard run by the British Retail Consortium

* IBWA (International Bottled Water Association): Trade association of companies in the bottled water industry

* IFS (International Food Standard) certification: Food safety standard for EU countries

* SQF (Safe Quality Food): US food safety and quality control certification

Listen to the Customer Feedback Meetings

We collect post-marketing information on Otsuka Pharmaceutical's nutraceutical products. Feedback provided to the Consumer Relations Office is shared with production and technology departments at monthly meetings of the Quality Assurance Office of the Quality Headquarters. The goal is to make and check the progress of product improvements. Listen to the Customer Feedback Meetings have been held every year since 2018, and they have gradually gotten bigger. At these meetings, representatives from purchasing, production, quality, compliance, legal affairs, and Otsuka Holdings share information and work to improve quality from a customer perspective.

Initiatives to Improve Product Quality through Collaboration between Pharmaceutical and Nutraceutical Businesses

Global Product Quality Meeting

In Otsuka Pharmaceutical's product quality operations, the Pharmaceutical Business and Nutraceutical Business jointly hold an annual Global Product Quality Meeting. The 2022 meeting was attended by approximately 120 managers and quality supervisors for pharmaceuticals and nutraceuticals from 12 countries/regions, including Japan, on the topic of creating new synergies for future quality management. Participants shared information on quality-related risks in the supply chain and their countermeasures as well as quality assurance initiatives within environmental conservation programs. In addition, a Quality Performance Award was established to recognize quality control initiatives, and we are training more people for quality control and to raise awareness.

Global Product Quality Meeting, Quality Achievement Award, Grand Prize



Quality Culture Secretariat* consisting of members from Otsuka Pharmaceutical's production, quality and quality assurance departments

* Leads and promotes "quality culture" development across divisions in the Pharmaceutical and Nutraceutical businesses.



PT Amerta Indah Otsuka's Quality Assurance Department Developed and started operating a digital management system that streamlines vendor management through vendor audits, the sharing of results from incoming inspections for raw materials and other materials online, and the centralized management of onsite data. This initiative was aimed at ensuring compliance with FSSC22000 Food Safety System Certification version 5.1.

Human Resource Development and Education System

In addition to regular training on quality for the employees and other people concerned in accordance with an annual plan, we provide training on topics including: company and manufacturing site rules; safety, health and the environment; and manufacturing management and quality control in relation to products and their manufacture. Depending on the content, human resource development includes practical programs for learning procedures and skills.

For example, Otsuka Pharmaceutical provides education for new recruits, training to improve skills for employees in their second or third year with the company, and training for people to confirm the content of tests, each around 10 times a year.



Building a Logistics Foundation with the Ultimate Mission of Ensuring Supply Stability

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.

The Otsuka group company Otsuka Warehouse takes a lead role in delivering products throughout Japan and handling a part of overseas logistics. Otsuka Warehouse has established a quality policy aimed at providing a level of quality that earns the trust of customers and society. All employees are fully on board with our policies and comply with all provisions to maintain and improve quality.

Otsuka Warehouse Quality Policy

1. We will pursue safe and secure services that reflect changes in the environment and social needs, and provide a level of quality that helps us earn the trust of customers and society.
2. We will appoint quality officers at the head office and all offices to maintain and manage quality.
In addition, we will formulate targets for quality for each business site and implement an action policy to achieve these targets. Results will be reviewed and improvements made, when required.
3. We will use a quality management system to investigate accidents and complaints, implement countermeasures, and manage conditions until they are resolved.
Employees comply with our code of conduct regarding environmental conservation, the prohibition of unfair trading, protection of personal information, and all other similar requirements.

Promoting Good Distribution of Pharmaceuticals

Otsuka Warehouse has set up the GDP¹ 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 the manufacture and distribution of pharmaceuticals through training and drills on temperature control during shipping and storage, security and other 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.

1: Good Distribution Practice

Measures to Enhance Distribution Quality

Systemization of Warehouse Operations²

Otsuka Warehouse has shifted to a paperless environment through the use of tablets. The introduction of this information technology has enabled anyone to work effectively in warehouse operations, reducing delays and mistakes. Warehouse conditions can now be determined in real time, which is not possible with conventional paper-based picking systems. This minimizes inaccurate shipments and picking errors, leading to improved work efficiency and quality.



Warehouse navigation system

2: [ID Warehouse \(Otsuka Warehouse\) \(Japanese version only\)](#) [↗](#)

Understanding Delivery Status in Real Time³

Delivery operations that are difficult to visualize can restrict the work flow, leading to long work hours, among other negative effects. Otsuka Warehouse standardizes specifications for the data management system to simplify collaboration and cooperation between shippers and logistics operators. Introducing IT systems for dispatching trucks and vehicle monitoring enables better tracking of transportation and delivery as well as improves the quality of logistics. At the same time, AI is used to visualize delivery operations, such as automatically recommending a delivery route, in line with the goal of streamlining work and increasing the quality of logistics.

3: [ID Transport \(Otsuka Warehouse\) \(Japanese version only\)](#) [↗](#)

Establishing the BCP System

Otsuka group companies coordinate with Otsuka Warehouse to ensure a stable supply of products so that business can continue to the extent possible even during a largescale earthquake or other disaster. Business continuity is aided by having logistics sites throughout Japan, diversified production inventory, and a robust nationwide network of sites based on securing new locations.

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.

Key Base for BCP: West Japan Logistics Center (Otsuka Warehouse)

Since 2015, Otsuka Warehouse has been operating the West Japan Logistics Center in Kobe City, Hyogo Prefecture—around two hours from Tokushima, where the main Otsuka group factories are located. The ground in the area is hard and there is a low probability of a major earthquake. By installing private emergency power generation equipment that can operate 24 hours a day even during a power outage due to an earthquake or other disaster, the Center can operate at full capacity for around three days. In addition, the quake-absorbing building structure can withstand a largescale earthquake or tremors. For this reason, we have created a BCP system, where supply can continue, by stopping products from falling and being damaged, and buildings are prevented from collapsing.



West Japan Logistics Center



Emergency private power generation facilities



Seismic isolation system

Reducing CO₂ Emissions

Among measures to reduce environmental impact, Otsuka Warehouse is moving forward with a modal shift to rail and sea transportation, which have lower CO₂ emission intensities. Use of a reservation system for booking access times when receiving and shipping at warehouses has reduced the average waiting time for drivers by more than half. Such measures contribute to reducing CO₂ emissions throughout the industry. Further, considering the optimal vehicles and routes for diverse products and transport destinations, the company is implementing joint logistics, which combines products from multiple companies in a single vehicle, in this way reducing the number of transportation vehicles across society.



Truck Reservation System

Otsuka Warehouse uses IT to increase efficiency in warehouses, connecting them to pre- and post-distribution operations. Drivers can connect with each warehouse and get an overall picture of logistics online in a system known as connected logistics. The aim is to resolve some of the issues that have plagued the logistics industry. A truck reservation system makes it possible to make reservations for unloading times online, in this way seriously reducing driver wait times, contributing to lower CO₂ emissions as well as improving the work environment for drivers and addressing the issue of a shortage of drivers and vehicles.



Basic Policy

The Otsuka group believes that we have a responsibility to deliver higher-value products and services to customers. To do this, we will engage in suitable promotion and advertising activities that comply with all laws and regulations, and communicate with customers in an effective way.

Promotion System for Pharmaceutical Business

Basic Approach and Policy

We have established standards of conduct that comply with the International Federation of Pharmaceutical Manufacturers & Association's Code of Practice and the codes of industry associations in each country and region to ensure a high level of ethics and transparency in interactions with stakeholders, including medical practitioners, medical institutions, and patient groups, and to meet the trust placed in us by society. For example, in Japan, every company has developed its own code* that reflects and improves upon the Japan Pharmaceutical Manufacturers Association (JPMA) Code of Practice and Promotion Code for Prescription Drugs, mainly for sales divisions. In addition, all activities of the Otsuka group from R&D to providing medical information and other corporate activities are subject to laws and regulations, such as the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Drugs and Medical Devices Law). We also comply with the Fair Competition Code concerning Restriction on Premium Offers in Ethical Pharmaceutical Drugs Marketing Industry (Fair Competition Code), voluntary codes such as the Guidelines for Provision of Sales Information on Prescription Drugs issued by the Ministry of Health, Labour and Welfare, administrative notifications, and other guidelines. Our compliance ensures responsible promotional activities based on high ethical standards suitable for a health-related company.

* Otsuka Pharmaceutical Code of Practice

* Otsuka Pharmaceutical Factory Code of Practice

* Taiho Pharmaceutical Code of Practice

Promotion System

All promotional activities of the Otsuka group comply with laws, regulations, and guidelines.

For example, Otsuka Pharmaceutical, under the guidance of top management, has established a review and supervisory committee that includes a third party and an investigation committee within the supervising department that includes administrative and human resource sections. We have also introduced a system for regular reviews to ensure that promotional materials comply with all applicable laws, regulations and guidelines. In the unlikely event of a violation, an investigation is undertaken swiftly, and guidance is provided to prevent a reoccurrence.

Review System for Providing Sales Information (Example: Otsuka Pharmaceutical)



Review System for Responsible Promotion of Prescription Drugs

The Otsuka group has established a department to supervise how sales information is provided for prescription drugs to ensure that promotional activities are conducted properly.

For example, at Otsuka Pharmaceutical, the compliance promotion committee meets once a year and includes the participation of company presidents and other directors in the value chain. In addition to reporting results from a review of activities related to information distribution and information training, top management are also given training. The compliance promotion committee closely follows the advice of external members (lawyers) when providing sales information. The Compliance Division takes charge of review and supervisory committee meetings twice a year that also include outside experts. The meetings cover the Company's response to reviewing reports on information distribution as well as the current state of activities. All promotional materials for prescription drugs are reviewed monthly by a committee that screens the product information. The committee includes outside experts but no sales representatives to ensure objectivity. In addition, a limit is set for how long materials that have passed the review process can be used, with any extension requiring a separate review.

Further, the slides used by medical professionals for lectures are checked in advance by the Medical Affairs Department.

Training System for the Responsible Promotion of Prescription Drugs

The Otsuka group holds regular training for all employees involved with promotions, including departments that prepare materials, and sales representatives, with the aim of raising awareness of compliance. We also provide regular training for employees so they can acquire knowledge of the laws, guidelines, and ethics related to the prescription drugs and other products that we handle, as well as any other knowledge considered necessary. In the unlikely event of a violation, special training is given as soon as possible to prevent a reoccurrence.

We provide periodic training on the Fair Competition Code, Guidelines for Provision of Sales Information on Prescription Drugs and Guidelines for Transparency of Relationship between Pharmaceutical Companies and Medical Institutions, etc. to those from Otsuka group companies that handle the sales and promotion of pharmaceuticals.

Implementation of Training on Sales and Promotional Activities for Pharmaceuticals (Example: Otsuka Pharmaceutical)

Participants	Main content	Frequency
Medical representatives, personnel affiliated with pharmaceutical sales division, etc.	<ul style="list-style-type: none">Fair Competition Code, other codes, providing sales informationGuidelines on activities and transparency, ethics, systems, PMS, etc.	<ul style="list-style-type: none">Once a year (basic training)Eight times a year (practical training)
Personnel in charge of preparing materials	<ul style="list-style-type: none">Important points when sharing the latest information and creating materials to ensure compliance with advertising restrictions under the Drugs and Medical Devices Law	<ul style="list-style-type: none">Twice a year (general training)Four times a year (each specialized area)
Pharmaceutical sales division, medical affairs department, academic affairs department, etc.	<ul style="list-style-type: none">Important points to ensure compliance with Guidelines for Provision of Sales Information on Prescription Drugs	<ul style="list-style-type: none">Most months
Medical representatives	<ul style="list-style-type: none">Ethics education (key points on compliance with guidelines)	<ul style="list-style-type: none">Twice a year
	<ul style="list-style-type: none">Fair Competition Code, Guidelines for Provision of Sales Information on Prescription Drugs	<ul style="list-style-type: none">Around 100 times a year (each branch and team)

Approach in the Nutraceutical and Consumer Products Businesses

Basic Approach and Policy

Sales and promotions for food and beverages are based on scientific evidence. Our basic policy is to comply with all laws, regulations, industry standards and guidelines in every country where we provide products and services, and to be sincere in our actions based on high ethical standards. We also partner with industry groups and government for maintaining suitable promotions.

Review System for Responsible Promotional Activities

The Otsuka Group has established a review system to ensure appropriate marketing and sales promotion activities in accordance with laws and regulations.

At Otsuka Pharmaceutical, the product information committee, chaired by an executive officer and consisting of managers from multiple departments such as administration, legal affairs, production and consumer-relations, meets every month to review sales promotion plans and advertising materials. The secretariat, meeting under the production information committee, which also includes staff from multiple departments, discusses individual sales promotion plans for each week.

At Otsuka Foods, the label review committee, also with people from different departments, meets once a week to review sales promotion plans and advertising materials. In addition, a debriefing session is held each month to share with management the content discussed by the committee. Directors from departments related to general affairs, legal affairs, and intellectual property as well as product managers and division heads take part in these debriefings.

Training System for Responsible Promotional Activities

To instill ethical compliance at group companies, the Otsuka group conducts universal training based on the content of the Global Code of Business Ethics, the Global Anti-Corruption Policy and the Global Conflict of Interest Policy. Officers, employees, contract employees, and dispatched employees at each operating company attend related training once a year. The levels of understanding of compliance and its penetration among employees are evaluated through a test during training, awareness surveys, and other measures. We also provide employee training on responsible sales and promotions that specifically focus on the business of each company.

At Otsuka Pharmaceutical, in addition to annual compliance training for all employees, we provide training with content specific to business divisions as well as training on laws, regulations and guidelines related to prescription drugs. By doing this, we are fostering an awareness of the need for strict promotional activities among all employees of a division from the perspective of a pharmaceutical company. Employees can also check regulations on promotional activities at any time on the company intranet.

Otsuka Foods raises awareness of compliance by sending emails on different topics twice a month and runs remote (online) compliance-related training for all employees five times a year to foster a comprehensive awareness of compliance.



Sincere Response to Inquiries and Reflection in Company Activities

Basic Policy

We recognize that respecting consumer rights is an important human rights issue. Our Declaration of Consumer-oriented Commitment, made in October 2018, establishes basic policies regarding our commitment to our social responsibilities as a corporation, which we fulfill by pursuing consumer-oriented management and making appropriate decisions that are based on dialogue with all stakeholders.

> [Declaration of Consumer-oriented Commitment](#)

Promotion System

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 and provide appropriate information. Comments and suggestions regarding products are shared with top management by the related department and reflected in product improvements.

At all company customer contact points, we work closely with related departments within the company. For example, at Otsuka Pharmaceutical, customer feedback is sent in a daily report to the Quality and Production Divisions as well as product managers. We work to foster a consumer-oriented approach by deepening cooperation among departments to ensure an effective response to a problem with a product or service. In addition, when inquiries are received from the National Consumer Affairs Center of Japan or other consumer centers around Japan, related departments and group companies work together to respond and earn the trust of consumers.

We also communicate with stakeholders on our activities at every stage of the value chain so that our business initiatives maintain a consumer-oriented.



Value Chain	Communication with Stakeholders
Procurement	The cross-group Otsuka Sustainable Procurement Task Force communicates closely with suppliers to promote sustainable procurement.
Production	Otsuka Pharmaceutical's Tokushima Itano Factory and Human Resource Development Institute, and Otsuka Foods' Tokushima Factory hold online factory tours as part of community outreach.
Quality Control and Patient/Customer Safety	In addition to collecting feedback through the Consumer-Relations Office, Otsuka Pharmaceutical collects and analyzes consumer comments from social media, and incorporates these comments in product improvements.
Logistics	Otsuka Warehouse, which handles the Otsuka group's logistics operations, holds meetings with transport partners as necessary to share policies and initiatives, and also engages in mutual employee exchanges aimed at promoting digital transformation and operational improvements.
Sales and Marketing	Swift dissemination of information using online tools enabled us to provide information about pharmaceuticals and nutritional products without compromising strict COVID-19 countermeasures.

Group-wide Customer Service Liaison Meeting

Since 2008, we have held a Group-wide Customer Service Liaison Meeting every year under the supervision of Otsuka Holdings directors. Meetings are attended by representatives of companies in the Pharmaceutical Business, Nutraceutical Business, Consumer Products Business, the daily necessities and e-commerce categories, and well as from other relevant departments. The various companies report on their customer service activities and initiatives for greater consumer orientation, thus fostering our consumer-oriented corporate culture. The 27th meeting, held in 2022, focused on evolving consumer trends amid social changes in the ongoing COVID-19 pandemic, and best practices for product improvements informed by customer feedback.

Examples of Product Developments and Improvements Based on Customer Feedback

Product Development to Improve Food-related QOL for Those Required Nursing Care (EN Otsuka Pharmaceutical)



EN Otsuka Pharmaceutical has established a system for sharing customer feedback received at the Consumer-Relations Office with all related departments, including management, in the form of a daily report. For example, this office received feedback from a family member of a customer requiring nursing care who has been using the iEat® for many years. This product is for people with mastication difficulties and the person was struggling as their physical condition worsened. EN Otsuka Pharmaceutical takes seriously all feedback, and in response, started developing new foods that are softer and retain their shape in the mouth while maintaining the taste and color of traditional iEat®. The new products were launched in July 2021 as “iEat® the shape-maintaining and softened meals”.

Improvement of Containers to Make Them Easier to Hold and Open (Otsuka Pharmaceutical Factory)

OS-1^{*} and *OS-1 Jelly*^{*} are produced by Otsuka Pharmaceutical Factory. These products are foods for people with medical conditions. We received input from elderly individuals, customers receiving treatment, those in need of nursing care, and others who reported difficulty opening the cap because of weakened muscles. Based on this input, we redesigned the container to be easier to open. Our pursuit of products that are better and easier to use was recognized with a Good Design Award in 2020. We have also created websites that provide product information in Japanese, English, Chinese, and Spanish, and we added QR codes to product labels that link to these websites. Currently, a Korean language site is being added.

^{*} *OS-1* is approved as a food for people with medical conditions and is intended to provide water and electrolytes to maintain the proper water and electrolyte balance in people with mild-to-moderate dehydration (Approved by the Consumer Affairs Agency)

Example of Improved Product: OS-1 500 ml plastic bottle

- To make it easier to hold, the bottle was redesigned from a round shape to an angled shape that narrows in the middle.
- A QR code was added to the label so that people can access more detailed information about the product.
- To make the cap easier to open, the grooves were made finer, and directions for how to open are indicated on the top.



Example of Improved Product: OS-1 Jelly

- Enlarged cap diameter by 5 millimeters.



Improvements to Easy-to-Open Boxes (Otsuka Pharmaceutical)

At Otsuka Pharmaceutical, personnel from the Quality Division use customer feedback on products to make improvements. One example is the Calorie Mate Block boxes now have a round perforated line on the back so they can be opened with little effort. Based on customer feedback, the packaging was made even easier to open in March 2022 by adjusting the perforations on the opening by a few millimeters.



Adoption of a Design that Considers Variations in Color Vision (Otsuka Pharmaceutical Factory)

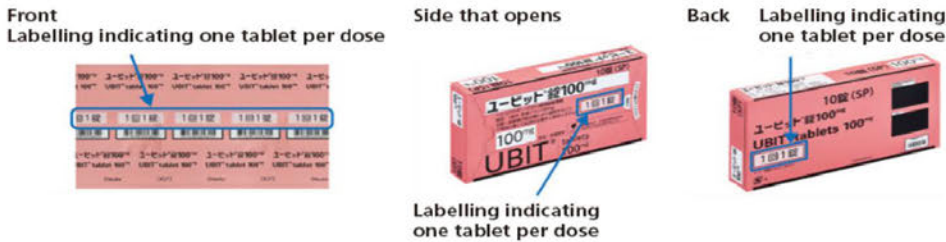
ENORAS® Liquid for Enteral Use, a line of enteral nutrition formulas (for both oral and tube feeding), which is a prescription drug manufactured and distributed by Otsuka Pharmaceutical Factory and EN Otsuka Pharmaceutical, uses a package design that takes into consideration variation in color vision among users and makes it easier to tell product variations apart. In recognition, the Color Universal Design Organization¹ granted the product line CUD certification² in June 2020. We expect this package design to help prevent medication errors, not only by those prescribed the product, but also by healthcare professionals who handle the product.



- 1: A nonprofit organization that contributes to the realization of a society where all people can live a fairer and more culturally rich life. It widely conveys information on color vision to the general public and organizations, evaluating and proposing improvements on color use, and improving the color environment of the real world such that society takes into consideration the variation in human color vision.
- 2: Third-party certification ensuring that a product has a color scheme that is easy for many people to understand.

Clearer Labels for Healthcare Professionals (Otsuka Pharmaceutical)

Inquiries from healthcare professionals led to a change in product labelling for Otsuka Pharmaceutical's UBIT Tablets, a diagnostic agent for Helicobacter pylori infection. Although the package inserts state that only one tablet is to be taken during an examination, the company received several inquiries as to whether two tablets were necessary because the product is packaged with two tablets per box. This seemed to call for a reminder, from the viewpoint of promoting proper use and preventing erroneous use. After consideration by the relevant departments, a warning to indicate one tablet per dose was added to the strip package and individual boxes.



Labelling That Is Easy for Consumers to Understand (Otsuka Foods)

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, an easy-to-read list of allergens (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 information easier to understand, so that consumers can purchase it with peace of mind.



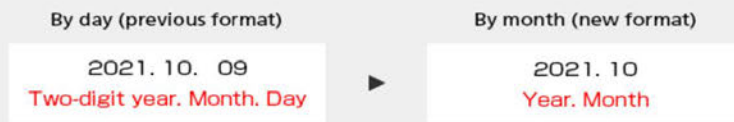
Change of Expiration Date Labeling to Prevent Food Loss

The Otsuka group aims to raise production efficiency through measures including improving production technology, flexibly handling production volume, efficiently using raw materials, and ensuring safety and stability, thereby reducing the occurrence of food loss. For example, Otsuka Pharmaceutical switched to month-based expiration dates and extended the shelf life for about 90 items. In addition, Otsuka Warehouse is working to minimize disposal by introducing a system for group employees to purchase products that would have been disposed of because they are nearing their expiration date, have some packaging damage or for other reasons. As a result of this initiative, food loss was reduced by approximately 116 tonnes in 2021.

Extending Shelf Life and Switching to Month-Based Expiration Dates

The expiration date is the date until which a product can be enjoyed with no change in quality if the container or bag is stored unopened in the way prescribed. Otsuka Pharmaceutical seeks to reduce food loss by extending shelf life and switching to labels that indicate the expiration date by month rather than day. Month-based expiration dates are meant to signify quality until the last day of the month indicated, enabling shelf lives of up to one month longer.

Reference: Example of an expiration date printed for a product manufactured on October 10, 2020



Labeling to Ensure Proper Nutrition (Nutrition and Santé)

Nutrition and Santé (N&S), which offers a range of healthy nutritious foods in more than 40 countries worldwide, mainly in Europe, seeks to deepen consumers' understanding of food and nutrition. For example, since 2020 the Nutri-Score nutritional rating system has been applied to all N&S products (excluding Isostar® brand products) so that consumers have a better understanding of a product's nutritional rating. The Nutri-Score system, a five-level scale (A to E) rating the nutritional quality of products, was started in France and has now been introduced in many European countries. The goal is to help consumers make healthier product choices based on nutrition, which is expected to help reduce the risks of developing cardiovascular disease, obesity, and diabetes. N&S aims to achieve a Nutri-Score rating of C or higher for all products.

NUTRI-SCORE



Release of Eco-Friendly Label-free Bottles (Otsuka Pharmaceutical)

In recent years, along with growing environmental consciousness, the Consumer-Relations Office at Otsuka Pharmaceutical has received an increasing number of inquiries and requests for labels that can be removed more easily from emptied PET or glass bottles. In Japan, although it is not necessary to remove paper labels before recycling bottles, Otsuka Pharmaceutical launched a label-free version of Oronamin C Drink in July 2021, a first in Japan for bottled beverages, in response to consumer concerns.



Shift to Eco-Friendly Packaging (Otsuka Pharmaceutical)

We responded to consumers indicating they would like more eco-friendly packaging in a questionnaire conducted regularly by the department in charge of online sales at Otsuka Pharmaceutical. So, in July 2021 the Company started to use paper in place of plastic for cushioning in packages. This change is expected to reduce plastic consumption by approximately 270 kg per year.



Remote Factory Tours (Otsuka Pharmaceutical's Tokushima Itano Factory)

The Tokushima Itano Factory, which produces pharmaceuticals and SOYJOY products, introduced remote (online) factory tours when onsite tours became difficult due to COVID-19. In fiscal 2021, 690 students from eight nearby elementary schools and special needs schools and six high schools and universities took part. Participants saw a video of the SOYJOY production process as well as hear explanations about Otsuka Pharmaceutical and the factory itself. Many students commented on how interesting it was to see the factory from above in drone shots and that the factory was operating in harmony with nature with various living creatures in the biotope,* including an endangered species, the golden venus chub. Others said that the remote tour stimulated their desire to learn more about the environment, including litter in the sea.



Running a remote factory tour (Tokushima Itano Factory)



* The word biotope, from the German words bios (meaning life) and topos (meaning place), refers to an area where native species can continue to thrive. At the Tokushima Itano Factory, many creatures live in the pond that is filled with the cooling water that we use.

Resolving Local Health Issues through Partnerships with 47 Prefectures (Otsuka Pharmaceutical)

Leveraging knowledge gained through product R&D and health-related education, the Nutraceuticals Division of Otsuka Pharmaceutical has collaborated with local governments across Japan to resolve local issues that include countermeasures for heat disorders, dietary education, sports promotion, women's health issues as well as disaster prevention and support. Partnership agreements have been concluded with all 47 prefectures, and the range of activities has grown to include cities and other municipalities who are focused on health promotion for local populations.

We have also started initiatives to resolve other local health issues by using our knowledge in medical-related fields. In addition to support being provided by the Nutraceuticals Division, such as distributing information on products and health, we are also collaborating with local governments in areas that include mental health, which has been intensifying alongside the spread of COVID-19.

Providing Information on Disease Prevention, Home Medical Care, and Nursing Care (Otsuka Pharmaceutical Factory)

Otsuka Pharmaceutical Factory uses knowhow in intravenous solutions and clinical nutrition for projects taken on together with local governments by providing detailed information ranging from disease prevention to home medical care and nursing care. A partnership agreement on preventive medicine was signed with Ono City, Hyogo Prefecture in September 2020 and a comprehensive partnership agreement was signed with Imizu City, Toyama Prefecture in October 2020.

Online Lectures on SDGs, Cancer and Drug Discovery for Junior High Schools (Taiho Pharmaceutical)

Taiho Pharmaceutical often collaborates with local governments where there are research and production bases. For example, the Tsukuba SDGs Partners agreement concluded with Tsukuba City. In 2021, online lectures were held for junior high schools in Ibaraki Prefecture, through this partners program. The lectures included an introduction to sustainability by public relations staff, an explanation of cancer and drug discovery by a researcher, and a description of work at a corporate venture capital company by an employee of Taiho Ventures, a subsidiary of Taiho Pharmaceutical that invests in bio startups. A short video on the Tsukuba area was also shown during the lectures. These lectures provide an excellent platform for two-way communication with students interested in pursuing a career in medicine.



Prof. Izumi Kado
Department of Business and
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Shikoku University, Junior College

High Hopes for Deeper Permeation of Consumer-oriented Management


I have the deepest respect for the people of the Otsuka group, who work hard to create a sustainable society together with consumers, inspired by the ideal of ethical consumption founded on three key concepts: the environment, workers' rights and happiness, and the community. In an age when we can no longer count on the future being a direct extension of the past, I am convinced that the Otsuka group's consumer-oriented management style, imbued with a spirit of altruism and defined by diverse, in-depth and, ethical communication with all stakeholders, will come to be shared widely around the world.

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Policy

In addition to improving management soundness, we work to enhance our corporate ethics and conduct appropriate risk management.

Otsuka Group's Materiality and Related SDGs

Materiality	Social Issues	Our Goals	Our Activities	Related SDGs
Governance	Fragile governance system Social change risk	Long-term improvement of corporate value	Strengthening corporate governance Thorough compliance Risk identification, evaluation and management	



Otsuka Holdings Co., Ltd. (“the Company”) is committed to promoting sustainable increase of its corporate value over the medium to long term by realizing its corporate philosophy, “Otsuka-people creating new products for better health worldwide.” To meet this commitment, it adopts a basic policy of making transparent, fair and timely decisions, and fulfilling its corporate social responsibility by living up to the expectations of all stakeholders, including customers, business partners, employees, local communities, and shareholders, through ongoing dialogue.

Initiatives to Strengthen Corporate Governance

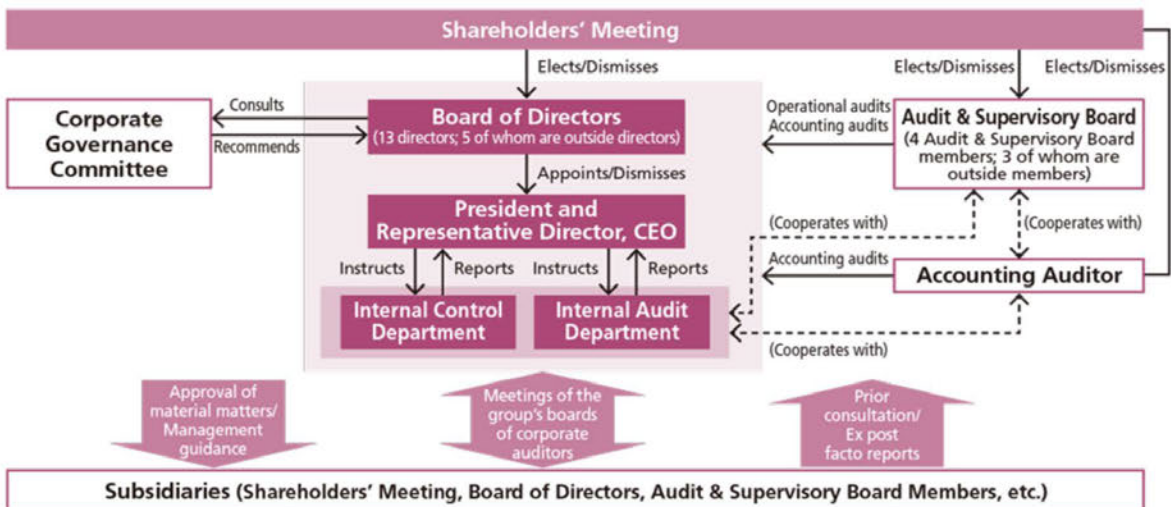
2008	<ul style="list-style-type: none">• Establishment of Otsuka Holdings• Term of directors set at one year• Decision not to adopt a directors' retirement benefits system• Corporate officer system adopted• Two outside Audit & Supervisory Board members
2010	<ul style="list-style-type: none">• Three outside Audit & Supervisory Board members• Stock options as performance-linked remuneration introduced• Stock publicly listed in December
2011	<ul style="list-style-type: none">• First Medium-Term Management Plan announced
2013	<ul style="list-style-type: none">• Two outside directors; three outside Audit & Supervisory Board members

2014	<ul style="list-style-type: none"> • Second Medium-Term Management Plan announced • Three outside directors; two outside Audit & Supervisory Board members • Otsuka Group Global Code of Business Ethics established • Otsuka Group Global Anti-Corruption Policy established
2015	<ul style="list-style-type: none"> • Corporate Governance Guidelines established • Internal whistleblowing system (for Otsuka Holdings and major group companies) established, with reporting to an independent body outside the Company
2016	<ul style="list-style-type: none"> • Three outside directors; three outside Audit & Supervisory Board members • Effectiveness of Board of Directors evaluated • System for granting stock options conditional on progress with the medium-term management plan introduced
2017	<ul style="list-style-type: none"> • Corporate Governance Guidelines revised • Corporate Governance Committee established • Started to evaluate the effectiveness of the Board of Directors based on questionnaires completed by all directors and Audit & Supervisory Board members • Started to hold reporting meetings for outside directors and outside Audit & Supervisory Board members to improve their understanding of the group's management and business
2018	<ul style="list-style-type: none"> • Two female directors • Corporate Governance Guidelines revised
2019	<ul style="list-style-type: none"> • Third Medium-Term Management Plan announced • Restricted stock-based compensation plan introduced
2020	<ul style="list-style-type: none"> • Four outside directors; three female directors • Otsuka Group Global Conflict of Interest Policy established
2021	<ul style="list-style-type: none"> • Corporate Governance Guidelines revised • Otsuka Group Global Anti-Fraud Policy formulated • Accounting auditors changed
2022	<ul style="list-style-type: none"> • Otsuka Group Global Speak-Up Policy formulated • Five outside directors; three female directors

Overview of Corporate Governance Structure

The Company has adopted the audit and supervisory board structure defined by the Companies Act, and as such has a Board of Directors and an Audit & Supervisory Board. It has also engaged an accounting auditor. Furthermore, as an advisory body to the Board, the Company has established the Corporate Governance Committee, consisting of the president, the director in charge of administration, and all outside directors. The Committee makes reports on matters relating to corporate governance, including the nomination of directors and Audit & Supervisory Board members, and the remuneration system and remuneration standards for directors and Audit & Supervisory Board members.

The Articles of Incorporation stipulate that the number of directors shall not exceed 18, and that the number of Audit & Supervisory Board members shall not exceed five. The Company's corporate governance structure is illustrated in the diagram below.



Reasoning behind Corporate Governance Structure

With the aim of promoting the sustainable growth of the Company and increasing corporate value over the medium to long term, the Board of Directors, which also includes outside directors, advances the execution of management plans, supervises the Company's management, and also assumes roles and responsibilities related to enhancing profitability and capital investment efficiency. The Company secures its soundness and has established a solid corporate governance structure that lives up to social expectations by ensuring that the Audit & Supervisory Board and its members, which are independent from the directors, can audit the directors' performance of their duties in collaboration with the accounting auditor, as well as the Internal Audit Department.

Directors and the Board of Directors

Guided by the Board of Directors Regulations, the Board of Directors convenes regularly (once a month) and holds extraordinary meetings as necessary to make important business decisions and supervise the execution of operations. As of March 30, 2022, there were 13 directors, five of these were outside directors. To clarify executive responsibilities for each fiscal year, the term of directors is set at one year.

Director Selection Criteria

The Company aims to become “an indispensable contributor to people's health worldwide” by targeting sustainable growth and enhanced corporate value over the medium to long term. Toward this aim, the Company works to ensure the overall diversity of directors, and appoints people with the insight, expertise, and experience needed to realize and maintain appropriate and effective corporate governance. For internal directors in particular, we comprehensively evaluate the experience, expertise, insight, and other attributes of candidates to ensure that they have the qualities needed to implement the group's corporate philosophy, Code of Business Ethics, and management strategies.

Major Matters Deliberated by the Board of Directors

Category	Major reports and discussions in fiscal 2021
Business performance and plan	<ul style="list-style-type: none"> • Monitoring of progress of consolidated results and plan • Discussions on current conditions and issues regarding the performance of each operating company and business segment • Monitoring of progress of Medium-Term Management Plan
Corporate governance	<ul style="list-style-type: none"> • Identification of issues in improving the effectiveness of the Board of Directors • Approval of officer election and remuneration • Monitoring of subsidiary activities • Confirmation of progress of measures to reinforce group governance • Review of cross-shareholdings
Sustainability	<ul style="list-style-type: none"> • Formulation of group energy strategies • Approval of support for the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD) • Confirmation of the status of execution of programs for cultivating management personnel • Formulation of 2050 Environment Vision, “Net Zero” and approval of revised material issues • Approval for joining the RE100 international initiative
M&A and partnerships	<ul style="list-style-type: none"> • Discussion of a license agreement for joint development and commercialization by Otsuka Pharmaceutical, and Sumitomo Dainippon Pharma (now Sumitomo Pharma) and its U.S. subsidiary Sunovion Pharmaceuticals • Discussion of Pharmavite's acquisition of Uqora

Risk management	<ul style="list-style-type: none"> • Approval of internal control reports, update on implementation of global training programs and on confirmation of conflicts of interest, and approval of activity reports and activity plans • Annual reporting on internal whistleblowing system (whistleblowing system improvement status, number of reports and overview) and approval of action plan • Formulation of new global policies (Otsuka Group Human Rights Policy, Otsuka Group Global Anti-Fraud Policy and Otsuka Group Global Speak-Up Policy) • Reporting on ERM monitoring activities • Reporting on progress of initiatives to reinforce overseas crisis management
Financial strategy	<ul style="list-style-type: none"> • Formulation of funding policy • Discussions of new capital investments • Formulation of dividend policy
IT	<ul style="list-style-type: none"> • Reinforcement of cyber security measures • Reporting on Otsuka group IT activities, etc.

Corporate Governance Committee

Otsuka Holdings established the Corporate Governance Committee in February 2017. As an advisory body to the Board of Directors, the committee discusses matters relating to the enhancement of the corporate governance structure, including the nomination of directors and Audit & Supervisory Board members, as well as succession plans and the remuneration system and remuneration levels for directors and Audit & Supervisory Board members, and reports the results of its deliberations to the Board of Directors. The committee has seven members: the president, the director in charge of administration, and all outside directors (five as of March 30, 2022). The president serves as the chair of the committee.

Content of Deliberations

(1) Nomination

The Corporate Governance Committee discusses the validity and fairness of matters related to the appointment and dismissal of directors and Audit & Supervisory Board members, and reports to the Board of Directors. Regarding candidates for Audit & Supervisory Board members, the committee obtains approval from the Audit & Supervisory Board prior to reporting to the Board of Directors.

Candidates are those put forward by the representative director(s).

(2) Remuneration

The Corporate Governance Committee discusses matters related to the remuneration system and remuneration standards for directors and Audit & Supervisory Board members, and reports to the Board of Directors.

(3) In addition, the Committee deliberates on matters related to the enhancement of the corporate governance structure, and reports to the Board of Directors as necessary.

Audit & Supervisory Board

Audit & Supervisory Board members attend and express opinions at meetings of the Board of Directors, and monitor the performance of duties of directors in terms of legal compliance and soundness of management through audits. As of March 30, 2022, there were four Audit & Supervisory Board members (including three outside members).

To ensure the effectiveness of auditing by Audit & Supervisory Board members, systems have been established by which Audit & Supervisory Board members can interview directors and employees about the status of business execution, review internal consultation documents and other important documents pertaining to business execution, and promptly receive reports on the execution of operations when requested. The Statutory Auditor's Office has been established to assist the duties of Audit & Supervisory Board members.

It convenes meetings of the Audit & Supervisory Board and assists in the duties of Audit & Supervisory Board members independent of directors' authority.

Internal Audit Department

The Company's Internal Audit Department reports directly to the president. The department regularly conducts audits based on the Internal Audit Rules to verify that operations are being executed appropriately and efficiently with regard to the assets and business of the Company and its affiliated companies. The department submits audit reports to the president, directors, and Audit & Supervisory Board members. Where there is need for improvement, the department recommends remedial actions and later confirms their implementation, thereby contributing to the optimization of business execution.

Internal Control Department

The Company views internal controls as an integral component of corporate governance that functions together with compliance and risk management, and has established the Internal Control Department as the department in charge of compliance and risk management to improve the internal control system. The Internal Control Department promotes the Otsuka Group Global Code of Business Ethics and other Otsuka group global rules at Otsuka Holdings and its affiliated companies. It also works to establish and promote compliance programs and risk management programs at each company. The status of the establishment and operation of those programs is regularly reported to the Board of Directors, the Audit & Supervisory Board, and the accounting auditor.

The Internal Control Department handles internal controls regarding financial reporting by the Company and its affiliated companies. The department formulates rules and manuals pertaining to internal controls, provides training, and ensures that employees thoroughly understand operational rules. The department also works in cooperation with the Internal Audit Department to continuously monitor the status of operations. This is the basis of an internal control system under which management personnel can be reliably evaluated.

Accounting Auditor

Otsuka has concluded an audit contract with KPMG AZSA LLC to serve as our accounting auditor, and we receive accounting audits from a fair and unbiased standpoint.

Board Members

In order to establish an effective corporate governance structure that supports sustainable growth, the Company appoints individuals with wide-ranging business experience, advanced expertise in broad fields, and extensive knowledge, as directors and Audit & Supervisory Board members. The table below summarizes areas of experience and expertise of directors and Audit & Supervisory Board members.

* Please see our web pages for Board Members.

For further information on each director and Audit & Supervisory Board member, including a skill matrix, reasons for nomination, and significant concurrent positions outside the Company, please see respective the Notice for the Calling of the Annual Shareholders' Meeting.

Evaluation of Effectiveness of Board of Directors

During January and February 2022, the Company conducted a questionnaire survey of all directors and Audit & Supervisory Board members. Results of the survey were reviewed by a company attorney, and then considered and evaluated at the Board of Directors meeting in March 2022.

Questionnaire items were as follows.

- (1) Composition of the Board of Directors
- (2) Each director's understanding and knowledge of business fields and specific management strategies and plans
- (3) Cooperation with outside directors
- (4) Cooperation with the Audit & Supervisory Board
- (5) Operation of Board of Directors meetings
- (6) Governance-related matters
 - i. Function of the Board of Directors in determining the direction of management strategy
 - ii. Monitoring of each business with respect to the execution of management strategy
 - iii. Understanding of the perspectives of major investors and stakeholders
 - iv. Risk management
 - v. Cooperation and information sharing with each operating company
- (7) Support system for outside directors
- (8) Operation of the Corporate Governance Committee meetings (frequency, agenda, etc.)
- (9) Overall functioning of the Board of Directors from the perspective of effectiveness

Summary of Evaluation in Fiscal 2021

The overall opinion was that improvements have been made from the previous year, and that the Board of Directors is functioning appropriately from the standpoint of effectiveness.

Nonetheless, the results confirmed the need for ongoing efforts to make further improvements in areas such as the role of the Company as a holding company, approaches for fully coordinating and sharing information with subsidiaries, and the stance of the Company with respect to investors and other stakeholders.

Status of Outside Officers

Outside Directors and Outside Audit & Supervisory Board Members

The role of outside directors is to strengthen the Board's governance function of supervising appropriate decision-making and business execution by providing effective advice from a neutral, objective standpoint based on their broad insight and wealth of experience. Outside directors also verify the status of the Internal Control Department as necessary, and strengthen and enhance oversight of management through their various activities at Board of Directors meetings.

The role of outside Audit & Supervisory Board members is to enhance management transparency and strengthen auditing functions. They audit operations from a neutral, objective standpoint based on their high level of insight in finance, accounting, legal affairs and management, and wealth of experience in business management. In striving to improve the effectiveness of audits by Audit & Supervisory Board members, outside Audit & Supervisory Board members also share information and exchange opinions as appropriate with relevant departments, including the Internal Audit Department, Internal Control Department, Administration Department, and Finance and Accounting Department, as well as the accounting auditor.

The Company believes that it appoints outside directors and outside Audit & Supervisory Board members whose independence is secured and who have extensive experience and a high level of insight in business management.

Standards for appointing outside directors and outside Audit & Supervisory Board members

When appointing outside directors and outside Audit & Supervisory Board members, the Company looks for individuals with a wealth of knowledge and extensive experience in a variety of fields. The Company requires that candidates have the ability to adequately exercise management oversight functions through fair and objective monitoring, supervision, and auditing of management from a neutral and objective viewpoint. The Company recognizes that one standard for ensuring neutrality and objectivity is independence from management, and therefore requires that candidates have no relationship with the Company that could lead to a conflict of interest with ordinary shareholders. The Independence Standards for Outside Directors are defined in our Corporate Governance Guidelines, and form the basis for judgments on the independence of outside directors. In addition, we require that they have not previously been engaged in the execution of operations at any Otsuka group companies. These standards also form the basis for judgments on the independence of outside Audit & Supervisory Board members.

Independence Standards for Outside Directors

The Company determines that an Outside Director is independent if none of the following applies:

- (1) A person who is a relative within the second degree of kinship of an Outside Director is currently or has been in the past three fiscal years a managing director, executive officer, executive operating officer or important employee (each an Executive) of the Company or one or more of the Company's subsidiaries.
- (2) A company to which an Outside Director belongs as an Executive has transactions with the Otsuka group of companies, in which the amount of such transactions in any fiscal year within the past three fiscal years exceeds two percent of consolidated revenue of either company.
- (3) An Outside Director, as a legal, accounting or tax expert or as a consultant, has received remuneration exceeding five million yen per fiscal year directly from the Otsuka group (excluding remuneration as the Company's Outside Director) in any fiscal year within the past three years
- (4) The amount of donations to a non-profit organization to which an Outside Director belongs as an Executive has exceeded 10 million yen in total for the past three fiscal years and such amount exceeds two percent of the income of such non-profit organization.

Mutual Cooperation Between Supervision/Audits by Outside Directors/Outside Audit & Supervisory Board Members, and Internal Audits, Audits by Audit & Supervisory Board Members and Accounting Audits, as Well as Relationships with the Internal Control Department

Mutual cooperation between outside directors and the Internal Audit Department is enhanced through regular exchanges of information (including information exchanges with the independent accounting auditor and the Internal Audit Department) and discussions on management by outside directors and Audit & Supervisory Board members.

The Company holds regular briefing sessions for outside directors and outside Audit & Supervisory Board members on such matters as the status of business operations and industry conditions. In addition, to deepen their understanding of the group's businesses, outside directors and outside Audit & Supervisory Board members are provided with explanations of group businesses and opportunities to visit manufacturing, R&D and other sites as appropriate.

Succession Plan

The Company continues to develop and implement executive human resource development programs to identify talented personnel early and systematically nurture next-generation management candidates equipped with the qualities and skills called on by the corporate philosophy. The status of these programs is regularly reported to the Board of Directors.

System to Ensure Appropriate Business Operations in the Corporate Group Comprising Otsuka Holdings and Its Subsidiaries

As a holding company whose role is to maximize the Otsuka group's corporate value, Otsuka Holdings has established a system to ensure appropriate business operations from the perspective of the group as a whole.

We have established a system for facilitating cooperation in the Otsuka group. Under this system, affiliated companies report to Otsuka Holdings as necessary regarding items specified in the Affiliated Company Management Regulations, and obtain approval on relevant important items.

Otsuka Holdings and its main subsidiaries have adopted an audit and supervisory board system and appointed Audit & Supervisory Board members, who audit the directors' performance of duties to increase their effectiveness. Audit & Supervisory Board members attend Board of Directors meetings as well as other important meetings, and monitor the performance of duties of directors in accordance with audit policies and audit plans. As a general rule, meetings of group companies' Audit & Supervisory Boards are held four times a year to share information, strengthen coordination, and report on each company's business conditions.

Additionally, the Internal Audit Department of Otsuka Holdings, pursuant to the Internal Audit Rules, supervises or conducts audits that also include affiliated companies. In this way, the Company has established a cross-company risk management system and compliance system that ensure appropriate business operations throughout the group.

Status of Risk Management System

To defend against potential risks relating to the performance of duties, Otsuka Holdings has established rules regarding risk management, provides thorough risk management training to all employees, and has established a risk management system. In the event of an unforeseen risk event, the Company will respond promptly, set up committees to manage each category of risk as needed, and establish a system to minimize the spread of damage.

[> Risk Management](#)

Basic Policy

The Company's remuneration plan for directors and Audit & Supervisory Board members is designed to achieve sustainable growth and enhanced corporate value over the medium to long term for the group based on the corporate philosophy, while also ensuring that functions such as business execution and management supervision are exercised appropriately, maintaining transparency and fairness.

Remuneration Levels

Considering the need to acquire and motivate outstanding personnel who will take responsibility for the Company's global business activities, the Company sets remuneration levels fully commensurate with the roles and responsibilities expected of such personnel, while also considering levels at companies that the Company considers benchmarks based on the scale, industry, and business model.

Remuneration System

With regard to remuneration for directors responsible for business execution, the Company has formulated a remuneration system that is closely linked to performance in individual fiscal years, as well as over the medium to long term, while emphasizing sustainable enhancement of corporate value. Remuneration consists of fixed remuneration as basic remuneration, performance-linked bonuses, and share-based payments, emphasizing the link to shareholder value. Remuneration for outside directors and Audit & Supervisory Board members comprises only fixed remuneration as basic remuneration in light of their duties.

Method of Determining the Content of Remuneration of Individual Directors

The Board of Directors receives recommendations on the appropriateness of the remuneration system and remuneration levels, and the performance evaluation for performance-linked bonuses and share-based payments from the Corporate Governance Committee, which consists of the president, the director in charge of administration, and all outside directors. Based on these recommendations, the Board determines the individual remuneration for directors as follows.

- The president is delegated with deciding the specific payment amounts of individual fixed remuneration as basic remuneration to directors and individual performance-linked bonuses for each director (excluding outside directors) pursuant to resolution of the Board of Directors. In accordance with this delegation, the president makes the final decision on remuneration amounts based on deliberation and reports by the Corporate Governance Committee regarding remuneration levels.
- Individual share-based payments for each director (excluding outside directors) are determined by resolution of the Board of Directors based on reports on performance evaluation, etc. by the Corporate Governance Committee.

Content of Remuneration to Directors (Excluding Outside Directors)

Remuneration type	Payment method Fixed/Variable	Remuneration content (Including policy for determining timing or conditions of remuneration)
Fixed remuneration	Cash/ Fixed	<ul style="list-style-type: none"> Remuneration for directors of the holding company is determined based on their duties and responsibilities including formulation of group strategies, monitoring group operations, and strengthening corporate governance. Remuneration for directors who serve concurrently as directors of subsidiaries that are operating companies is determined based on their duties and responsibilities including execution of business based on group strategies formulated by Otsuka Holdings, formulation of strategies for operating companies, and strengthening corporate governance. (Remuneration shall not to exceed the upper limit of remuneration resolved at the Shareholders Meeting.) Fixed remuneration is paid out equally every month.
Performance-linked bonus	Cash/ Variable	<ul style="list-style-type: none"> Remuneration is paid in a lump sum at a certain time every fiscal year, with the amount or calculation method determined based on (1) rate of achievement of the fiscal year's targets for consolidated revenue, consolidated operating profit, and consolidated business profit before R&D expenses; (2) progress with respect to medium-to-long-term consolidated performance targets; and (3) appropriate business management in compliance with corporate governance, along with the individual's personal performance.
Share-based payment	Non-cash (restricted stock)/ Variable	<ul style="list-style-type: none"> The Company has introduced a share-based payment plan that reflects progress in achieving the targets in the Third Medium-Term Management Plan covering the period from fiscal 2019 to fiscal 2023. Under the plan, restricted stock allocation agreements stipulating conditions including transfer restrictions for a set period are concluded with the grantees. The plan is designed to function as an effective remuneration system by combining multiple release conditions for the transfer restrictions, including a set performance evaluation period and performance achievement, and by, in principle, granting restricted stock requiring evaluation of performance over several fiscal years at the same time in the first fiscal year. Specifically, stock is granted each fiscal year for items requiring evaluation of performance in a single fiscal year, and at the same time in the first fiscal year of the evaluation period for items requiring evaluation of performance over several fiscal years.

Overview of non-cash remuneration (restricted stock)

To determine the number of shares to be allocated to grantees of restricted stock, a standard number of shares is set for each fiscal year for each individual, giving consideration to his or her performance of duties, responsibilities, and the weighting versus fixed remuneration as basic remuneration. Based on this standard number of shares, shares are allotted for each series each fiscal year or at the same time in the first fiscal year of an evaluation period of several fiscal years, according to the specified release conditions.

The restricted stock allocation agreements concluded with the grantees stipulate that in certain cases, the transfer restrictions on restricted stock shall not be released and the Company shall acquire all of the restricted stock without paying compensation.

For example,

- if a director of the Company retires before the end of the transfer restriction period, the Company shall acquire without paying compensation all of the director's restricted stock upon the retirement of the director, except when the Company recognizes a just reason, such as completion of the term of office or death;
- if a director retires before the end of the transfer restriction period due to a just reason, such as completion of the term of office or death, the number of shares of restricted stock to be released and the timing of the release shall be reasonably adjusted as necessary, and the Company shall acquire without paying compensation all of the shares for which it has decided that the transfer restriction is not to be released; or
- if the performance-based release conditions have not been met, the Company shall acquire without paying compensation all of the shares for which it has decided that the transfer restriction is not to be released.

	Allotment ratio	Fiscal year for evaluation and allocation timing	Summary of release conditions
Series A (Incumbency condition)	40% of the standard number of shares	Allocated each year, taking a single fiscal year as the evaluation period	On condition of incumbency in the subject fiscal year (single fiscal year) (However, the shares will not be released if the combined consolidated revenue and consolidated operating profit target achievement rate is less than 80%)
Series B (Achievement of medium-term performance targets)	30% of the standard number of shares	Evaluation Period 1 is the three fiscal years from fiscal 2019 through fiscal 2021, with the shares for the three years allocated at the same time at the start of the period Evaluation Period 2 is the two fiscal years from fiscal 2022 through fiscal 2023, with the shares for the two years allocated at the same time at the start of the period	In each evaluation period, the value of (2) below may not fall below the value of (1) (1)The cumulative amount of the planned value of "consolidated business profit before R&D expenses" of the Third Medium-Term Management Plan (2)The cumulative amount of the actual value of "consolidated business profit before R&D expenses" for the evaluation period
Series C (Satisfaction of the medium-term cost of capital condition)	30% of the standard number of shares	Evaluation Period 1 is the three fiscal years from fiscal 2019 through fiscal 2021, with the shares for the three years allocated at the same time at the start of the period Evaluation Period 2 is the two fiscal years from fiscal 2022 through fiscal 2023, with the shares for the two years allocated at the same time at the start of the period	In each evaluation period, the value of (2) below may not fall below the value of (1) (1) The cumulative amount of the "consolidated cost of capital" calculated in accordance with the consolidated capital cost ratio for the evaluation period (2) The cumulative amount of the actual value of "consolidated net operating profit after tax" for the evaluation period

Reason for selection of the indicators

For the performance indicators for performance-linked bonus, by combining consolidated revenue, consolidated operating profit, and consolidated business profit before R&D expenses, it is possible to evaluate the results of business management for a single fiscal year from multiple perspectives.

For the performance indicators for share-based payment, by selecting incumbency contribution for achievement of single-fiscal year financial results, consolidated business profit before R&D expenses from a medium-term perspective, and consolidated cost of capital as evaluation items, it is possible to comprehensively evaluate the level of contribution to increasing corporate value.

Composition of Remuneration to Directors (Excluding Outside Directors)

The remuneration plan emphasizes medium-to-long-term enhancement of corporate value, and is designed so that performance-linked remuneration as a percentage of total remuneration varies according to the Company's single-year and medium-to-long-term consolidated performance.

As a rough guide to the ratio of remuneration by remuneration type, performance-linked bonuses are designed to be variable over the range of 0%-100% of fixed remuneration, and share-based payments over the range of 0%-100% of fixed remuneration. Performance-linked bonuses and share-based payments combined are roughly a maximum of 66% of total remuneration (200% of 300% total).

Composition of Outside Director Remuneration

Remuneration for outside directors comprises only fixed remuneration, with no variable components based on business performance.

Composition of Audit & Supervisory Board Member Remuneration

Remuneration for Audit & Supervisory Board members comprises only fixed remuneration, with no variable components based on business performance.

Total Remuneration to Directors and Audit & Supervisory Board Members

	Total amount of remuneration (¥ million)	Total amount by type of remuneration (¥ million)			Number of eligible officers
		Fixed remuneration	Performance-linked bonus	Share-based payment	
Directors [of which Outside Directors]	764 [39]	342 [39]	129 [-]	292 [-]	13 [4]
Audit & Supervisory Board Members [of which Outside Audit & Supervisory Board Members]	56 [32]	56 [32]	-	-	4 [3]
Total [of which Outside Directors and Outside Audit & Supervisory Board Members]	820 [72]	398 [72]	129 [-]	292 [-]	17 [7]

Notes: There are no directors of the Company who concurrently serve as employees.

During fiscal 2021, outside directors and Audit & Supervisory Board members received total remuneration of ¥2 million from the Company's subsidiaries for their services as directors and Audit & Supervisory Board members.



Legal compliance is the cornerstone of all our business activities. The Otsuka group maintains high ethical standards and conducts its business activities with integrity in order to secure the trust of all stakeholders and achieve sustainable growth.

Basic Policy

The Otsuka group seeks to earn the trust of stakeholders and to achieve sustained growth by contributing to people's health worldwide, acting in good faith and with the highest level of ethics in accordance with the corporate philosophy: "Otsuka-people creating new products for better health worldwide." That commitment is encapsulated in the Otsuka Group Global Code of Business Ethics, which outlines the standards of behavior expected of everyone involved in our work. This is reinforced with a range of global policies that reflect our behavioral standards in core areas. Regular training helps ensure that our compliance stance is thoroughly embedded.

Otsuka Group Global Code of Business Ethics

The Otsuka Group Global Code of Business Ethics is consistently applied at all of our worldwide business operations and serves as the group's ethical foundation in pursuing our corporate philosophy. We openly convey information about our stance on related initiatives on our website in the form of a message from the president of Otsuka Holdings. The content of this code of ethics will be reviewed, as required, in light of changes to the social environment, and revisions will be made following resolutions by the Board of Directors.

[> Otsuka Group Global Code of Business Ethics](#)

Otsuka Group Global Anti-Corruption Policy

The Otsuka Group Global Anti-Corruption Policy expresses and reinforces our strong commitment to conducting business with integrity and in compliance with all anticorruption laws. We have clearly defined the ethical standards to be upheld as the global anticorruption standard for employees. This policy outlines how to prevent, detect, and deter violations of anticorruption laws. It sets out our global minimum standards regarding the prevention of corruption and applies this to all our worldwide business operations.

In addition, the Board of Directors monitors the operation of the policy, which includes regulations on bribery, and decides on key revisions and amendments.

[> Otsuka Group Global Anti-Corruption Policy](#)  303KB

Otsuka Group Global Conflict of Interest Policy

The Otsuka group recognizes conflicts of interest between the group and individual employees as a matter that could impact the integrity of the organization, and one that has a great bearing on the group's future. Based on this thinking, we formulated the Otsuka Group Global Conflict of Interest Policy to prevent such conflicts and we are working to instill the policy at a global level.

[> Otsuka Group Global Policy for Conflict of Interest](#)  242KB

Otsuka Group Global Privacy Policy

In recent years, many countries have enacted privacy protection legislation, such as the European Union's General Data Protection Regulation (GDPR) implemented in May 2018. The Otsuka group is working to strengthen privacy protection. In addition to formulating the Otsuka Group Global Privacy Policy to define our stance and guiding principles on privacy protection, we establish related rules and review management systems in accordance with the laws and regulations related to privacy protection in each country.

[Otsuka Group Global Privacy Policy](#)  183KB

Otsuka Group Global Anti-Fraud Policy

Corporate scandals and other misconduct not only cause short-term loss, such as penalties for violating laws and regulations, but they have a major medium- to long-term impact on management. This impact could include damage to our brand image, as well as lower corporate value and compensation to shareholders. We are keenly aware of the importance of taking a strict antifraud approach as part of our business risk management. The Otsuka Group Global Anti-Fraud Policy was established to clarify our stance and basic policy on fraud prevention as a global company. We are implementing initiatives and working to raise awareness of this topic among executive officers and employees throughout the group.

(Basic Policy)

- Fraud is never tolerated
- Misconduct and questionable behavior must be reported without fear of discrimination or retaliation
- Sincere reports will cause no disadvantage
- Training and awareness will be conducted on the risk of fraudulent activities

Compliance Promotion System

As a holding company whose role is to maximize the group's corporate value, Otsuka Holdings has established a system for appropriate business operations from the perspective of the group as a whole. We have established a system for facilitating cooperation in the Otsuka group. Under this system, group companies report to Otsuka Holdings as necessary regarding items specified in the Affiliated Company Management Regulations, and obtain approval on relevant important items. The Board of Directors has built a group-wide risk management system, which includes the establishment of the Risk Management Committee (chaired by the President and Representative Director), and oversees the system's operation. The Risk Management Committee and the Board of Directors receive regular reports on compliance and risk management action plans and results from the Internal Control Department. These reports and plans form the basis for discussion of issues and additional measures.

To instill thorough compliance at group companies, the Otsuka group conducts universal training providing to all employees of worldwide subsidiaries based on policies such as the Otsuka Group Global Code of Business Ethics, the Otsuka Group Global Anti-Corruption Policy and the Otsuka Group Global Policy for Conflict of Interest. Training materials (available in English, French, Chinese, Korean, Indonesian, and other languages) are distributed to group companies, and executives and employees (including contract and temporary employees) attend related training at least once annually. Depth and breadth of compliance understanding among employees is evaluated through a test during training, awareness surveys, and other measures.

Trainees are required to submit a signed declaration that they will observe the regulations, and the results of training and the status of submission of declaration forms are regularly reported at meetings of the Board of Directors. The operational status of the internal reporting systems and internal audits at group companies is likewise reported. Other examples of initiatives include the appointment of compliance officers at overseas group companies and regular meetings for sharing the status of progress in each country. In Asia, for instance, the director in charge of compliance visits companies to gather information and offer suggestions on how improvements can be made.



Monitoring System

The Company's Internal Audit Department reports directly to the president. The department conducts regular audits based on the Internal Audit Rules to verify that operations are being executed appropriately and efficiently with regard to the assets and business in general of Otsuka Holdings and Otsuka group companies. Audit reports are submitted to the president, directors, and Audit & Supervisory Board members. Where there is need for improvement, the department recommends remedial actions and later confirms their implementation, thereby contributing to the optimization of business execution. The department also shares information and works in cooperation with Audit & Supervisory Board members and the accounting auditor.

The Otsuka group operates an crisis management system that enables a swift, cohesive response if a risk event demanding an urgent response occurs in or outside Japan. When a critical or time-sensitive event does occur, the group company immediately shares information with the main operating companies and Otsuka Holdings, and the relevant departments mount a coordinated response to mitigate impact. Otsuka Holdings maintains and updates regulations, manuals, and other documentation setting out fundamental approaches to risk management and response, and enhances group-wide readiness through regular training and exercises.

Whistleblowing Hotline

Internal Whistleblowing Hotline

At Otsuka group, we have established internal reporting systems within each group of companies. Through this hotline, we work to ensure that any improper acts, including acts of bribery, as well as violations of policies, laws and regulations, can be quickly uncovered and corrected. Rules for accepting reports extend beyond full-time employees to include contract, dispatched, and part-time employees. Hotlines have also been set up outside the Company, such as at a law office, with anonymous reporting allowing whistleblowers to make a report with peace of mind and without fear of reprisal. Information on whistleblowers and their reports is strictly managed in order to prevent any repercussions. No information will be shared with anyone except those who must know in order to provide an effective response, given the necessity of conducting an investigation and taking corrective action. Information on the operational status of the internal reporting systems at major group companies is regularly reported at meetings of the Board of Directors of Otsuka Holdings.

Formulation of Otsuka Group Global Speak-Up Policy

The Otsuka group has established the Otsuka Group Global Speak-up Policy with the aim of clarifying the basic principles of the internal reporting system and enhancing its effectiveness so that employees can speak up when they become aware of fraudulent or wrong behavior or actions that go against the group's values, policies, and processes, or any other suspect behavior.

(Basic Principles)

- People have the right and obligation to report in good faith
- Information will be strictly managed
- Anonymous reports will be accepted
- Reporters will not suffer any repercussions
- Investigations as well as corrective and preventive actions must be carried out

External Inquiries and External Whistleblowing Hotline

Otsuka Holdings and its major group companies have established a whistleblowing hotline that accepts inquiries and opinions from external stakeholders and general customers. Furthermore, certain channels of the hotline also accept anonymous consultations and reports.

System for Dealing with Individual Cases

People with knowledge of infractions or concerns about any noncompliance issues are required to consult with and report to their immediate supervisor, the Legal Affairs or Human Resources department, or the department in charge of compliance.

Reprisals against reporting parties are strictly prohibited.

Depending on the nature of the violation, the Compliance Department, or the Human Resources & General Affairs Department are in charge as the secretariat and form an investigative team that includes external experts, such as lawyers, certified public accountants, and data forensics experts. These investigative parties examine the facts, while managing the protection of personal information and ensuring that there are no acts of reprisal against the whistleblower. Cases determined to be serious violations are reported to the chair of the Risk Management Committee and the Board of Directors to respond and take the initiative to prevent a reoccurrence given the circumstances, and all cases are used in planning and implementing group-wide compliance.

Anticorruption Measures for Business Partners

All group companies have established a due diligence policy, and we conduct due diligence for business partners, as needed, to evaluate risks from corruption, violations of human rights, abuse of privacy, and other issues.

➤ [Initiatives for Sustainable Procurement](#)

Basic Policy

The Otsuka group operates around the world and recognizes that the appropriate payment of taxes in accordance with relevant laws and regulations in each country and region contributes to the local economy in those countries and regions. The group fulfills its tax obligations in accordance with the Otsuka Group Global Code of Business Ethics.

Approach

The Otsuka group complies with the Otsuka Group Global Code of Business Ethics, the group's tax policy, country-specific laws, regulations and tax treaties of the countries in which they operate, as well as international taxation rules, and does not engage in transactions designed to evade the payment of taxes, but carries out the appropriate filing and payment of taxes in each country. We endeavor to appropriately disclose information and ensure a degree of transparency and trust when dealing with tax authorities in each country. The increased globalization of business makes tax oversight more complex, but by continuously updating information and preliminary consulting tax experts where necessary, we are appropriately responding to minimize tax risk.

Correspondence with Tax Authorities

The Otsuka group remains committed to building constructive relationships with tax authorities in the countries and regions in which it operates. As economies become more global and digital, the Organization for Economic Co-operation and Development (OECD) and other organizations have been reviewing the basic rules of international taxation. The shift toward a system in which even enterprises without permanent facilities in a location are liable for tax on income earned in that market means that the process of reporting to local tax authorities will become more complex and far-reaching. We will continue to improve the reliability of tax data and establish systems to provide it promptly.

Transfer Pricing Policy

The Otsuka group calculates transfer prices based on the OECD guidelines that were created for the prevention of double taxation and fair application of the transfer price tax system, as well as each country's transfer price tax system, and makes efforts to ensure proper transactions between related parties. In addition, we are appropriately responding to the reporting of corporate information based on the common format published by the OECD. Also, when necessary, we make use of advance pricing agreements (APAs) to obtain ahead-of-time consensus with tax authorities.

We work to maintain and improve tax-related governance, recognizing that this contributes to the enhancement of corporate value. To this end, with the active involvement of the CFO, Otsuka Holdings' tax department is taking the lead, we are strengthening cooperation with other departments and operating companies as well as securing and training capable human resources, thereby maintaining an appropriate system that enhances the group's tax compliance and reduces tax risks. Furthermore, we have established reporting obligations to the Board of Directors and the Audit & Supervisory Board regarding the abovementioned policies and processes, as well as their ongoing implementation and maintenance.

Tax Policy

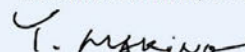
As a multinational enterprise, the Otsuka group recognizes that the appropriate payment of taxes in adherence with applicable laws and regulations in each country and region contributes to local economies. Among increased calls for tax transparency worldwide, we are committed to making improvements in this regard. In accordance with the Otsuka Group Global Code of Business Ethics, the Otsuka group works to ensure appropriate payment of taxes under a principle of compliance that is shared by all employees, including those at departments outside the purview of the CFO.

Moreover, we strive to build constructive relationships with relevant tax authorities by maintaining and providing reliable data.

In accordance with its tax compliance policy, the Otsuka group will implement effective management, strengthen governance, build constructive and positive relationships with respective tax authorities and fulfill its tax obligations in all countries and regions.

June 26, 2020

Executive Director, CFO



Risk Management

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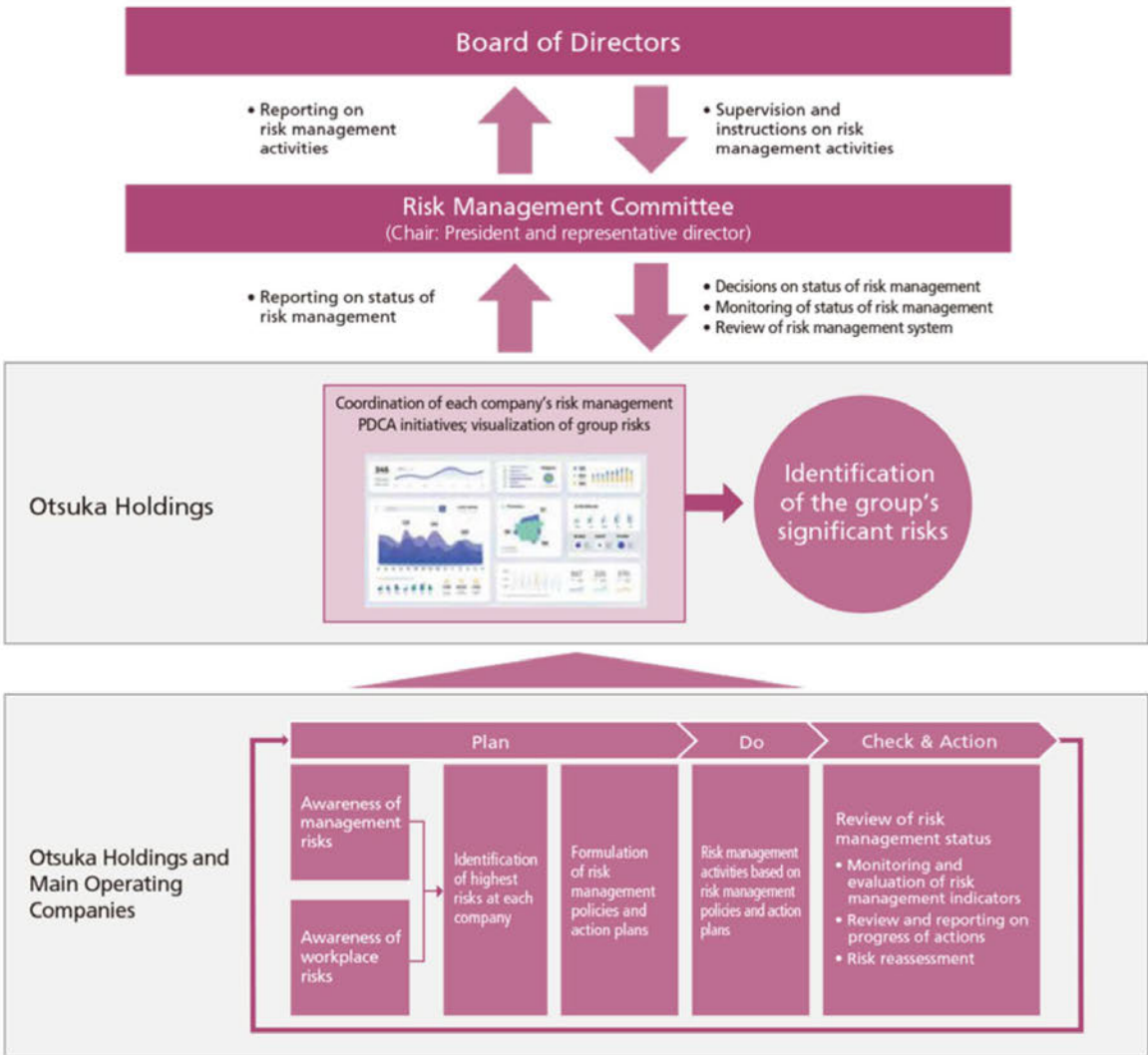
The Otsuka group recognizes that pursuing management efficiency and controlling the risks inherent in business activities are important for improving corporate value. For this reason, it is vital to establish a group-wide system that enables all executives and employees to swiftly uncover, identify, and deal with risks related to their work. The Otsuka group manages risk via the initiatives outlined below, under the supervision of top management.

Risk Management System

To further improve risk management at Otsuka Holdings and the main operating companies, the Company introduced enterprise risk management (ERM) in July 2020 for recognizing and assessing group-wide risks as well as prioritizing the allocation of resources for the control of significant risks.

As part of ERM, we define uncertainties that could have a major impact on our ability to fulfill our corporate philosophy and achieve business strategy goals as risks, and have established a group-wide risk management framework and a system for risk assessment to effectively and efficiently manage significant risks faced by the group. Under this framework and system, we perform risk assessments to identify and gauge the significant risks faced by the group's main operating companies; determine whether to mitigate, transfer, avoid, or accept risks; develop and implement risk management policies, and conduct monitoring activities on an ongoing basis.

At Otsuka Holdings, the Risk Management Committee oversees the group's ERM as a whole. The committee participates in deliberations on significant risks and reports on them at meetings of the Board of Directors, formulates and monitors the implementation of policies for the management of significant risks, and provides instructions and support to the main operating companies when needed. The Board of Directors receives reports on committee activities, issues instructions as necessary, and oversees the efficacy of the group's ERM structure.

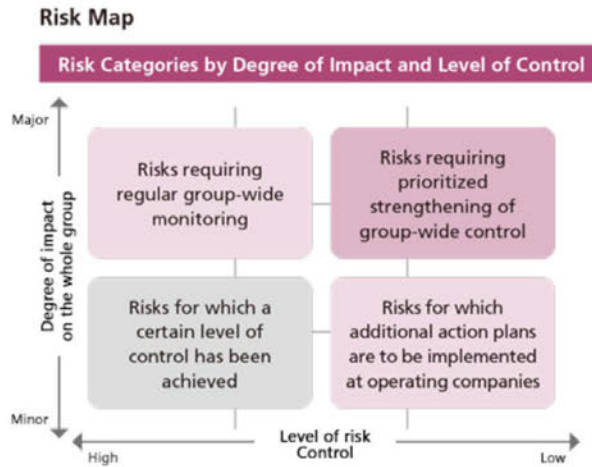


Details of Risk Management Activities

Identification of significant risks begins with the sharing of risk awareness by senior management through interviews at Otsuka Holdings and the main operating companies (top down approach), as well as assessments of risks and controls by frontline employees (bottom up approach). This enables us to comprehensively identify the risks that exist in the group. Each group company develops risk management policies and risk management action plans for the risks that are judged to be significant risks, and regularly monitors and reviews the status of those risks and the progress of action plans.

Otsuka Holdings aggregates and visualizes the significant risks faced by each group company so as to grasp a comprehensive understanding of the existing risks and the status of controls in the group. Common risks that apply to the whole group are studied closely and the significant risks are gathered and identified. Based on the results of this process, the Risk Management Committee assigns priority to significant risks that could have major impact on the group's business, for such as financial losses or business continuity.

Otsuka Holdings and our main operating companies develop and implement countermeasures to each significant risk based on the characteristics and risk tolerance. Otsuka Holdings provides the necessary guidance and support to group companies, which submit reports and seek advice from Otsuka Holdings, as appropriate. In these activities, the whole group coordinates closely to promote and practice ERM. Moreover, Otsuka Holdings and group companies work to prevent risks from becoming real by regularly monitoring them and confirming that they are within their respective tolerance levels.



Business Continuity Planning and Management

The Otsuka group has business continuity plans (BCPs) in place to minimize the impact on our business activities and ensure that the group continues to operate as effectively as possible in order to maintain the stable supply of products, even when largescale earthquakes and disasters strike.

In terms of business continuity management (BCM), Otsuka Holdings and all major group companies (Otsuka Pharmaceutical, Otsuka Pharmaceutical Factory, Taiho Pharmaceutical, Otsuka Warehouse, Otsuka Chemical, etc.) have partnered to create a system to tackle business continuity on a group-wide scale. Since acquiring ISO 22301 certification for the production and stable supply of pharmaceutical products, beverages, and foods in 2012, we have gradually expanded the scope of certification to include the stable supply of intravenous solutions (in 2015) and the stable supply of anticancer agents (in 2016). The acquisition of ISO 22301 certification demonstrates that our organization complies with international standards and is fully covered, from a BCP standpoint. In addition, the Otsuka group as a whole is working to strengthen measures and systems to minimize the impact on business activities in the event of an emergency. Every year, we conduct joint simulation drills for different scenarios, such as natural disasters and the spread of infectious diseases. These drills provide the opportunity to test our framework for cooperation under close-to-realistic conditions, with a focus on ensuring stable product supply.

Risk Management Training

Risk management training is held annually for directors, Audit & Supervisory Board members, executive officers, and department heads of major group companies. Training includes simulation drills and lectures by outside experts, and involves discussions and reviews on domestic and overseas risks, referencing serious incidents and other matters. Topics include the initial response and coordination of information among the group when a crisis occurs, measures to ensure business continuity, and corporate social responsibility.

Information Security

The Otsuka group has established the Otsuka Group Global Security Policy as its basic policy on information security. We endeavor to ensure shared awareness of the policy at all group companies, including overseas subsidiaries. In striving to raise the level of, and constantly improve, comprehensive security across the group, we set up the Otsuka Group Information Security Committee to examine specific measures and to share up-to-date information with regard to information security based on the policy. To counter the risk of cyberattacks, the Otsuka group employs a number of measures, such as arranging system security audits by external specialists, diagnosing website vulnerabilities, conducting drills related to targeted email attacks, and monitoring posts on social media. The group also conducts regular emergency drills with a focus on the core systems that construct data. In addition, we have built capabilities for responding to cybersecurity emergency situations, including the establishment of the Computer Security Incident Response Team (CSIRT), which preempts the occurrence of damage from cyberattacks targeting personal information and trade secrets held by respective group companies.

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Contribution to Communities

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The Otsuka group contributes to regional development by working together with local residents on social and cultural projects. In particular, we are investing in areas that include maintaining and improving people's health as well as disaster relief, and other projects connected to our business domains from a medium- to long-term perspective. In 2021, the Otsuka group donated ¥6.6 billion for initiatives that included disaster relief.

Examples of Activities

SATU HATI (One Heart) in Indonesia

PT Amerta Indah Otsuka (AIO) has implemented a social action program for over 15 years in Indonesia based on the three pillars: education, the environment, and health.



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POCARI SWEAT manufacturer and distributor P.T. Amerta Indah Otsuka (AIO) developed a social action program called SATU HATI after providing support to areas affected by the 2006 Yogyakarta earthquake to give back to the local community in Indonesia. The scope of the activities has been increased every year, and focus is on now the three pillars: education, the environment, and health.

In 2020, the Otsuka Eco Village initiative was launched as part of the SATU HATI to promote waste disposal and resource recycling. With the aim of encouraging building a community that can manage waste independently together with local residents, AIO supports initial awareness raising as well as building the infrastructure in several ways, including donating facilities for a recycling bank.

Initiatives of US-based Sozosei Foundation

The Sozosei Foundation was established to spread awareness of medical issues, distribute information, and promote education on medical care and health, as well as contribute to related organizations in the United States.



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The Sozosei Foundation was established in 2019 by Otsuka America Pharmaceutical Inc., a US group company, to spread awareness of medical issues, distribute information, and promote education on medical care and health, as well as contribute to related organizations in the U.S. The name *sozosei* means “creativity” in Japanese. In addition to support in the psychiatric and neurological areas, the Foundation centers its activities on disaster relief and contributions to local communities.

Social Contribution Program Using

Crowdfunding

Taiho Pharmaceutical implements a social contribution program to support groups and individuals working to solve issues in the field of oncology that cannot be resolved with drugs alone.



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The company launched the Taiho Smile Support program in 2021. Taiho Pharmaceutical uses a website to call for organizations and individuals who plan to use crowdfunding to raise funds to address social issues. Selected organizations and individuals will conduct a crowdfunding campaign and if they raise 50% of the funds required for the project, Taiho Pharmaceutical will match this amount through a donation.

Contributing to Local Communities through

Sports

In addition to supporting soccer teams, we are involved in corporate sports through the Otsuka Pharmaceutical Track and Field Club.



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Tokushima Vortis is a J.League soccer team formed in 2004 as a way of contributing to the vitalization of the local community. The team has its origins as the Otsuka Pharmaceutical corporate soccer team initially formed in 1955. After changing its name to Tokushima Vortis, the team was promoted to the J.League in 2005. Since 2005, the Otsuka group continues to sponsor the team and offer support by advising players on health and nutrition and by assisting with events at the team's home stadium. Beyond playing soccer, Tokushima Vortis also works to solve issues affecting Tokushima Prefecture. Activities include soccer workshops for diverse age groups, from children to seniors. Furthermore, the team has been working with Otsuka Pharmaceutical and Mima City on a new project, the Vortis Conditioning Program, the first example of a social impact bond (SIB)* in the healthcare field involving a J.League team. Through these activities, players and coaches from Tokushima Vortis are helping local residents to maintain and improve their health as well encouraging them to take a greater interest in sport.

*Social impact bonds are outcome-based programs where private-sector funds are used for initiatives that address social issues. Local governments then later reimburse or subsidize the costs according to the program's level of success.

Established in 1990, the Otsuka Pharmaceutical Track and Field Club sends

Established in 1990, the Otsuka Pharmaceutical Track and Field Club sends athletes to represent Japan at international championships. In addition to their participation in training sessions, club members contribute to the local community by holding track and field workshops. Furthermore, since 2016, with the help of the Tokushima Track and Field Association, the club has held the Tokushima Athlete Meeting, which aims to encourage and support junior athletes in Tokushima Prefecture.

These are just a few examples of the wide range of sports-related projects that the Otsuka group continues to support as part of its contribution to the development of local communities.

Disaster Relief

We deliver Otsuka products and other items in a disaster.



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[— close](#)

The Otsuka group provides support by delivering Otsuka products and making donations following a disaster. As an example, when the Great East Japan Earthquake struck, the Otsuka group mobilized local offices to provide emergency relief supplies, such as beverages, water, and food. Otsuka group employees from across Japan took turns assisting relief efforts from a base in Sendai City, supplying oral rehydration solutions to evacuation centers to address dehydration among evacuees and leveraging Otsuka's assets for relief efforts. The Otsuka group also provided relief supplies in response to requests from government agencies and industry associations, and Otsuka Holdings made a large donation to the Japanese Red Cross Society on behalf of the 39,000 employees of the Otsuka group following calls for assistance from overseas group employees.

Initiatives related to COVID-19

We played a part to help contain the spread of infection.



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The Otsuka group provided its products such as POCARI SWEAT, BODYMAINTÉ, Calorie Mate, and OS-1, as well as masks and protective clothing across Japan through local governments and affiliated organizations to prevent the spread of COVID-19. Overseas, we donated to local medical facilities and the Red Cross, and other institutions in addition to providing Otsuka beverages, foods, and medicines. For example, the US-based Sozosei Foundation donated \$939,000 (approximately ¥100 million) to five charitable organizations and four organizations related to mental health and kidney disease.

Together with the Local Communities in

Tokushima

As a company that originated in Tokushima, we continue to implement initiatives deeply rooted in the local communities.



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[— close](#)

The Traditional Culture of the Awa Odori

As a company with its origins in Tokushima, we are keen to promote traditional Tokushima culture, and the most well-known aspect of Tokushima culture has to be the Awa Odori. Boasting 400 years of history, the Awa Odori is the most famous of many dance festivals held across Japan. At Awa Odori events, each team is known as a “*ren*,” and every year, four *rens* from the Otsuka group join the festival. The first is the Otsuka *ren*, which consists of more than one hundred workers from Otsuka Pharmaceutical. The second is the Otsuka Uzumaki *ren*, which inherited its name from the oldest *ren* from Naruto City, and consists of members from Otsuka Pharmaceutical Factory. The third is the Tiovita *ren*, from Taiho Pharmaceutical, which has a very fun and friendly spirit. Finally, taking its name from the Japanese word for ‘energetic,’ the Otsuka Hatsuratsu *ren*, which celebrated its 30th anniversary in 2016, comprises members from Otsuka Chemical, Otsuka Warehouse, and Otsuka Foods.

As well as dancing, members of the *ren* also play musical instruments, such as shamisen, gongs, drums, and flutes. Learning how to play these instruments, as well as coming up with new dance formations, creates new challenges for our staff—everyone takes it seriously and gives their best performance so that both participants and onlookers have a memorable experience.

An Annual Concert Held for Around 30

Established Otsuka Museum of Art

The Otsuka Museum of Art was founded in Naruto City, Tokushima Prefecture, the birthplace of Otsuka, to commemorate our 75th anniversary.



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[— close](#)

To commemorate the 75th anniversary of our founding, we opened The Otsuka Museum of Art in Naruto City, Tokushima Prefecture, the birthplace of the Otsuka group of companies. This museum is one of the largest permanent exhibition spaces in Japan,* and houses over 1,000 ceramic reproductions of major works of Western art. Otsuka Ohmi Ceramics used special techniques to make actual-size ceramic reproductions of various works of art, from ancient wall paintings to modern paintings, originally exhibited in around 190 art museums in 26 countries. It is typical for original artworks to become discolored or to deteriorate due to environmental pollution, or sometimes even to suffer more extensive damage from disasters such as earthquakes or fires, but these ceramic reproductions should maintain their original color and shape for more than 2,000 years.

This unique approach of creating ceramic reproductions of masterpieces has incorporated many creative and unique ideas. For instance, the six parts of El Greco's “Santo Domingo el Antiguo Altarpiece” cannot usually be seen together at one time. However, our approach to creating a reproduction of this famous altarpiece has made it possible. We have also created a comparative exhibition of *The Last Supper* by Leonardo da Vinci, where visitors can see it before and after its restoration. Furthermore, we chose to exhibit our reproduction of Monet's *The Water Lilies* outdoors to fulfill the painter's

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An Annual Concert Held for Around 30 Years

Exciting Summer in WAJIKI

Each year during the Awa Odori season, Otsuka Pharmaceutical, with the help of local authorities, holds Exciting Summer in WAJIKI, a free outdoor concert on the premises of the Tokushima Wajiki factory. The event started in 1990, the year following the founding of the town of Wajiki (which in 2005 became incorporated into the new town of Naka), with the hope that with the help of young people from local authorities, industries, and associations, we could transform the rural community into a place where young people could come together. In 2019, around 3,500 people from all over Japan attended the concert. In addition, the Oronamin C Drink Presents Awa Odori Sound Festival, another free concert, has been held every year in Tokushima City since 1990 on the eve of the Awa Odori festival. The lineup boasts a large variety of artists and genres, and people of all ages can enjoy a delightful summer night of music.

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* Total floor space: 29,412 m²

Sustainability Data

Key environmental, social, and governance data can be found in a list.

- > [Key Sustainability Data](#)  386KB
- > [Environmental Data](#)  423KB
- > [Fiscal Goals 2023 and Fiscal 2020 Progress](#)  557KB

ISO Management System Certification Status

- > [ISO Certification \(in Japan\)](#)  156KB

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Key Sustainability Data

Employees

Classification	Items	Scope	Unit	FY2017	FY2018	FY2019	FY2020	FY2021	
Employees	by region	169 consolidated companies	total	persons	32,817	32,935	32,992	33,151	33,226
			Japan	%	42.3%	41.8%	40.5%	40.2%	39.7%
			Outside Japan	%	57.7%	58.2%	59.6%	59.8%	60.3%
	by gender ^{*1}	19 companies ^{*4}	Men	%	73.4%	72.7%	72.0%	71.5%	71.8%
			Women	%	26.6%	27.3%	28.1%	28.5%	28.2%
Percentage of employees by age group	19 companies ^{*4}		Under 30	%	15.2%	15.6%	15.8%	15.9%	16.2%
			30-49	%	54.7%	54.1%	53.9%	53.0%	53.8%
			50 and over	%	30.1%	30.3%	30.3%	31.1%	30.0%
Newly hired ratio by gender ^{*2}	19 companies ^{*4}		Men	%	61.3%	62.9%	60.1%	63.7%	59.4%
			Women	%	38.7%	37.1%	39.9%	36.3%	40.6%
Turnover ratio ^{*3}	19 companies ^{*4}		total	%	3.6%	4.1%	4.5%	4.0%	5.1%
Female manager ratio	19 companies ^{*4}		Women	%	7.8%	8.1%	10.3%	10.4%	10.4%
Employees taking parental leave ^{*7}	19 companies ^{*4}		Men	persons	101	136	210	280	341
			Women	persons	177	151	303	268	296
Rate of men's taking parental leave	19 companies ^{*4}		Men	%	18.7%	17.0%	23.6%	29.8%	35.6%
Employees with disabilities	16 companies ^{*6}		Japan	%	2.0%	2.2%	2.3%	2.1%	2.3%
Health checkup rate ^{*7}			Japan	%	—	—	—	76.5%	80.0%
Implementation of specified healthcare guidance ^{*7}			Japan	%	—	—	—	47.5%	72.8%
Work-related fatalities (employees)	19 companies ^{*8}		total	number	—	—	—	0	0
Work-related fatalities (contractors)	19 companies ^{*8}		total	number	—	—	—	0	0
Lost time injury/illness frequency rate	19 companies ^{*8}		total	%	—	—	—	1.11	0.70
Lost time injury/illness severity rate	19 companies ^{*8}		total	%	—	—	—	0.00	0.02
Average age	Otsuka Holdings		Japan	years old	44.3	44.0	43.8	44.1	43.8
Average length of service	Otsuka Holdings		Japan	years	3.5	3.3	2.9	3.6	3.7
Average annual pay	Otsuka Holdings		Japan	yen	10,762,985	10,549,652	10,323,328	9,916,447	10,445,476

*1 Regular employees including operating officers

*2 Newly hired regular employees including mid-career recruitment

*3 Ratio of employees retiring for personal reasons

*4 FY2017- FY2019 ; The data of 9 major companies(Otsuka Pharmaceutical, Otsuka Pharmaceutical Factory, Taiho Pharmaceutical,Otsuka Warehouse, Otsuka Chemical, Otsuka Foods, Otsuka Pharmaceutical Development & Commercialization, Otsuka America Pharmaceutical, Pharmavite);FY2020 ; The data of 11 major companies (9 major companies + Otsuka Holdings and Otsuka Medical Devices) - FY 2021 ; The data of 19 major companies (11 major companies +Otsuka Electronics, Otsuka Techno, Okayama Taiho Pharmaceutical, Otsuka Packaging Industries, Otsuka Ohmi Ceramics, Higashiyama Film, Otsuka Wellness Vending, and JIMRO)

*5 FY2017-2018 ; The data of 6 major companies (Otsuka Pharmaceutical, Otsuka Pharmaceutical Factory, Taiho Pharmaceutical,Otsuka Warehouse, Otsuka Chemical, Otsuka Foods) FY2019 ; The data of 9 major companies (*4), FY2020 ; The data of 11 major companies (*4), FY 2021 ; The data of 19 major companies (*4)

*6 Otsuka Holdings, Otsuka Pharmaceutical, Otsuka Pharmaceutical Factory, Taiho Pharmaceutical,Otsuka Warehouse, Otsuka Chemical, Otsuka Foods, Otsuka Medical Devices,Otsuka Electronics, Otsuka Techno, Okayama Taiho Pharmaceutical, Otsuka Packaging Industries, Otsuka Ohmi Ceramics, Higashiyama Film, Otsuka Wellness Vending, and JIMRO

*7 Insured persons and their dependents who are members of the Otsuka Pharmaceutical Health Insurance Association (for Otsuka group companies in Japan)

*8 FY2020- FY2021 ; The data of 19 companies is the same as the data of FY2021(*4)

Corporate Governance

Organization Company with an Audit & Supervisory Board

Term of Directors One year

Classification	Items	Scope	Unit	2018MAR	2019MAR	2020MAR	2021MAR	2022MAR
Structure	Board of Directors	Directors	persons	11	12	13	13	13
		Outside directors	persons	3	3	4	4	5
		Female directors	persons	2	2	3	3	3
	Audit & Supervisory Board	Audit & Supervisory Board	persons	4	4	4	4	4
		Outside Audit & Supervisory Board	persons	3	3	3	3	3
	Corporate Governance Committee	Members	persons	5	5	6	6	7
Outside directors		persons	3	3	4	4	5	
Chair		—	CEO	CEO	CEO	CEO	CEO	

Classification	Items	Scope	Unit	FY2017	FY2018	FY2019	FY2020	FY2021
Remuneration	Directors (excluding outside directors)	Officers who receive basic remuneration	persons	7	8	9	10	9
		Total remuneration	¥ mil	580	350	544	868	724
		Basic remuneration	¥ mil	259	273	296	302	302
		Amount charged as cost of stock options	¥ mil	197	-45	—	—	—
		Remuneration provided through restricted stock remuneration plan	¥ mil	—	—	104	421	292
		Bonus	¥ mil	123	123	144	144	129
	Audit & Supervisory Board (excluding outside Audit & Supervisory Board members)	Officers who receive basic remuneration	persons	1	2	1	1	1
		Total remuneration	¥ mil	30	25	24	24	24
	Outside directors	Officers who receive basic remuneration	persons	6	8	7	7	7
		Total remuneration	¥ mil	54	54	54	59	72

Shareholders	Name of shareholders	Number of shares held (thousand)	Shareholding ratio (%)
FY2020 <small>(As of December 31, 2020)</small>	The Master Trust Bank of Japan, Ltd. (trust account)	68,567	12.64
	The Nomura Trust and Banking Co., Ltd.	—	—
	Otsuka Founders Shareholding Fund Trust Account	56,216	10.36
	Otsuka Estate Co., Ltd.	23,316	4.29
	Custody Bank of Japan, Ltd. (trust account)	23,137	4.26
	Otsuka Group Employee Shareholding Fund	13,175	2.42
	The Awa Bank, Ltd.	10,970	2.02
	JP MORGAN CHASE BANK 385635	8,862	1.63
	JP MORGAN CHASE BANK 380072	7,964	1.46
	SMBC Nikko Securities Inc.	7,933	1.46
Otsuka Asset Co., Ltd.	7,380	1.36	

1. Number of shares held is rounded down to the nearest thousand.

2. Although the Company holds 15,443,722 of its own shares, treasury shares are excluded from the above list.

3. Shareholding ratio is calculated after treasury shares are deducted.

Materiality (Material Issues)

In 2019, the Otsuka group determined its material issues based on their importance to society and to the group's businesses. They are: *society (health, people, quality in all we do)*, *environment (climate change, resource recycling and conservation, and water conservation)*, and *governance*.

Materiality	Social Issues	Our Goals	Our Activities	Related SDGs	Social Issues	Our Goals	FY 2023 Goals	FY 2020 Progress			
Society (Healthier Society)	Health	<ul style="list-style-type: none"> 1 Unmet medical and health needs 2 Spread of infectious diseases 3 Nutritional needs 4 Increasing aging issues 	<ul style="list-style-type: none"> Contribution to unmet needs solutions R&D of antituberculosis drugs Creation of a system for the realization of a healthful life Healthy life extension 	<ul style="list-style-type: none"> Promotion of R&D for unmet needs R&D of antituberculosis drugs and improvement of drug access Support and awareness activities for people's health maintenance/improvement mainly on exercise and nutrition etc. Promotion of problem solving by strengthening partnerships 		<ul style="list-style-type: none"> 1 Contribute to unmet needs solutions 	<ul style="list-style-type: none"> Promotion of R&D for unmet needs Address unmet needs in the psychiatry and neurology areas Create first-in-class products in the oncology area Create first-in-class products in the cardiovascular and renal area In areas with unmet needs: <ul style="list-style-type: none"> New development projects: 10 or more Late-phase development projects advancing to the next phase: 30 or more 	<ul style="list-style-type: none"> In areas with unmet needs¹ New development projects: 9 projects² Late-phase development projects: 9 projects³ 			
	People	<ul style="list-style-type: none"> 5 Presenteeism⁴ 6 Unprepared for diversification 	<ul style="list-style-type: none"> Creation of a corporate culture that stimulates creativity Enhance employee engagement 	<ul style="list-style-type: none"> Human resource development Diversity promotion Healthful management 		<ul style="list-style-type: none"> 2 Eradication of tuberculosis 	<ul style="list-style-type: none"> Provide DELTYBA (generic name: delamanid) for a cumulative total of 60,000 cases Supply DELTYBA for pediatric patients Launch a clinical trial for new treatment regimen Increase access to DELTYBA by collaborating with partners 	<ul style="list-style-type: none"> DELTYBA <ul style="list-style-type: none"> Provided DELTYBA for 40,000 a cumulative total of cases in more than 110 countries/regions Acquired the indication of DELTYBA for children in Europe in October 2020 8-pharm acquired marketing approval for DELTYBA in Russia in May 2020 Implemented supply through the Global Drug Facility (GDF) of the Stop TB Partnership and alliance partners Participated in Pan-TB collaboration and accelerated the development of new TB treatment regimen Continued participation in the Global Health Innovative Technology (GHIT) Fund 			
	Quality in All We Do	<ul style="list-style-type: none"> 7 Consumption and production that impairs sustainability 	<ul style="list-style-type: none"> Gaining stakeholder trust Pursuing sustainability at all levels of the value chain Establishing a quality assurance system for safety and security 	<ul style="list-style-type: none"> Sustainable procurement and product design Thorough quality control and stable supply Responsible promotional activities and information provision Deepening communication with stakeholders Promotion of "Customer-centric management" 		<ul style="list-style-type: none"> 3 Creation of a system for the realization of a healthful life 	<ul style="list-style-type: none"> Challenge new categories and new areas Create new systems and reinforce existing systems for realizing healthy lifestyles Create new concepts and products keeping an eye on changes in environments 	<ul style="list-style-type: none"> Further increased the supply of plant-based food products by starting operations at a new manufacturing site Executed cooperation agreements with all 47 prefectures and promoted collaboration in health and other fields Continued to hold the Women's Health Seminars 30th anniversary of the Otsuka Health Comic Library Cumulative total OAHAS⁵ registrants: Approximately 20,000 Started the "Healthy President" service 			
Environment (Healthier Planet)	Climate Change	<ul style="list-style-type: none"> 8 Global warming 	<ul style="list-style-type: none"> FY 2030 Goal 30% reduction in CO₂ emissions compared to FY 2017 	<ul style="list-style-type: none"> Reduce CO₂ emissions throughout the value chain 		<ul style="list-style-type: none"> 6 Creation of a corporate culture that stimulates creativity Enhanced employee engagement 	<ul style="list-style-type: none"> Further instill the corporate culture and philosophy Build systems for ongoing human resource development aligned with changes in society and in the times Further promote and instill diversity as a source of innovation 	<ul style="list-style-type: none"> Cumulative total participants in the executive human resource development programs of Otsuka Global Academy (OGA): 17⁶ Cumulative total participants in Health Seminars: approx. 1,500 Implemented health and safety measures for employees during the COVID-19 pandemic Formulated the "Otsuka Group Human Rights Policy" 			
	Resource Recycling and Conservation	<ul style="list-style-type: none"> 9 Environmental load increase 	<ul style="list-style-type: none"> FY 2030 Goal 50% reduction in simple incineration and landfill compared to FY 2019 50% or higher content of recycled and plant-based materials in our PET bottles 	<ul style="list-style-type: none"> Reduce environmental impact by improving resource efficiency Promotion of business activities aimed at a sustainable state of society and the earth 					<ul style="list-style-type: none"> 7 Pursuing sustainability at all levels of the value chain 	<ul style="list-style-type: none"> Self-assessment questionnaire (SAQ) survey conducted on: 200 companies Sustainable procurement Conducted supplier briefings for 160 suppliers Original goal: Over 30 times/companies by fiscal 2023) 	<ul style="list-style-type: none"> Cumulative total of companies implementing SAQ: 80 Companies participating in supplier briefings: 73 Stable supply of products during the COVID-19 pandemic Held global production meetings and environmental management information exchange meetings Held global product quality meetings Improved products based on customer feedback
	Water Conservation	<ul style="list-style-type: none"> 10 Reducing in freshwater availability due to water resource risks 	<ul style="list-style-type: none"> FY 2030 Goal Improvement of water use efficiency by 15% compared to FY 2017 	<ul style="list-style-type: none"> Understanding water resource risks Management and effective use of water resources 					<ul style="list-style-type: none"> 8 FY 2030 Goal 30% reduction in CO₂ emissions compared to FY 2017 	<ul style="list-style-type: none"> Introduce renewable energy and raise the usage rate of CO₂-free electricity 	<ul style="list-style-type: none"> Acquired ISO14001 integrated certification Expanded the introduction of CO₂-free electricity⁵ Introduced co-generation system and solar power generation facilities Switched supply to green power for office departments of five group companies
Governance		<ul style="list-style-type: none"> 11 Fragile governance system 12 Social change risk 	<ul style="list-style-type: none"> Long-term improvement of corporate value 	<ul style="list-style-type: none"> Strengthen corporate governance Thorough compliance Risk identification, evaluation and management 		<ul style="list-style-type: none"> 9 FY 2030 Goal 50% reduction in simple incineration and landfill volume Build an internal group system for improving the usage rate of recycled and plant-based materials 	<ul style="list-style-type: none"> Established the Otsuka Group Plastic Policy 				
		<ul style="list-style-type: none"> 10 FY 2030 Goal Improved water use efficiency by 15% compared to FY 201 	<ul style="list-style-type: none"> Understanding water resource risks Management and effective use of water resources 	<ul style="list-style-type: none"> 10 Promote of R&D for unmet needs 	<ul style="list-style-type: none"> Build a system to strengthen compliance within the group Strengthen corporate governance to further raise effectiveness Build a governance system capable of global business development and response to various changes 	<ul style="list-style-type: none"> Carried out water resource risk assessments using Aqueudat⁶ Formulated water resource risk analysis charts at each manufacturing site, and identified watershed issues around the sites 					
<p>* The situation where productivity does not go up due to the poor condition of the mind and body despite coming to work</p>					<p>1. Unmet needs areas defined by Otsuka based on PatientsMap2020IP and PatientsMap2020US, M3 & SSR 2. Cumulative total since 2019 3. Otsuka Advanced Training for Healthy Aging Supporters: A program that supports pharmacies as health information hubs with strong connections to local communities 4. As of December 31, 2020 5. Including carbon-neutral electricity 6. Water resource risk assessment tool developed by the World Resources Institute</p>						

Fiscal Goals 2023 and Fiscal 2020 Progress

Among the 12 social issues determined to be Otsuka group's materiality, we selected nine issues that we regard as especially important at present, and set goals related to them for fiscal 2023.

(As of September 30, 2020)

International Certification at Manufacturing Sites of Major Group Companies in Japan

Company	Manufacturing Site	Products Manufactured	Environment ISO 14001*	Quality ISO 9001 (ISO 9002)	Food Safety FSSC 22000 (ISO 22000)
Otsuka Pharmaceutical	Itano, Tokushima	Pharmaceuticals and food products	●		● (●)
	Wajiki, Tokushima	Pharmaceuticals and food products	●		●
	Tokushima	Pharmaceuticals	●		
	Second Tokushima	Pharmaceuticals and food products	●		●
	Takasaki	Food products	●		●
	Fukuroi	Food products	●		●
	Saga	Pharmaceuticals and food products	●		● (●)
Otsuka Pharmaceutical Factory	Toyama	Pharmaceutical products	●		
	Kushiro	Pharmaceutical products	●		
	Naruto	Pharmaceutical products	●		
	Matsushige	Pharmaceutical products	●		
Taiho Pharmaceutical	Saitama	Pharmaceutical products	●		
	Tokushima	Pharmaceutical products	●		
	Kitajima	Pharmaceutical products	●		
Otsuka Chemical	Tokushima	Chemicals	●	(●)	
	Naruto	Chemicals	●	(●)	
	Matsushige	Chemicals	●	●	
Otsuka Foods	Tokushima	Food products	●	●	
	Kushiro	Food products	●	●	
	Shiga	Food products	●	●	
	Gunma	Food products	●	●	

ISO 14001: International standard for environmental management systems (EMS)

* In August 2020, five companies in Japan (Otsuka Pharmaceutical, Otsuka Pharmaceutical Factory, Taiho Pharmaceutical, Otsuka Chemical, Otsuka Foods) and Otsuka Holdings Co., Ltd. as the supervising organization acquired integrated ISO 14001 certification.

ISO 9001: International standard for product design, development, manufacturing, installation and quality of incidental services

ISO 9002: International standard for product manufacturing, installation and quality of incidental services

ISO 22000: International standard for food safety management systems (FSMS)

FSSC 22000: An international standard for food safety management systems that supplements ISO 22000 with additional requirements

[For reference]

(As of September 30, 2020)




Facilities Certified as Meeting the Requirements of ISO 14001

(Total: 28 facilities)

Facilities		Facilities	
Otsuka Holdings			Environment Management General Affairs Dept.
Otsuka Pharmaceutical	Production Headquarters	Taiho Pharmaceutical	Tokushima Site (including the Tokushima Factory)
	Tokushima Factory		Saitama Site (including the Saitama Factory)
	Second Tokushima Factory		Kitajima Site (including the Kitajima Factory)
	Tokushima Wajiki Factory		Okayama Site: Okayama Taiho Pharmaceutical Co., Ltd.
	Tokushima Itano Factory		
	Saga Factory		
	Takasaki Factory	Naruto Site (including the Naruto Factory)	
	Fukuroi Factory	Otsuka Chemical	Matsushige Site (including the Matsushige Factory)
	Fujii Memorial Research Institute	Otsuka Foods	Tokushima Factory
	Otsu Skin Care Research Institute		Shiga Factory
Otsu Nutraceuticals Research Institute	Kushiro Factory		
	Gunma Factory		
Otsuka Pharmaceutical Factory	Naruto Site (including the Naruto Factory)		
	Matsushige Factory		
	Toyama Factory		
	Kushiro Factory		

ESG control chart







* Links in the following table are inactive.

Item			Policies, commitments and systems	Initiatives
Overall			<ul style="list-style-type: none"> • Signatory to the United Nations Global Compact • Sustainability Mission • Materiality • Approach to Sustainability • Goals and progress • Stakeholder engagement • Sustainability management structure • External recognition • Key Sustainability Data(people, the environment, and governance) 	
	Health		<ul style="list-style-type: none"> • Basic policy 	
		Pharmaceutical Business	<ul style="list-style-type: none"> • Basic policy • Goals and progress 	<ul style="list-style-type: none"> • Contribution to unmet medical needs • Initiatives for access to medicine • Initiatives for infectious diseases including tuberculosis
		Nutraceutical Business	<ul style="list-style-type: none"> • Basic policy • Goals and progress 	<ul style="list-style-type: none"> • Catering to yet-to-be-imagined needs • Initiatives for Access to Nutrition
	People		<ul style="list-style-type: none"> • Basic policy 	
		Human resource development	<ul style="list-style-type: none"> • Basic policy 	<ul style="list-style-type: none"> • Human resource development programs (including management human resource development programs) • Internship programs • Systems for leveraging abilities (open recruiting system, self-assessment system, etc.)
		Diversity & Inclusion	<ul style="list-style-type: none"> • "Otsuka Group Global Code of Business Ethics" ("Diversity and Inclusion")  • Basic policy • Signatory to the Women's Empowerment Principles (WEPs) • Iku Boss (managers supportive of work-life balance) declaration by group companies (Otsuka Pharmaceutical Co., Ltd.) 	<ul style="list-style-type: none"> • Diversity • Systems for diversity promotion (including mindset and establishing structure to help diverse human resources play active roles regardless of nationality, race, age, gender, disability, sexual orientation, etc.) • Examples of external recognition
		Health and Safety	<ul style="list-style-type: none"> • Otsuka Group Global Code of Business Ethics("Human Rights and Labor Standards" and "Employee Health")  • Basic policy • Declaration on health by group companies • "Health and Safety Committee" and other promotion structures 	<ul style="list-style-type: none"> • Initiatives for employee health maintenance and promotion • Initiatives for workplace health and safety • Initiatives for reduction overtime and encouraging employees to take paid leave • Examples of external recognition
	Fair employment and working condition	<ul style="list-style-type: none"> • Otsuka Group Global Code of Business Ethics("Human Rights and Labor Standards," "Discrimination and Harassment," and "Reporting Concerns")  • Basic policy 	<ul style="list-style-type: none"> • Internal training on bullying, harassment and other issues • Employee survey, and improvement activities based on survey results 	

Society

	Human rights initiatives	<ul style="list-style-type: none"> • Otsuka Group Global Code of Business Ethics("Human Rights and Labor Standards," "Discrimination and Harassment," and "Reporting Concerns")  • Basic policy • Otsuka Group Human Rights Policy • Promotional structure 	<ul style="list-style-type: none"> • Implementing human right risk assessment to identify salient human right risks • Identifying salient human right issues and implementing corrective measures • Whistleblowing hotline • Employee training on Otsuka Group Human Rights Policy • External collaboration
	Quality in All We Do	<ul style="list-style-type: none"> • Basic policy • Otsuka Group Global Code of Business Ethics ("Business Integrity," "Maintaining Books and Records," etc.)  • Certification status of ISO 9001 (quality), ISO 22000, FSSC 22000 (food safety), etc. 	
	Research and development	<ul style="list-style-type: none"> • Commitments in R&D (compliance with laws and guidelines, ethical considerations, etc.) 	<ul style="list-style-type: none"> • Ethical considerations in research involving animals • Ethical considerations in research Involving human-derived specimens • Ethical considerations in research involving pathogenic microorganisms (pathogens) and genetically modified organisms • Ethics in clinical trials • Compliance in R&D by Otsuka group companies • Management of public research funds
	Procurement	<ul style="list-style-type: none"> • Basic policy • Otsuka Group Procurement Policy • Otsuka Group Sustainable Procurement Guidelines  • Sustainable procurement Promotional structure (establishment of the Otsuka Sustainable Procurement Task Force) • Goals and progress 	<ul style="list-style-type: none"> • Promotion of sustainable procurement with consideration for the environment, human rights other matters. (including due diligence investigation on new suppliers, and the common SAQ and briefing sessions for business collaborators) • Joint business collaborator audit by pharmaceutical companies • Global initiatives for streamlining production and supply of products
	Production, quality control and patient/customer safety	<ul style="list-style-type: none"> • Basic policy • Measures including global product quality policies for the pharmaceutical products of Otsuka Pharmaceutical • Promotion structure including Global Production Meeting and Global Product Quality Meetings. 	<ul style="list-style-type: none"> • Production, quality control and patient/customer safety in compliance with and regulatory requirements, and governmental and industry standards • Acquisition of ISO 9001 (quality), ISO 22000, FSSC 22000 (food safety), etc.  • Quality control based on GQP and GVP, and post-marketing safety management • Global implementation of pharmacovigilance activities • Measures against falsified medicines • Employee training • Examples of external recognition (Initiatives for improvement at Otsuka Pharmaceutical Factory, Inc.)
	Logistics	<ul style="list-style-type: none"> • Basic policy • Establishment of the GDP Promotion Office and other promotion structures for control and maintenance of product quality and stable supply in logistics 	<ul style="list-style-type: none"> • Initiatives for quality control and maintenance (promotion of logistics in compliance with the Good Distribution Practice (GDP) guidelines, employee training, etc.) • Initiatives for streamlined cooperation among shippers and distributors (standardization of IT-based data systems, digitization of forms, etc.) • Initiatives for stable supply (distribution storage of inventory, registration of vehicles for authorized access to restricted areas, etc.) • Environmentally friendly measures (the promotion of modal shift to reduce CO₂ emissions) • Examples of external recognition (Initiatives for CO₂ emission at Otsuka Warehouse CO.,Ltd.) (in Japanese)

		Sales and Marketing	<ul style="list-style-type: none"> • Basic policy • Establishing internal code of practice that expand on the JPMA Promotion Code for Prescription Drugs, for activities targeted at healthcare professionals • Structural measures such as establishing the Scientific Affairs Department for gathering and disseminating information about products, related knowledge, and the latest academic information, and dedicated review unit to ensure appropriate marketing and promotion activities 	<ul style="list-style-type: none"> • Conducting appropriate marketing and promotion activities in compliance with laws and regulations • Gathering and disseminating information about products, related knowledge, latest academic information, etc. • Employee training • Reducing food loss (extending shelf life, switching to month-based expiration dates, etc.)
		Customer Service	<ul style="list-style-type: none"> • Basic policy • Declaration of Customer-centric Commitment • Group-wide Customer Service Liaison Meeting, cross department "Listen to Customer Feedback Meeting," and other promotion structures for consumer-centric management 	<ul style="list-style-type: none"> • Promoting customer-centric management • Ensuring appropriate communication with customers • Improved products based on customer feedback • Establishing dedicated contact points for patients, healthcare professionals and customers respectively
Environment	Environmental management		<ul style="list-style-type: none"> • Otsuka Group Global Code of Business Ethics ("Environmental Protection")  • Otsuka Group Environmental Policy • Otsuka Group Environmental Activity Guidelines • Group promotional structures centering on the Otsuka Group Global Environmental Council • Disclosure of ISO 14001 certification status  	
	Carbon Neutrality		<ul style="list-style-type: none"> • Basic policy • Goals and progress 	<ul style="list-style-type: none"> • Initiatives for efficient energy use and CO₂ reduction (expanded use of renewable energy sources, such as by introduction of CO₂-free electricity, including solar power generation for in-house consumption, and purchase of Green Power Certificates, etc.) • Validation of goals under the Science Based Targets (SBT) initiative • Disclosure of CO₂ emissions and other data 
	Circular Economy		<ul style="list-style-type: none"> • Basic policy • Goals and progress 	<ul style="list-style-type: none"> • Initiatives to achieve zero waste • Initiatives for plastic resource and marine plastic pollution • Disclosure of waste volume (effective use volume and final disposal volume) and other data 
	Water Neutrality		<ul style="list-style-type: none"> • Basic policy • Goals and progress 	<ul style="list-style-type: none"> • Water risk evaluation at manufacturing sites • Disclosure of water usage, water use efficiency and other data. 








Governance	Corporate Governance		<ul style="list-style-type: none"> • Basic policy • Corporate Governance Guidelines 	
		Governance Structure	<ul style="list-style-type: none"> • Basic policy • Overview of governance structure 	<ul style="list-style-type: none"> • Initiatives to Strengthen Corporate Governance • Board of Directors, Audit & Supervisory Board and Corporate Governance Committee • Rationale for selection of directors and evaluation of board effectiveness • Skill matrix for directors and Audit & Supervisory Board members • Succession plan
		Remuneration for Directors and Audit & Supervisory Board Members	<ul style="list-style-type: none"> • Basic policy 	<ul style="list-style-type: none"> • Remuneration standards, system and method of determination
	Compliance	Overall	<ul style="list-style-type: none"> • Basic policy • Compliance promotion structure 	
		Tax Compliance	<ul style="list-style-type: none"> • Basic policy • Tax policy • Transfer pricing policy 	<ul style="list-style-type: none"> • Correspondence with tax authorities
		Anti-Corruption	<ul style="list-style-type: none"> • Otsuka Group Global Code of Business Ethics ("Bribery and Corruption," etc.)  • Otsuka Group Global Anti-Corruption Policy  	<ul style="list-style-type: none"> • Due diligence • Training for employees • Monitoring
		Conflicts of Interest	<ul style="list-style-type: none"> • Otsuka Group Global Code of Business Ethics ("Conflicts of Interest," etc.)  • Otsuka Group Global Policy for Conflict of Interest  	<ul style="list-style-type: none"> • Training for employees • Monitoring
		Protecting Privacy	<ul style="list-style-type: none"> • Otsuka Group Global Code of Business Ethics ("Privacy and Confidentiality," etc.)  • Otsuka Group Global Privacy Policy  	<ul style="list-style-type: none"> • Training for employees • Monitoring
		Whistleblowing Hotline		<ul style="list-style-type: none"> • Provision of internal and external whistleblowing hotlines
		Risk Management	Overall	<ul style="list-style-type: none"> • Basic policy • Risk Management Policy • Enterprise risk management Page 68 • Risk management system operated through the Risk Management Committee
Contribution to Communities		<ul style="list-style-type: none"> • Policy 	<ul style="list-style-type: none"> • Activities to Contribute to communities • Volunteer leave (Otsuka Pharmaceutical Co., Ltd.) 	







GRI Content Index

HOME > Sustainability > GRI Content Index

Otsuka group has reported the information cited in this GRI content index for Fiscal 2021 (January 1, 2021 to December 31, 2021) with reference to the GRI Standards.


* Links in the following table are inactive.

GRI Standards	Disclosures	References
1. The organization and its reporting practices		
2-1	Organizational details	Corporate Profile
		The Otsuka Group at a Glance
		Group Companies
2-2	Entities included in the organization's sustainability reporting	Integrated Report (P.82) Scope of Reporting 
		Environmental Report (P.2) Scope of Reporting 
2-3	Reporting period, frequency and contact point	Fiscal 2021 (January 1, 2021 to December 31, 2021)
		Annual
		Contacts (Japanese only)
2-4	Restatements of information	—
2-5	External assurance	Annual Securities Report (P.172-173 Japanese only) 
		Environmental Report 2021 (P.23) Third-Party Verification 
		Environment (Carbon Neutrality Third-Party Verification)
2. Activities and workers		
2-6	Activities, value chain and other business relationships	Our Four Businesses and R&D
2-7	Employees	The Otsuka Group at a Glance
		Sustainability Data 
		Annual Securities Report (P.19 Japanese only) 
2-8	Workers who are not employees	Annual Securities Report (P.19 Japanese only) 

3. Governance		
2-9	Governance structure and composition	Governance Structure
		Sustainability Management Structure
		Notice for the Calling of the 14th Annual Shareholders Meeting (P.7-24) 
		Sustainability Data 
		Risk Management System
		Environmental Management System
		Environmental Report (P.7) Environmental Management System 
		Human Rights Initiatives (Promotion System)
2-10	Nomination and selection of the highest governance body	Governance Structure
		Governance Structure
2-12	Role of the highest governance body in overseeing the management of impacts	Governance Structure
		Message from Outside Directors
		Sustainability Management Structure
		Risk Management System
		Environmental Management System
		Environmental Report (P.7) Environmental Management System 
		Human Rights Initiatives (Promotion Framework, Human Rights Due Diligence)
		Health and Productivity Management (Promotion System)
2-13	Delegation of responsibility for managing impacts	Governance Structure
		Sustainability Management Structure
		Environmental Management System
		Environmental Report (P.7) Environmental Management System 
		Human Rights Initiatives
		Health and Productivity Management (Promotion System)
2-14	Role of the highest governance body in sustainability reporting	Major Matters Deliberated by the Board of Directors
		Sustainability Management Structure
		Environmental Management System
		Environmental Report (P.7) Environmental Management System 
		Human Rights Initiatives
		Health and Productivity Management (Promotion System)













GRI2 : General Disclosures 2021

2-15	Conflicts of interest	Corporate Governance Guidelines  Otsuka Group Global Policy for Conflict of Interest 
2-16	Communication of critical concerns	Governance Structure
		Sustainability Management Structure
		Approach to Compliance
2-17	Collective knowledge of the highest governance body	Governance Structure
		Sustainability Management Structure
		Environmental Management System
		Environmental Report (P.7) Environmental Management System 
		Initiatives to Strengthen Corporate Governance
		Evaluation of Effectiveness of Board of Directors
2-18	Evaluation of the performance of the highest governance body	Sustainability Management Structure
		Evaluation of Effectiveness of Board of Directors
2-19	Remuneration policies	Remuneration for Directors and Audit & Supervisory Board Members
2-20	Process to determine remuneration	Remuneration for Directors and Audit & Supervisory Board Members
2-21	Annual total compensation ratio	Annual Securities Report (P.19, P.75 Japanese only) 
4. Strategy, policies and practices		
2-22	Statement on sustainable development strategy	Management Message
		Message from the Director in Charge of Sustainability
2-23	Policy commitments	Otsuka Group Global Code of Business Ethics
		Initiatives and Commitments
		Otsuka Group Human Rights Policy
		Otsuka Group Procurement Policy
		Otsuka Group's Environmental Vision and Policy
2-24	Embedding policy commitments	Approach to Compliance
		Human Rights Initiatives
		Otsuka Group Procurement Policy
		Otsuka Group's Environmental Vision and Policy
2-25	Processes to remediate negative impacts	Approach to Compliance
		Customer Service
2-26	Mechanisms for seeking advice and raising concerns	Otsuka Group Global Code of Business Ethics
		Approach to Compliance (Promotion System)
		Human Rights Initiatives
2-27	Compliance with laws and regulations	Environmental Report (P.21) Environmental Data 
2-28	Membership associations	Initiative and Commitment
		ISO Management System Certification Status 
		Acquisition of International Certification (Nutraceutical and Consumer Products)

5. Stakeholder engagement			
	2-29	Approach to stakeholder engagement	Stakeholder Engagement
			Information Meeting of Tuberculosis Project
			Procurement
			Customer Service
2-30	Collective bargaining agreements	Engagement with employees	
GRI 3: Material Topics 2021	3-1	Process to determine material topics	Process for Determining Materiality (Material Issues)
	3-2	List of material topics	The Otsuka Group's Materiality (Material Issues) and Related SDGs
	3-3	Management of material topics	Integrated Report 2021 P.18-21 (Fiscal 2023 Goals and Fiscal 2021 Progress) 
			Promotion System
Risk Management			
			Business Risks



Environmental


GRI Standards	Disclosures		References
GRI201: Economic Performance 2016	201-1	Direct economic value generated and distributed	Annual Securities Report (Japanese only) 
	201-2	Financial implications and other risks and opportunities due to climate change	Integrated Report (P.53) Initiatives for TCFD Recommendations 
			Environmental Report (P.97) Initiatives for TCFD Recommendations 
	201-3	Environmental Report (P.7 Initiatives for TCFD Recommendations	Annual Securities Report (P.126 Japanese only) 
	201-4	Financial assistance received from government	
GRI202: Market Presence 2016	202-1	Ratios of standard entry level wage by gender compared to local minimum wage	
	202-2	Proportion of senior management hired from the local community	
GRI203: Indirect Economic Impacts 2016	203-1	Infrastructure investments and services supported	Contribution to Communities
			Otsuka Group Initiatives Related to COVID-19 
			Annual Securities Report (P.45-50 Japanese only) 
	203-2	Significant indirect economic impacts	Contribution to Communities
GRI204: Procurement Practices 2016	204-1	Proportion of spending on local suppliers	


GRI205: Anti-corruption 2016	205-1	Operations assessed for risks related to corruption	Otsuka Group Global Anti-Corruption Policy (Scope) 
	205-2	Communication and training about anti-corruption policies and procedures	Compliance Promotion System
			Otsuka Group Global Anti-Corruption Policy 
			Risk Management
205-3	Confirmed incidents of corruption and actions taken		
GRI206: Anti-competitive Behavior 2016	206-1	Legal actions for anti-competitive behavior, anti-trust, and monopoly practices	
GRI207: Tax 2019	207-1	Approach to tax	Tax Policy
	207-2	Tax governance, control, and risk management	Tax Policy
	207-3	Stakeholder engagement and management of concerns related to tax	Tax Policy
	207-4	Country-by-country reporting	
GRI Standards	Disclosures		References
GRI301: Materials 2016	301-1	Materials used by weight or volume	Environmental Report (P.21) Environmental Data 
	301-2	Recycled input materials used	
	301-3	Reclaimed products and their packaging materials	
GRI302: Energy 2016	302-1	Energy consumption within the organization	Environmental Report (P.19) Environmental Data 
	302-2	Energy consumption outside of the organization	Environmental Report (P.19) Environmental Data 
	302-3	Energy intensity	Environmental Report (P.19) Environmental Data 
			Environmental Report (P.9) Initiatives for TCFD Recommendations 
	302-4	Reduction of energy consumption	Environmental Report (P.19) Environmental Data 
	302-5	Reductions in energy requirements of products and services	
GRI303: Water and Effluents 2018	303-1	Interactions with water as a shared resource	Water Neutrality
			Environmental Report (P.19) Environmental Data 
	303-2	Economic	
	303-3	Water withdrawal	Environmental Report (P.19) Environmental Data 
	303-4	Water discharge	Environmental Report (P.19) Environmental Data 
303-5	Water consumption	Environmental Report (P.14) Water Neutrality 	

GRI304: Biodiversity 2016	304-1	Operational sites owned, leased, managed in, or adjacent to, protected areas and areas of high biodiversity value outside protected areas	Environmental Report (P.15) Biodiversity 	
	304-2	Significant impacts of activities, products and services on biodiversity		
	304-3	Habitats protected or restored	Environmental Report (P.14) Biodiversity 	
	304-4	IUCN Red List species and national conservation list species with habitats in areas affected by operations	Environmental Report (P.15) Biodiversity 	
GRI305: Emissions 2016	305-1	Direct (Scope 1) GHG emissions	Environmental Report (P.20) Environmental Data 	
	305-2	Energy indirect (Scope 2) GHG emissions	Environmental Report (P.20) Environmental Data 	
	305-3	Other indirect (Scope 3) GHG emissions	Environmental Report (P.20) Environmental Data 	
	305-4	GHG emissions intensity	Environmental Report (P.20) Environmental Data 	
	305-5	Reduction of GHG emissions	Carbon Neutrality	
			Environmental Report (P.10) Carbon Neutrality 	
	305-6	Emissions of ozone-depleting substances (ODS)		
305-7	Nitrogen oxides (NOx), sulfur oxides (SOx), and other significant air emissions	Environmental Report (P.156) Management of Chemical Substances 		
GRI306: Waste 2020	306-1	Waste generation and significant waste-related impacts		
	306-2	Management of significant waste-related impacts	Environmental Report (P.20) Environmental Data 	
	306-3	Waste generated	Environmental Report (P.20) Environmental Data 	
	306-4	Waste diverted from disposal	Environmental Report (P.20) Environmental Data 	
	306-5	Waste directed to disposal	Environmental Report (P.20) Environmental Data 	
GRI307: Environmental Compliance 2016	307-1	Non-compliance with environmental laws and regulations	Environmental Report (P.20) Environmental Data 	
GRI308: Supplier Environmental Assessment 2016	308-1	New suppliers that were screened using environmental criteria	Environmental Report (P.17) Supply Chains 	
	308-2	Negative environmental impacts in the supply chain and actions taken	Environmental Report (P.8) Carbon Neutrality 	

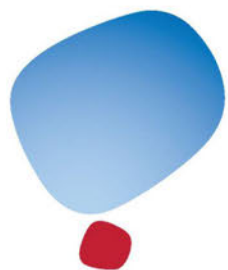
Social

GRI Standards	Disclosures		References
GRI401: Employment 2016	401-1	New employee hires and employee turnover	Sustainability Data 
	401-2	Benefits provided to full-time employees that are not provided to temporary or part-time employees	
	401-3	Parental leave	Sustainability Data 

GRI402: Labor/Management Relations 2016	402-1	Minimum notice periods regarding operational changes	
GRI403: Occupational Health and Safety 2018	403-1	Occupational health and safety management system	Occupational Health and Safety
	403-2	Hazard identification, risk assessment, and incident investigation	Occupational Health and Safety
	403-3	Occupational health services	Health and Productivity Management
	403-4	Worker participation, consultation, and communication on occupational health and safety	Occupational Health and Safety
	403-5	Worker training on occupational health and safety	
	403-6	Promotion of worker health	Health and Productivity Management
	403-7	Prevention and mitigation of occupational health and safety impacts directly linked by business relationships	Occupational Health and Safety
	403-8	Workers covered by an occupational health and safety management system	Occupational Health and Safety
	403-9	Work-related injuries	Occupational Health and Safety
	403-10	Work-related ill health	
GRI404: Training and Education 2016	404-1	Average hours of training per year per employee	
	404-2	Programs for upgrading employee skills and transition assistance programs	Human Resource Development
	404-3	Percentage of employees receiving regular performance and career development reviews	Human Resource Development
GRI405: Diversity and Equal Opportunity 2016	405-1	Diversity of governance bodies and employees	Board Members Sustainability Data 
	405-2	Ratio of basic salary and remuneration of women to men	
GRI406: Non-discrimination 2016	406-1	Incidents of discrimination and corrective actions taken	
GRI407: Freedom of Association and Collective Bargaining 2016	407-1	Operations and suppliers in which the right to freedom of association and collective bargaining may be at risk	Human Rights Initiatives
			Procurement
GRI408: Child Labor 2016	408-1	Operations and suppliers at significant risk for incidents of child labor	Human Rights Initiatives
			Procurement
GRI409: Forced or Compulsory Labor 2016	409-1	Operations and suppliers at significant risk for incidents of forced or compulsory labor	Human Rights Initiatives
			Procurement
GRI410: Security Practices 2016	410-1	Security personnel trained in human rights policies or procedures	
GRI411: Rights of Indigenous Peoples 2016	411-1	Incidents of violations involving rights of indigenous peoples	

GRI412: Human Rights Assessment 2016	412-1	Operations that have been subject to human rights reviews or impact assessments	Human Rights Initiatives
			Procurement
	412-2	Employee training on human rights policies or procedures	Human Rights Initiatives
	412-3	Significant investment agreements and contracts that include human rights clauses or that underwent human rights screening	
GRI413: Local Communities 2016	413-1	Operations with local community engagement, impact assessments, and development programs	Contribution to Communities
	413-2	Operations with significant actual and potential negative impacts on local communities	
GRI414: Supplier Social Assessment 2016	414-1	New suppliers that were screened using social criteria	Procurement
	414-2	Negative social impacts in the supply chain and actions taken	Procurement
GRI415: Public Policy 2016	415-1	Political contributions	
GRI416: Customer Health and Safety 2016	416-1	Assessment of the health and safety impacts of product and service categories	ISO Management System Certification Status 
			Customer Service
			Acquisition of International Certification (Nutraceutical and Consumer Products)
	416-2	Incidents of non-compliance concerning the health and safety impacts of products and services	
GRI417: Marketing and Labeling 2016	417-1	Requirements for product and service information and labeling	Customer Service
			Sales and Marketing
	417-2	Incidents of non-compliance concerning product and service information and labeling	
417-3	Incidents of non-compliance concerning marketing communications		
GRI418: Customer Privacy 2016	418-1	Substantiated complaints concerning breaches of customer privacy and losses of customer data	
GRI419: Socioeconomic Compliance 2016	419-1	Non-compliance with laws and regulations in the social and economic area	

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Otsuka

Otsuka-people creating new products
for better health worldwide

Environmental Report 2021



Otsuka Holdings Co., Ltd.

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How to Use This Report

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Editorial Policy

Editorial Policy

The editorial policy of this environmental report is to ensure accuracy of information, comprehensiveness, and response to requests from stakeholders. In terms of the environment, the report is based on specific numerical targets and progress in the results of initiatives.

For information on social (S) and governance (G) initiatives, please refer to the Integrated Report or our website.

 [Integrated Report](#)

Information on the environment is available on our website.

 [Environment](#)

Reporting Period

Data for FY 2021 (from January 1 to December 31 of 2021) are used.

Initiatives reported include the most recent ones.

Scope of Reporting

In principle, all Otsuka group consolidated production sites are covered.

In case of any limit on the scope of initiatives or data, a note on the details is provided in this report.

Issuing Date

August 2022 (once a year)

Guidelines Referenced

- International Integrated Reporting Framework, International Integrated Reporting Council (IIRC)
- GRI Sustainability Reporting Standards, Global Reporting Initiative (GRI)
- ISO 26000
- Environmental Reporting Guidelines 2018, Ministry of the Environment, etc.

Disclosure of Information on Otsuka Group



 [Integrated Report 2021](#)



 [Investor Relations](#)



 [Sustainability](#)



 [Sustainability Handbook](#)

Contact Information

Otsuka Holdings Co., Ltd.
 Section for Environmental Affairs, Sustainability Promotion Department
 Shinagawa Grand Central Tower, 2-16-4 Konan,
 Minato-ku, Tokyo 108-8241, Japan
 TEL: +81-3-6717-1410

Third-Party Verification

In order to improve reliability, we are verified by third-party organizations.

 [Third-Party Verification](#)

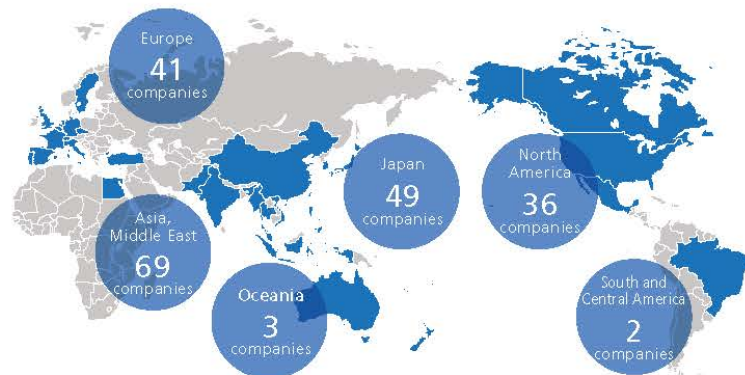
Corporate Profile

Corporate Profile (As of December 31, 2021)

Company Name	Otsuka Holdings Co., Ltd.
Established	July 8, 2008
Capital	¥81.69 billion
Head Office	2-9 Kanda-Tsukasamachi, Chiyoda-ku, Tokyo 101-0048, Japan
Tokyo Headquarters	Shinagawa Grand Central Tower, 2-16-4 Konan, Minato-ku, Tokyo 108-8241, Japan
Telephone	+81-3-6717-1410
Number of Employees	137 (Consolidated: 33,226)
Business Description	Control, management and related activities with respect to the Company's subsidiaries and affiliates operating in pharmaceutical, nutraceutical, consumer product, and other businesses

Global Network (As of December 31, 2021)

Otsuka operates in **33** countries/regions



Approach to Sustainability

Corporate Philosophy

Otsuka-people creating new products for better health worldwide

Otsuka's Goal

To become an indispensable contributor to people's health worldwide

Sustainability Mission

Address social issues such as the evolution toward a healthier and more sustainable society, while simultaneously achieving growth. These activities are all supported by a comprehensive governance system.

Contribution to a More Sustainable Society

Otsuka's business is fully synchronized with our efforts to address social issues
Otsuka-people creating new products for better health worldwide



Message from the Director in Charge of the Environment Affairs



2050 Environmental Vision of “Net Zero” Zero environmental impact of all our business activities.

We aim to contribute to making people and the earth healthier.

Based on its corporate philosophy of “Otsuka-people creating new products for better health worldwide,” the Otsuka group works to solve social issues through its businesses and contribute to the creation of a healthy and sustainable society, while achieving its continued growth. As a unique total healthcare company that contributes to maintaining and improving people's health through innovative and creative products, we are committed to reducing the impact of our businesses on the global environment and contributing to a sustainable society that leads to prosperous future.

The Otsuka group aims to help resolve social issues through its business activities. Amid the increasing seriousness of climate change and various other environmental issues, we have adopted the 2050 Environmental Vision, “Net Zero,” which calls for us to reduce the total environmental impacts of our business activities to zero. We identified three environmental material issues: “carbon neutrality,” “circular economy,” and “water neutrality”; set new medium-term targets that include “reducing 50% in CO₂ emissions compared to 2017 levels by 2028”; and raised the target of the Otsuka Group Plastic Policy to 100% use of recycled and plant-derived raw materials in our PET bottles by 2030.

In addition, we joined the international RE100 initiative, which asks companies to commit to using 100% renewable energy in their business activities. As a new initiative that maximizes the Otsuka group synergy, we have established an integrated energy service structure, with the aim of efficient power supply and maximization of energy efficiency.

The Otsuka group will work as one to achieve its 2050 Environmental Vision, “Net Zero,” by pursuing unique initiatives, and will continue to carry out environmental management that will lead to a society in which people and the earth can coexist in the future.

Yoshiro Matsuo

Executive Deputy President and Director
Otsuka Holdings Co., Ltd.

Environmental Management

Sustainability Management

The Otsuka Group Sustainability Promotion Committee was established in 2018 and is chaired by the director in charge of sustainability promotion at Otsuka Holdings. The committee promotes sustainability for the entire Otsuka group, acting as an engine for discussions and decision-making regarding the direction of sustainability-related activities, plans, and other measures. Committee meetings are held regularly to discuss direction and evaluate activities, develop systems in each area of sustainability promotion, and update promotion plans, as necessary. Committee members comprise group officers in charge of various areas such as supply chain, environment, human resources, corporate governance, compliance risk management, and public relations. The Committee, together with persons in charge from group companies, carries out close examination, with the Sustainability Promotion, IR and Corporate Planning Departments of Otsuka Holdings functioning as the secretariat.

Sustainability Management Structure



1. Activities are promoted through various conference bodies, WGs, TFs, and others (including time-limited PJ)
 2. Consumer Relations: Activities to build trust between companies and consumers

Otsuka Group's Environmental Policy

The Otsuka group strives to advance as an essential company that contributes to the health of people and global environment. We will help to realize a society in which people and the earth can coexist in the future by continuing to work on the issues with creativity.

Guidelines

1. Carbon Neutrality

We are committed to carbon neutrality throughout our business activities, aiming to create a decarbonized society.

2. Circular Economy

We are committed to the elimination of fossil resources-derived materials and the achievement of zero waste, aiming to create a circular economy society.

3. Water Neutrality

Promote sustainable use of water through conservation, recycling and clean return.

4. Environmental Compliance

Continue to improve our environmental management system, increase effectiveness of compliance, and reduce risks.

5. Communication

We will proactively disclose environment-related information in a transparent manner, and promote communication with stakeholders.

(Revised June 2022)

Environmental management system

Acquisition of Integrated ISO 14001 Certification for the Otsuka Group

To strengthen group-wide efforts toward more efficient and effective environmental activities, the Otsuka group began acquiring ISO 14001 integrated certification in August 2020. In 2021, the certification expanded to include six companies* in Japan and Otsuka Holdings, the supervising organization. Under the integrated environmental goals and management systems outlined in the certification, we will further strengthen our environmental initiatives and make group-wide efforts to achieve the goals.

The Otsuka group has acquired ISO 14001 certification including integrated certification at 10 companies in Japan and 13 overseas (as of the end of December 2021).

* Otsuka Pharmaceutical, Otsuka Pharmaceutical Factory, Taiho Pharmaceutical (including its subsidiary, Okayama Taiho Pharmaceutical), Otsuka Chemical, and Otsuka Foods, Otsuka Techno



ISO 14001 Certification

2050 Environmental Vision of "Net Zero"

The Otsuka group has established a 2050 Environmental Vision, "Net Zero", which aims to reduce the total environmental impact of our business activities to zero.

Under this vision, we identified three environmental material issues: "carbon neutrality," "circular economy," and "water neutrality." As global action aimed at a decarbonized society gathers speed, we have established a new set of medium-term targets with the aim of being more proactive in our own initiatives. We will promote activities to improve employees' understanding and recognition of environmental issues through environment-related training, generate synergy among Otsuka group companies, and act from a unified standpoint.



	Social Issues	Our Goals	Our Activities	FY 2021 Progress	Related SDGs
Carbon Neutrality ¹	Global warming	2028 target • Reduce 50% in CO ₂ emissions compared to 2017	• Reduce CO ₂ emissions throughout the value chain	<ul style="list-style-type: none"> • Joining the RE100 Initiative • Installation of co-generation system equipment and fuel conversion equipment • Introducing CO₂-Free Electricity at Four Indonesian Group Companies • Building a New Integrated Energy Service Structure 	
Circular Economy ²	Environmental load increase	2028 target • Reduce 50% in simple incineration and landfill disposal compared to 2019 2030 target • 100% content of recycled and plant-based materials in our PET bottles	<ul style="list-style-type: none"> • Reduce environmental impact by improving resource efficiency • Promotion of business activities aimed at sustainability for both society and the earth 	<ul style="list-style-type: none"> • Containers and Packaging for a Sustainable Society • Launch of PET Bottles Made Using Recycled Materials 	
Water Neutrality ³	Reduced freshwater availability due to water resource risks	2028 target • Expand the plant water management program to all locations globally • Develop a water use strategy for business locations in water-stressed areas	<ul style="list-style-type: none"> • Risk analysis and understanding of sustainable water use • Management and effective use of water resources 	<ul style="list-style-type: none"> • Develop a plan to establish a water management program 	

1. To reduce CO₂ emissions from business activities to substantially zero (calculated by subtracting uptake from emissions)
 2. To establish an economic system that recycles resources by reusing waste discharged from business activities as new raw materials
 3. To reduce the impact of water intake and discharge from business activities on water resources to zero

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					Carbon Neutrality	Circular Economy	Water Neutrality			

Carbon Neutrality

Approach and Policy

Climate change due to global warming is causing serious environmental issues on a worldwide scale, such as by severely impacting biological and water resources. We recognize it as a major risk to our global operations.

In aiming to contribute to a decarbonized, more sustainable society, the Otsuka group is working to reduce greenhouse gas (GHG) emissions throughout the value chain in line with the international targets and indicators adopted under the Paris Agreement.

Initiatives for TCFD Recommendations

In October 2021, Otsuka Holdings announced its support for the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD). Accordingly, we are moving forward with the disclosure of information on climate-related risks and opportunities in governance, strategy, risk management, and metrics and targets, according to the framework recommended by the TCFD.



Governance

As a global group that contributes to the health of people worldwide, the Otsuka group works sincerely to reduce the impact its businesses have on the global environment, and seeks to contribute to the creation of a sustainable society that protects nature and the future of the earth. Therefore, we have built a system of governance.

The Otsuka group’s environmental policies and initiatives are discussed and determined by the Otsuka Holdings Environmental Committee, which consists of the executive deputy president and director of Otsuka Holdings and the directors and executive offices in charge of environmental management in our group companies. Matters on the direction of the entire Otsuka group will be discussed and approved by the Otsuka Holdings Board of Directors, and will be shared with group companies as the Otsuka group’s policy. Then, they will be implemented as an implementation scheme of the Otsuka Group Global Environmental Council (hereafter referred to as “OGG Environmental Council”), which consists of directors from the production departments of group companies and persons in charge of environmental management. In 2021, the Board of Directors approved 2050 Environmental Vision, “Net Zero,” with the aim of reducing the total environmental impact across all its business activities to zero. The OGG Environmental Council assesses the risks and opportunities examined and reports the results of monitoring. The Otsuka Holdings Environmental Committee gives instructions for improvement and approves planning. In addition, if the monitoring results have an impact on business strategy and management resources, they will be incorporated

into the management plan as matters to be resolved at the Board of Directors as needed. The Committee is positioned as a subordinate organization of the Otsuka Group Sustainability Promotion Committee, which decides overall sustainability strategies and directions, and plays a role as one of the group’s sustainability initiatives.

Otsuka Group Environmental Management System



Strategy

Process of Scenario Analysis

With the purpose of assessing the financial and business impacts under various scenarios, as well as assessing the resilience of our strategies to climate-related risks and opportunities, we carry out scenario analysis using IEA World Energy Outlook 2020 and other resources, following the steps below.

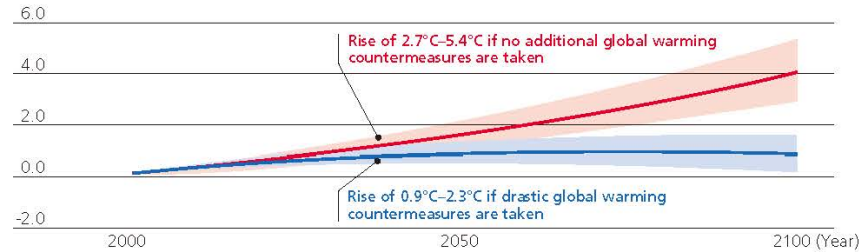
Steps of Scenario Analysis



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Climate-related scenarios

Change in Global Mean Surface Temperature



4°C Scenario

A scenario in which development is dependent on fossil fuels and climate change measures are not introduced. Rising temperatures cause an increase in natural disasters, negative impact on crops, and loss of biodiversity.

Below 2°C Scenario

A scenario in which development is sustainable and climate change measures are proactively implemented to keep the temperature rise below 2°C. Measures to achieve a decarbonized society are enhanced, including the introduction of CO₂ emissions regulations and expansion of the renewable energy market.

Based on the Ministry of the Environment's Japanese translation of Summary for Policymakers, Working Group II Report, Fifth Assessment Report published by the IPCC Main Scenarios Referenced

- IEA World Energy Outlook 2020 (Sustainable Development Scenario, Stated Policy Scenario)
- IPCC (RCP2.6, RCP8.5)
- OECD-FAO Agricultural Outlook 2021–2030

Measures to Deal with Risks and Opportunities

The Otsuka group carried out the first scenario analysis for each business sector to reduce risks and expand opportunities. Transition risks include energy shortages as well as steep rise in energy prices due to increased demand for renewable energy and other forms of energy.

To deal with these risks, we are promoting the introduction of CO₂-free electricity, mega solar power systems, fuel conversion, and so forth, at all locations globally.

In Japan, we established the Otsuka group integrated energy service structure to maximize energy use utilizing new power sources. In this way, the Otsuka group will strive to promote both business growth and improving environmental issues, and will strive to enhance its resilience against climate change.



Financial Impacts and Responses Associated with Climate-Related Risks and Opportunities

Category	Contents	Business/Financial Impacts		Our Response/Resilience	
		Below 2°C	4°C		
Transition Risks	Policies and regulations	Increased costs due to tightened regulations such as carbon pricing	Large	Large	<ul style="list-style-type: none"> • Introduction of internal carbon pricing • Introduction of CO₂-free electricity • Introduction of solar power generation systems including mega solar power systems
	Market	<ul style="list-style-type: none"> • Steep rise in renewable energy prices • Steep rise in energy prices 	Large	Large	<ul style="list-style-type: none"> • Improving energy efficiency through energy saving and fuel conversion • Investment in environmental facilities in Japan and overseas
	Reputation	• Reputation risk and investment-related risk associated with inadequate response to climate change and water resource risks	Large	Medium	
Physical Risks	Acute	<ul style="list-style-type: none"> • Risks of damage to production and other facilities due to intensification of extreme weather, and cost increases to prepare for extreme weather events • Risks in raw material procurement such as disruption to supply chains and stable procurement 	Medium	Large	<ul style="list-style-type: none"> • Decentralized production of major products • Formulation, disclosure, and sharing of procurement policies and guidelines with suppliers • Strengthening communication with our supply chains (expanding the number of suppliers that are subject to our supply chain questionnaires, improving and enhancing contents of the questionnaires, and holding discussions)
	Chronic	<ul style="list-style-type: none"> • Increased energy costs associated with temperature rise • Effects of climate change on drug discovery using crop and other natural products 	Large	Large	<ul style="list-style-type: none"> • Systematic renewal of facilities
Opportunities	Resource efficiency	• Reduction of operating costs through the introduction of energy-efficient equipment	Large	Medium	<ul style="list-style-type: none"> • Collection of information on new technologies (such as membrane water treatment technology that does not require steam) and examination of introduction of such technologies in a timely manner
	Energy sources	• Reduction of energy procurement risk due to proactive introduction of renewable energy	Large	Small	<ul style="list-style-type: none"> • Introduction of internal carbon pricing • Collection of information on next-generation energy sources (such as hydrogen and ammonia) and examination of introduction of such sources in a timely manner
	Products and services	• Increased revenue from increased demand for products that mitigate or address climate change (e.g., products for preventing heat stroke and the spread of infectious diseases)	Large	Large	<ul style="list-style-type: none"> • Formulation of the Otsuka Group Plastic Policy (in 2020) that aims at reducing reliance on fossil fuel-derived materials • Examination of introduction of recycled PET resin or plant-based bio-PET resin for PET bottle beverage containers • Examples: Expand sales of products for preventing heat stroke, and expand sales of products with low environmental impact throughout their lifecycles
	Market	• Increased revenue from expansion into new market categories with products that address climate change	Medium	Medium	<ul style="list-style-type: none"> • Development of products that mitigate or address climate change (e.g., plant-based products)
	Resilience	• Strengthening business continuity planning (measures against disaster and supply chain disruptions)	Medium	Large	<ul style="list-style-type: none"> • Strengthening of promotion of energy saving and renewable energy through internal carbon pricing • Business continuity plan measures at manufacturing sites (anti-seismic measures and measures against flooding)

Assessment of business/financial impacts

Large: One billion yen or more (equivalent to 1% of operating income assuming a minimum operating income of 100 billion yen)

Medium: From negligible to less than one billion yen

Small: Negligible

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Risk Management

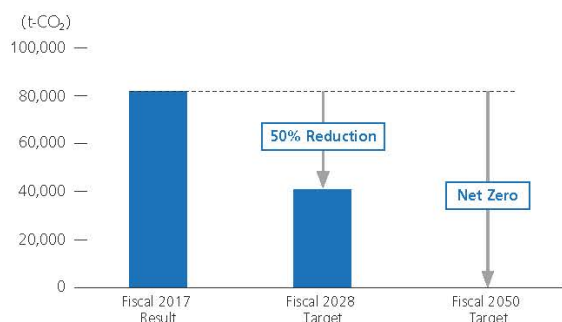
The Otsuka group examines and assesses climate-related risks that have the potential to impact its financial affairs and strategies. The Otsuka Holdings Environmental Committee considers related risks, and committee members in charge of environmental management report on any matters that are deemed to be significant in the risk assessment process to the Board of Directors. Resolutions on matters approved by the Board of Directors are communicated to each company in the form of Otsuka group policies, and the whole group works to minimize climate-related risks.

Metrics and Targets

The Otsuka group has established 2050 Environmental Vision, "Net Zero," with the aim of reducing the total environmental impact across all its business activities to zero. In addition to revising our CO₂ emissions reduction target upward (from a 30% reduction by 2030 to a 50% reduction by 2028; compared to 2017), we have joined the international RE100 initiative and continue to promote activities aimed at decarbonization. Looking ahead, we will maximize group synergy and proactively engage in efforts to achieve carbon neutrality.

- [PDF Our Goals of Carbon Neutrality](#)
- [PDF Joining the RE100 Initiative](#)

Target Values of CO₂ Emission



CO ₂ Emissions Scope 1, 2	Fiscal 2017 Result	Fiscal 2021 Result		2028 Target
		Compared with 2017		
	818,000t-CO ₂	-16.5%	683,000t-CO ₂	50% reduction compared with 2017

Initiatives to Reduce CO₂ Emissions

Increasing Utilization of Renewable Energy and Maximizing Energy Efficiency

The Otsuka group has set the target of reducing CO₂ emissions by 50% (compared to 2017) by 2028. To achieve this target, we are increasing our renewable energy usage through the introduction of CO₂-free electricity and solar power generation equipment, and maximizing our energy efficiency through the adoption of co-generation systems¹.

In 2021, we introduced CO₂-free electricity at all 23 manufacturing sites of five² Otsuka group companies, and as a result reduced our annual emissions by approximately 109,800 t-CO₂.³

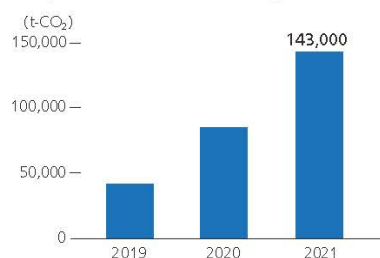
In addition, the introduction of renewable energy reduced CO₂ emissions by 143,000 metric tons.

In Tokushima Prefecture, which is home to many Otsuka group production facilities, we have begun upgrading the co-generation facility at Otsuka Chemical's Tokushima Factory. This will enable us to supply electricity and steam to neighboring Otsuka group manufacturing sites and improve our energy efficiency. The new co-generation system is scheduled to begin operation in 2024, and is expected to cut annual emissions by approximately 8,000 t-CO₂. In addition, we have introduced a new co-generation system and changed boiler fuel at Otsuka Pharmaceutical Factory's Naruto Factory, which should result in an annual reduction of approximately 4,800 t-CO₂.

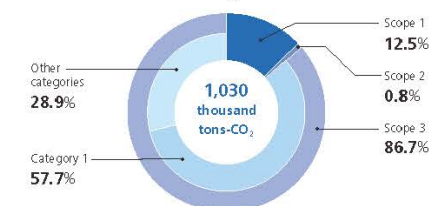
To assess the environmental impact of the entire supply chain, we calculate greenhouse gas emissions across the entire value chain, including emissions from our business activities (Scope 1 and 2) as well as emissions from the activities of suppliers and customers (Scope 3), and promote initiatives for grasping emissions trends and improving the situation.

- The engines, turbines, or fuel cells of co-generation systems generate electricity from natural gas, LPG, or other fuel sources. At the same time, the systems collect the waste heat, thereby achieving efficient use of both heat and electricity
- Otsuka Pharmaceutical, Otsuka Pharmaceutical Factory, Taiho Pharmaceutical, Otsuka Chemical, and Otsuka Foods
- Compared to 2017

Reduction in CO₂ Emissions Through Adoption of Renewable Energy



GHG Emissions throughout the Value Chain



Scope: Five group companies: Otsuka Pharmaceutical, Otsuka Pharmaceutical Factory, Taiho Pharmaceutical, Otsuka Chemical, and Otsuka Foods

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Joining the RE100 Initiative

In April 2022, the Otsuka group joined the international RE100 initiative, which asks companies to commit to using 100% renewable energy in their business activities. As the world transitions to a decarbonized society, under our 2050 Environmental Vision, "Net Zero," through which we aim to reduce the total environmental impact across all business activities to zero, we will continue to proactively implement measures to reduce CO₂ emissions.



Introducing CO₂-Free Electricity at Four* Indonesian Group Companies

Among our overseas businesses, the highest generator of CO₂ emissions after Japan is Indonesia, where we are engaged in the pharmaceutical, nutraceutical, and chemical businesses. In Indonesia, we have introduced CO₂-free electricity from geothermal power, which we forecast will reduce CO₂ emissions by approximately 94,000 ton per year, which is approximately 60% of the plants' annual CO₂ emissions. Moving forward, we will continue increasing our use of renewable energy and maximizing energy efficiency both in Japan and around the world, and make use of group synergy to contribute to a decarbonized, more sustainable society.

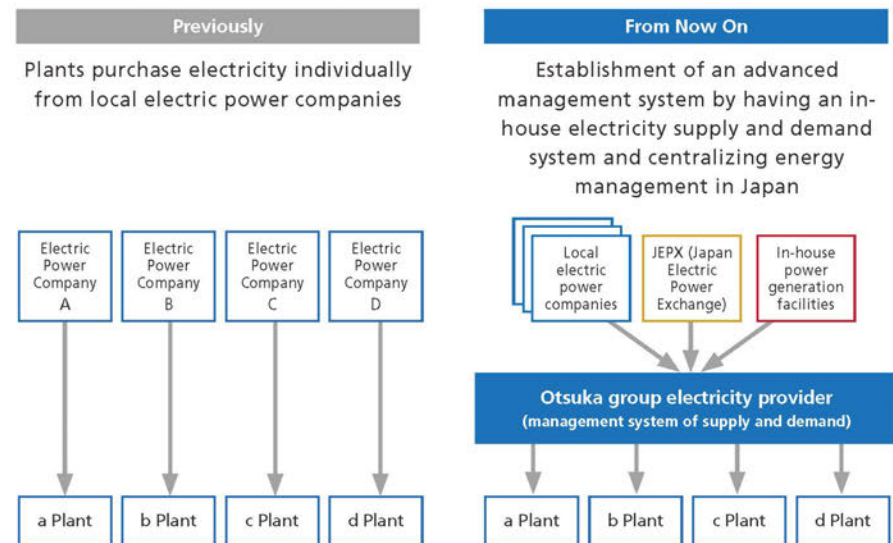
* PT Otsuka Indonesia, PT Amerta Indah Otsuka, PT Widatra Bhakti, and PT Lautan Otsuka Chemical



Sukabumi Factory, PT Amerta Indah Otsuka

Building a New Integrated Energy Service Structure

The Otsuka group established the Energy Support Department in Otsuka Business Support Co., Ltd., which aims to procure renewable energy from power producers and to more efficiently supply electricity generated within the Otsuka group to group business sites. By centralizing energy management in Japan and establishing an advanced management system of supply and demand, we will pursue the optimal energy mix in the Otsuka group while expanding renewable energy use, and work to both contribute to business growth and solve environmental issues.



Circular Economy

Approach and Policy

In line with global trends, for us to be able to create a more sustainable society and achieve sustainable corporate growth, we must shift to a circular economy-type business model whereby we can achieve growth without having a serious impact on the environment. We regard the use of fossil resources-derived materials and waste discharge to the natural environment as environmental impacts that must be reduced to zero. We are committed to eliminating fossil resources-derived materials and achieving zero waste* as our vision. We will also continue to increase resource efficiency throughout the value chain and build a harmonious and sustainable relationship with bioresource and other resource sources.

* Approach to reduce waste discharge (simple incineration and landfill disposal) to the natural environment to zero and utilize all resources effectively

Our Goals

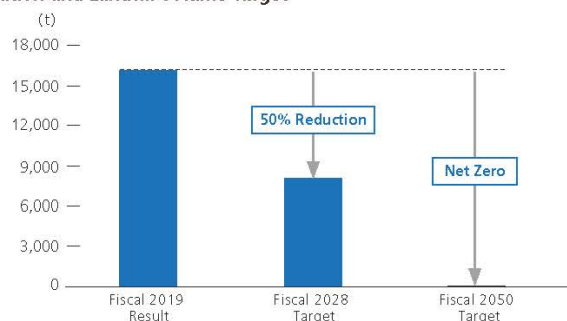
The Otsuka group has established a 2050 Environmental Vision, "Net Zero," which aims to reduce the total environmental impact of our business activities to zero, along with setting the 2028 goal that aims to reduce simple incineration and landfill by 50% compared to FY 2019.

PET bottles for beverages constitute most plastic containers and packaging used for consumer products by Otsuka group companies. For this reason, we have established the Otsuka Group Plastic Policy to achieve 100% use of recycled and plant-based materials in our PET bottles globally by 2030. We are working to achieve this goal.

Our main initiatives include reducing the use of plastic containers and packaging for various products, reducing the use of materials for logistics, and promoting recycling activities to achieve zero waste*.

* Approach seeking to reduce waste generation and waste of resources to zero

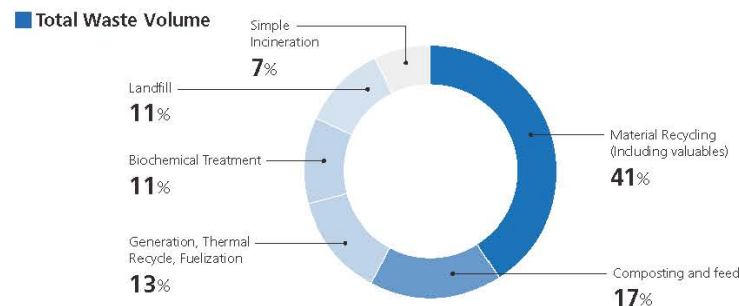
Simple Incineration and Landfill Volume Target



	Fiscal 2019 Results	Fiscal 2021 Results		2028 Targets
			Compared with 2019	
Total Waste Volume	97,400t	90,100t	-7.5%	—
Simple Incineration and Landfill Volume	16,100t	16,400t	+1.9%	50% reduction

Initiatives toward Zero Waste

Global emissions in FY 2021 were 90,100 metric tons, and simple incineration and landfill volume was 16,400 metric ton. The Otsuka group is working with each group companies in Japan and overseas to achieve the 2028 goal of a 50% reduction in simple incineration and landfill compared with FY 2019.



Volume of waste simply incinerated and landfilled

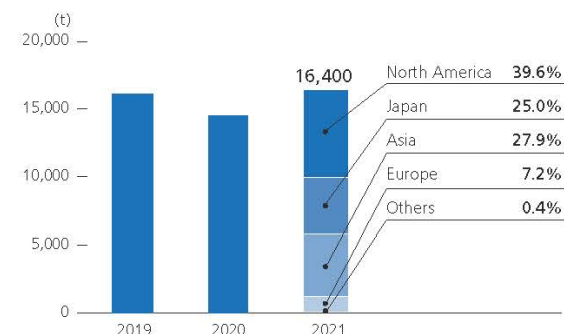


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Otsuka Group Plastic Policy

Fundamental Concept

PET bottles comprise the majority of plastic containers and packaging used for consumer products by our group companies. For this reason, we believe that by promoting PET bottle recycling, we can reduce our reliance on fossil fuel and thereby contribute to environmental conservation. Our plan is to use PET bottles manufactured from recycled and plant-based materials and increase the percentage of such sustainable resource use in our production processes globally to 100% by 2030 and by 2050, we aim to eliminate the use of petroleum-based raw materials in all consumer products.

Our Vision for 2050

For our entire line of consumer products, we will endeavor to use packaging that supports a sustainable society:

- No use of plastics made from petroleum-based materials
- Promote use of recycled, plant-based, and biodegradable materials
- Promote use of reusable packaging

Our Goal for 2030

- Achieve a 100 percent or higher content of recycled and plant-based materials in our PET bottles.
- Introduce alternative packaging (e.g., paper) and increase use of cans for our drink products.
- Step up promotion of drink bottle recycling by introducing reusable packaging through a zero-waste sales and circular distribution model, which also includes the use of sports bottles for our powder products.
- We will promote the use of alternative packaging and concurrently pursue using more recyclable materials for drink containers.

To advance PET material recycling, it is essential to recycle PET bottles for use as raw material. Together with our various stakeholders, we will advance our global efforts on proper collection and recycling of used PET bottles.

Revised July 2022

Guided by the Otsuka Group Plastic Policy, we are taking swift and appropriate actions regarding every aspect of our use of plastic, and thereby contributing to the sustainable use of plastic and effective resource recycling. Specific initiatives include developing an action plan for PET bottles, using recycled and plant-based materials, and examining options for alternative packaging.

Initiatives to Use Packaging that Supports a Sustainable Society

Containers and Packaging for a Sustainable Society

Based on the Otsuka Group Plastic Policy, we are quickly moving forward with measures to reduce the environmental impact caused by our plastic containers and packaging. In doing so, we are contributing to sustainable closed-loop recycling for plastics and other resources.



Launch of PET Bottles Made Using Recycled Materials

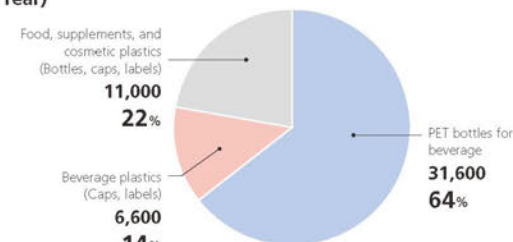
We launched a PET bottle made using 50% recycled PET resin for Crystal Geyser in April 2021, and a 30% recycled PET bottle for POCARI SWEAT in March 2022. While moving forward with further technological development, we will gradually extend the use of recycled PET bottles to other products.



2021 Amount of Plastic Containers and Packaging Used for Consumer Products* (Metric Tons/Year)

*16 Companies

Otsuka Pharmaceutical, Otsuka Pharmaceutical Factory, Otsuka Foods, Taiho Pharmaceutical, Shanghai Otsuka, Interpharma Praha, N&S, PT Amerta Indah Otsuka, Pharmavite, Ridge, Crystal Geyser, Korea Otsuka Pharmaceutical, Otsuka Sims (Guangdong), Tianjin Otsuka, FoodState, and Daiya Foods



Water Neutrality

Approach and Policy

Since its establishment, the Otsuka group's operations have had a deep connection to water, a resource essential to life. Through products that use water as a raw material, we have actively contributed not only to the treatment and prevention of diseases, but also the maintenance and promotion of health. We therefore recognize the importance of water to us as a resource, and consider its conservation to be a critical global issue. Moreover, water resources are unevenly distributed across different countries and regions, each of which faces different risks. We cooperate with all stakeholders, and conduct ongoing water conservation initiatives from intake to discharge (including cultivation of water resources, conscientious use and clean return), in the aim of sustainable water use.

Our Goals

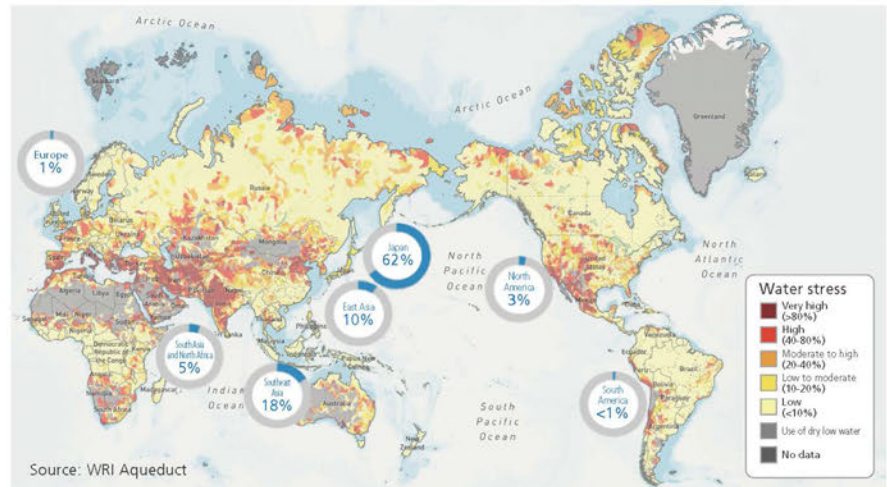
The Otsuka group has established a 2050 Environmental Vision, "Net Zero," which aims to reduce total environmental impact of our business activities to zero. Under the vision, we have revised our targets to include developing and implementing a water use strategy for business sites in water-stressed areas, and expanding the plant water management program to all locations globally, both by 2028. We are working on the realization of sustainable water use by improving water use efficiency and working to preserve water resources from intake to discharge (including cultivation of water resources, conscientious use of water, and return of clean water to the environment).



Evaluating Water Risk at Manufacturing Sites

Considering environmental risks in each region is also important for sustainable growth in the diverse business models of the Otsuka group operating around the world. Since 2017, the Otsuka group has conducted water risk assessments using the water risk assessment tool "Aquaduct," developed by the World Resources Institute (WRI), so as to understand and minimize the impact of water-related risks on the group's business activities. In order to conduct a more detailed analysis, we conducted a questionnaire survey of 87 sites of 51 companies (all consolidated manufacturing sites) to evaluate the impact on our business in terms of seven water-related risks in line with our business (water resource risk, groundwater resource risk, drought risk, flood risk, water quality risk, intake risk, and drainage risk) from 2020, and completed water risk assessments. Water resources are unevenly distributed across different countries and regions, each of which faces different risks. Thus, we draw up model cases for water management and water usage targets tailored to each country or region. In the future, we will verify and evaluate the result of this initiative and promote management and effective use in accordance with each region, pursuing conservation and improvement of water resources.

■ Aquaduct Water Risk Atlas and Breakdown by Region of Water Consumption in the Otsuka Group

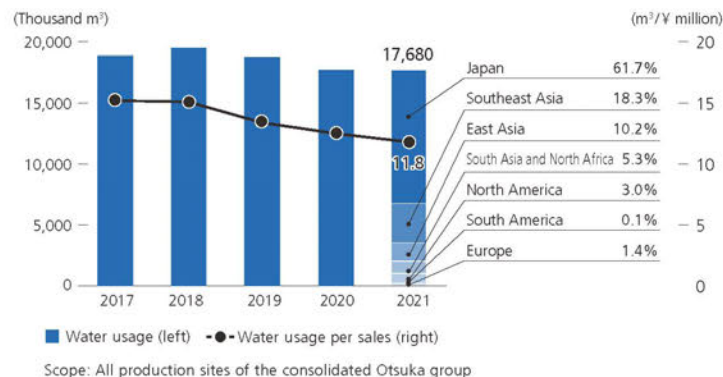


Initiatives to Reduce Water Usage

About 60% of the water used by the Otsuka group comes from production activities in Japan. The Otsuka group strives to ensure the proper use of water in order to continuously preserve water resources from intake to discharge. In Japan, the Tokushima Factory of the Otsuka Foods improved the water use process on the production line, and the Naruto Factory of the Otsuka Pharmaceutical Factory reduced the amount of water used in the treatment of wastewater from the factory to a level that does not affect water quality. As a result, the reduction in water use in Japan reached 696,000 m³ (6% reduction year on year).

 [Limiting Emissions to the Atmosphere and Water Systems](#)

Water Usage, Water Usage per Sales



Initiatives that Protect Water Sources¹ through Forestry

One of our initiatives to preserve water resources uses water conscientiously and returns clean water using water source protection through forestry. Group employees and family members voluntarily participate in conservation drives, such as planting trees, in turn developing a sense of closeness with forests.

Projects

In Japan

The Otsuka group has signed a partnership agreement with Tokushima Prefecture's Tokushima Cooperative Forestry Project, taking part in intensive forest management that is focused on large-scale forests covering 100 ha or more.

Tokushima Forests – Forestry in Collaboration with Tokushima Prefecture

In 2010, Otsuka Pharmaceutical Factory and Taiho Pharmaceutical signed partnership agreements with the Tokushima Cooperative Forestry Project, based on Tokushima Prefecture's Ordinance on Promotion of Global Warming Countermeasures. In fiscal 2021, eight group companies² planted broad-leaved trees and others in an area of 21.29 hectares, equivalent to 139.81 metric tons of CO₂ absorbed by forests.



Outside Japan

PT Widatra Bhakti Watershed Conservation in Pasuruan Regency

In the Pasuruan Regency region in Indonesia, employees of PT Widatra Bhakti helped protect water sources by planting 6,080 saplings in Andonosari Village in the Tukur subdistrict.



1. Water source protection means nurturing and maintaining water resources, as well as using the natural capacity of forests to mitigate flooding and droughts. Forests soak up falling rain and snow, then allow that water to slowly flow into rivers as groundwater.
2. Otsuka Pharmaceutical Factory, Otsuka Pharmaceutical, Taiho Pharmaceutical, Otsuka Warehouse, Otsuka Chemical, Otsuka Foods, Otsuka Packaging Industries, and Otsuka Techno Corporation

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Biodiversity

Approach and Policy

Otsuka Group's Biodiversity Policy

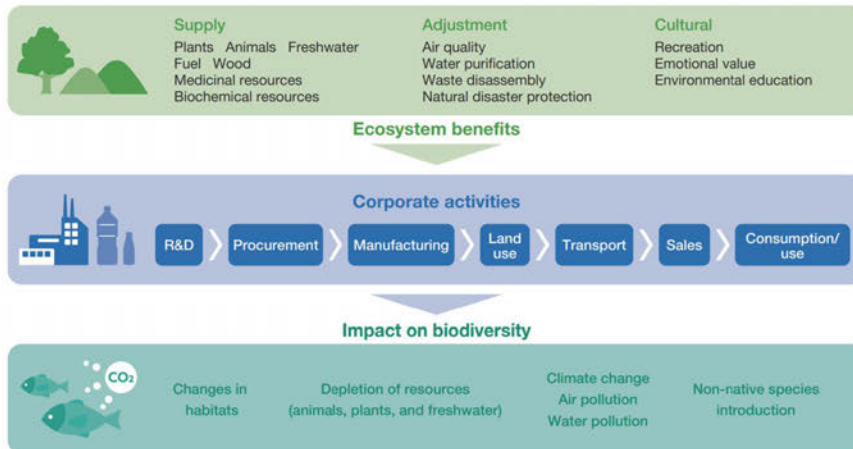
Basic Approach

The Otsuka group recognizes the invaluable benefits provided by the global environment, and thus deeply values the wonder of life. It understands that nature's gifts are the key to our future, and is consequently committed to protecting biodiversity worldwide.

Guidelines

- 1 The group will deepen its understanding of the relationship between business activities and biodiversity.
- 2 The group will strive to reduce the environmental impact of business activities that impact biodiversity.
- 3 The group will strive for sustainable use of resources (including ecosystem services), and for fair and equitable distribution of genetic resources in accordance with international arrangements.
- 4 The group will work on conservation of biodiversity by communicating, cooperating and collaborating with stakeholders worldwide.
- 5 The group will help foster public awareness of biodiversity.

Relationship between Biodiversity and Business Activities



Business Activities That Take Local Ecosystems into Account

Initiatives for Nature Conservation

The Otsuka group is committed to protecting the natural environment at each of its business sites and conserving animals and plants based on laws and regulations. We have been conducting our environmental survey of globe-spanning operating companies to monitor the status of compliance with laws and regulations on animals and plants to be protected that are defined by laws and others (IUCN protected area management categories, the Ramsar Convention, domestic laws and regulations) and conservation activities for them. We will continue to grasp ecological risks in the areas surrounding our plants, and take measures against them.

Creating Biotopes*

A biotope at the Tokushima Itano Factory of Otsuka Pharmaceutical was created in 1998 when the plant was built under the theme of "symbiosis with nature." The biotope, with a total length of about 450 m, is fed by cooling water from the plant and provides an environment for diverse aquatic creatures to flourish, including dragonfly larva, water scorpions, and pygmy water lilies.

The Okayama Taiho Pharmaceutical plant created a biotope in 2011. Reusing the water (purified water) used for cleaning and sterilizing glass bottles of the Tiovita Drink series and the cooling water, the water is discharged into ditches that reproduce the natural environment. Freshwater fish such as Japanese Medaka (killifish) breed in the biotope creek, seasonal flowers bloom around the water, and insects and wild birds also fly in.

* Biotope : Restoring ecosystems that have been lost due to the establishment of factories, etc., and creating an environment for plants and animals that originally lived in the area can return.



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Management of Chemical Substances

Approach and Policy

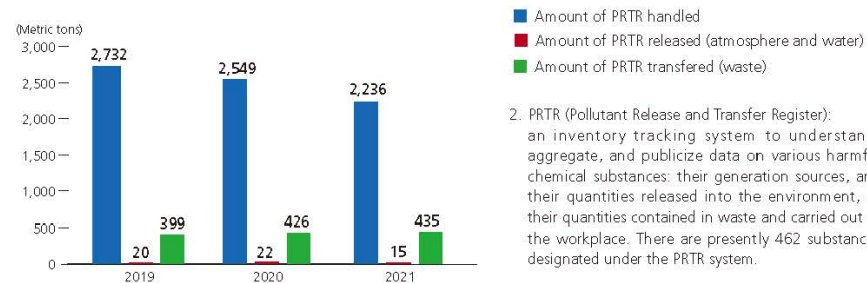
Chemical substances used and emitted in business activities of our group companies and our manufacturing contractors are appropriately managed. Our policy is as follows.

- 1 Prevent the adverse effects of chemical substances on humans and ecosystems**
- 2 Comply with laws and regulations in each country and further promote voluntary initiatives**
We will comply with the laws and regulations of each country regarding the use and discharge of chemical substances and will further promote voluntary initiatives.
- 3 Monitoring**
We will monitor the amount of chemical substances used and emitted in our business activities, check the status of compliance and progress of voluntary initiatives regularly, and take necessary corrective actions.
- 4 Response in the event of violations or disasters**
We prepare the procedures for dealing with violations and disasters, and share them with relevant employees to prevent the occurrence of chemical contamination even in a state of emergency.

Proper Management of Chemical Substances¹

We handled 2,236 metric tons of PRTR substances² in our business activities. We will continue to strive for proper management of chemical substances.

Changes in Handling, Release of PRTR Substances



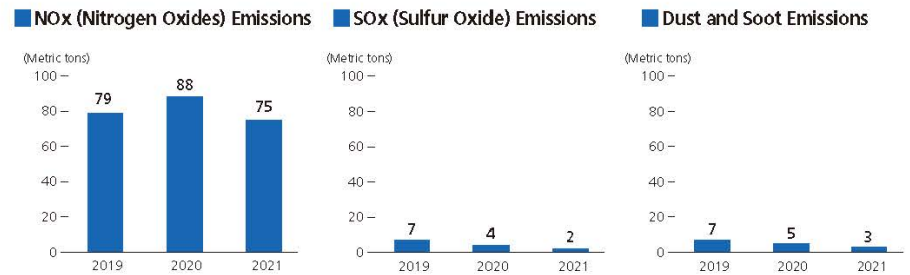
2. PRTR (Pollutant Release and Transfer Register): an inventory tracking system to understand, aggregate, and publicize data on various harmful chemical substances: their generation sources, and their quantities released into the environment, or their quantities contained in waste and carried out of the workplace. There are presently 462 substances designated under the PRTR system.

1. Five group companies: Otsuka Pharmaceutical, Otsuka Pharmaceutical Factory, Taiho Pharmaceutical, Otsuka Chemical, and Otsuka Foods

Limiting Emissions to the Atmosphere and Water Systems¹

Prevention of Air Pollution

Emissions of nitrogen oxides and sulfur oxides from our business activities amounted to 75 metric tons and 2 metric tons, respectively. We will continue to consolidate boiler facilities, switch to cleaner fuels, and continue to improve its energy efficiency in an effort to minimize emissions of NOx (nitrogen oxides) and SOx (sulfur oxides) into the atmosphere.



Prevention of Water Pollution

The total amount of wastewater discharged during business activities was 11,844,000 m³, COD (chemical oxygen demand), which indicates the environmental impact of water quality, was 52 metric tons, and SS (suspended solid) emissions were 41 metric tons.

Total Amount of Wastewater, COD (chemical oxygen demand) Emissions, and SS (Suspended Solids) Emissions

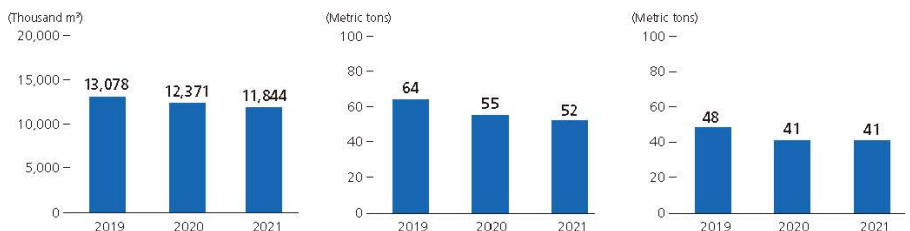


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Supply Chain

Initiatives for Sustainable Procurement

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 collaborators. To further these initiatives, we formulated the Otsuka Group Procurement Policy, which considers factors such as human rights, labor issues, the environment, and anti-corruption measures, and the Otsuka Group Sustainable Procurement Guidelines to promote the initiatives with the aim of embedding sustainable procurement. Starting in 2022, the Otsuka group has also begun focusing on a new area—stability of supply, which addresses natural disasters and geopolitical risks—in addition to the four existing areas of attention: human rights, labor, the environment, and anti-corruption.

Otsuka Group Procurement Policy

The Otsuka group of companies, in accordance with our corporate vision, "Otsuka-people creating new products for better health worldwide", and international norms, conducts procurement activities in a responsible way. Otsuka delivers innovative, safe, secure, and high-quality products in order to contribute to the construction and maintenance of a sustainable society, as well as to the health of people around the world.

1. Relationships with suppliers

As a collaborator with many suppliers, the Otsuka group aims to build good relationships for mutual sustainable development through shared understanding, based on a fair exchange of appropriate information and opinions.

2. Supplier selection

The Otsuka group selects suppliers in a fair, and transparent manner based on comprehensive assessments of supplier quality, costs, quantity, delivery terms, compliance with laws and regulations, promotion of environment preservation, etc.

3. Responsibilities toward society

For the realization of sustainable society, the Otsuka group strives to maintain procurement activities that reflect consideration for human rights, labor, the environment, and non-tolerance of corruption.

4. Compliance

The Otsuka group of companies observes all applicable laws and rules, and all Otsuka employees and supplier employees must act at all times with the highest level of ethics, consistent with social norms.

Otsuka Holdings Co., Ltd.

Related Information

[Basic Policy](#)

[Implementation of Briefings](#)

[Promotion System](#)

[Implementation of SAQ](#)

Otsuka Group Sustainable Procurement Guidelines

(Excerpts involved environment)

We require the following in accordance with the Otsuka Group Environment Policy:

1. Observance of environmental law as well as international treaty as well as in the countries and areas of business activities
2. Pursuing activities such as chemical management, reduction and appropriate disposal of waste and the prevention of pollution, to consider the health and safety of local communities and environments
3. Consideration of the impacts of activities on the global environment, such as reduction of greenhouse gas emissions, responses to climate change, and environmental load reduction
4. Recycling, efficient usage and reduction in the consumption of resources such as energy, water, and raw materials
5. Promotion of comprehensive conservation activities for biodiversity considering the diversity in ecosystems, species, and genetics. Fair and equitable allocation of benefits resulting from utilization of genetic resources

Briefings on Sustainable Procurement Practices

By 2021, we had held briefings for 126 suppliers on sustainable procurement practices. Attendees are expected to comply with the Otsuka Group Procurement Policy and the Otsuka Group Sustainable Procurement Guidelines. Also, we had training sessions where the attendees had opportunities to stay up to date on human rights and environmental issues and share the significance of improving sustainability.

Suppliers that agree to uphold our policies sign a pledge affirming their intention to cooperate in achieving sustainable procurement as business partners.

Self-Assessment Questionnaire (SAQ) on Sustainable Procurement

Suppliers that sign the pledge conduct a self-assessment, which consists of the common SAQ* published by Global Compact Network Japan, and the Human Rights SAQ and Environmental SAQ that we have developed taking into account characteristics of the Otsuka group business activities. Based on the results, we conduct interviews with suppliers, and promote sustainable procurement with them.

*SAQ (Self-Assessment Questionnaire)

	2019	2020	2021
Number of implemented SAQ	34 companies	46 companies	57 companies

Initiatives with Business Partners

The Otsuka group is making concrete efforts to build relationships of trust with various stakeholders, including business partners

[Stakeholder Engagement](#)

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Engagement

Initiatives That We Are Engaged In

Participation in TCFD

The Otsuka group has announced its support for recommendations issued by TCFD in October 2021. Scenario analysis assesses climate-related risks and opportunities, including carbon taxes, physical risks, and crop demand. We promote various measures based on the assessment result.



[PDF Initiatives for TCFD Recommendations](#)

Joining the RE100 Initiative

Otsuka Holdings has endorsed RE100, an international initiative that aims for 100% use of renewable energy for business operations, and joined it in April 2022.



Support for Climate Change Initiatives

Otsuka Holdings supports for Japan Climate Initiative that declares "joining the front line of global push for decarbonization from Japan," and participates in various activities.



Certification by Science Based Targets (SBT)* Initiative

Greenhouse gas (GHG) emissions reduction targets set by Otsuka Pharmaceutical and Taiho Pharmaceutical have been certified by the Science Based Targets (SBT) initiative. In order to achieve these new goals, we will optimize energy use and introduce renewable energy, and continue to promote reduction of GHG emissions throughout the value chain.



*An international initiative led by the United Nations Global Compact (UNGC), World Resources Institute (WRI), and World Wide Fund for Nature (WWF). It certifies the CO₂ emission reduction targets of companies that are in line with emissions reduction scenarios based on scientific facts, for achieving the Paris Agreement-mandated objective of limiting the average global temperature rise to below 2°C.

External Recognition

CDP Evaluation

In 2021, CDP, an international NGO that works on environmental issues, scored the Otsuka Holdings "A-" for climate change and water resources respectively, which means we are at the leadership level for these fields.



Communication with Local Communities

Participation in "the Adopt an Eco-School Program," an Initiative through a Public-private and University Partnership

Concluded agreements with local schools; Otsuka Pharmaceutical, Otsuka Chemical, and Taiho Pharmaceutical have been participating in the Adopt an Eco-School program since 2008. As the name of this initiative represents, three group companies adopt local schools as foster parents to support environmental learning activities. In spite of the COVID-19 pandemic, the companies continued their activities and provided support activities, including a remote tour of the Tokushima Itano Factory of Otsuka Pharmaceutical (introduction of the factory environment from the air using images taken by a drone, introduction of the factory, explanation of the manufacturing line, live broadcasting of the biotope). We hope that the Adopt an Eco-School program will serve as an opportunity for students to pay attention to environmental issues around them.



Relationship with Stakeholders

The Otsuka group is promoting environmentally conscious efforts to build relationships of trust with various stakeholders.

[Stakeholder Engagement](#)

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Environmental Data

Materiality	Classification	Sources	Scope	Unit	FY2018	FY2019	FY2020	FY2021	
Carbon Neutrality	Energies	Electricity	Global total		800,413	736,508	533,095	503,399	
			Japan	thousand kWh	381,748	311,456	127,521	93,177	
			Outside Japan		418,665	425,052	405,573	410,221	
		CO ₂ free electricity	Global total			82,549		201,858	265,242
			Japan	thousand kWh		74,805		194,051	226,690
			Outside Japan			7,744		7,807	38,552
		Natural gas & City gas	Global total			75,892		71,600	68,084
			Japan	thousand m ³		32,812		31,498	31,153
			Outside Japan			43,080		40,101	36,930
		Coal	Global total			58,695		57,968	60,203
			Japan	t		0		0	0
			Outside Japan			58,695		57,968	60,203
		Steam	Global total			374,805		343,067	355,317
			Japan	t		163,871		152,076	152,010
			Outside Japan			210,934		190,991	203,307
		LNG	Global total			12,061		14,104	16,142
			Japan	t		11,887		13,823	15,729
			Outside Japan			174		281	413
		A HFO	Global total			10,350		7,945	5,025
			Japan	kL		10,113		7,945	5,025
			Outside Japan			237		0	0
		LPG	Global total			5,486		5,870	5,990
			Japan	t		5,154		5,596	5,664
			Outside Japan			332		274	327
		Diesel	Global total			968		436	452
			Japan	kL		54		58	20
Outside Japan				914		378	432		
Kerosene	Global total			148		130	133		
	Japan	kL		148		130	133		
	Outside Japan			0		0	0		
Gasoline	Global total			56		115	48		
	Japan	kL		56		115	48		
	Outside Japan			0		0	0		
Steam (non industrial)	Global total			988		1,084	1,198		
	Japan	GJ		988		1,033	1,198		
	Outside Japan			0		0	0		
Hot water	Global total			193		2,567	1,371		
	Japan	GJ		192		173	138		
	Outside Japan			1		2,393	1,233		
Cold water	Global total			5,842		11,774	3,897		
	Japan	GJ		5,842		11,774	3,897		
	Outside Japan			0		0	0		

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Materiality	Classification	Sources	Scope	Unit	FY2018	FY2019	FY2020	FY2021	
Carbon Neutrality	Renewable Energies	Solar power	Global total		420	1,674	3,869	6,727	
			Japan	thousand kWh	342	356	1,409	4,069	
			Outside Japan		78	1,318	2,459	2,658	
		Solar water heater	Global total		271	222	222	0	
			Japan	GJ	0	0	0	0	
			Outside Japan		271	222	222	0	
		Biomass power	Global total		7	1	7	13	
			Japan	thousand t	0	0	0	0	
			Outside Japan		7	1	7	13	
		CO ₂	CO ₂ emissions	Global total	thousand t-CO ₂	842	821	706	684
	Japan			t-CO ₂	324,162	282,243	207,281	188,999	
	Outside Japan				518,329	538,525	498,754	494,704	
	CO ₂ emissions per sales		Global total	t/¥ million	0.65	0.59	0.50	0.46	
	GHG emissions throughout the value chain			thousand t-CO ₂	1,399	1,320	1,118	1,030	
	Scope1				96,308	138,583	125,038	128,464	
	Scope2				179,389	92,444	36,647	8,255	
	Scope3 breakdown		Category 1			748,933	730,219	635,542	592,537
			Category 2			84,157	85,119	52,402	38,763
			Category 3			31,518	29,633	45,579	34,167
			Category 4			82,176	79,981	70,621	70,519
Category 5					12,143	11,851	12,836	13,535	
Category 6			Japan ¹		11,677	10,882	6,030	5,413	
Category 7				t-CO ₂	5,801	5,888	5,773	5,917	
Category 8					9,121	8,463	6,356	7,258	
Category 9				22,936	22,484	20,407	20,736		
Category 10						N/A			
Category 11				78,554	81,034	80,209	79,452		
Category 12				34,766	23,681	20,751	21,163		
Category 13					N/A				
Category 14					N/A				
Category 15					N/A				
Water Neutrality	Water	Water usage	Global total		19,463	18,756	17,732	17,680	
			Japan	thousand m ³	13,010	12,274	11,605	10,909	
			Outside Japan		6,453	6,482	6,127	6,772	
		Water use efficiency	Global total	t/¥ million	15.1	13.4	12.5	11.8	
		Water intake by water source	Municipal water (including industrial water)		14,110	13,561	12,793	13,548	
			River water	thousand m ³	1,417	1,382	1,312	125	
			Ground water		3,936	3,813	3,627	4,007	
		Wastewater by destination	Rivers, lakes and marshes			12,345	11,717	11,194	
			Underground seepage	thousand m ³		61	60	4	
			Area of ocean			1,267	1,002	1,051	
Third-party processing (municipal sewage, etc.)				3,109	2,886	2,873			
Total Amount of Wastewater	thousand m ³		16,782	15,666	15,122				

TABLE OF CONTENTS	Editorial Policy	Corporate Profile	Message from the Director in Charge	Policy and Management	Material Issues			Biodiversity	Management of Chemical Substances	Supply Chains	Engagement	Environmental Data and Third-Party Verification
					Carbon Neutrality	Circular Economy	Water Neutrality					

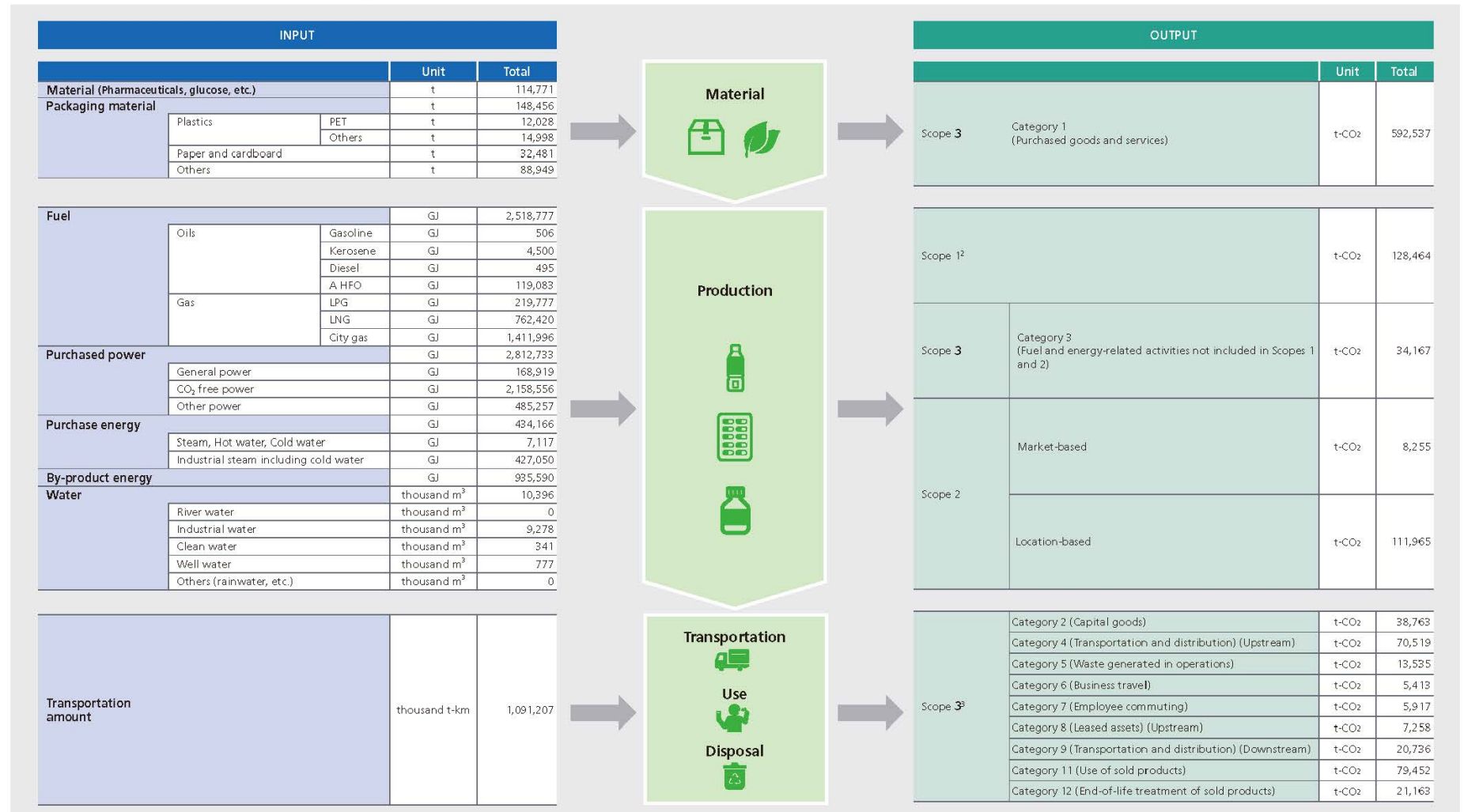
Materiality	Classification	Sources	Scope	Unit	FY2018	FY2019	FY2020	FY2021	
Circular Economy	Material	Material	Japan ¹	t	127,473	125,289	114,847	114,771	
		Plastics	PET		16,888	14,376	11,963	12,028	
	Packaging material	Others			17,660	17,783	16,028	14,998	
		Paper and cardboard		Japan ¹	t	37,465	36,388	33,149	32,481
		Others				97,843	95,658	89,826	88,949
	Waste ²	Total (Including valuables)	Total amount of waste	Global total		97,441	88,878	90,147	
				Japan	t	38,378	43,083	35,723	
				Outside Japan		54,358	53,155	54,901	
			Recycled materials	Global total		74,618	64,027	64,395	
				Japan	t	34,930	38,805	30,647	
				Outside Japan		35,813	33,380	34,043	
		Global Breakdown	Material Recycling	t	42,236	39,243	36,804		
			Thermal Recycle		12,121	9,528	11,911		
			Composting and feed ⁴		20,261	15,256	15,680		
		Final disposal	Global total		5,048	4,841	6,171		
			Japan	t	4,163	4,068	3,983		
			Outside Japan		885	773	2,188		
		(landfill)	Global total		11,075	9,632	10,226		
			Japan	t	166	115	99		
			Outside Japan		10,960	9,533	10,114		
	Bio-processing and chemical processing	Global total		10,379	9,355	9,355			
		Japan	t	909	799	799			
		Outside Japan		9,470	8,556	8,556			
	Hazardous ³	Total amount of waste	Global total		9,761	9,793	10,703		
			Japan	t	4,250	3,771	3,836		
			Outside Japan		5,990	5,958	6,190		
		Recycled materials	Global total		5,318	4,549	5,450		
			Japan	t	2,480	1,638	1,653		
			Outside Japan		3,680	2,897	3,276		
		Global Breakdown	Material Recycling	t	2,634	96	2,257		
Thermal Recycle				2,441	1,556	3,193			
Composting and feed ⁴				243	0	0			
Final disposal		Global total		2,389	2,443	2,694			
		Japan	t	2,124	2,047	2,235			
		Outside Japan		265	396	459			
(landfill)		Global total		1,572	1,824	2,137			
		Japan	t	2	9	1			
		Outside Japan		1,563	1,822	2,136			
Bio-processing and chemical processing	Global total		978	421	421				
	Japan	t	135	102	102				
	Outside Japan		843	319	319				

1. Five group companies: Otsuka Pharmaceutical, Otsuka Pharmaceutical Factory, Taiho Pharmaceutical, Otsuka Chemical, and Otsuka Foods 2. Since 2019, the scope of disclosure has expanded from Japan to Global.
 3. Hazardous waste by Japanese regulations; in other countries, the classification is based on the respective national standards. 4. Composting and conversion to feed in FY 2019 include other wastewater treatment.

Reporting of Violations of Environmental Laws and Regulations

In FY 2021, we did not have any serious accidents, violations, or environmental fines related to water quality or hazardous chemical substances.

Material balance over the life cycle of the business¹



1. Five group companies: Otsuka Pharmaceutical, Otsuka Pharmaceutical Factory, Taiho Pharmaceutical, Otsuka Chemical, and Otsuka Foods 2. Indirect emissions from energy sources and indirect emissions from freon leak volume and during the production of carbonated beverages, etc.
3. Categories 10 and 13 to 15 are not applicable

Otsuka Group's subsidiaries' acquisition of ISO 14001 certification

Acquisition rate 55.3 (Japan77.8%, Outside Japan34.7%)

* All production sites of the consolidated Otsuka Group

Japan: 10 Companies (Certified Companies)

Integrated certification as Otsuka Holdings (Otsuka Pharmaceutical Co., Ltd., Otsuka Pharmaceutical Factory, Inc., Taiho Pharmaceutical Co., Ltd., Otsuka Chemical Co., Ltd., Otsuka Food Co., Ltd., Otsuka Techno Corporation)
 EN Otsuka Pharmaceutical Co., Ltd.
 Otsuka Packaging Industries Co., Ltd.
 Higashiyama Film Co., Ltd.
 J.O. Pharma Co., Ltd.

Tianjin Otsuka Beverage Co., Ltd.
 Korea Otsuka Pharmaceutical Co., Ltd.
 Nutrition & Sante SAS
 Nutrition & Sante Iberia SL
 Otsuka Pakistan Ltd.
 PT Amerta Indah Otsuka
 PT Otsuka Indonesia

Outside Japan : 13 Companies (Certified Companies)

Zhejiang Otsuka Pharmaceutical Co., Ltd.
 Egypt Otsuka Pharmaceutical Co., S.A.E.
 PT Widatra Bhakti
 P.T.Lautan Otsuka Chemica
 Zhangjiagang Otsuka Chemical Co., Ltd.
 Hebron S.A.

As of December, 2021

Third-Party Verification

In order to improve the transparency and reliability of its environmental data, the Otsuka group has its GHG emissions Scopes 1 and 2 (CO₂ emissions from energy sources, including energy consumption), and Scope 3 (Category 1) verified by third-party organizations. This helps us identify emissions trends and implement improvements. We will continue to expand the scope of verification and further enhance the reliability of our data.

