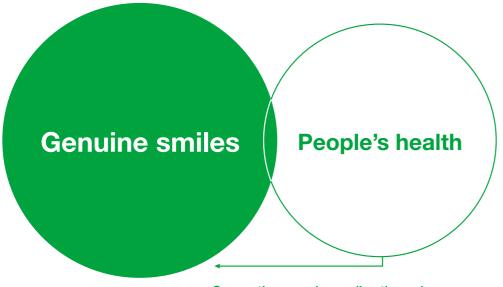


# TOWA PHARMACEUTICAL INTEGRATED REPORT 2024



# We contribute to people's health We are dedicated to people's genuine smiles



Supporting genuine smiles through everything that is contributing to health

Towa Group contributes to people's health by creating superior products and services. Through our corporate activities, we aim to be a company that is valued and needed by patients, healthcare professionals, local communities, and others.



[Editorial Policy]	We issue Towa Pharmaceutical Integrated Report to communicate to shareholders, investors, and other stakeholders Towa Group's efforts to enhance our corporate value. In this issue, feature topics cover the synergies of our overseas business and the Group's initiatives to ensure reliability. In addition, the sections titled "Our Value Creation Process" and "Message from the President" outline our value creation story and 6th Medium-term Business Plan 2024–2026 PROACTIVE III. We strive to improve the content of our report to respond to various opinions and interests of our stakeholders. We look forward to your candid feedback.
[Scope Covered]	Towa Group's consolidated accounts including some consolidated and non-consolidated figures in Japan.
[Period Covered]	FY2023 (From April 1, 2023 to March 31, 2024) Note: The financial information is as of March 31, 2024. The report also covers some initiatives that were taken before April 1, 2023 or after March 31, 2024.
[Guidelines for Reference]	IFRS Foundation's International Integrated Reporting Framework; and the Japanese Ministry of Economy, Trade and Industry's Guidance for Collaborative Value Creation 2.0.
[Forward-looking Statements]	In this report, statements other than historical facts are forward-looking statements that reflect our plans and expectations. Because these statements contain risks and uncertainties, actual results and performance may differ from the expectations expressed herein.

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# **Embracing the Challenge** of a New Era for the Future **Beyond People's Health**



Itsuro Yoshida President and Representative Director

# For a production system to fulfill our social mission during a period of change in the generics industry

The generics business in Japan is currently undergoing a major transformation. Japan's social security benefits expenses are expected to reach about JPY 140 trillion by 2025. To address this, the Japanese government has promoted the use of generic drugs since the early 2000s. As a result, the percentage of generics use has already achieved the target of an 80% volume share. On the other hand, trust in generics and the industry has declined due to a series of supply insecurity incidents caused by guality problems of generics manufacturers that came to light in 2020. The Basic Policy on Economic and Fiscal Management and Reform 2023 approved by the Cabinet in June 2023 stated that measures should be taken to secure the stable supply of drugs, including generics, based on medical needs and to review the structure of the generics industry. In July of the same year, a Study Group on Industry Structure to Achieve Stable Supply of Generic Pharmaceuticals was held to discuss a future vision for the industry.

In the generics business in Japan, the Towa Group has been working to build a system to increase production to help achieve the 80% volume share target in accordance with the previous Medium-term Business Plan. In 2018, we put the 2nd solid formulation building into operation at our Yamagata Plant. Together with our Osaka and Okayama Plants, we secured a total annual production capacity of 12.0 billion tablets in FY2021 as initially planned. However, we are now in the extraordinary situation in which the industry as a whole is unable to deliver stable product supply. For this reason, we brought forward our plans for additional investments in the 2nd solid formulation building at the Yamagata Plant, adding 2.0 billion tablets to achieve a production system of 14.0 billion tablets. We also completed the construction of the 3rd solid formulation building at the same plant in November 2023, which started operations in April 2024. In FY2026, we plan to achieve a production capacity of 17.5 billion tablets per year across the three plants. With the construction of the 2nd sterile formulation building at the Yamagata Plant, we will enhance the production capacity of liquid formulations and freeze-dried formulations, in our efforts to further expand our tangible facilities.

On the intangible front, we are also working to install automation and unmanned facilities and systems to enhance production efficiency, in addition to promoting the development of smart factories. The major purpose of these initiatives is not only to enhance production efficiency and expand production through automation, but also to reduce



the burden on employees working in our plants, for the improvement and advancement of work styles. We will work to evolve the working environment into one where our employees can engage in their work with a sense of job satisfaction. For example, while machines and AI will handle tasks that require speed and accuracy, human workers will be responsible for further improving efficiency, conceiving plans and ideas, and making high-level decisions. Starting with the Yamagata Plant, we will later roll out these measures at the Okayama and Osaka Plants as well.

In the manufacturing control and quality assurance systems, our products are manufactured at all of our plants through procedures that are in compliance with the three GMP principles. Consistent education and training for employees have ensured that each employee works with a high awareness of quality. To build a stricter quality assurance system, we also proactively incorporate international standards such as PIC/S GMP and ICH Guidelines, and we are building a structure that will thoroughly eliminate human error. Moreover, to maintain and strengthen the system for stable product supply, we will push forward with efforts such as purchasing APIs from multiple suppliers and audits of manufacturing sites. We are also engaging in initiatives aimed at the strengthening of governance and penetration of compliance across the Group, from the manufacturing of APIs to the manufacturing of formulations, logistics, and distribution. At the same time, in addition to the Manufacturing Execution System (MES) and the Laboratory Information Management System (LIMS) already in operation, we will introduce the Quality Management System (QMS) from MasterControl K.K., to further improve manufacturing and quality control.

We will continually share the latest market trends and future outlooks across the Group. To fulfill our social infrastructure role, we will continue our efforts with a great sense of mission, namely that we play a central role in stable product supply and quality control.

# Aim to create various innovations with synergies generated by Towa Quality

As all Group companies work together to achieve stable product supply, new synergies have been created. The Martorelles Plant of Towa Pharmaceutical Europe, S.L., which is under the umbrella of Towa Pharma International Holdings, S.L., itself a consolidated subsidiary of Towa Pharmaceutical, has begun manufacturing Esomeprazole Capsules 10mg/20mg "Towa". This plant is a manufacturing base that complies with European Medicines Agency (EMA) and U.S. Food and Drug Administration (FDA) standards, and in February 2024, it also obtained approval for the manufacture of products for the Japanese market. The Martorelles Plant uses large granulation machines to produce large volumes efficiently, a strength that it draws on to provide products to European and U.S. markets. Now, by manufacturing products for the Japanese market, the plant has made significant progress not only toward the Group's production backup system, but also toward the current issue of stable product supply in Japan.

We will also work to further strengthen cooperation through joint development utilizing the technologies of Group companies. One area in which we can expect to see synergies is the leading-edge formulation and capsule technologies held by Group companies, Sunsho Pharmaceutical Co., Ltd. and Greencaps Pharmaceutical Co. Ltd. A strength of Sunsho Pharmaceutical is its proprietary technology of UniORV®, which has the potential to combine any ingredient in a variety of formulations that cover the weak points of APIs, and seamless capsules that offer a high degree of freedom in product design. It is now working to increase its manufacturing capacity using this technology. We are conducting research and development that combines these various technologies with Towa's formulation technologies, with the aim of connecting them to the creation of innovation.

All research and development of new products is based on Towa Quality. Towa Quality means the manufacture of products that society wants and needs and that have been upgraded to the latest and the best of the times through continuous modifications and improvements, using all the latest technologies in the Towa Group's possession. For example, Towa Group is actively trying to clarify the formation mechanism of nitrosamine, which are feared to be carcinogenic, and develop analytical methods. The results of this research were published in ACS Omega, the journal of the American Chemical Society. These results are expected to greatly contribute to the assessment of the risk of admixture of nitrosamine impurities in formulations and to the improvement of quality.

Other examples include orally disintegrating (OD) tablets, which disintegrate in the mouth without water and are thus easy to take, techniques for masking bitter taste, and drug imprinting that makes it easy for doctors and pharmacists to distinguish tablets. A representative example of the Towa Group's value-added formulation technology is RACTAB, our proprietary technology combining the disintegrating feature that makes a tablet easy to take, and the hardness that enables a tablet to be handled like an ordinary tablet. We are confident that the clarification of the mechanism of nitrosamine formation and the added value of Towa Quality will better address the concerns of people and healthcare-related issues around the world.

The objective of the Group's globalization is also to deliver Towa Pharmaceutical's highly value-added products widely throughout the world. Individual countries and regions have different laws concerning the quality, efficacy, and safety of pharmaceuticals, and their standards and approaches are constantly being updated. The ability to share these global circumstances is one of the significant benefits of synergy, and there are expansive opportunities to contribute to new markets, such as those in emerging countries where increased demand is expected, with the creation of innovation.

# Start of the 6th Medium-term Business Plan, declaring "Challenges toward a new phase"

The Towa Group started the 6th Medium-term Business Plan 2024–2026 PROACTIVE III in FY2024. The basic Policies of the Plan are:

Evolution of generics business in Japan toward a new phase

Establishing foundation for new markets / new businesses and realizing group synergies

Strengthening sustainability management and building fundamentals for sustainable growth

The sub-title of the 6th Medium-term Business Plan is "Challenges toward a new phase." One of our key challenges will be for all companies in the Group to work proactively to create health-related businesses that are adapted to the medical system of the future and realize a future that provides full coverage, from medical care to the care and prevention of presymptomatic diseases, catering to a society with a long and healthy life expectancy. Based on the Towa Philosophy of "We contribute to people's health," we will work to acquire new technologies and to integrate new knowledge and technologies. We will actively engage in the creation of health-related businesses adapted to the medical system of the future.

The key to "Challenges toward a new phase" will be the creation of innovation. The Towa Group is working to create technological innovation and product value through the manufacture of sophisticated products with No. 1 total product performance. Our ideal is manufacturing based on local production for local consumption. One area in which we are drawing closer to this ideal is the research and development of continuous flow precision synthesis technology that offers a high degree of safety. Flow synthesis, a next-generation method for the manufacture of APIs that is environmentally friendly, can be achieved with a smaller environmental footprint (green chemistry) at compact automated plants. As such, this technology will contribute significantly to raising the competitiveness of the Japanese industry. We are currently proceeding with development in the synthesis of intermediates, based on multiple candidates. At the same time as increasing the number of those intermediates, we are also aiming to establish technology that will enable synthesis from starting materials. By cultivating technological capabilities of such a high standard in Japan and developing the human resources to support those capabilities, we believe that we will be able to contribute significantly to the Japanese government's policy of making the supply chain more resilient and increasing national capacity.

Other technological innovations include research of molecular control technology, including spherical crystallization, for the development of pharmaceuticals that have no bitter taste, making them easy to take, tackling the issue of carcinogenic nitrosamine that I described above, and drug repositioning with iPS drug discovery. These are the kinds of new technologies that we are pursuing to deliver added value to patients, address social issues, and create synergies between Group companies. Our aim for molecular control technologies, including spherical crystallization, is to market products using these technologies within the next several years. Drug re-positioning refers to research to discover and commercialize new medical effects from existing drugs whose safety and biokinetics have already been confirmed through actual results. We have completed the selection of candidate substances using iPS cells, and we are now proceeding with clinical testing. Clinical data on safety, the most time-consuming and expensive part of new drug discovery, has already been secured, and once we have confirmation of efficacy, we will be able to deliver a wide variety of drugs to the market efficiently. In fields where new drug manufacturers are more reticent due to drug price considerations, I believe that manufacturers of generics have a major role to play.

# Aim to create a future that provides full coverage from medical care to the prevention of pre-symptomatic diseases

In our new health-related businesses, we are selling the Healthcare Passport, a cloud-based regional healthcare information coordination service, in partnership with TIS Inc. Ltd. This is being rolled out to address the key challenge of realizing a future that provides full coverage, from medical care to the care and prevention of pre-symptomatic diseases, catering to a society with a long and healthy life expectancy. Through this, we will contribute to the realization of the Comprehensive Community Care System, which is scheduled for completion in around 2025.

The Comprehensive Community Care System is based on the development of a platform that will allow medical professionals to easily share information with ordinary citizens by utilizing cuttingedge technologies, such as big data, to enable appropriate, efficient treatment and care-giving by medical professionals and the promotion of the health of ordinary citizens (coordination and sharing of data from facilities such as hospitals, pharmacies, and those for nursing care).

To this end, we are currently working on the realization of the "Exa Port" concept, which will make use of personal health records (PHR) and electronic health records (EHR), with the Healthcare Passport as the hub of this system. This concept involves analyzing data on individuals' condition before they become ill (pre-symptomatic) and providing information on support such as diet and exercise. We will also enhance our lineup of products and services for the maintenance and improvement of health. A particularly large challenge in our society, which has entered an era of hyper-aging, is health support that caters to the individual. Advice in response to concerns about aging will also become important. We also hope to make a major contribution to the realization of the Comprehensive Community Care System, which will help the elderly to continue living in their own fashion, as much as possible, in communities that are familiar to them.

of the basic policies of the 6th Medium-term Business Plan. By carrying out operations under the Towa Corporate Vision while feeling satisfied with their jobs, each employee will be able to sense changes in society and create new value. As DX and Al further penetrate our work, many tasks will be replaced by digital technologies. The role of people is to grow themselves and the company while feeling a sense of job satisfaction.

As initiatives to support that on the production frontlines, we have established a Work Flow system and an Expert Scheme. In the Work Flow system, the series of operational processes for each product are converted into data that can be checked at any time on a tablet. This clarifies for each individual worker their own role and mistakes that are easily made, and prompts them to think about efficiency and improvements for themselves. The Expert Scheme is a program for the evaluation of employees who are highly knowledgeable about the tasks and machinery and who are pursuing efficiency improvements and achieving high productivity. In both of these initiatives, we are teaching all employees to be more conscious of costs. By thinking about their own productivity in terms of costs in their work, their motivation will become clear, and the company will be able to evaluate that productivity fairly. Always thinking about their immediate goals and future career, taking initiative, and acting systematically toward achieving those goals will lead to job satisfaction.

To promote sustainable management with enhanced consideration of the global environment and society, we established a new Environment, Health and Safety Management Department in April 2022. This department controls and manages the environment and safety throughout the Towa Group in a unified manner and aims to further improve the environment and safety for Towa employees and regional communities. In regard to the impact of climate change on our business activities, profits, and other factors, we will strive to disclose information based on the TCFD recommendations while carrying out scenario analyses of our own business activities and taking stock of greenhouse gas emission reduction measures. We will connect these initiatives to the launch of a green sustainable chemistry industry, hoping to further contribute to raising the competitiveness of the Japanese industry.

Creating work environment with job satisfactions and fostering talented human resources will underpin sustainable growth

Creating work environment with job satisfactions and fostering talented human resources will be key sources of "Strengthening sustainability management and building foundation for sustainable growth," one

# Delivering genuine smiles to the people of Mongolia The 100-Year Plan, a challenge for the creation of a local industry

The basis of the Towa Group's fundamental thinking and vision is the Towa Corporate Vision of "We are dedicated to people's genuine smiles." "Genuine smiles" refers to a state in which happiness wells up from within when the body is healthy and the spirit is fulfilled, bringing a smile to a person's face. What we should be like in the future represents a company that continues to be needed by people living in the region and to deliver the products and services that they need, at any age and in any region.

The Towa Pharmaceutical Group 100-Year Plan is a symbolic initiative that embodies this philosophy as a group. As part of this plan, we embarked on the challenge of growing licorice in Mongolia in 2014. Mongolia faces significant challenges as the mining of finite underground resources caused desertification and, consequently, climate change. However, mining is a key industry that underpins the nation's economy.

In light of these facts, we focused on licorice, a plant that grows wild in Mongolia and is used as an ingredient not only in food products and cosmetics, but also in pharmaceuticals. We felt that if we could cultivate licorice in a systematic way, sell the harvested crop, and cultivate new licorice plants with the seeds, making it an unlimited green resource, it could grow into an industry for sustainable development, which would help raise the standard of living of the Mongolian people and bring more genuine smiles to their faces. We also believe that the cultivation of licorice will help reduce CO<sub>2</sub> emissions, prevent the desertification of the land, and suppress the dispersion of yellow sand into the atmosphere.

We began in 2014 by ascertaining the situation in Mongolia, and in 2017, we secured about 1,000 hectares of land in Kherlen, a district in the Khentii province of Eastern Mongolia. Although the initiative stalled due to the COVID-19 pandemic, in September 2021, we were able to plant 600 licorice seedlings on a trial basis. In 2023, with the approval of the chief of the Kherlen district, we contracted 100 local residents who are actively participating in raising seedlings and growing the plants in a cultivation trial.

## Cultivation of licorice in Mongolia



Licorice plants growing (August 2024)

In this way, we are proceeding with the project together with the local community. This initiative has also been exceptionally well received by the local residents. Some of the seedlings have since been transplanted to the land, and we are now observing their germination and growth. Licorice has a long growing cycle of about seven years from fertilization of the soil to harvest, and its cultivation on vast tracts of land is certainly not a straightforward task. For this reason, we plan to expand the growing area in stages so we can harvest the plants progressively. We are making effective use of the vast land area, including growing pasture on the vacant land to feed livestock during Mongolia's harsh winters.

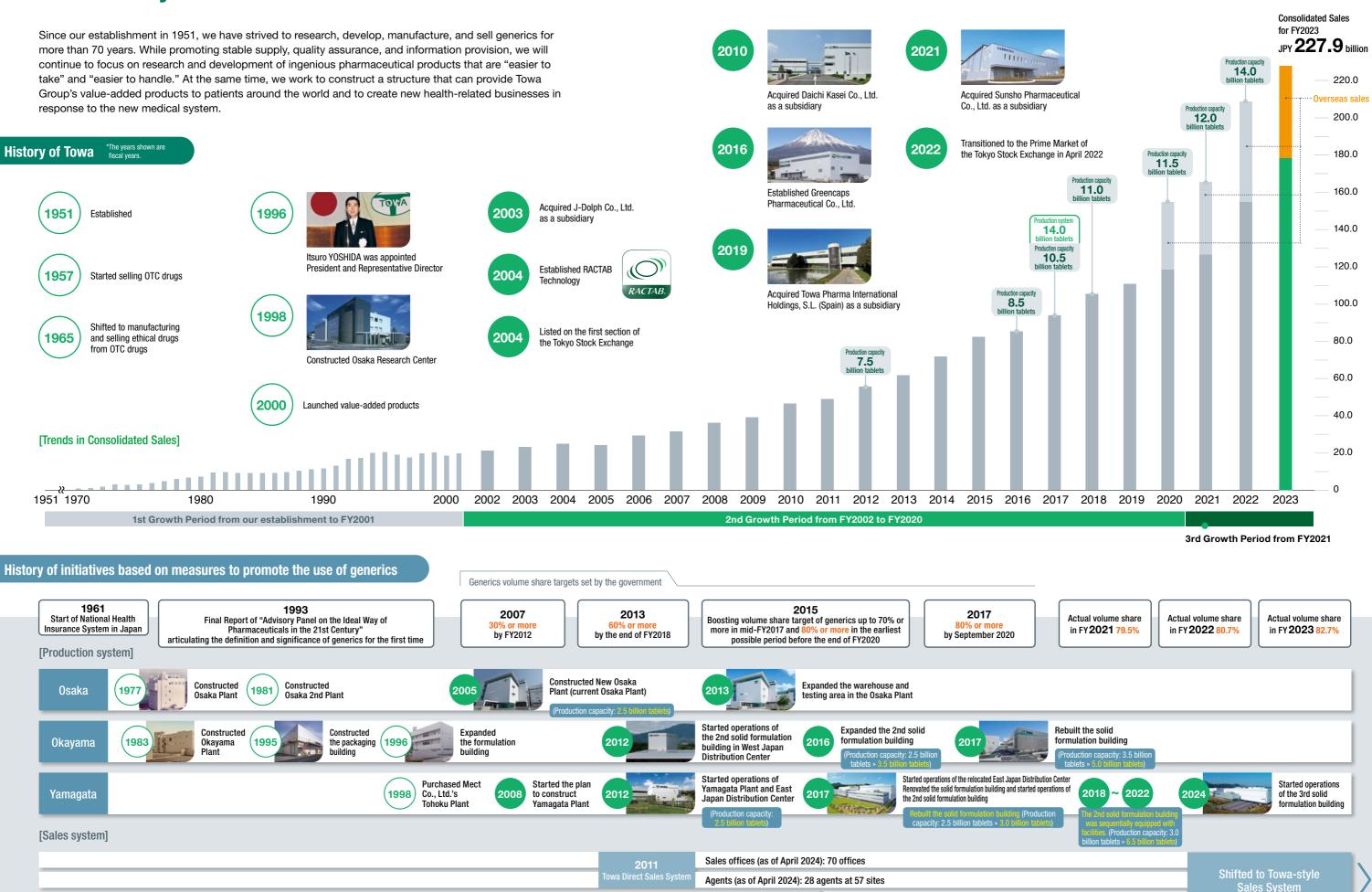
Future milestones for the project will be the start of full-scale cultivation in 2026, the launch of sales of licorice in 2031, which is the 80th anniversary of our foundation, and the start of operations of a factory to produce concentrated licorice extract in 2051, our 100th anniversary. We will focus our efforts on ensuring that the business can be managed autonomously in Mongolia. If, in the future, it leads to the expansion of the business into domains such as processing into APIs and exports, we expect it to have a tremendous significance for the revitalization of the regional community and economy. The entire Group wants to continue this project as a symbol of our determination to be a company that continues to be needed by people living in the region and to deliver products and services that they need, at any age and in any region, for the genuine smiles of the people.

With a view to realizing people's genuine smiles through a wide variety of health-related businesses, the Towa Group will continue in its efforts to roll out these businesses both in Japan and around the world. We would like to ask for your continued support in these endeavors.



Pasture cultivation (use of land not being used to grow licorice)

# **Our History**



Started collaboration with two wide-area wholesalers in 2017

9 TOWA PHARMACEUTICAL Integrated Report 2024

# Social Issues Addressed by Towa Group 1

# **Helping Cut Medical Costs through Generics**



# How to address the ever-increasing medical costs

Japan's medical cost problem and the importance of generics

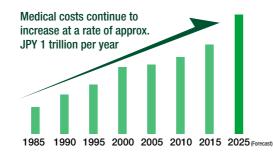
In Japan, medical costs continue to increase each year due to factors such as an aging population, reaching approximately JPY 45 trillion in FY2021. The Ministry of Health, Labour and Welfare estimates that the amount will exceed JPY 60 trillion in 2025. Rising medical costs threaten the sustainability of the National Health Insurance System, making it imperative to find a solution.

Meanwhile, as the workforce supporting insurance premiums and taxes decreases, the prerequisites for the National Health Insurance System are likely to collapse. If medical costs continue to swell as estimated, some undesirable events may happen: an increase in patients' burden of medical costs and the taxes, and a loss of access to medical care that we naturally have had up to now. Stemming the increase in medical costs is essential to keep the National Health Insurance System in the future.

In this situation, generics have come to play an increasingly vital role. Generics are just as effective as brand-name drugs, but they are cheaper and can reduce medical costs by approximately JPY 1.6 trillion per year. They also help lower out-of-pocket drug costs for patients. Furthermore, the wider use of generics will reduce costs for medical institutions

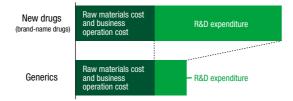
and pharmacies, thereby improving the efficiency of the entire healthcare system.

Source: https://www.mhlw.go.jp/toukei/saikin/hw/k-iryohi/21/dl/kekka.pdf



Ministry of Health, Labour and Welfare: "Outline of National Medical Care Expenditure in 2015" and "Materials for the Medical Insurance Subcommittee, 76th Social Security Council'

### Comparison of drug prices (conceptual chart)



# Restoring confidence in generics and the sustainability of the healthcare system

Given the increasing importance of generics, we consider it highly deplorable that some pharmaceutical companies significantly undermined confidence in pharmaceutical products, especially generics, by engaging in misconduct. Restoring confidence in generics is crucial for creating an environment where patients can receive treatment with peace of mind. With ongoing concerns about the quality and reliability of generics, strict control of the manufacturing process and the provision of highly transparent information are essential to dispel these concerns. Creating an environment where patients can confidently choose generics is key to achieving a sustainable healthcare system.

- I. Strengthen compliance, governance, and risk management
- II. Strengthen the system that gives utmost priority to quality
- III. Take action to ensure stable supplies
- IV. Provide and disclose information actively
- V. Enhance association activities, cooperate with the government, etc., and take other measures



# Generics

# Further improving the quality of generics and strengthening the stable supply system

Towa is committed to developing and providing generics to help reduce medical costs in Japan and contribute to realizing a sustainable healthcare system. We currently have the lineup consisting of more than 700 products to cover various therapeutic areas.

In developing products, we conduct research to enhance the value of our products using the latest technology and equipment, while ensuring the same efficacy and safety as new drugs. We also work to improve product quality and create added value to provide Towa Quality products that are continuously improved and modified.

To ensure a stable supply of generics, we have established a comprehensive supply system encompassing raw material procurement, manufacturing, and inventory management. Currently, we have production sites in Osaka, Okayama, and Yamagata, with a combined capacity of 14.0 billion tablets per year from these three plants. To meet growing demand, we are expanding

# Towa Group's drug discovery innovations

In addition to manufacturing generics that are as effective and safe as new drugs, Towa Group is working to develop pharmaceutical products



# **FINEST-Pow®**

RACTAB is our proprietary technology for manufacturing orally disintegrating (OD) tablets that can be taken without water. The technology pursues the coexistence of two contradictory properties: easy disintegration and sufficient hardness. We developed this technology in the hope of delivering easy-to-take tablets to patients who have difficulty swallowing due to old age, etc. or limit water intake, as well as producing drugs that can be taken without water whenever necessary, including when patients are not at home.

These coating technologies add various functions, such as bitterness suppression and controlled release, to functional particles. They effectively cover the bitterness, making drugs less bitter and easier to take. We have developed three types of coating technologies according to the functions we intend to add, such as API bitterness suppression, controlled release. enteric coating, and improved dispersibility.

# Manufacture of sophisticated products with No. 1 total product performance by improving product quality and creating added value

our production system to increase capacity to 17.5 billion tablets per year.

Under this production system, we will strengthen our efforts to ensure continuous supply in order to provide medical institutions and patients with the necessary pharmaceutical products at all times. This enhanced supply system is the foundation for building trust with medical professionals and supporting patient treatment.



through technological innovation in drug discovery from the perspective of the patients who will take them.

# **FINEST-Gran® FINEST-Core®**

# **ARTICRE®** Technology

ARTICRE is a technology that improves drugs' solubility by dispersing systematically arranged API atoms or disrupting their order. When an API with low stability or solubility is dispersed in a watersoluble polymer that serves as a carrier, the carrier captures the API, improving the stability. In addition, the state of crystallization of the API changes or the crystals become dispersed, which facilitates disintegration.

# Social Issues Addressed by Towa Group 2

# **Helping Extend Healthy Life Expectancy and Prevent Diseases**

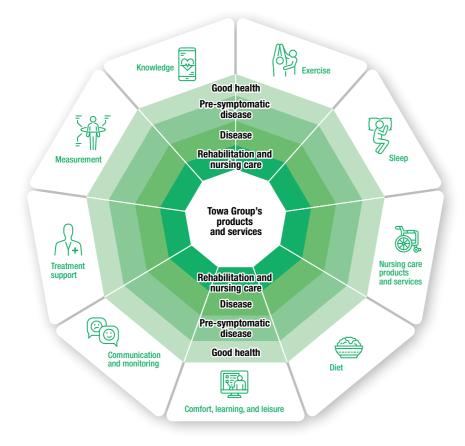


# Advancing super-aging society

# Extension of healthy life expectancy and disease prevention

Extending the healthy life expectancy toward the era of the 100-year life is a major issue in Japan facing a super-aging society. The healthy life expectancy was proposed by World Health Organization (WHO) in 2000. In the past, we had emphasized the average life expectancy of a child aged 0, indicating how many years he or she can live. However, the healthy life expectancy, a period of healthy living, has attracted attention in recent years. Preventing disease and staying healthy and active are key to prolonging the healthy life expectancy. Moreover, extending the healthy life expectancy is essential from the viewpoint of curbing medical costs.

We aim to contribute to the extension of healthy life expectancy as a comprehensive healthcare company for the era of the 100-year life. We will not only manufacture and sell generics but also strive to provide optimal solutions through all types of products and services related to healthcare. A specific initiative in this regard is our entry into health-related businesses. We have classified the state of health into four categories: "good health," "pre-symptomatic disease," "disease," and "rehabilitation and nursing care." We seek to resolve challenges for each category, and provide a wide range of products and services by combining the four categories with the nine focus areas we are committed to. In addition, we are engaged in health co-creation initiatives with the local community, aiming to become a company that is needed by all community members by addressing their diverse issues. As a coordinator connecting people and communities, we will actively engage in healthrelated businesses.





# **Health-related businesses**

We will provide optimal solutions through all types of products and services related to healthcare.



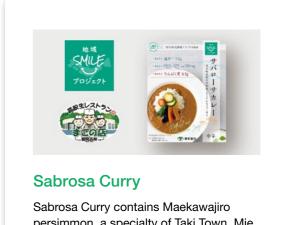
# **Cognitive Function Self Checker**

The service tests users' cognitive functions by combining virtual reality with eye-tracking technology. It presents questions in five areas: memory, attention, language, arithmetic, and spatial recognition, based on a neuropsychological test. Cognitive function is assessed in five minutes by simply having users look at the correct answers.



# Mino Plus

This is a hair growth treatment classified as Category 1 pharmaceutical. We have thoughtfully designed it to fit naturally into user's daily routine and ensure it is comfortable to use even for those who have only recently become concerned about their hair. The formula contains the hair growth ingredient minoxidil and four additional active ingredients\*. \*Pantothenyl ethyl ether, pyridoxine hydrochloride, tocopherol acetate, and I-menthol



persimmon, a specialty of Taki Town, Mie Prefecture, allowing customers to enjoy a touch of mildness and sweetness along with the spicy flavor. Each serving contains 1.2 g of salt and a total of 320 mg of DHA and EPA, which are derived from the mackerel used as an ingredient. \*According to the survey by the Japan Food Research Laboratories



# **Healthcare Passport**

This is a cloud-based personal health record (PHR) platform service. It manages health and medical information linked to ordinary citizens and shares it with both medical professionals and family members to enable the provision of appropriate medical care and health promotion.



Note: The fiscal year ended March 31, 2023 was a transitional period for the change in the fiscal period for nine consolidated subsidiaries. The consolidated subsidiaries had a irregular accounting period of 15 months from

1: The fiscal year ended March 31, 2023 was a transitional period for the change in the fiscal period for hine consolidated subsidiaries. The consolidated subsidiaries had a frequilar accounting period of 15 months from January 1, 2022 to March 31, 2023. During the fiscal year ended March 31, 2023, the Company finalized provisional accounting treatments for the business combination. Accordingly, the figures for the fiscal year ended March 31, 2022 reflect contents of the finalization of provisional accounting treatments.

# **Non-Financial Highlights**

Water usage

(m<sup>3</sup>) 800,000 -

- 1.0

-0.5

-0.10

-0.05

(%) 10-

1.04

0.026

5.912

(FYE March

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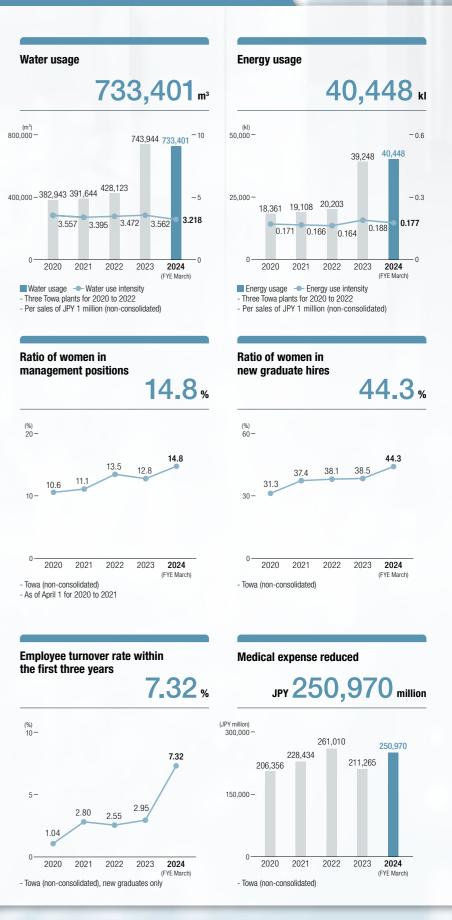
0 365

83.274

2024

(EVE March

0.372





# The Towa Group delivers pharmaceuticals that are needed by patients worldwide

With Towa International (current name) acquired in 2020 serving as a bridgehead for our overseas expansion, we have expanded sales in global markets through increasing self-sold products with a lineup based on medical needs in the U.S. and Europe, and through the competitive CMO business that utilizes large granulation machines. At the same time, we have conducted joint development of global products in Japan and Spain, and the manufacturing of products for Japan in Spain, as we work to realize global synergies.

Going forward, we will further combine the technological capacities of the Group and deliver pharmaceuticals of Towa Quality with added value to many patients throughout the world. We are thereby aiming to create "genuine smiles," which is our philosophy.

The Towa Group's human resources respect diverse cultures and values, think globally, and act locally so that we continue being a company that contributes to society.



Feature Topic

Overseas

**Business** 

Towa Pharmaceutical Europe, S.L.'s Martorelles plant

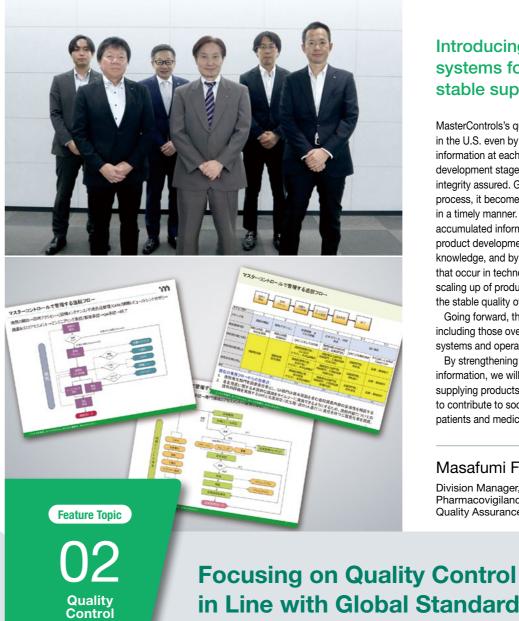
**Striving to Expand Overseas Business and Strengthen Global Manufacturing** 

Developing business in over 30 countries worldwide through Group companies under Towa INT

At the Company, we are aiming to provide added-value pharmaceuticals in overseas markets. Utilizing sales networks in the U.S. and multiple countries in Europe, as well as a manufacturing site in Spain that conforms with U.S. and European standards, we are accelerating business development overseas. In 2020, we acquired Pensa Investments, S.L., which consolidates the generic business, from the Esteve Group in Spain and made it a Group company of Towa Pharmaceutical. From there, in order to clarify its membership in the Towa Group and promote further collaboration with the Group, we changed its name to Towa Pharma International Holdings, S.L. (hereafter, "Towa INT"). There are currently seven group companies in Europe and the U.S. under Towa INT, and together they develop the pharmaceutical B2B business in over 30 countries as of FY2023

In particular, the Martorelles plant of Towa Pharmaceutical Europe, S.L., which is under Towa INT, uses large granulation machines to produce large volumes efficiently, and drawing on this strength, it provides products to the European and U.S. markets. Moreover, in February 2024, the Martorelles plant

acquired approval to conduct manufacturing for the Japanese market from the Pharmaceuticals and Medical Devices Agency (PMDA), and it was added to the Towa manufacturing sites for Esomeprazole Capsules 10mg/20mg "Towa" used to treat digestive system diseases. Going forward, we will work to further strengthen business through joint development utilizing the technologies of Group companies.



# in Line with Global Standards and Enhancing Reliability

# Through installation of a quality management system, all data is saved

In order to be a trustworthy company, we comply with the government's strict quality control standards, ranging from product R&D, manufacturing, and marketing to after-sales operations, and have established a quality assurance system required for ethical drugs. In particular, in manufacturing pharmaceuticals, we will comply with GMP, GQP, and GVP ministerial ordinances and the GDP guidelines to maintain and strengthen our quality assurance system. Additionally, through our proprietary systems and training programs, we will work diligently to ensure appropriate quality and safety.

Moreover, in January 2024, we deployed Master Control Quality Excellence (Qx), a quality management system. The system is the global standard, having been adopted for use by over 200

# Introducing quality assurance systems for the resilience of the stable supply system

MasterControls's quality management system has been adopted in the U.S. even by the FDA. It offers integrated management of information at each stage of the lifecycle, from the drug development stage to final sale. It also offers tracking with data integrity assured. Given the transparency of the guality assurance process, it becomes possible to make more appropriate decisions in a timely manner. In addition, by searching and sharing accumulated information, the information obtained through product development and quality improvements can be utilized as knowledge, and by increasing the efficiency of solutions to issues that occur in technology development and tying it to the smooth scaling up of production, we expect the system to help maintain the stable quality of production and product supply.

Going forward, the system will be installed at Group companies, including those overseas, as we plan to further integrate quality systems and operating standards throughout the Towa Group.

By strengthening quality systems and utilizing accumulated information, we will increase the resiliency of systems for steadily supplying products of consistent quality, allowing the Towa Group to contribute to society and live up to the trust placed in us by patients and medical practitioners.

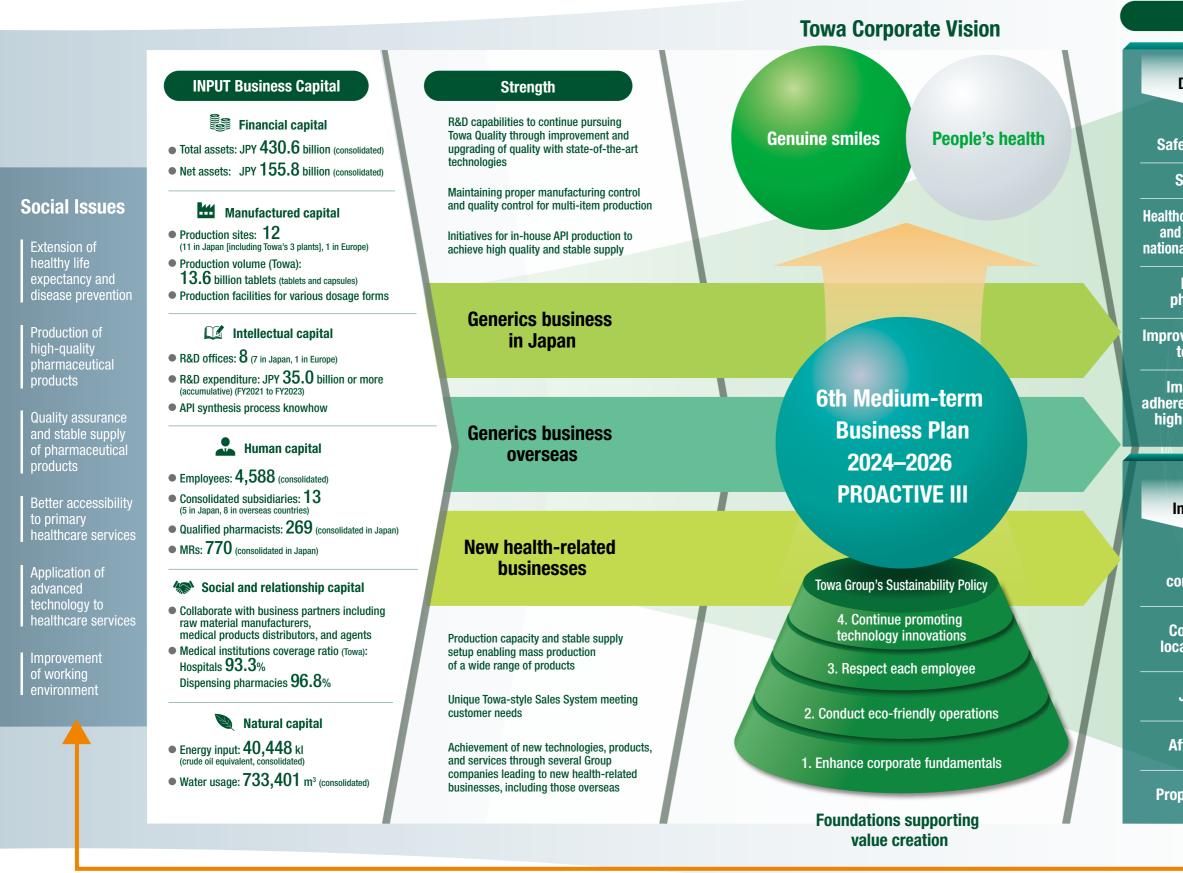
# Masafumi Fukae Division Manager, Pharmacovigilance and Quality Assurance Division

companies and organizations around the world, including the FDA in the U.S. Use of the system keeps data and records organized and prevents them from getting lost and also allows all data to be saved objectively, completely, and accurately.

In addition, we are utilizing the knowledge and experience of our overseas Group companies for quality event management. With a global perspective we work to maintain or improve our quality assurance system, which makes it possible to prevent human errors in advance. In order to ensure quality and reliability at a global level going forward, we will actively accumulate and utilize technology and know-how to provide products in line with international standards.

# **Our Value Creation Process**

To address social issues, Towa Group has created value by allocating its business capital to every business that contributes to people's health. We will contribute to the health of all people and help them achieve a genuine smile based on the "6th Medium-term Business Plan 2024–2026 PROACTIVE III."



# OUTCOME

# **Direct value**

Safety and security

Stable supply

Healthcare cost reduction and maintenance of national insurance system

Mental and physical health

Improvement in access to healthcare

Improvement in adherence by providing high-value products

# Indirect value

Industrial competitiveness

Contribution to local development

Job creation

Affluent society

**Proper tax payment** 

# Create the future beyond people's health

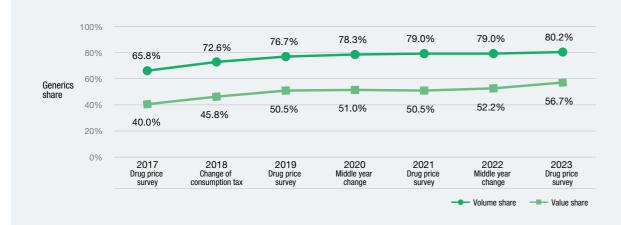
# **External Environment Surrounding Towa Group**

# The social role of generics and policy developments

In recent years, generics have come to play an increasingly vital role in the society. Under the Basic Policy on Economic and Fiscal Management and Reform 2017 approved by the Cabinet in 2017, the government set a target to increase the generics volume share to over 80% by September 2020.

In response to this, the generics industry including Towa has focused on enhancing production capacity and ensuring stable supply. NHI drug price survey in 2023 revealed that the volume share of generics reached 80.2%. With regard to the current promotion of the use of generics, the volume share target was maintained and a new value share target was set (value share of FY2029 was set at 65% or more). Regarding the selective medical treatment for long-listed products, in the Medical Fee Revision in 2024, the modality of insurance benefits for longlisted products was reviewed, and a system of selective medical treatment was introduced. The change is applied to long-listed products that have been on the market for five years since their first generics were put on the market, or that have substitution rates for generic products exceeding 50%. For biosimilars, a target has been set: By the end of FY2029, the number of molecules that have replaced 80% or more on a volume basis will be 60% or more of the total number of molecules.

### Changes in volume and value shares of generics in NHI drug price survey



Source: The 176th Meeting of the Medical Insurance Committee of the Social Security Council on March 14, 2024

# Generics industry's efforts to restore confidence and ensure stable supply

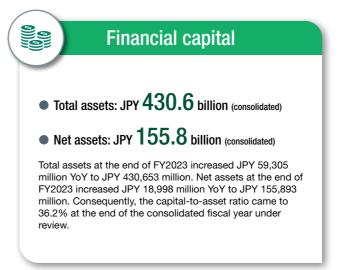
While the use of generics is on the rise, there have been scandals in the industry and concerns about stable supply. Several pharmaceutical companies violated the Pharmaceuticals and Medical Devices Act due to the inadequacies in their manufacturing control and quality control, and became subject to administrative penalties such as suspension of operations as well as frequent product recalls and suspension of shipments. As a result, there is a shortage of medicines, and medical institutions and pharmacies are unable to secure sufficient supplies.

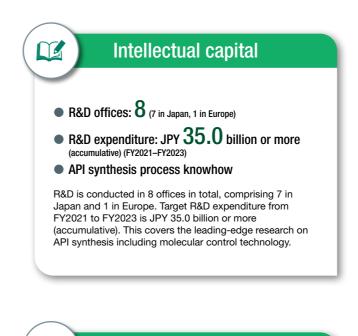
The Ministry of Health, Labour and Welfare believes that simply setting new targets for generics "will not gain sufficient understanding from patients and medical professionals," and that measures are needed to implement strict manufacturing and quality control across the industry and ensure a stable supply.

The industry is moving forward with making corporate information regarding stable supply more visible and is beginning to develop indicators for evaluating companies that can ensure a stable supply of generics and to begin trial implementation of these indicators. In pursuit of Towa Quality, we are making efforts to strengthen our pharmaceutical lineup, maintain stable supply and quality assurance systems, and strengthen our information provision systems, thus doing our utmost to restore trust in the industry.

# **Towa Group's Capital**

Towa focuses on creating value across its Group by working sincerely to solve social issues while leveraging various capitals gained in the past business operations. By solving issues including the extension of healthy life expectancy, we will contribute to the health of people around the world.





# Social and relationship capital

 Collaborate with business partners including raw material manufacturers, medical products distributors, and agents

 Medical institutions coverage ratio (Towa): Hospitals 93.3% Dispensing pharmacies 96.8%

We engage in nationwide marketing activities through 71 sales offices, 30 agents at 60 sites, and medical products distributors, among others, in Japan. Towa has a high coverage ratio of medical institutions: 93.3% for hospitals and 96.8% for dispensing pharmacies.

Manufactured capital
10
<ul> <li>Production sites: 12         (11 in Japan [including Towa's 3 plants], 1 in Europe)     </li> </ul>
Production volume (Towa):
<b>13.6</b> billion tablets (tablets and capsules)
Production facilities for various dosage forms
Towa Group has 12 production sites in total, comprising of 11 in Japan and 1 in Catalonia, Spain. Production volume of Towa, the largest producer, stands at 13.6 billion tablets for tablets and capsules, which is near its maximum production capacity. Our subsidiaries produce ointment, soft capsules, etc. and the Group is distinguished by its capacity to produce diverse dosage forms.
$\frown$
Human capital
4 500
• Employees: 4,588 (consolidated)
<ul> <li>Consolidated subsidiaries: 13</li> <li>(5 in Japan, 8 in overseas countries)</li> </ul>
<ul> <li>Qualified pharmacists: 269 (consolidated in Japan)</li> <li>MRs: 770 (consolidated in Japan)</li> </ul>
Towa Group hires 770 MRs and 269 qualified pharmacists (both consolidated in Japan). In addition, we have introduced an internal qualification system for business operations (experts, etc.) to nurture professionals.
Natural capital
• Energy input: 40,448 kl (crude oil equivalent, consolidated)
• Water usage: 733,401 m <sup>3</sup> (consolidated)
We use good quality water and energy resources to produce high-quality pharmaceutical products. In this regard, from an environmental perspective, we manage chemical substances properly, enhance the plants' water discharge and air emission systems, take energy-saving measures, and make other efforts.

# **Towa Group's Strength**

Generics are marketed later than new drugs (brand-name drugs); therefore, we can produce better products with the same efficacy, quality, and safety as the new drugs by utilizing the latest formulation technologies. We are engaged in various initiatives to provide easy-to-take, easy-to-handle and safe drugs, let alone quality and safety.

# **Development of APIs**

# Developing and selecting the best APIs for manufacturing products

Shigenobu Nishiguchi Manager, API Process Research I Department, API Business Unit, R&D Division

We use APIs meeting our original strict quality standards among countryauthorized APIs. We also actively research APIs and select the best APIs for creating products based on our accumulated know-how. Additionally, we have established manufacturing methods for the APIs in-house and a system to outsource the production of the APIs to Daichi Kasei Co., Ltd., a group API manufacturer, and collaborative API manufacturers. We regularly inquire and confirm each manufacturer whether it manufactures APIs in accordance with standards, laws, and regulations to enable the stable procurement of the APIs.



nformation See page

29.

See page

Without being bound by conventional manufacturing methods, we aim to establish revolutionary and efficient API manufacturing methods to overcome various challenges, including those in quality, environmental load, and productivity. We thus work on the R&D of APIs to let patients take their medicines with peace of mind.

# Product development

# Based on our technologies and experiences, developing products that can be more easily taken and handled

We have the lineup consisting of more than 770 products to cover various therapeutic areas. With the desire to serve as many patients as possible, we offer value-added generics by responding to voices and requests from medical professionals and reflecting them in our manufacturing process. Among them, we have developed better dosage forms and tastes so that drugs can be easily taken by pediatric and elderly patients, and enhanced visibility and stability against light, temperature, and humidity so that drugs can be easily handled at hospitals and pharmacies.



We work day and night to develop high quality and high added value pharmaceuticals that patients and medical professionals are comfortable using. To establish a stable supply system, we strive to design reproducible manufacturing methods, with an eye to manufacturing at multiple sites.

## Quality control

# Working diligently to ensure reliable quality and safety

In order to be a trustworthy company, we comply with strict quality control standards stipulated by the government, from product R&D, manufacturing, and marketing to after-sales operations. We carry out company-wide quality control initiatives to establish the quality assurance system required for ethical medicines. Especially in manufacturing pharmaceutical products, we strive to ensure adequate quality and safety through our specific system, education and training, and other ways as well as to comply with the Good Manufacturing Practice (GMP) established by the government and other related laws and regulations.



Delivering trusted Towa Quality to the world. We take on challenges every day to deliver trusted pharmaceuticals not only in Japan but overseas. We will improve pharmaceutical quality systems, ensure thorough manufacturing control and quality control, and move forward with close attention paid to what patients are thinking.



# Established production capacity with three plants to ensure stable supply at any time

By adopting a back-up system supported by three sites, we ensure that any production disruption at one plant can be compensated by efforts at the other plants. Furthermore, by dividing the physical distribution bases in East Japan and West Japan, we have established an efficient arrangement and a reliable back-up system even in a worst-case scenario. The 3rd solid formulation building at Yamagata Plant was completed in December 2023, and the three plants have a combined annual production capacity of 17.5 billion tablets\*. Shipment has commenced sequentially since April 2024, with the aim of being fully operational (a production of 17.5 billion tablets) in three years.

Developm of APIs

\*Production capacity of tablets/capsules

# Information provision

# Active provision of relevant information to enable patients and medical professionals to feel comfortable while using ethical medicines

We have established a system that enables the prompt and appropriate provision of information on the proper use of our products and academic information to medical professionals, mainly through specially trained medical representatives (MRs), to ensure that generics are used with reassurance. We also provide patients and their families with information to ensure their safe use of pharmaceuticals. In addition to providing information, we collect opinions from medical institutions and share feedback internally for creating better products.

# Fostering of talented human resources

# Focusing on making job satisfaction and fostering talented human resources, aiming for being a reliable company

We aim to be a more trusted and needed company as a comprehensive generics manufacturer. Under the belief that talented human resources are the foundation of a trusted company, we work to make job satisfaction, foster talented human resources, and strengthen our organization. Under the 6th Medium-term Business Plan starting from FY2024, we aim to realize the "genuine smiles" of Towa Group employees by supporting their individual growth and career development, and by striving to remain a company that makes every employee happy to work for us. We also promote the acquisition and development of human resources as well as diversity.

ent

Quality control

table product supply

provis



Fostering of talented human resources

Tetsuya Yamamoto Manager, Production Planning Department, Production Division



To fulfill the responsibility for stable product supply, the Production Division actively prepares efficient production plans and improves productivity. We also attach importance to cooperation between plants and information sharing with other divisions.

Keisuke Watanabe Manager, Academic Promotion Department, Sales and Marketing Division



We plan and create sales and marketing tools to advertise our company and increase sales, with the Company's aspiration in mind and in cooperation with other divisions and departments. The task is rewarding as it aims to strengthen sales and marketing capabilities of the entire Sales and Marketing Division.

Masakazu Kawashima Deputy-General Manager, Recruitment Promotion Department, Human Resources Division



Human Resources Division staff have career development meetings with more than 2,000 employees a year to understand what each and every employee is thinking and help them develop the careers they want. We will continue to plan and implement policies that enrich employees' careers.

# **PROACTIVE** II um-term Business Plan

Under our 5th Medium-term Business Plan, we focused our efforts on enhancing the generics business as a core business, expecting generics to reach an 80% volume share of the pharmaceuticals market in Japan. Through those efforts, we achieved results by building stable supply based on manufacturing control and quality control.

2021-2023

As these three years marked the start of our third growth period, with the Company marking its 70th anniversary in 2021, we declared as a goal our intention to expand into new health related businesses that would contribute to people with presymptomatic diseases and people in good health. This was in addition to our existing aspiration of curing diseases with our pharmaceutical products. With these goals, we made steady progress in entering into new health related businesses.



[Policy 1] Enhancing generics business as a core	In our goal to become a comprehensive generics manufacturer, we launched 30 molecules / 65 products and marketed our first authorized generic drug. We also set up distribution centers in both the Kansai and Kanto regions and increased our manufacturing capacity to 14.0 billion tablets per year. In addition, we completed construction work on our Yamagata Plant with the aim of increasing that capacity to 17.5 billion tablets.
[ Policy 2 ] Expanding and growing business in overseas market	We expanded our sales into 39 markets, mainly in Europe and North America, and worked to establish the foundations of a global business. As part of our global production system, our Martorelles Plant in Spain obtained manufacturing approval for Esomeprazole for sale in the Japanese domestic market.
[ Policy 3 ] Entering new health related businesses	In March 2021, we promoted the research and development of reagents for clinical laboratory tests with the aim of entering the disease risk testing service business. We also launched a cloud-based regional healthcare information coordination service with the aim of coordinating the medical and health information of individuals. In addition, we acquired shares in Sunsho Pharmaceutical in 2022, and we are rolling out health related businesses as a pillar of our new business.
[ Policy 4 ] Creating technology innovations and product values	We established a variety of new technologies for use in APIs and formulations, including spherical crystallization technology for the full masking of the bitter taste of APIs and coating technology for the improvement of production efficiency. We also worked on their practical application in future products.
[ Policy 5 ] Making job satisfaction and fostering talented human resources	To enhance the job satisfaction of each and every employee, we supported career development through a rotation model and enriched e-learning contents. In April 2024, we established Human Resource Development Center, where we are engaged in the strengthening of human resources development.

# Major financial targets and results

Financial targets	Net sales [Consolidated] Achieve JPY 200.0 billion [Non-consolidated] Achieve JPY 150.0 billion	Operating profit (cumulative) JPY 36.5 billion or more	Dividend policy Stable dividend payment	R&D expenditure (cumulative) JPY 35.0 billion or more	Capital investment (cumulative) JPY 75.0 billion or more
Results	[Consolidated] JPY 227.9 billion Achieved in final year [Non-consolidated] JPY 149.2 billion Not achieved in final year	JPY 42.4 billion Achieved	Target achieved	JPY 40.0 billion Achieved	JPY 90.4 billion Achieved

Medium-term Business Plan

# **PROACTIVE** III

In the 6th Medium-term Business Plan, while carrying on the contents of the five policies of the previous Medium-term Business Plan, we added a new goal of "Job reform through DX promotion" and established three basic policies. Going forward, we will advance the establishment of our three businesses and the foundations that underpin them

in our efforts to achieve sustainable growth.

5th Medium-term Business Plan

(FY2021-FY2023)

Investment in production

facilities and strengthening

pharmacovigilance & quality

assurance setup for addressing

abnormal situation of unstable

drug supply situation in Japan

collaboration between Towa

Setup of management structure of Towa Group, including

Japan and Towa INT with

Expansion of overseas

business regions, and

COVID-19 under control

Sunsho Pharmaceutical

2024-2026

# 6th Medium-term Business Plan (FY2024-FY2026)

### Generics business in Japan

Growth as a company that is trusted and needed by society when domestic generics market is facing major changes

#### **Overseas generics business**

Diversification of our products with competitive superiority while further expanding our overseas business regions Necessary investment for growth (R&D and manufacturing facilities) by striking a balance with financial situation of Towa Group

### New health-related business

Continuous business exploration and investment in a certain cap Promotion of the concept of health information platform

**Building management foundation** for sustainable growth

Ensuring financial soundness in order to make continuous arowth investments Realization of the "linkage of management

Setup of future-oriented organizational structure and succession planning of key posts

# Create the future beyond people's health

Towa Group values "genuine smiles" which spring from the bottom of people's hearts when they stay healthy and achieve a well-being.

Our final goal is not just to make people healthy by providing products and services, but ultimately to deliver a future where each and every person can enjoy their lives. Based on this belief, we set out our message "to become a company that creates the future beyond people's health" as our vision.

# **New Medium-term Business Plan**

strategy and personnel strategy" required for human capital management

### Vision of Towa Group for 2040

Japan-based global generics group company that will conduct manufacturing and marketing both in Japan and overseas

Towa Group's new health-related businesses that will be recognized by society and will be independent as a pillar of group management

A culture of innovation creation that includes not only innovative but also evolutionary technologies will be nurtured, take root, and bear fruit as products and services

"People's Heath" and "Genuine Smiles" will be shared by our group employees, their family members, former employees, and people in local communities

# **Towa Group's Vision**

Policy 1 Evolution of generics business in Japan toward a new phase Establishing foundation for new markets / new businesses and realizing group synergies Policy 2 Policy 3 Strengthening sustainability management and building fundamentals for sustainable growth

In the 6th Medium-term Business Plan, based on the results of the previous Medium-term Business Plan, we will aim to achieve sustainable growth through the domestic generics business, the overseas generics business, and new health-related businesses.

ealth-related Business erseas Generics Business Generics Business in Japan Creating technology innovations and product values Job reform and work environment with satisfaction through DX promotion



#### Policy 1 **Evolution of generics business in Japan toward a new phase**

Moving towards a new phase of the generics business in Japan, we will continue the strengthening of API procurement, improvement of production capacity, and optimization of our sales system, initiatives on which Towa Pharmaceutical has been

## Set up stable supply

- Set up a system for stable supply of generics
- Ensure preparedness in case of emergency
- Strengthen supply chain management
- Improve production and supply capacities
- Improve production efficiency and productivity

# Strengthen manufacturing control / quality control

- Ensure manufacturing control / quality control systems
- Supply safe and secure pharmaceuticals
- Disclose and provide appropriate information

### Contribute to building social infrastructure by pharmaceutical industry

- Enrich product lineup, including biosimilars
- Promote collaborations with external partners for realizing a stable supply of generics

focusing its efforts on to date for the improvement of our stable supply chain. We will also work to strengthen our manufacturing control and quality control systems and to contribute to the building of social infrastructure in the pharmaceutical industry.

# **Specific Initiatives**

### Enhance supply chain management

- Strendthen API procurement
- Improve production and supply capacities
- Optimize Towa-style Sales System
- Response in case of emergency (reserve capability)

Strengthen pharmacovigilance and quality assurance

Enrich product portfolio

Disclose information in a proper / timely manner

# Stable supply structure

To establish a stable supply structure, we will set up systems to visualize and properly control the entire supply chain, from procurement of APIs to manufacturing, distribution, and sales. In this way, we will promote the enhancement of the supply chain with the aim of improving the stable supply structure for generics.

# Procurement of APIs

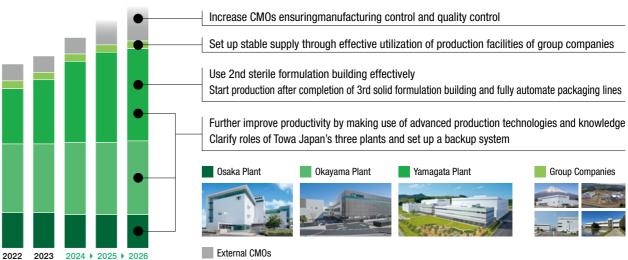
To date, Towa Pharmaceutical has engaged in the in-house manufacture of APIs. Going forward, we will work to reduce the risks to stable supply by developing synthesis processes and manufacturing at our group company, Daichi Kasei, or partnering companies. We are also planning to build a manufacturing building at Daichi Kasei that will have

# Ongoing enhancement of production capacity

Our current production system enables us to manufacture 14.0 billion tablets across our three plants, namely the Yamagata, Okayama, and Osaka Plants. To further strengthen production capacity, we plan to build a new formulation building in the Yamagata Plant and to gradually enhance supply capacity within the period of the 6th Medium-term

## Production capacity of 17.5 billion tablets/capsules per year at Towa Japan's three plants

\*Calculation on production capacity for Japan \*Production setup referring to theoretical maximum production capacity based on plant buildings areas while production capacity referring to realistic production volume based on the numbers of production lines, products, and staff.





Details See page 39.

Specific measures to achieve these goals include securing reserve capacity to enable a response in the event of an emergency and making the supply chain more resilient. Further, in addition to improving production and supply capacity, we will work to improve production efficiency and productivity to further fortify the stable supply structure.

advanced technologies to enable the manufacture of highly potent APIs such as anticancer drugs. In addition, to combat the quality-related risk of mutagenic impurities, we will apply the latest knowledge in our efforts to reduce the risks in API procurement.

Business Plan. In so doing, we aim to achieve an annual production capacity of 17.5 billion tablets from the three plants in FY2026, the final year of the Plan. Further, we will leverage the production sites of the Towa Group and thoroughly implement manufacturing and quality controls with the aim of further enhancement of supply capacity.

#### Production capacity of sterile products of 33 million V/A per year

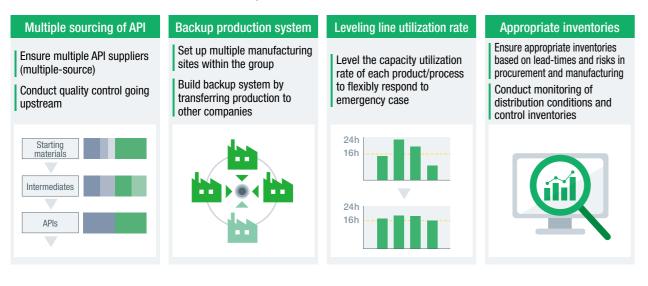
Start production after completion of 3rd solid formulation building and fully automate packaging lines



# Securing a stable supply by establishing a system to increase production in case of emergency

An essential element of the stable supply of generics is the establishment, during normal times, of systems that will allow flexible increases in production in the event of an emergency. To ensure reserve capacity, Towa Pharmaceutical will work to realize multiple

sourcing of APIs, build backup production systems to enable manufacturing at multiple sites, level out capacity utilization rates to give equal capacity to all production lines, and ensure appropriate inventories.



# Pharmacovigilance & guality assurance

We have introduced a quality management system with the aim of further strengthening quality control. This system allows us to establish a system for the digitally centralized control of events and documents related to the manufacturing and marketing of pharmaceuticals. The use of this system in combination with our existing

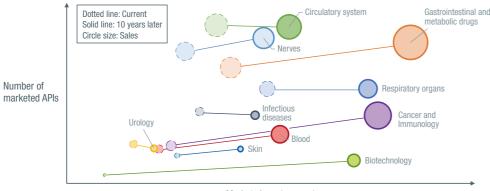
# Enrichment of product portfolio

For the enhancement of our drug lineup, we are promoting the development of small-molecular drugs with a focus on drugs considered necessary for future drug therapies. In particular, we are targeting a wide range of disease areas that are expected to

Details See page 18.

manufacturing process management and quality testing management systems will prevent human error. To ensure the reliability of pharmaceuticals at a global level, we will actively accumulate and utilize technology and know-how and strive to provide products that meet Japanese, U.S. and European standards.

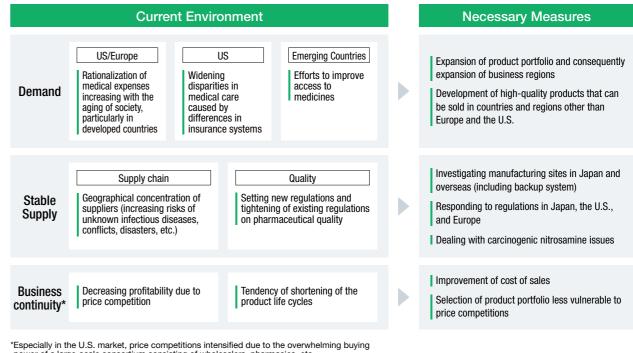
grow in the future, including gastrointestinal and metabolic drugs, and cancer/immunology. We will also work to optimize the drug lineup in light of future changes in drug therapies.



Market share (average)

# Policy 2

To establish the foundations for new markets and new businesses, we will expand our overseas generics business and roll out new health-related businesses. In our overseas generics business, we will expand access to Towa Group products in international markets and aim for the overseas expansion of excellent generic drugs developed in Japan. Meanwhile, in our new businesses,



power of a large-scale consortium consisting of wholesalers, pharmacies, etc.

# Expanding access to Towa Group products to international markets

### 5th Medium-term (2021–2023): Infrastructure development

- Expanded B2B business (39 countries)
- · Started development of global products
- Promoted collaboration by utilizing Towa INT's manufacturing technologies

## 6th Medium-term (2024-2026): Ensuring business scale

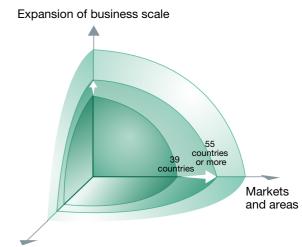
- Secure sales and profits by maintaining and strengthening existing businesses and further expanding markets and business regions (55 countries or more)
- Create synergies by sharing development and manufacturing technologies among group companies
- Make necessary investment in R&D and manufacturing facilities for the future

### 7th Medium-term and beyond (2027-): Expansion and diversification

- · Grow through enrichment of product portfolio
- · Develop products by utilizing Towa's unique technologies
- · Establish a global production system

# Establishing foundation for new markets / new businesses and realizing group synergies

we will pursue the realization of a service solution concept that centers on the Healthcare Passport (interactive health and medical information services). To realize group synergies, by leveraging the strengths of Towa Pharmaceutical and Sunsho, we will promote the joint development, manufacture, and sale of "Sunsho Made" Towa Pharmaceutical-original products.



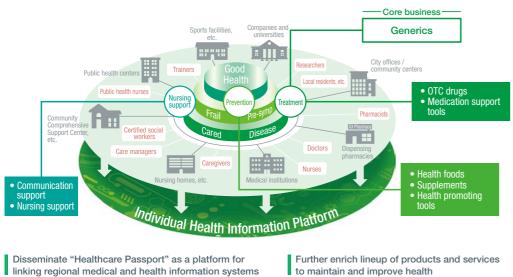
Diversification of products

# Entry into new health-related businesses

In the roll-out of new health-related businesses, we are working on the creation of synergies with Group companies and existing businesses while continuing to explore new businesses and making investments within a certain cap, in our efforts to further enrich our lineup of products and services.

Further, we are also developing data service solution businesses, with the aim of realizing a society in which medical professionals and ordinary citizens can share individual health data interactively through medical institutions in the local community.

## Based on "Healthcare Passport" (interactive health and medical information services) as a hub of this system, aim to realize "Exa Port" concept as a service solution

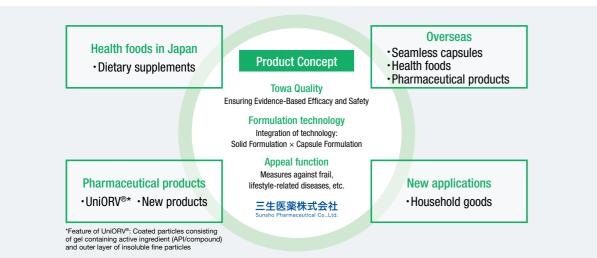


Contribute to Comprehensive Community Care System

Create synergies among group companies and with existing businesses

# Synergy with Sunsho Pharmaceutical

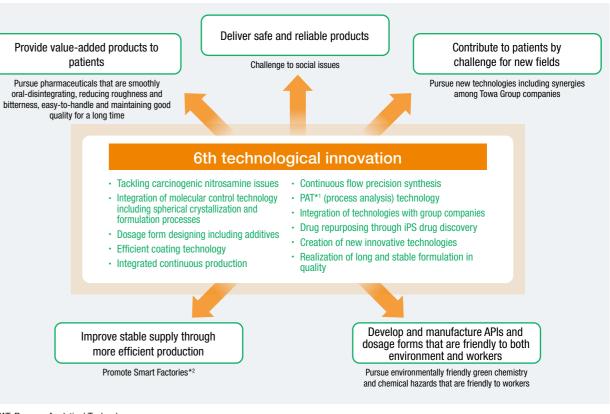
For the creation of synergy with Sunsho Pharmaceutical, a consolidated subsidiary of Towa Pharmaceutical, we will leverage Towa Pharmaceutical's and Sunsho's respective strengths. We will promote the joint development of Towaoriginal health foods and healthcare goods manufactured by Sunsho, with the Japanese market as our main focus.



Policy 3

We have been focusing our efforts on the creation of innovation in APIs, formulations, and manufacturing technologies. This is an approach that we will continue into the future. In the 6th Medium-term Business Plan in particular, we will pursue the commercialization of products based on new technologies that we have

# Creating technology innovations and product values



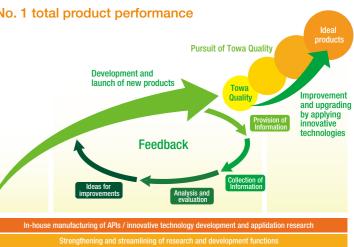
\*1 PAT: Process Analytical Technology \*2 Smart Factory: A plant that continuously uses digital technology to reform business processes and improve productivity and quality

### Manufacture of sophisticated products with No. 1 total product performance and pursuit of Towa Quality

Manufacture of sophisticated products with No. 1 total product performance refers to our initiatives in providing the market with products characterized by "Towa Quality" that are desired and needed by customers.

This guarantees the guality of the products that we supply under thorough quality control. We are constantly using the latest technologies to improve and modify the quality of the products, and we are constantly upgrading the products to the latest and best.

Product Refinement Department was set up in April 2024 in order to promote these initiatives.



# Strengthening sustainability management and building foundation for sustainable growth

established. For example, we will pursue pharmaceuticals that disintegrate easily in the mouth and that are less rough and bitter, making them easier to take, using molecular control technologies such as spherical crystallization. In this way, we will aim to realize high value-added products for patients.

# Towa Group's Sustainability

# Balanced growth investment and financial soundness

To promote sustainable growth and sound management, we will work to achieve growth through the stable supply of generics in Japan and the improvement of return on invested capital (ROIC). We have set ROIC as

> Achieve further growth through contribution to stable supply of generics in Japan

a new financial target, and we will work to improve operating profit and strengthen investment project management with the aim of achieving ROIC above weighted average cost of capital (WACC).

Realization of ROIC above weighted

average cost of capital (WACC)

Improve return on invested capital (ROIC) in consideration of capital costs

# Sustainable growth and sound management

# Targets during the med-term business plan



Continuous dialogue with stakeholders

Net Sales (Final year)	Operating Income (cumulative)	<b>ROIC*</b> (Final year)
[Consolidated] Achievement of JPY 300.0 billion [Non-consolidated] Achievement of JPY 200.0 billion Annual sales target achieved	[Consolidated] JPY 68.0 billion or more Achievement of cumulative operating Income to invest in sustainable growth and return profits to shareholders	[Consolidated] 6% or more (with influence of goodwill) 7% or more (without influence of goodwill) Achievement of ROIC* exceeding WACC
R&D Expenditure (cumulative)	Capital investment (cumulative)	Dividend Policy
[Consolidated]	[Consolidated]	Implementation of
[Consolidated] JPY 55.0 billion or more	JPY 60.0 billion or more	stable dividends

Now that the volume share of generics has reached about 80%, we believe that it is our social responsibility to strive for a more stable product supply and to further improve the quality of our products. Accordingly, we will thoroughly implement product management and quality control. At the same time, we are committed to contributing to building a foundation for the creation of an ideal local society through new businesses and regions, providing necessary services to promote health to those who need such services, and thereby contributing to extension of healthy life expectancy.

Under such policies, in order to develop a long-term vision for major changes in the future while integrating all of the strengths of the Group, it is necessary for each business or company to define the goals that they should aim for, for each company to become an We will aim to realize the Company's vision, "We contribute to people's health. We are dedicated to people's genuine smiles." As a group governance system to realize the foregoing, the Risk Management Committee (chief risk officer: Itsuro Yoshida, President and Representative Director), which is consulted by the Board of Directors regarding risks including climate change, collects and analyzes information in collaboration with departments and affiliate companies. It then examines expected risks (including opportunities related to climate change) and initiatives related thereto. The Board of Directors receives reports from the Risk In addition, the Executive Strategy Meeting chaired by President and Representative Director Itsuro Yoshida, meets once a week in principle and deliberates on important items related to management issues. The Meeting deliberates on our management policies and

autonomous organization to discover new social issues, and for us to use the collective strengths of the Group to solve such issues. Management Committee on the status of this examination twice a year, determines the policies, and supervises the Committee. the Medium-term Business Plan including personnel measures and clearly defines the basic strategies and management targets.



# **Enhance corporate fundamentals**

PROACTIVE	Maintain and improve people's health by providing products and services	Pursue To safety a
Realize autonomous management and create synergies	Thoroughly pursue compliance	Enhanc gove

In formulating a sustainability policy, we identified important issues that we need to engage in based on social issues and changes. Next, these issues were mapped on two axes based on their importance to society and their importance to the Towa Group and categorized into four themes. We will strengthen the

# Approach toward sustainability

business foundation, make considerations for the global environment, and continue the challenge of technology innovation while valuing each and every employee, and in doing so the Towa Group will work to bring about a sustainable society.

# Sustainability Environment

#### Basic approach

We act based on the principles in "the Charter of Corporate Behaviors in Towa Group" with high ethical standards and social good sense to promote proper corporate activities enabling us to gain trust and support from society. In our action, we strive to reduce global environmental load as part of our social responsibility as a good corporate citizen.

Concretely, we are dedicated not only to proper management of chemical substances and prevention of pollution, but also to actions for alleviating environmental concerns through plant drainage and emission systems, and taking energy-saving and decarbonization measures through effective uses of mega solar systems. Furthermore, we are aggressively working to achieve an eco-friendly manufacturing method of APIs.



# Contributing to a Decarbonized Society through Our Business

Efforts to counter problems related to the global environment and safety and health of our employees are part of our important management issues, and based on the Towa Group Environmental, Health, and Safety Policy formulated in FY2023, we are promoting activities that make considerations for the global environment and workplace safety. The Environment, Health and Safety Management Department supervises the entire Group in three areas, namely, environmental management and the global environment; chemical substance management; and occupational health and safety.

In the area of environmental management and the global environment, the department plays a central role

in TCFD-related projects, and discloses information related to climate change-related risks and profitmaking opportunities associated with global warming. In the area of chemical substance management, it has formulated company-wide rules related to issues such as appropriate management and legal compliance of chemical substances used in plants and laboratories, and prevention of exposure to highly potent compounds. In the area of occupational health and safety, it is working to establish a framework and provide education to prevent recurrence of occupational accidents.

# Information disclosure based on the TCFD recommendations

The Group recognizes that global warming is a worldwide issue, and thus has long been working on initiatives such as installation of solar power generation systems and energy saving at its plants, laboratories, offices, etc. In addition, in the recognition that climate change is a management risk of the Group, we launched a TCFD (Task Force on Climate-related Financial Disclosures) project and commenced company-wide initiatives in FY2022.

The Towa Group announced in December 2022 its support for the TCFD recommendations established by the Financial Stability Board (FSB). Since FY2022, examination has been conducted with a single entity of Towa as the scope of the examination. We assessed and identified risks and opportunities posed by climate change issues on society and corporations, and estimated the level of impact on Towa's businesses. In FY2023, the scope was expanded to include all of the Towa Group, both domestic and overseas. Risks and opportunities were reviewed and impact levels reassessed.

In the future, we will contribute to the creation of a sustainable society by reflecting specific countermeasures against risks and opportunities that have been materialized to our strategies, and aim to achieve continuous growth of the Company's businesses.



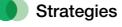
## Organizational structure and processes

The TCFD Subcommittee was established as a subcommittee under the Risk Management Committee and responds to climate change-related issues. The Board of Directors consults the Risk Management Committee, determines their policies, and supervises the Committee.

The Risk Management Committee deliberates on the status of initiatives undertaken by the TCFD Subcommittee, and reports to the Board of Directors on the status twice a year.

The TCFD Subcommittee collects and analyzes information in collaboration with departments and affiliate companies, identifies and assesses expected risks and opportunities related to climate change, and reviews the assessment. In addition, the Subcommittee formulates the action plans, countermeasures, etc., checks and follows up on the status of implementation on a periodic basis, and reports the status of implementation to the Executive Strategy Meeting as appropriate. Furthermore, it reports each important matter to Risk Management Committee members. Departments and affiliate companies implement

various measures that are formulated in collaboration with the TCFD Subcommittee, and provide data related to climate change.



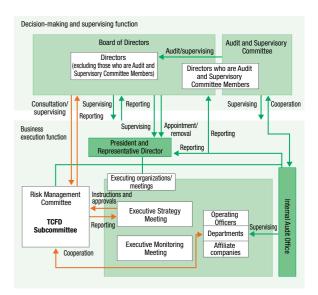
### Assumptions for scenario analysis

The Group conducted a scenario analysis for the manufacturing and sales business, etc. of its ethical drugs, assuming global conditions as of 2030. In the scenario analysis, we formulated three scenarios, namely for  $1.5^{\circ}$ C,  $2^{\circ}$ C, and  $4^{\circ}$ C, referring to various reports issued by IPCC, IEA\*, etc. In the  $1.5^{\circ}$ C scenario, it is assumed that various regulations, including a carbon tax, will be introduced to realize a

### Results of scenario analysis

We identified risks and opportunities based on each scenario, assessed the criticality on the businesses depending on the likelihood of occurrence and the level of impact of each risk and opportunity, and considered countermeasures. As a result, no serious

\*IPCC: Intergovernmental Panel on Climate Change IEA: International Energy Agency The Executive Strategy Meeting receives reports from the TCFD Subcommittee as appropriate and issues instructions and approvals when necessary. The Audit and Supervisory Committee and the Internal Audit Office conduct audits on these initiatives.



decarbonized society and there will be increasing demands from various stakeholders to respond to climate change, while new needs may arise due to changes in society and lifestyles. In the 4°C scenario, it is assumed that the progress of global warming will increase the risk of disasters such as extreme heavy rainfall and health risks such as heat stroke, while new needs may also arise for adaptation to climate change.

business risks associated with climate change were identified in the businesses subject to the analysis. Risks and opportunities expected in the 1.5°C scenario and the 4°C scenario are as listed in the following page.

# Sustainability Society

Scope of calculation: TOWA PHARMACEUTICAL CO., LTD., J-Dolph Co., Ltd., Daichi Kasei Co., Ltd., Greencaps Scenario analysis Pharmaceutical Co., Ltd., Towa Pharma International Holdings, S.L., and Sunsho Pharmaceutical Co., Ltd. Period subject to analysis: FY2021-FY2030

	Item	Event	Business impact	Countermeasure	Level of impact
		Introduction of a carbon tax	[Risk] An increase in business operating costs due to higher carbon tax burden	<ul> <li>Implementation of evaluation, factor analysis, measures to control frequency of CO<sub>2</sub> emissions</li> </ul>	Medium
Transition	Policy	Policy Tightening of regulations for CO <sub>2</sub>	[Risk] An increase in energy procurement costs associated with a shift to energy with less environmental load	<ul> <li>Introduction of low-carbon facilities and energy-saving equipment</li> <li>Establishment of manufacturing methods with low</li> </ul>	Low
Risk and opportunity		emissions/ energy saving	[Opportunity] Promotion of energy saving, reduction of business costs by reviewing supply chains, and promotion of decarbonization	environmental load	Medium
1.5°C scenario	Technology	Promotion of decarbonization of	[Risk] An increase in capital investment costs to promote decarbonization	•Collection of information and introduction of various decarbonization technologies (while investment costs are incurred, subsequent business operating costs are reduced)	Low
	Market	entire society	[Risk] An increase in costs for procuring raw materials due to promotion of decarbonization at suppliers	Risk hedge by securing multiple suppliers     Conducting risk assessment related to raw material     procurement	Low
Physical	Acute	Increases in frequency and magnitude of meteorological disasters	[Risk] Suspension of operations due to damage to company-owned locations and/or supply chains	•Establishment of a backup system among business sites •Operation of a crisis management system in preparation for meteorological disasters	Low
Risk and opportunity			[Risk] An increase in air conditioning costs, etc. for quality control	<ul> <li>Introduction of energy-saving facilities</li> </ul>	Low
4°C scenario	Chronic	An increase in extreme weather (extremely hot days, etc.)	[Opportunity] An increase in demand for drugs for diseases increasing with climate change	<ul> <li>Development and launch of products with an eye on trends in demand for pharmaceutical products</li> </ul>	Low
			[Opportunity] Establishment of competitive advantage by leveraging proprietary technologies and an increase in demand for value-added products	•Strengthening of information disclosure •Diversification of sales channels and user contact points	Low

# **Risk Management**

The TCFD Subcommittee conducts an annual review of the risk and opportunity assessment to manage climate change-related risks and opportunities.

Risks and opportunities are assessed from such perspectives as the likelihood of occurrence, level of impact, presence or absence of countermeasures, respectively, to determine the criticality.

In addition, we also subdivide them into value chains\* to assess them and consider countermeasures.

When assessing risks and opportunities, we conduct interviews with relevant business departments as necessarv.

Those with high criticality are reviewed by the Risk Management Committee and reported to the Board of Directors through the Risk Management Committee as necessary.

In addition, the TCFD Subcommittee formulates countermeasures against climate change-related risks and opportunities and manages the progress of such countermeasures based on preset indicators.

#### \*Value chains:

Value chains are a classification of businesses by function, and the Company categorizes businesses into "R&D; Purchase/Procurement; Manufacturing; Distribution; Sales/Marketing; and Administration Management."

# Indicators and Targets

The Group has calculated greenhouse gases emissions as an indicator to manage climate changerelated risks and opportunities and set mid- to longterm reduction targets. For Scopes 1 and 2, we will aim for emissions reduction by 30% in FY2030 as compared with FY2021, and for carbon neutrality by FY2050.

## Emissions in Scopes 1, 2 and 3 (CO<sub>2</sub> emissions (t-CO<sub>2</sub>))

	FY2021	FY2023
Scope1	30,098	27,994
Scope2	43,180	55,280
Scope3	662,167	764,982

Scope of calculation: TOWA PHARMACEUTICAL CO., LTD., J-Dolph Co., Ltd., Daichi Kasei Co., Ltd., Greencaps Pharmaceutical Co., Ltd., Towa Pharma International Holdings, S.L., Sunsho Pharmaceutical Co., Ltd., etc.

Period of calculation: From April 2021 to March 2022 and from April 2023 to March 2024, including Sunsho Pharmaceutical Co., Ltd. and Towa Pharma International Holdings, S.L. which changed the fiscal year end to March 31 starting from the fiscal year ended March 31, 2023



## **Responsible Business Activities**



To ensure Towa Quality products and services are used safely and securely, we continue to actively disclose and communicate information related to stable supply



# Information Provision by Medical Representatives

Our medical representatives, whose number is proudly reported to be the largest among the domestic manufacturers of generics, work on the provision, collection, and transmission of pharmaceutical information. We are also enhancing the network of medical representatives to be able to respond to various needs of diverse medical service



To promote the correct uses of medicines, we provide various explanatory materials for patients, e.g., about how to take medicines, and conduct studies, e.g., on combinations of medicines and other food/beverages other than water to alleviate the bitterness for family caregivers trying to help their children or those they are caring for to take medication. The materials and results of these



and manufacturing and quality control. Through this process, we ensure management transparency and will strengthen trust with patients and medical practitioners.

Announced November 28, 2023

providers, including clinics, local flagship hospitals, and health insurance pharmacies. Further, we have established a qualification system for medical representatives who have enhanced specialized capabilities in cancer, immunology, CNS areas, etc. through in-house training, so that we can provide information requiring more specialized expertise.

studies are provided to patients and their family members through medical institutions.

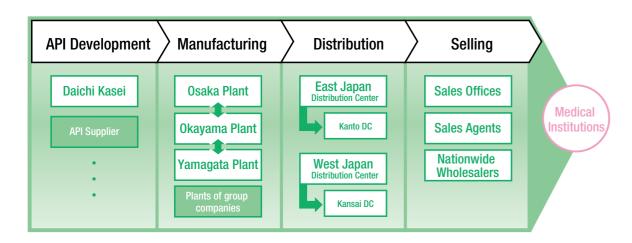
People can access information about medicines by scanning a QR code\* printed on a product package with their smartphone or cell phone. For formulations for children, QR codes provide information to parents about the taste of medication and how to help patients (their children) take medication smoothly.

\*QR code is a registered trademark of DENSO WAVE INCORPORATED.

# Stable Supply System

In order to further fortify the stable supply system that we have focused on up to this point, we will build a mechanism to make the information currently held by

each function visable to the entire supply chain and to control it appropriately. Through this, we plan to further improve the stable supply system for pharmaceuticals.



# **Our Efforts for Stable API Procurement**

In order to further strengthen in-house manufacturing of APIs which we have been involved in to date, we are planning to construct a manufacturing building at Group company Daichi Kasei with advanced technologies that

#### In-house production of APIs

Reduce the risk of stable supply caused by external factors by developing synthetic processes and manufacturing at Daichi Kasei or cooperative partners

#### Production of high pharmacologic active APIs

Construct a building equipped with advanced technology for manufacturing of high pharmacological active APIs in responding to growing demand, e.g. anti-cancer drugs (Completed in August 2024)

## Strengthen auditing system for manufacturing sites

- · Conduct audits in accordance with international standards as well as domestic laws and regulations
- · Conduct audits by technical experts (synthetic and physicochemical analyses)

#### Promote multiple procurement, including starting materials and intermediates

- Maintain a multiple procurement rate of at least 60% for APIs related to the products that Towa manufactures and sells, and establish a system enabling a stable supply in case of emergency
- · Select suppliers avoiding the overlap in supplies of starting materials and intermediates

#### Respond to mutagenic impurities

- Implement appropriate measures by clarifying the mechanism of formation
- of mutagenic impurities with sophisticated measurement technique Predict risks of mutagenicity formation based on the latest knowledge
- \*1 Mutagenic impurities: Substances that cause concern for humans due to the potential to cause mutagenic effects \*2 ICH: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

# **Risks of API procurement**

can handle the manufacture of highly potent APIs such

as anticancer drugs. In addition, for mutagenic impurities,

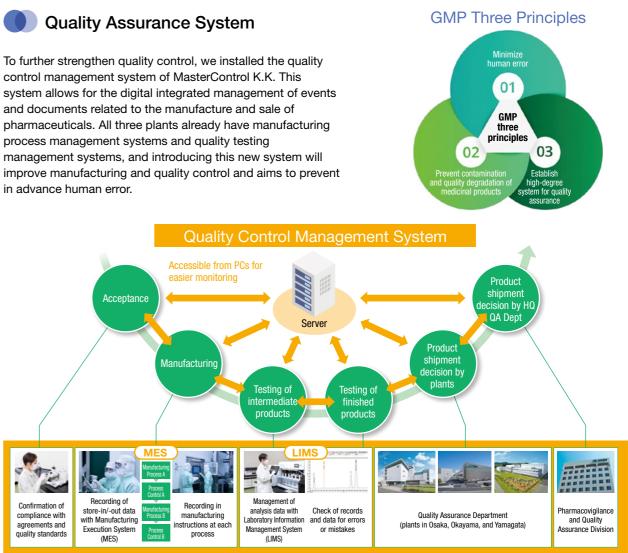
which are a quality-related risk, we are applying the latest

knowledge to try to reduce the risk in API procurement.

- · Discontinuation of shipment / manufacturing of APIs (Risks of environment, natural disasters, infectious diseases, accidents)
- Non GMP compliance at API manufacturing sites (Quality / regulatory discrepancies in manufacturing)
- Mutagenic impurities<sup>\*1</sup> (In accordance with ICH\*2-M7 guidelines)
- Starting materials and intermediates (Overlap in upstream suppliers of APIs)



control management system of MasterControl K.K. This and documents related to the manufacture and sale of process management systems and quality testing in advance human error.



# Efforts to further strengthen manufacturing control and quality control in light of Towa Quality

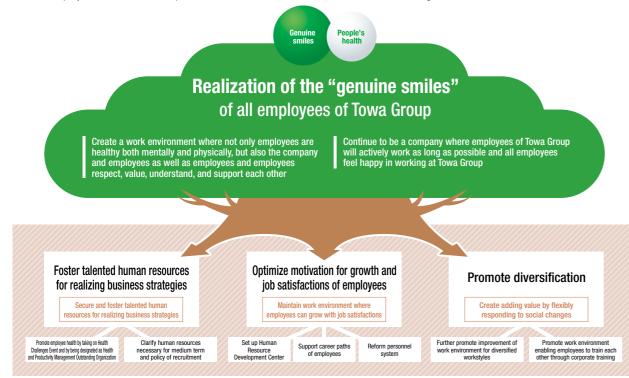
In order to ensure quality and reliability are at a global level, we will actively accumulate and utilize technology and know-how to strive to provide



products that clear Japanese, U.S. and European standards. In doing so, we will maintain high quality in international markets and provide trusted products. Enhance subcontractor management as a manufacturing and selling company of pharmaceuticals with a sense of responsibility for manufacturing control and quality control

Enhance subcontractor management as a manufacturing and selling company of pharmaceuticals with a sense of responsibility for manufacturing control and guality control

To achieve one of the basic policies of our 6th Medium-term Business Plan, which is "Strengthening sustainability management and building foundation for sustainable growth," making an environment for job satisfaction and fostering talented human resources are essential. We are creating a mutually supportive workplace environment that recognizes diversity and enables employees of the Towa Group to maintain sound mental and physical health. Furthermore, we are working to ensure employees each feel their own growth and are fostering human resources to steadily carry out business strategy. Important themes are "Foster talented human resources for realizing business strategies," "Optimize motivation for growth and job satisfactions of employees," and "Promote diversification." Each theme will be integrated into initiatives and executed.



# Health & Productivity Management 2024

We were certified as a Health & Productivity Management Outstanding Organization 2024 (large enterprise category), which is selected jointly by the Ministry of Economy, Trade and Industry and the Nippon Kenko Kaigi.

The program was started in 2017 to certify companies that think about employees' health management from a business-management perspective and strategically implement relevant initiatives. The Company has been certified for seven consecutive years.

The TOWA Health Challenge is an annual event held each year within the company to measure the physical condition of all employees. Initiatives are conducted to provide employees the opportunity to think deeply about their own health and improve their lifestyle habits.



# Our Efforts for Diverse Work Styles

We perform various activities to help employees who raise their children or take care of their family members in need of nursing care. In 2010, we were awarded the next-generation certification mark called Kurumin.

We have various parental and nursing care systems for our employees. For example, they can take parental leave until their children turn three years old, they can extend using the shorter working hour system for parenting until their children finish the sixth grade at elementary school, and we provide family support leave to which employees are entitled when they need to take care of their sick family members requiring nursing care.

Indicator	Target	Result
Interview rate	100% (October 2022 to the end of February 2024)	95.9% (June 2022 to the end of February 2024)
Ratio of women in management positions	Achieve 13%	14.8% (as of March 2024)
Ratio of paid leave taken	Achieve 65%	70.8% (FY2023)



Company-sponsored Daycare Centers



Company-sponsored daycare centers are childcare facilities established by companies to provide their employees with flexible childcare services according to the employees' different ways of working. We established our companysponsored daycare centers near the Okayama and Yamagata Plants in 2018 to realize a work environment where childrearing employees can work for the Company without any concerns and to contribute to local communities by reducing the number of children on waiting lists at daycare centers. We also have joint-use contracts with company-sponsored daycare centers of other companies to provide employees with additional options. In this way, we are committed to creating an environment where employees find it easier to return to work after parental leave.

# Generics Awareness-Raising Seminars



We served as instructors at generics awareness-raising seminars to help further the public's understanding of generics. We explained the effectiveness and safety of generics and also introduced our initiatives related to quality and safety and our efforts to provide reassuring medicine that is easy to swallow and easy to handle.

# High School Student Business Contest

We held a "High School Student Business Contest for the Future and People's Health" for the fifth time in FY2023. As a part of our efforts to widely disseminate the Group's vision "We contribute to people's health"

and contribute to a wide variety of health-related industries, the contest is aimed at seeking fresh ideas from high school students who will lead the future of Japan and creating a social contribution opportunity for them.



# Dona Kado

# Donating "comuoon" to Kadoma City

The Nursing Care Department at Kadoma City sees a large number of elderly visitors, and conversation at the reception desk and consultation booths had been an issue. By using our product "comuoon," a speaker to help people who have difficulty hearing, the number of cases of city employees having to explain in a loud voice decreased. The product has received positive reviews

from city residents visiting the department, with comments such as "It's now easier to hear what other people are saying" and "Conversations have become smoother."



# Cultivation of Pharmaceutical Product Raw Materials in Mongolia

As an example of social contribution activities in overseas countries, the Company has been implementing a project in Mongolia for more than 10 years to cultivate licorice used as herbal medicine.

The Company has initiated a "100-Year Plan" in which we support activities ranging from securing

cultivation land to planting, managing, harvesting, drying, chipping, and selling licorice. Going forward, we will contribute to the development of industries in Mongolia through cooperation with local people.



# Sustainability Governance

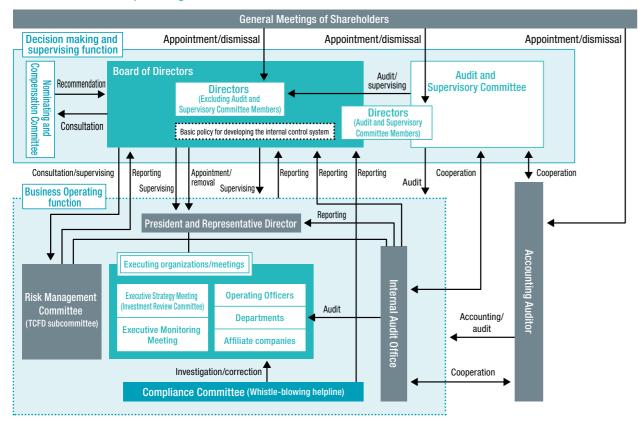
### - Basic approach

We consider enhancing corporate governance to be an important managerial task. By ensuring complianceoriented management and raising management efficiency and transparency, we will continue to increase our corporate value. To achieve this, we endeavor to respect and protect shareholders' rights as well as establish and maintain good relationships with all of our stakeholders including shareholders. At the same time, we continuously make efforts to achieve our social missions as a healthcare company by focusing on maintaining and improving corporate ethics and ethical standards of officers and employees.

This policy also applies to the Towa Group companies. Each of the Group companies fulfills required roles and obligations to increase the corporate value of the Towa Group as a whole.

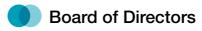


#### Overview of the corporate governance structure



# Enhancement of the corporate governance structure

Towa continuously makes efforts to enhance its corporate governance structure. Towa is a company with an audit and supervisory committee. The Company is governed mainly by the Board of Directors consisting of nine Directors and the Audit and Supervisory Committee consisting of four Directors who are Audit and Supervisory Committee Members (including three Outside Directors). One of the main roles of the Board of Directors is to make decisions on mid- to long-term management policies and important operations. Its important roles also include resolving the basic policy of the internal control system and supervising Directors' business execution. To ensure the effectiveness of such decisionmaking and supervision, we need to reduce the number of Directors, separate Directors and Operating Officers and clarify their roles, and build an environment that encourages Outside Directors to express their opinions. Under these policies, Towa has made several efforts. These include the transition to a company with an audit and supervisory committee, introduction of a mid- to long-term performance-based stock compensation system, establishment of the Nominating and Compensation Committee, enhancement of functions of Outside Directors, and stimulation of the Board of Directors. Going forward, Towa will continue to focus on enhancing the corporate governance structure.



The Board of Directors of the Company is chaired by the Representative Director. Meetings of the Board of Directors are held monthly in principle. The Board discusses important management matters at the meetings and makes decisions promptly. With regard to business execution, the Company has introduced an operating officer system and built a governance structure to clarify the Directors' responsibilities. With the structure, Operating Officers bear the responsibility for business execution while the Board of Directors focuses on decision-making and supervision of management issues.

# Audit and Supervisory Committee

The Audit and Supervisory Committee of the Company consists of four members including three Outside Audit and Supervisory Committee Members. Audit and Supervisory Committee Members conduct effective audits according to audit plans formulated by the Audit and Supervisory Committee. Specifically, they attend important meetings such as the Board of Directors meetings; receive reports from Directors, Operating Officers, employees, and the Accounting Auditor; and conduct on-site audits of major offices. In addition, the Audit and Supervisory Committee

## Skill matrix

		Gender	Corporate management	Management strategy Business strategy	Finance/ Accounting	Legal affairs/ Risk management	Personnel	IT/Digital	Purchasing	R&D	Production	Quality control/ Reliability assurance	Sales/ Marketing	Global
	Itsuro Yoshida	Male	•	•	•	•	•							
Inside	Osamu Uchikawa	Male	•							٠				•
e Dire	Toshikazu Kokubun	Male	•	•			•	•						
Directors	Masaaki Takeyasu	Male	•	•				•						•
	Masao Tanaka	Male	•	•	•	•	•							
Qu	Norikazu Eiki	Male	•	•		•				•	•	•		•
Outside	Kaori Oishi	Female				•								
Director	Kenryo Goto	Male	•	•	•	•								
tor	Nobuki Ando	Male	•	•									•	•

has established its own whistle-blowing helpline, which accepts whistle-blowing on matters involving officers as a highly independent contact.



# Nominating and Compensation Committee

The Nominating and Compensation Committee of the Company is chaired by the Representative Director and more than half of whose members are Independent Outside Directors. The purpose of the Nominating and Compensation Committee is to deliberate matters on the appointment and dismissal of Directors and Operating Officers, nomination of candidates, succession planning, and compensation in consultation with the Board of Directors, and to make recommendations to the Board of Directors.

# Analysis and evaluation of the effectiveness of the Board of Directors as a whole

In February to March 2024, the Company conducted a self-evaluation survey for Directors to analyze and evaluate the effectiveness of the Board of Directors. The survey used a questionnaire consisting of 21 questions including those on the structure, operations, and discussions of the Board of Directors. Results of the survey were reported at the Board of Directors meeting held on April 15, 2024.

Although the survey showed no significant issues on the effectiveness as a whole, it reminded us that we need to further discuss the discovery and development of human resources from a mid- to long-term perspective as well as mid- to long-term management challenges. Based on those results of the evaluation, the Company will further endeavor to enhance the effectiveness of the Board of Directors.

# Roles and independence of Outside Directors

The Company believes that fair and efficient corporate management can be achieved through Outside Directors' advice and opinions on the promotion of sound and efficient management at Board of Directors meetings. The Company has established the Nominating and Compensation Committee as an advisory body to the Board of Directors in order to further enhance and strengthen the corporate governance structure. In particular, the committee contributes to appropriately providing the Outside Directors with opportunities for involvement and advice so as to increase the objectivity and transparency of the decision-making process on the matters such as the appointment or dismissal of and compensation for Directors and other officers.

Currently, all of the Outside Directors are Audit and Supervisory Committee Members. The Company has built a system to help them fulfill their duties as Audit and Supervisory Committee Members. Specifically, agenda items of the Board of Directors are sent to them in advance by the General Affairs Department, the administrative office of the Board of Directors, so that the Members can consider matters to be discussed thoughtfully. In addition, they are provided with necessary support by the assistant staff of the Audit and Supervisory Committee as well as reports and explanations on important matters by the full-time Audit and Supervisory Committee Member.

#### **Reasons for nomination of Outside Directors**

Name and position	Reasons for nomination	Atten	dance
Outside Director <b>Norikazu Eiki*</b> Assumed the office in June 2019	Norikazu Eiki has wide-ranging insights and extensive experience at a global company, and the Company expects that he will provide advice and opinions from an independent perspective concerning the promotion of sound, efficient, and objective management, for which reason it has appointed him as an Outside Director.	Board of Directors meetings (held 14 times) 100%	Audit and Supervisory Committee meetings (held 13 times) 100%
Outside Director (Audit and Supervisory Committee Member) Kaori Oishi Assumed the office in June 2020	Kaori Oishi is well versed in corporate legal affairs as an attorney-at-law. The Company expects that she will provide advice and opinions based on her wealth of experience and expertise from a female perspective as well as from an independent perspective, for which reason it has nominated her as an Outside Director.	Board of Directors meetings (held 14 times) 100%	Audit and Supervisory Committee meetings (held 13 times) 100%
Outside Director (Audit and Supervisory Committee Member) Kenryo Goto Assumed the office in June 2021	Kenryo Goto has expertise in fields including finance and accounting as a certified public accountant and extensive experience as a corporate manager of an audit firm. The Company expects that he will provide advice and opinions from an independent perspective based on the above background about improving the transparency and objectivity of management, for which reason it has nominated him as an Outside Director.	Board of Directors meetings (held 14 times) 100%	Audit and Supervisory Committee meetings (held 13 times) 100%
Outside Director (Audit and Supervisory Committee Member) <b>Nobuki Ando</b> Assumed the office in June 2024	Nobuki Ando has extensive knowledge of Japan's health insurance system cultivated through his work in health insurance administration, as well as deep knowledge of logistics and experience as a manager in companies operating both domestically and overseas. The Company expects that he will provide advice and opinions from an independent perspective based on the above background about the promotion of sound, efficient, and objective management, for which reason it has nominated him as an Outside Director.		_

\* At the 68th Ordinary General Meeting of Shareholders held on June 25, 2024, he was appointed as a Director who is not an Audit and Supervisory Committee Member.

#### History of Towa's corporate governance





The Company formulated the basic policy for the determination of Directors' compensation. Under the policy, compensation shall:

- Contribute to secure talented people to ensure Towa Group Philosophy, Our Commitments, Corporate Policy, and the Charter of Corporate Behaviors in Towa Group;
- Be linked with clear targets for corporate and individual performance to increase Directors' motivation and morale as they perform their duties;
- Help to raise awareness of the contribution to improving mid- to long-term performance and corporate value; and
- Be determined with a focus on raising awareness of sharing interests with shareholders and shareholdercentered management.

With the basic policy above, in 2019 the Company introduced the mid- to long-term performance-based stock

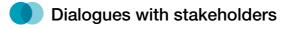
### Total amount of compensation for Directors

	Total amount of		Number of eligible					
Position		Basic compensation	Annual bonuses (based on		Performance-based compensation			
	(JPY million)		individual performance)	Monetary compensation	Non-monetary compensation	officers		
Directors (excluding those who are Audit and Supervisory Committee Members)	153	104	11	33	3	4		
Directors who are Audit and Supervisory Committee Members (of which Outside Directors)	45 (26)	45 (26)	— (—)	()	— (—)	5 (3)		
Total (of which Outside Directors)	199 (26)	149 (26)	11 ( <del></del> )	33 (—)	3 ( <del></del> )	9 (3)		

# Cross-shareholdings

The Company may hold cross-shareholdings upon request from a business partner as a means to build, maintain, and strengthen long-term and stable transactional relationships with the business partner. In that case, however, the Company holds cross-shareholdings only when it is deemed that holding of such shares will contribute to the enhancement of its corporate value over the medium to long term.

Whether to hold cross-shareholdings is determined yearly by the Board of Directors with consideration of mid- to long-term economic rationality and future outlook. The Company exercises its voting rights of cross-shareholdings appropriately after closely examining the proposals and determining whether



The Company discloses the information on its management strategies, finance/performance status, among other matters, to shareholders, investors, and other stakeholders through investor relations activities in an appropriate and timely manner. In addition, the Company emphasizes constructive dialogues with stakeholders including shareholders and investors so as to deliver opinions, requests, and other similar things obtained from such dialogues to the Board of Directors for the compensation system for Directors (excluding Outside Directors and Directors who are Audit and Supervisory Committee Members). This introduction was made to further clarify the link between compensation and the Company's mid- to long-term performance and shareholder value, as well as to improve corporate value over the medium to long term by granting incentives while raising Directors' awareness of contribution to the improvement of corporate value and shareholder-centered management.

In addition, the Company has established the Nominating and Compensation Committee as an advisory body to the Board of Directors with the aim of increasing the objectivity and transparency of the decision-making process of compensation for Directors or other matters as well as further enhancing and strengthening the corporate governance structure.

the holding of such shares will contribute to the enhancement of shareholder value. The Company does not make an affirmative determination on proposals that may damage shareholder value. In addition, the Company will be against proposals of appointment of directors and other officers who committed any antisocial act or violation of legal obligations.

If a cross-shareholder expresses an intention to sell the shares, the Company does not hinder the sale or other acts. When conducting transactions with cross-shareholders, the Company will thoughtfully examine the economic rationality of those transactions, just as with those with other business partners.

improvement of corporate value. The Company recognizes the importance of appropriate collaboration with not only shareholders and investors but also other stakeholders including patients, medical professionals, business partners, local communities, and employees. For creating corporate value, we are committed to disclosing information in an appropriate and timely manner to all of our stakeholders in order to maintain good and smooth relationships with them.

# **Risk Management**

# Basic approach to risk management

To ensure company-wide risk management, the Company has formulated the "Basic Regulations for Risk Management," which shall be complied with by all the departments, officers, and employees of the Towa Group. It is critical for the Group's continuation and growth to respond to the risks surrounding the Group promptly and appropriately. We aim to prevent risks as well as to minimize the loss of stakeholders' profits and impacts on corporate management when a risk occurs. The Group's risk management is administered by the Risk Management Committee, established under the President and Representative Director, who is the chief risk officer.



# **Risk Management Committee**

The Risk Management Committee is headed by President and Representative Director Itsuro Yoshida, chaired by Division Manager of Administration Division Norikazu Inoue, and is made up of 16 other members (as of the filing date): Director Osamu Uchikawa, Director Toshikazu Kokubun, Director Masaaki Takeyasu, Senior Operating Officer Tetsuro Tabata, Senior Operating Officer Yutaka Okuda, Operating Officer Shiro Hatagami, Operating Officer Yasuyuki Oishi, Operating Officer Takeshi Sugiura, Division Manager of Corporate Strategy Division Hideshi Nakamura, Division Manager of Human Resources Division Naomichi Hashizume, Division Manager of Purchasing Division Takeyuki Yamamoto, Division Manager of Pharmacovigilance and Quality Assurance Division Masafumi Fukae, Division Manager of International Business Division Kensuke Ogihara, and General Manager of Logistics Department Wataru Yoshimura. In addition, Director (Full-time Audit and Supervisory Committee Member) Masao Tanaka and General Manager of Internal Audit Office Taro Miyoshi attend meetings of the committee as observers. The Risk Management Committee addresses the risks surrounding the Group promptly and appropriately with the aim to minimize the loss of stakeholders' interests and impacts on corporate management when a risk occurs while preventing risks.



# Information security

To increase the Company's trustworthiness and competitiveness, the Company has formulated its information security regulations. The regulations consist of basic rules for appropriate use, maintenance, and operation of information assets that all the officers and employees must comply with in the course of their duties. Based on the regulations, the Company works to secure information security as part of daily management activities, business promotion, and organizational operation.

# Disaster countermeasures

Towa Group takes various measures to prepare for a large-scale disaster.

Specifically, those measures include: (1) provision of emergency supplies, (2) clarification of initial responses and preparation of manuals, and (3) introduction of a safety verification system. In addition, we hold twice-a-year meetings of the Risk Management Committee to share information.

In October 2023, Okayama Plant conducted its 2023 comprehensive disaster prevention drill with the fire department in attendance. We conducted an evacuation drill and a water extinguisher drill based on the assumption that an actual fire had broken out to ensure that all employees had a sense of crisis and acted safely.



Fire evacuation drill

# **Risk Information**

Towa Group mainly handles prescription products, and among them, generics are our leading products. A generic drug has the same active ingredients, indications, dosage, and administration as a branded drug that has been on the market after its efficacy and safety have been confirmed for a certain period

Control in accordance with the Pharmaceutical and Medical Device Act. etc. The Group has been manufacturing and marketing prescription products in accordance with the Pharmaceutical and Medical Device Act and related laws and regulations. Any violation of those laws and regulations may cause administrative sanctions by the authorities concerned, which may affect the Group's business activities. To address risks related to various regulations, the Group collects information on the laws and regulations to conduct business in accordance with them. In addition, we have developed a company-wide plan and system for compliance promotion.

Patent and re-examination periods The active ingredients of branded drugs are usually protected by patent rights, and the period is 20 years from the date of application (the period may be extended for up to 5 years). Since generics are approved for marketing after the expiration of the patent period, the extension of the patent period is expected to affect the Group's launch of new products (new generics). The Group collects information on patents and re-examination periods as well as facilitates collaboration among related departments. We strive to resolve discrepancies in indications by obtaining approval for partial changes, such as additional indications as soon as possible, after the patent period on a branded drug expires, or by applying for partial changes after the re-examination period.

Re-evaluation based on the Pharmaceutical and Medical Device Ac Re-evaluation of drugs is a system in which the quality, efficacy, and safety of approved drugs are reviewed from the current academic standards. If the drug efficacy re-evaluation shows no usefulness, the product is recalled and disposed of. If the quality re-valuation shows that the drug is not equivalent to that of a branded drug, subsequent marketing may be discontinued. Also, with international regulations on mutagens being strengthened, a problem found such as a failure to meet standards can create a risk of the product being recalled, disposed of, or stopped from being sold. These situations may affect our group's financial position and operating results. The Group collects information on scientific and technological progress to appropriately evaluate drugs.

Adverse drug reactions Generics are released after branded drugs have been used for many years. Their safety information has been confirmed, and they have been re-examined. Therefore, the risk of serious adverse reactions is minimal. However, if they occur, it may affect the Group's financial position and operating results. The Group collects information on drugs including that on the occurrence of adverse drug reactions in compliance with each country's regulations. This allows us to determine and conduct necessary measures based on the results obtained through assessment and consideration.

Drug price system and medical cost containment policy To sell ethical drugs, which are our mainstay products, the products have to be listed in the NHI price list specified by the Minister of Health, Labour and Welfare. The Group's financial position and operating results could be affected if the medical insurance system is reviewed, the drug price system is significantly changed, or the medical cost containment policy is reinforced. The Group aims to sell products at fair prices that match their values while improving profitability by expanding the market share of recently launched products. The Group also aims to reduce costs by cutting procurement costs for raw materials and improving production efficiency.

Patent litigation

Since our generic drugs sometimes use API that still has patent rights for their crystal form, formulations, use of the drug, etc., a patent suit may be filed by a manufacturer of new drugs. Such cases may affect the Group's financial position and operating results. The Group responds to such risks by collecting patent information and strengthening collaboration among related departments, such as engineering and development departments. This enables us to develop drug formulations that have not been covered by patents held by other companies.

of time. Thus, the Group faces specific risks as a generic business in addition to risks as a holder of marketing authorization for drugs. After recognizing these risks, the Group makes every effort to avoid their occurrence and set up a system for unexpected events.

Risks in the competitive environment	The competitive market for generic drugs is composed mainly of a switch from brand-name drugs and is greatly affected by the number of sales promotion companies. In recent years, companies have been planning strategies, such as introducing authorized generic products. Our actual sales revenue may differ from planned revenues, depending on their trends. In addition, competitors' supply status impacts demand for our products, which could risk a stable supply. The Group responds to such risks by increasing production capacity through capital investment, improving the backup system for manufacturing sites, and ensuring a stable supply of products from the production and sales aspects by monitoring the volume of demand and inventory daily. We are also making efforts to ensure reliability through transparent disclosure of information.
Mark-to-market valuation of derivatives	The Group imports certain semi-finished products and raw materials from overseas manufacturers in foreign currencies. If the costs increase due to a weak yen, it is extremely difficult to shift the increase onto the sales price under the drug price system in Japan. To avoid the risk of cost increase due to the depreciation of the yen and to provide a stable supply of our products, we conduct long-term derivative transactions. Such transactions are subject to mark-to-market valuation at the time of financial closing, and valuation losses may occur if the yen is stronger, or the long-term interest rate spread between Japan and the U.S. is larger, than at the end of the previous fiscal year. Therefore, valuation loss may occur depending on the exchange rate and the interest rate trend in Japan and the U.S. In the opposite case, valuation gains may occur. The Company estimates the future amount of import transactions made in foreign currencies to conduct long-term derivatives transactions within the estimated range. This helps us prevent derivatives transactions from being speculative.
Stagnation and elay of production wing to disasters and other causes	The Group has production sites in Japan (Osaka, Okayama, Yamagata, Shiga, Hyogo, Shizuoka, and Chiba Prefectures) and Spain (Province of Catalonia), and any of these production sites could be forced to cease business operations owing to the occurrence of natural disasters or technical/ regulatory issues to affect the stable supply of products. Besides, if natural disasters and other causes force us to halt purchasing raw materials from some specific supplier(s) and these halted raw materials are challenging to substitute, our business performance could be affected. The Group strives to organize a mutual backup system among our domestic plants and promote multiple sourcing of APIs. Moreover, the Group possesses its own API manufacturing plant to secure a stable supply of APIs.
Global risks	We completed the acquisition of Pensa Investments, S.L. (Headquarters: Catalonia, Spain, currently Towa INT) in January 2020. We expect that the acquisition of Towa INT contributes to building our global structure and providing our value-added products to the markets in Europe and the United States. However, the Group's financial position and business performance could be affected if the acquisition of Towa INT fails to produce the expected effects owing to changes in business environments and business operations of Towa INT, effects of local systems and regulations, possible delay in the progress of the integration process between Towa INT and us, or events unrevealed during due diligence. The Group strives to strengthen a global management structure through the integration process between Towa INT and us.
isks of corporate acquisition	Protosera Inc. became our subsidiary in March 2021. We also completed the acquisition of Sunsho Pharmaceutical Co., Ltd. by acquiring all of its shares in March 2022. If we fail to achieve the expected effects of the acquisition of these companies due to changes in the management environment and business operations, possible delay in progress of the integration process, and events unrevealed during due diligence, the financial position and operating results of the Group may be affected. The Group is in the process of developing a business plan and creating synergies through the integration process between the Company and its subsidiaries, as well as strengthening a management structure by, for example, dispatching directors.
isks related to IT security and information management	The Group is in possession of large amounts of confidential information, including sensitive personal information, through its business activities. Such confidential information is always subject to leaks due to cyber attacks or internal fraud. This, combined with the enactment of laws to protect personal information and increased awareness of rights regarding personal information, makes information management all the more important. Leakage of important confidential information could result in legal damage and loss of credibility. We guard against these risks and strengthen security by continuously conducting in-house education to raise awareness about information security and working with our Group company, T Square Solutions Co., Ltd.
Others	The legal status of COVID-19 under the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases has changed to Class V Infectious Disease, and the impact of the infection on the Group has lessened. On the other hand, there is a continued risk of a new viral pandemic affecting our sales and production. There is also a risk that changes in the Russia-Ukraine situation will affect the global economy and cause prices of energy and raw materials to soar, thus affecting the management of the Group.

# Compliance

# Compliance policy

In order to be committed to ethical and law-abiding corporate behavior in accordance with the "Towa Group Code of Conduct," the Group promotes measures as well as training and education to raise compliance awareness of the officers and employees. Furthermore, we develop and appropriately utilize a whistle-blowing helpline so as to promptly detect and correct fraudulent acts of the Group's officers and employees.

The Internal Audit Office, which is under the direct supervision of the President and Representative Director, conducts internal audits and reports the results directly to the top management. In the case where the Internal Audit Office finds anything that needs improvements, it conducts a follow-up audit to check the improvements.

# Compliance structure

We have established the Compliance Committee consisting of inside and outside committee members under the officer in charge of compliance to promote compliance activities. Under the Group's compliance policy, the officers and employees shall promptly report to Directors and the Compliance Committee when they find a problem that may cause damage to the Group's business and financial condition.

The Compliance Committee is in charge of the whistleblowing helpline (group helpline). It regularly reports the information from the officers and employees of the entire Group collected through the helpline to the Board of Directors. The Audit and Supervisory Committee shares information with the Internal Audit Office and the Compliance Committee on a regular basis. It has a right to request report submission.

In addition, because each organization needs to carry out activities such as promotion of and corrective actions for compliance autonomously, we have designated Division Managers and Plant Managers as Departmental Compliance Promotion Supervisors, and Department Managers

as Departmental Compliance Promoters. The Compliance Committee works together with Departmental Compliance Promotion Supervisors to plan and implement measures such as identification, analysis, and correction of compliance risks for the Group as a whole.



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# Compliance activities/education

The Company conducts awareness-raising activities for the officers and employees on a daily basis under the leadership of the officer in charge of compliance and the Compliance Committee. In addition, we set specific periods to promote compliance to take various measures across the Group. Specifically, we conveyed a message from the president and displayed a poster to raise awareness of compliance. We also conducted an awareness survey for all officers and employees of the Group, officer training, and workplace meetings related to compliance at each department.

In addition, we provided e-learning on such themes as how to use the whistle-blowing system and handle privacy information. For overseas subsidiaries as well, legal affairs and compliance departments at the regional headquarters undertook measures such as provision of training.



Delivered easy-to-understand compliance example cases through group newsletters

# Whistle-blowing helpline

The Company's whistle-blowing system appropriately deals with problems while protecting whistle-blowers. Together with the monitoring by the Internal Audit Office, the system has contributed to prompt detection and correction of problems. The Group has two contacts to deal with issues under the Whistleblower Protection Act: a group helpline and a whistle-blowing helpline of the Audit and Supervisory Committee. The group helpline is used as a helpline shared within the Group companies in Japan. The whistle-blowing helpline of the Audit and Supervisory Committee addresses only cases involved with the officers of the Group companies in Japan as a contact point independent from execution. As for overseas, we have established whistle-blowing helplines in Towa Pharma International Holdings, S.L., which is our EU/U.S. Regional Headquarters, for the officers and employees of our subsidiaries overseas. We regularly receive their reports on the status of whistle-blowing received and investigated.

# **Message from the Outside Directors**

# **Board Members**

# Toward realization of our vision, "to become a company that creates the future beyond people's health"



Norikazu Eiki **Outside Director** 

Under the new Medium-term Business Plan that started this term, the Company is seeking to create "the future beyond people's health." This vision is intended to deliver a future where wonderful lives can be celebrated beyond the goal of health. To realize this vision, while bearing in mind that we are an honest, trusted company, which is our strength, I want to further contribute to it as an outside director, drawing on the experience and knowledge I have acquired so far.

# Participating in formulating the new Medium-term Business Plan and moving toward achieving it going forward

The new Medium-term Business Plan started this term (April 2024), but in formulating the plan, outside directors participated in discussions from an early stage, and we held lively exchanges of opinions on how the Group wants to be in the future and on addressing issues. In the generic drug industry, the role the Company is to play is growing larger and larger, but I intend to contribute to help ensure the initiatives set forth in the plan are steadily executed and the goals steadily achieved.



Kaori Oishi Outside Director (Audit and Supervisory Committee Member)

# I want to contribute in this major transition period for the industry



Kenryo Goto Outside Director (Audit and Supervisory Committee Member)

Toward solving supply shortages of generics, this year's drug price reforms will introduce company requirements that evaluate companies that can ensure stable product supply. The Company will promote a new Medium-term plan starting this year that includes augmenting production capacity, and I will contribute to this transition period. I hope to support this from the perspective of corporate governance.

I hope that, with my perspective from outside the company, I can help ensure a stable supply for products that support "genuine smiles" by contributing to people's health, and that can be used with peace of mind in Japan and the rest of the world.

# I want to contribute to maintaining and further developing Towa Quality

The role of generics in Japan's current medical insurance system is increasing in importance due in part to government policy. However, supply problems that began in 2020 still do not have a clear path to a solution. At the same time, due to the low birthrate and aging population, employee health insurance finances are tightening, and there is not such a large amount of time remaining to make the medical insurance system sustainable. Amid this, the Company is expected to play an important role in the generics industry. I intend to draw on my experience to date and express my opinions on the Board of Directors and on the Audit and Supervisory Committee as well so that production is steadily expanded while above all maintaining Towa Quality.



Nobuki Ando Outside Director (Audit and Supervisory Committee Member)



 
 May 1979
 Joined the Company

 October 1983
 General Manager of Finance & Accounting Department
 December 1983 Director / General Manager of Finance & Accounting Department August 1986 Director / General Manager of General Affairs Department Director / General Manager of President Office April 1990 . June 1990 Senior Managing Director / General Manager of President Office June 1991 Senior Managing Director / Division Manager of Production Division / General Manager of President Office November 1991 Senior Managing Director / General Manager of President Office June 1996 President and Representative Director (to present)

Itsuro Yoshida President and Representative Director

October 2003 Chairman and Representative Director of J-DOLPH Co., Ltd. (currently J-DOLPH Pharmaceutical Co., Ltd.) October 2010 Chairman and Representative Director of Daichi Kasei Co., Ltd. Chairman of the Board of Directors of J-DOLPH Pharmaceutical Co., Ltd. (to present)



Operating Officer / Division Manager of API Business Division April 2019 Senior Operating Officer / Division Manager of API Business Anril 2021

April 2023

June 2023

June 2024

Osamu Uchikawa Director April 2022

Division / In charge of Product Strategy Division and Innovative Technology Research Division Senior Operating Officer / Division Manager of API Business Division / In charge of Product Planning Division, Innovative Technology Research Division, Pharmaceutical Research and

Joined the Company / Senior Advisor, API Business Division

Technology Division, Pharmaceutical CDMO Management Division and Pharmaceutical Development Division Chairman and Representative Director of Daichi Kasei Co., Ltd. (to June 2021 nresent)

Joined Ciba-Geigy Japan Limited

Joined Bayer Yakuhin, Ltd.

Senior Operating Officer / Division Manager of API Business Division / In charge of Pharmacovigilance and Quality Assurance Division, Product Planning Division, Innovative Technology Research Division, Pharmaceutical Research and Technology Division, Analytical Technology Center, Pharmaceutical CDMC Management Division, and Pharmaceutical Development Division Senior Operating Officer / In charge of R&D Division. Pharmacovigilance and Quality Assurance Division, and Pharmaceutical CDMO Management Division Director (to present)

**Outside Director** 



Chairman and Representative Director of Bayer Yakuhin, Ltd. Chairman and Director of Baver Yakuhin, Ltd. Outside Director of AnGes MG, Inc. (currently AnGes, Inc.) (to Director of FunPep Co., Ltd. (to present) Outside Director of the Company Outside Director of Solasia Pharma K.K. (to present) Outside Director of Gene Techno Science (currently Kidswell Bio Corporation) (to present) Outside Director of the Company (Audit and Supervisory Committee Member) August 2023 Outside Director of AwakApp Inc. (to present) Outside Director of the Company (to present) June 2024

Director / Plant Manager of Shiga Plant, Bayer Yakuhin, Ltd.

President and Representative Director of Bayer Yakuhin, Ltd.



October 2001 Registered as an attorney at law October 2001 Joined Kitahama Law Office (currently Kitahama Partners) January 2013 Partner of Kitahama Partners (to present) Outside Director of PALTAC CORPORATION (to present) Outside Director (Audit and Supervisory Committee Member) of the Company (to present) June 2022 Outside Director of FUJITEC CO., LTD. Outside Director of ESLEAD CORPORATION (to present

Kaori Oishi **Outside Directo** (Audit and Supervisor) Committee Member)

Toshikazu Kokubun Director	April 2014 April 2020 April 2021 April 2022 April 2022 June 2024	Joined the Company / Sales and Marketing Division General Manager of Regional Medical Strategy Department, Business Development Division / General Manager of Next Generation Business Promotion Department Operating Officer / Deputy General Manager of Business Development Division / General Manager of Regional Medical Strategy Department Operating Officer / General Manager of Corporate Strategy Division in charge of Human Resources Division Operating Officer in charge of Corporate Strategy Division, Human Resources Division, Sales and Marketing Division, Logistic Department, and Production Division Director (to present)
Masaaki Takeyasu Director	April 1988 April 2006 April 2008 April 2012 April 2018 April 2019 January 2021 January 2023 April 2024 June 2024	Joined Shionogi & Co., Ltd. General Manager of Corporate Planning Division General Manager of Marketing Division Operating Officer / General Manager of Overseas Business Division General Manager of Public Relations Division Deputy General Manager of Planning and Management Division, H.U. Group Holdings, Inc. President and Representative Director of Ishinban, Inc. Joined the Company / Deputy General Manager of Corporate Strategy Division In charge of Corporate Strategy Division under Pharmaceutical CDMO Management Division / International Business Division / Business Development Unit / Digital Health Planning and Promotion Office Representative Director of T Square Solutions Co., Ltd. (to present) Director (to present)
	April 2009 April 2011 October 2016 June 2017 April 2019 June 2020 April 2021 July 2021 June 2024	Joined the Company / Deputy-General Manager of Internal Audit Office General Manager of Internal Audit Office General Manager of Public Relations and Investor Relations Office / General Manager of Human Resources Department Director / Director in charge of Administration Division Director / Director in charge of Administration Division Director Chairman and Representative Director of Protosera Inc. President and Representative Director of Protosera Inc.

Masao Tanaka Director (Full-time Audit and Supervisory nmittee Member



Kenryo Goto **Outside Director** (Audit and Supervisory mittee Member

September 1981 Joined Asahi & Co., Osaka Office (currently KPMG AZSA LLC) Registered as a certified public accountant March 1984 Partner of KPMG AZSA & Co. (currently KPMG AZSA LLC) May 2005 Board member, Head of Division 3, Osaka Office, KPMG AZSA LLC July 2010 Senior Executive Board member of KPMG AZSA LLC July 2013 July 2015 Osaka Office Managing Partner of KPMG AZSA LLC Established Kenryo Goto Certified Public Accountant Office (to July 2020 April 2021 Auditor of Hyogo Medical University (to present) Outside Director (Audit and Supervisory Committee Member) of June 2021 the Company (to present) External Director of West Japan Railway Company (to present) June 2022 Outside Auditor of HI-LEX CORPORATION (to present) January 2024



Nobuki Ando Outside Director (Audit and Supervisor Committee Member)

April 1978	Joined NIPPON EXPRESS
January 2002	Manager of NIPPON EXPRESS USA, INC. Seattle Branch
February 2004	Manager of NIPPON EXPRESS USA, INC. Los Angeles Branch Air Service Division
October 2008	General Manager of Sales Planning Department / General Manager of Customer Service Center, NIPPON EXPRESS
June 2011	Executive Officer in charge of Sales Planning Department, Sales Department 3, and Customer Service Center
May 2013	Executive Officer in charge of Sales Planning Department, Global Logistics Services Department, and Customer Service Center
May 2014	Managing Executive Officer
May 2015	Chairman of the NIPPON EXPRESS Health Insurance Association
April 2017	Alumni Association Chairman and Councillor of Ryutsu Keizai University
October 2017	Director of Japan Health Insurance Association
April 2022	Director and Councilor of Ryutsu Keizai University (to present)
November 2023	Advisor of SIGMAXYZ Holdings Inc. (to present)
June 2024	Outside Director (Audit and Supervisory Committee Member) of the Company (to present)

# **11-Year Financial Summary**

	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024 (FYE March)
	Lott	2010	2010	2011	2010	2010	2020	2021	LULL	2020	
Net sales (JPY million)	61,351	71,470	82,115	84,949	93,430	105,104	110,384	154,900	165,615	208,859	227,934
Operating profit (JPY million)	7,706	11,105	11,134	6,869	11,643	15,968	16,143	19,923	19,205	5,514	17,647
Ordinary profit (JPY million)	8,834	15,437	10,157	7,417	11,717	18,865	20,990	18,677	22,739	5,141	24,477
Profit attributable to owners of parent (JPY million)	5,992	11,118	7,684	5,576	6,495	13,475	14,503	13,958	15,914	2,201	16,173
Comprehensive income (JPY million)	5,999	11,175	7,313	5,858	6,533	13,409	14,948	14,469	17,960	7,825	21,949
Net assets (JPY million)	60,147	70,048	70,605	74,945	79,920	91,771	104,665	116,599	132,169	136,894	155,893
Total assets (JPY million)	103,318	121,187	156,851	165,247	177,181	188,803	230,016	245,668	332,097	371,347	430,653
Net assets per share (JPY)	1,179.69	1,373.89	1,434.79	1,522.99	1,624.09	1,864.92	2,126.72	2,369.21	2,685.18	2,781.17	3,167.27
Earnings per share (JPY)	117.54	218.07	154.19	113.32	132.00	273.85	294.74	283.62	323.36	44.72	328.59
Diluted earnings per share (JPY)		_	436.29	314.23	122.03	253.32	272.62	271.93	316.19	_	_
Capital-to-asset ratio (%)	58.2	57.8	45.0	45.4	45.1	48.6	45.5	47.5	39.8	36.9	36.2
ROE (Return on equity) (%)	10.4	17.1	10.9	7.7	8.4	15.7	14.8	12.6	12.8	1.6	11.0
Price-earnings ratio (%)	12.63	10.50	9.98	16.56	16.79	10.64	7.69	8.61	8.50	42.37	8.84
Cash flows from operating activities (JPY million)	8,144	8,037	3,732	10,195	19,230	19,002	19,164	12,008	22,129	2,544	8,212
Cash flows from investing activities (JPY million)	(11,300)	(8,230)	(19,032)	(22,206)	(20,093)	(3,994)	(39,541)	(9,100)	(59,729)	(30,284)	(40,394)
Cash flows from financing activities (JPY million)	3,529	238	27,970	(92)	4,670	(809)	11,748	184	46,540	17,481	35,407
Cash and cash equivalents at end of year (JPY million)	4,675	5,208	18,526	7,112	11,511	26,652	18,713	22,915	32,830	24,257	29,650
Number of employees	1,879	2,060	2,203	2,408	2,449	2,472	3,325	3,456	4,078	4,298	4,588
R&D expenditure (JPY million)	5,296	6,144	8,924	9,352	7,725	7,916	8,566	10,642	11,488	15,265	13,242
Capital investment (JPY million)	9,727	13,816	15,792	25,026	12,166	6,011	6,236	10,353	14,848	39,645	35,967
Depreciation (JPY million)	5,407	5,724	7,329	7,980	8,173	8,340	8,285	9,674	10,153	14,261	13,659
Dividend per chare (IDV)	75.0	05.0	05.0	05.0	05.0	107.5	44.0	44.0	60.0	60.0	60.0
Dividend per share (JPY)	75.0	95.0	95.0	95.0	95.0	107.5	44.0	44.0	60.0	60.0	60.0
Dividend payout ratio (%)	21.3	14.5	20.5	27.9	24.0	13.1	14.9	15.5	18.6	134.2	18.3

Note: The Company conducted a 3-for-1 stock split of common shares effective April 1, 2019. We calculated net assets per share and earnings per share assuming that the said stock split was conducted at the beginning of the fiscal year ended March 31, 2014.

During the fiscal years ended March 31, 2021 and March 31, 2023, the Company finalized provisional accounting treatments for the business combination. Accordingly, major management indices and other relevant data for the fiscal years ended March 31, 2020 and March 31, 2022 reflect contents of the finalization of provisional accounting treatments.

The Company has applied the "Accounting Standard for Revenue Recognition" (ASBJ Statement No. 29, March 31, 2020) and other standards from the beginning of the fiscal year ended March 31, 2022. Major management indices and other data for the fiscal year ended March 31, 2022 and the following years reflects these accounting standards. Diluted earnings per share for the fiscal year ended March 31, 2023 are not stated since there were no dilutive shares.

The fiscal year ended March 31, 2023 was a transitional period for the change in the fiscal period for nine consolidated subsidiaries. The consolidated subsidiaries had a irregular accounting period of 15 months from January 1, 2022 to March 31, 2023.

# **Management Discussion and Analysis of Financial Position, Operating Results, and Cash Flows**

The details of the financial reports are excerpts from the Annual Securities Report (from April 1, 2023 to March 31, 2024).

# Overview of performance

#### [1] Business environment

Under the "Basic Policy on Economic and Fiscal Management and Reform 2017" approved by the Cabinet in 2017, the Japanese government set the target of increasing the volume share of generics to 80% by September 2020. To meet the target, the generics industry including Towa strived to enhance production systems and ensure a stable supply of products. The resultant wider use of generics led to an 82.7% volume share in December 2023 (according to the survey by the Japan Generic Medicines Association in October-December 2023).

On the other hand, following Cabinet approval in 2020, the regular drug price revision, previously conducted biennially, has become an annual process since 2021. This has made the business environment for the pharmaceutical industry extremely difficult.

Furthermore, based on discussions at relevant panels and councils, the FY2024 drug price revision adopted corporate indices on a trial basis to evaluate companies' stable supply systems and incorporated these evaluation results into price revisions. This measure aims to ensure a stable supply of pharmaceuticals with a focus on generics.

Amid such drastic changes in the industry, we announced the 5th Medium-term Business Plan 2021-2023 PROACTIVE II in May 2021 in keeping with our vision, "We contribute to people's health, and we are dedicated to people's genuine smiles." Based on the Medium-term Business Plan, we implemented various initiatives with the aim of developing health-related businesses that contribute to the realization of healthcare and nursing care for society with a long and healthy life expectancy and also to society that shifts from medical care to care of pre-symptomatic disease and prevention, while positioning the generics business at home and abroad as our core.

#### [2] Initiatives for sales growth

In 2023, we launched five new items of two APIs in June and four new items of two APIs in December. As a result, the number of our generics reached 781 items of 339 APIs.

#### [3] Initiatives for entering overseas markets

To expand and grow our business in overseas markets, we develop our generics business in the European and U.S. markets through Towa Pharma International Holdings, S.L. ("Towa INT"). Leveraging Towa INT's distribution network in multiple European countries and the U.S., as well as its European manufacturing sites that meet U.S., European, and other standards, we will establish a global business foundation to provide high-guality, value-added generics to patients around the world from three main regions: Japan, the U.S., and Europe.

#### [4] Creation of new businesses

As one of our challenges, we aim for contributing to the realization of healthcare and nursing care for society with a long and healthy life expectancy and also to society that shifts from medical care to care of pre-symptomatic disease and prevention. With such recognition, we are working to develop new businesses. We will develop a diversified portfolio of health-related businesses by responding to the new medical system, such as the Comprehensive Community Care System, and creating new businesses related to pre-symptomatic disease prevention and health maintenance to extend healthy life expectancy.

#### [5] Operating results

For the fiscal year under review, the Group recorded net sales of JPY 227,934 million, gross profit of JPY 81,383 million, selling, general and administrative expenses of JPY 63,735 million, operating profit of JPY 17,647 million, ordinary profit of JPY 24,477 million, and profit attributable to owners of parent of JPY 16.173 million.

Operating results by segment are as stated below. Note that profit from each reporting segment is before goodwill amortization. Net sales from the domestic segment amounted to JPY 178,715 million with segment profit of JPY 21,889 million. Net sales from the overseas segment amounted to JPY 49,324 million with segment profit of JPY 11 million.

# Financial position

#### The Group's financial position for the fiscal year under review is as follows:

#### [1] Assets

Total assets at the end of the fiscal year under review amounted to JPY 430,653 million, up JPY 59,305 million YoY. This was mainly due to increases in construction in progress of JPY 24,762 million, in notes and accounts receivable - trade of JPY 16,121 million, and in inventories of JPY 8,145 million.

#### [2] Liabilities

Liabilities amounted to JPY 274,759 million, up JPY 40,306 million YoY. This was mainly due to an increase in long-term borrowings of JPY 38,810 million.

The Group's cash and cash equivalents at the end of the fiscal year under review amounted to JPY 29,650 million, down JPY 5,393 million YoY. Each cash flow for the fiscal year under review and factors behind it are as follows:

#### [1] Net cash provided by (used in) operating activities

Net cash provided by operating activities amounted to JPY 8,212 million (up JPY 5,668 million in the inflow YoY). This was mainly due to profit before income taxes of JPY 24,459 million (up JPY 19,853 million YoY), depreciation of JPY 13,659 million (down JPY 602 million YoY), and amortization of goodwill of JPY 4,229 million (down JPY 918 million YoY), which were partially offset by an increase in trade receivables of JPY 15,523 million (up JPY 13,931 million YoY), a decrease in trade payables of JPY 10,509 million (compared to an increase in trade payables of JPY 6,554 million for the previous fiscal year), and an increase in inventories of JPY 6,288 million (down JPY 12,208 million YoY).

In regard to distribution of profits, we have a basic policy of paying dividends continuously and steadily in accordance with our performance, while enhancing internal reserves to prepare for future business development, such as strengthening research and development capabilities and securing capital expenditure funds.

Based on this policy, for the fiscal year under review we paid a dividend of JPY 60 (an interim dividend of JPY 30 and a year-end dividend of JPY 30) per share. Our basic policy is to pay dividends of

#### [3] Net assets

Net assets amounted to JPY 155,893 million, up JPY 18,998 million YoY. This was mainly due to increases in retained earnings of JPY 13,219 million and in foreign currency translation adjustment of JPY 5,691 million. Consequently, the capital-to-asset ratio came to 36.2% at the end of the fiscal year under review.

# Cash flows

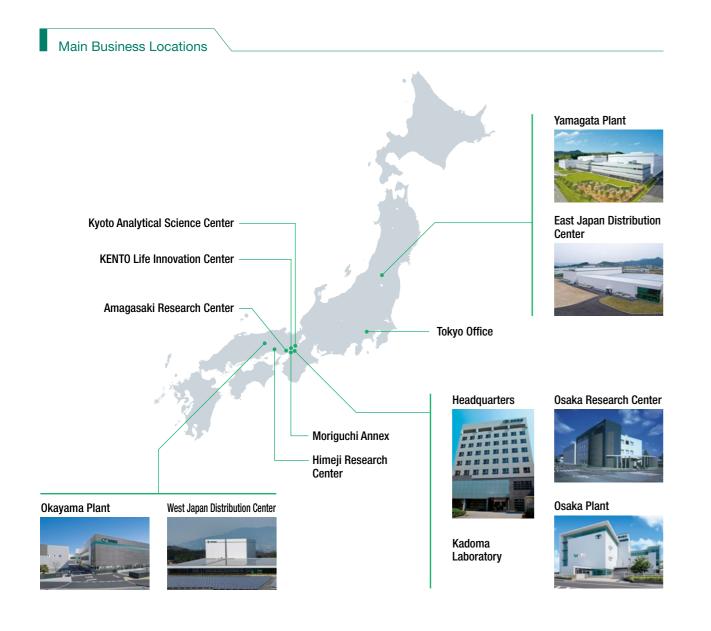
[2] Net cash provided by (used in) investing activities Net cash used in investing activities was JPY 40,394 million (up JPY 10,109 million in the outflow YoY). This was mainly attributable to purchase of property, plant and equipment of JPY 37,851 million (up JPY 9.119 million YoY).

[3] Net cash provided by (used in) financing activities Net cash provided by financing activities amounted to JPY 35,407 million (up JPY 17,926 million in the inflow YoY). This was mainly due to proceeds from long-term borrowings of JPY 46,935 million (down JPY 31,895 million YoY), which cancelled out repayments of long-term borrowings of JPY 7,607 million (down JPY 510 million YoY) and dividends paid of JPY 2,952 million (down JPY 148 million YoY).

# **Dividend policy**

surplus twice a year for the interim dividend and the year-end dividend. The decision-making bodies for these dividends of surplus are the General Meeting of Shareholders for the year-end dividend and the Board of Directors for the interim dividend.

We have stipulated in the Articles of Incorporation that the Company, by resolution of the Board of Directors, may pay an interim dividend as of September 30 of each year, which is set to be the record date for the interim dividend.



#### Major Group Companies



J-DOLPH Pharmaceutical Co., Ltd.

Manufacturing and selling of ethical drugs Headquarters: Koka, Shiga

Non-consolidated subsidiaries

T Square Solutions Co., Ltd.

Provision of healthcare related IT services Headquarters: Moriguchi, Osaka



Greencaps Daichi Kasei Co., Ltd. Pharmaceutical Co. Ltd.

Producing soft capsules for

pharmaceutical products

Headquarters: Fujinomiya,

Disease risk testing service business and

research and development of diagnostic drugs

Shizuoka

Protosera Inc.

Headquarters: Settsu, Osaka

R&D and manufacturing of APIs and intermediates Headquarters: Fukusaki, Kanzaki, Hyogo



Sunsho Pharmaceutical Co., Ltd.

Planning, development, and contract manufacturing of health foods, pharmaceutical products, etc. Headquarters: Fuji, Shizuoka

Kyushu Pharmaceutical Co., Ltd.

Towa Pharma

S.L.

International Holdings,

Manufacturing and selling of

Headquarters: Barcelona, Spain

ethical and OTC drugs

Sales of pharmaceuticals and quasi-drugs Headquarters: Kagoshima, Kagoshima

Company Outline

As of March 31, 2024

# **Overview of company**

Company name	TOWA PHARMACEUTICAL CO., LTD.
Headquarters	2-11, Shinbashi-cho, Kadoma-shi, Osaka 571-8580 Main phone: +81(0)6-6900-9100
Representative	President and Representative Director Itsuro Yoshida
Established	June 1951
Incorporated	April 1957
Listing	The Prime Market of the Tokyo Stock Exchange (Securities Code: 4553)
Capital stock	JPY 4,717.70 million
Business operations	Manufacturing and selling of ethical drugs

# **Business locations and sales outlets**

Headquarters	Headquarters, Moriguchi Annex, Tokyo Office
Research & Development Laboratories	Osaka Research Center, Kadoma Laboratory, Kyoto Analytical Science Center, KENTO Life Innovation Center, Amagasaki Research Center, and Himeji Research Center
Plants	Osaka, Okayama, and Yamagata Plants
Distribution Centers	East Japan Distribution Center, West Japan Distribution Center, Kanto Distribution Center, and Kansai Distribution Center
Sales offices and sales sites	71 sales offices, 57 distributors

\*The Kagoshima office closed on March 31, 2024. As a result, the total number of sales offices is 70 from April 1, 2024.

# **Consolidated subsidiaries**

J-DOLPH Pharmaceutical Co., Ltd. Daichi Kasei Co., Ltd. Greencaps Pharmaceutical Co. Ltd. Sunsho Pharmaceutical Co., Ltd. (and one other company) Towa Pharma International Holdings, S.L. (and seven other companies)

# Stock Price (JPY) 3,500 3,000 2,500 2,000 1,500 1,000

# Stock Data

### As of March 31, 2024

Shares authorized	 147,000,000 shares
Shares issued	 51,516,000 shares
Number of shares constituting one unit	 100 shares
Number of shareholders	 7,285 shareholders

# Major shareholders (Top 10)

Shareholder name	Number of shares (Thousand)	Ownership (%)
Yoshida Office Co., Ltd.	20,100	40.84
The Master Trust Bank of Japan, Ltd. (Trust Account)	3,793	7.71
BNYM AS AGT/CLTS NON TREATY JASDEC	2,313	4.70
TOWA PHARMACEUTICAL Kyoeikai	1,539	3.13
Custody Bank of Japan, Ltd. (Trust Account)	1,526	3.10
Itsuro Yoshida	1,455	2.96
TOWA PHARMACEUTICAL Employee Stock Ownership Group	965	1.96
Custody Bank of Japan, Ltd. (Trust Account 4)	845	1.72
Yoshida Estate Ltd.	648	1.32
Nippon Life Insurance Company	438	0.89

Note: The Company holds 2,295,857 shares of treasury stock but is excluded from the above major shareholders. The Company calculated the ownership by deducting the number of treasury shares.

# Share breakdown by shareholder type

