

2020

Nichi-Iko Group Integrated Report



Nichi-Iko Pharmaceutical Co., Ltd.

Mission Statement

We shall excel as an outstanding generic pharmaceutical company, making every effort to continue to serve and deliver our products needed by our patients and their families, pharmacists, doctors, distributors and other pharma companies around the world.

Our Pledge of Trust and Confidence

Nichi-Iko Group Quality Policy

Every member of the Nichi-Iko Group complies with all drug-related laws and regulations. We have made the following promises so that we can provide trust and confidence to patients and their families, pharmacists, doctors, distributors and other pharma companies around the world and to contribute to people throughout the world as a generic pharmaceutical company that serves with compassion the patients suffering from illnesses by developing, manufacturing, selling, and managing drugs with self-awareness and a sense of responsibility at all times.

[Quality Action Guidelines]

1. I will comply strictly with laws and regulations based on ethics and morals as a person involved in pharmaceuticals.
2. I will tirelessly dedicate myself to maintaining and improving quality.
3. I will share information I have learned and make appropriate decisions to provide reliable and safe drugs.
4. I will value the handing down of skills, human resource development, and continuing education and raise awareness regarding quality.
5. I will reliably perform my roles so that we can stably supply our drugs to patients.

Each of us will provide trust and confidence while earnestly addressing Nichi-Iko quality and working together to enhance and protect Nichi-Iko quality in accordance with the five Action Guidelines.

Guide to Information Disclosures

Corporate Information Website
<https://www.nichiiko.co.jp/english/>

Shareholder and Investor Information Site
<http://nichiiko-ir.irbridge.com/en/Top.html>

CSR Information Site
<https://www.nichiiko.co.jp/english/csr/>

Securities Reports
<http://nichiiko-ir.irbridge.com/ja/Library/Securities.html>

Editorial Policy

The Nichi-Iko Group's Integrated Report is created with reference to the "International Integrated Reporting Framework" put forth by the International Integrated Reporting Council (IIRC). It is designed as a communication tool that systematically brings together our value creation story from the perspective of both financial and non-financial information, with the goal of further deepening management based on corporate value improvement. We will strive to further enhance the contents of this Report to allow our shareholders, investors and a wide range of other readers to deepen their understanding of the Group.

Reporting Period

April 1, 2019 to March 31, 2020
(some information may be included that falls outside this period)

Organizations Subject to Reporting

Nichi-Iko Pharmaceutical Co., Ltd. and its domestic and overseas consolidated subsidiaries and affiliated companies.

Notes

Materials and information provided in this Integrated Report include items based on current expectations, goals, assessments, forecasts, assumptions subject to risk and other uncertainties. Future forecasts may thus diverge significantly from actual results due to changes in a variety of factors. Also note that target figures shown in this Report are strictly intended to indicate medium-term strategy, directional goals and vision, etc., and are not official earnings forecasts. For official earnings forecasts, refer to disclosures based on Tokyo Stock Exchange rules, including the annual summary of financial results and others. Elements that may have an impact on future prospects include, but are not limited to changes in economic conditions and competitive pressures surrounding the Nichi-Iko Group's business environment; revisions to laws and regulations; exchange rate fluctuations; and third party infringement of intellectual property. In addition, while the Report includes information regarding drugs (including those under development), that information is not intended as advertising or as medical advice. Note that detailed information regarding risks is also included in the Group's securities report, which should be referred to along with this Report.



One Heart One Vision ONE NICHI-IKO

The new Quality Policy comprises the five Action Guidelines, each starting with “I.”

Each employee will strive to provide trust and confidence by earnestly addressing quality as a stakeholder.

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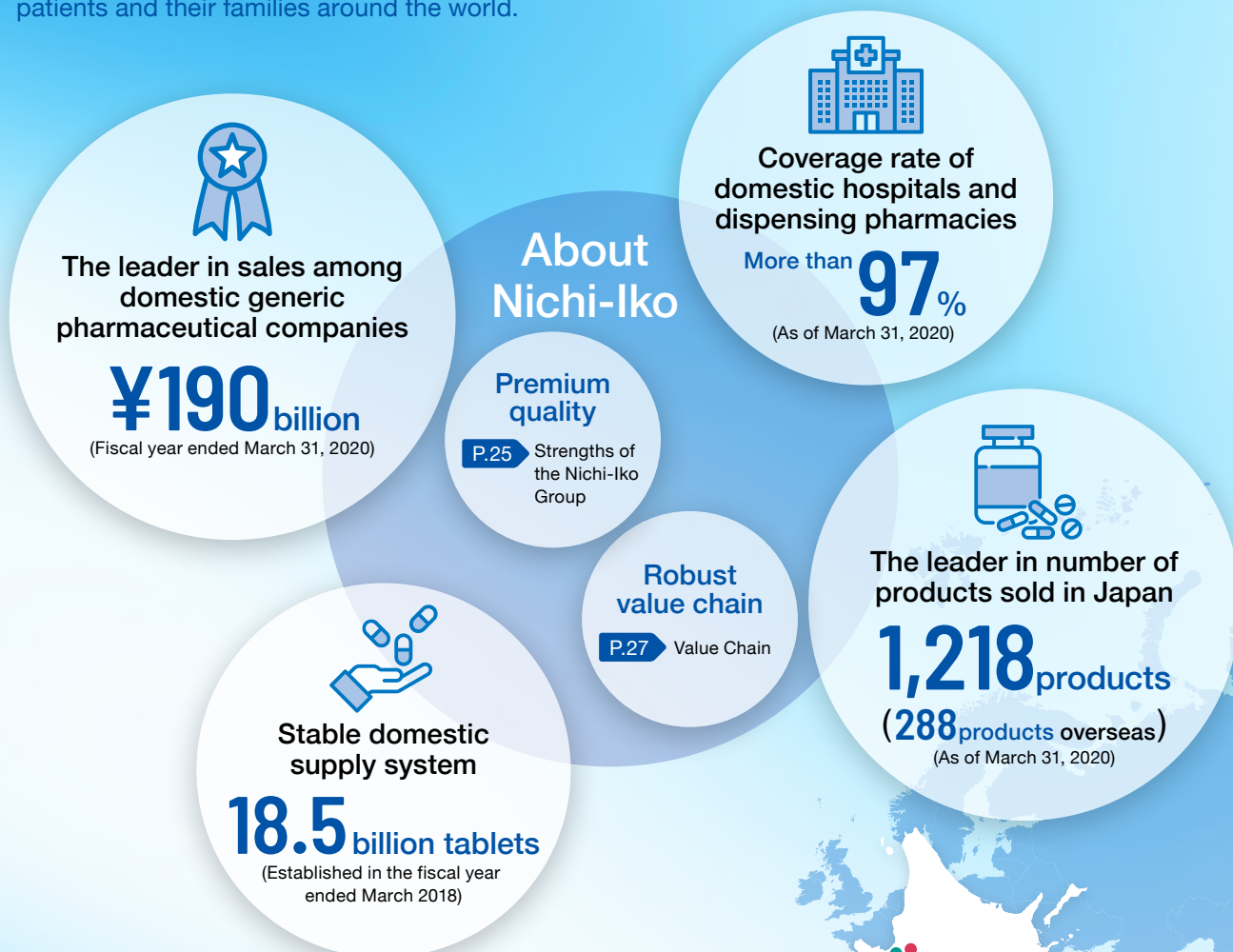
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* COVID-19: new coronavirus

At a Glance

Becoming a Global Comprehensive Generic Pharmaceutical Company

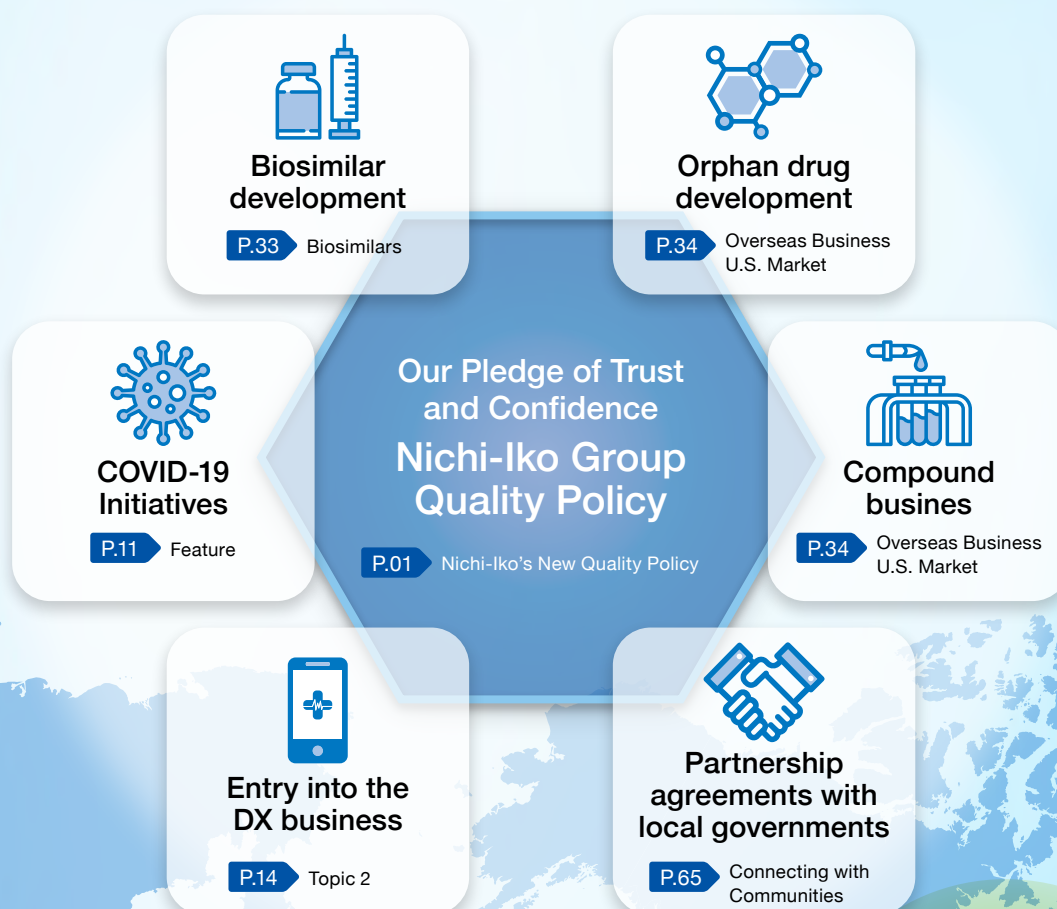
As the leading generic pharmaceutical company in Japan in terms of sales and the number of products on the market, the Nichi-Iko Group has continuously advanced so that we can provide premium quality to patients and their families around the world.



Offices (Japan)

- **Headquarters** (Toyama City, Toyama Prefecture)
- **Tokyo Headquarters** (Chuo-ku, Tokyo)
- **R&D Sites**
Global Development and Quality Control Center
(Namerikawa City, Toyama Prefecture)
- **Production Sites**
Seven sites: Hokkaido, Yamagata, two sites in Toyama, Saitama, Shizuoka, and Aichi
- **Distribution Centers**
Four sites: Hokkaido, Toyama, Saitama, and Hyogo
- **Sales Offices**
Ten sites: Hokkaido, Miyagi, Saitama, two sites in Tokyo, Aichi, Kyoto, Osaka, Hiroshima, and Fukuoka
- **Group Companies**
Four companies: Hokkaido, Toyama, and two companies in Osaka

Nichi-Iko's New Initiatives



“Going Beyond the Status Quo with Unlimited Collaborative Capabilities” Nichi-Iko Is Advancing to the Next Stage

To achieve the objectives of the current 8th Medium-term Management Plan, referred to as “NEXUS ∞ ,” Nichi-Iko is boldly tackling new challenges including expanding its business fields and bolstering global competitiveness.

Offices (Overseas)

● Production Sites

Three sites: Montreal, Canada
Raleigh and Plattsburg, United States

● Group Companies

Five companies: Montreal, Canada
Chicago, Plattsburg, and Kansas City, United States
Bangkok, Thailand

Message from Top Management

We will remain a presence needed by society as a global comprehensive generic pharmaceutical company that serves with compassion the patients suffering from illnesses



Yuichi Tamura
President and CEO

To mark the 55th anniversary of the Company's founding, we adopted a new Long-term Vision setting forth the ideal that we are pursuing

I would like to begin by extending my deepest condolences to all those who have lost loved ones to COVID-19 as well as all affected patients and their families. I would also like to express my sincere respect and gratitude to all healthcare personnel involved in the treatment of patients. I pray that all patients will recover quickly and that the spread of infection can be brought to an end.

In July 2020, Nichii-Iko marked the 55th anniversary of its founding. Since the 2000s, we have focused management resources on the development and manufacture of generic drugs, and we have achieved substantial growth as the leading domestic manufacturer in the industry. Currently, however, society is in disarray due to the COVID-19 pandemic, and the outlook for the future is unclear. It is precisely because of these uncertain conditions that we believe that a new expression of the ideal that we are pursuing is necessary on the occasion of the 55th anniversary of the Company's founding, and we recently adopted a new Long-term vision*.

This new vision does not set numerical targets for ranking in the industry, market share and so on. Rather than simply pursuing quantitative targets, if we are not a company truly needed by customers, then we will not be able to survive in the coming era. This is why we clarified what Nichii-Iko needs to achieve, that is, the value of Nichii-Iko's existence, within the vision that we recently established. Specifically, we are pursuing premium quality, stable supplies, product lineup, global development, creation of new value, and unwavering business foundations, and at the base of these is the strong conviction that our mission is to serve with compassion the patients suffering from illness and their families. We hope that by all employees working together to become a global comprehensive generic pharmaceutical company that continuously supplies drugs that offer trust and confidence for the benefit of patients and their families, we can be a permanent presence needed by society.

* **P.19** Nichii-Iko's Long-term Vision

We are fulfilling "Our Pledge of Trust and Confidence" to all stakeholders

In the Long-term Vision, we place the highest priority on premium quality. Nichii-Iko has long conducted business by pursuing the world's highest levels of quality, but for Nichii-Iko to remain a company that is truly needed by society, we need to solidify this attitude even further. It was with this understanding that we established a new Quality Policy and announced "Our Pledge of Trust and Confidence—Nichii-Iko Group Quality Policy,"^{*1} on July 15, 2020, the corporate foundation day. When rolling out this Quality Policy, we ensured that all employees fully understood the policy, individually pledged to fulfill Our Pledge of Trust and Confidence to all stakeholders, and gained a comprehensive awareness. We will continue our efforts to instill a corporate culture that prioritizes quality in the future.

One development that we expect will make significant contributions to enhancing the quality of drugs is the

acquisition from Teva Takeda Pharma Ltd. of its Takayama Plant and related business involving numerous generic drugs,^{*2} which was announced in July 2020. Teva Takeda's Takayama Plant possesses generic drug quality control know-how complying with the global standard and has built an advanced quality and production management system for ensuring data integrity. Combining Teva Takeda's knowledge with our pharmaceutical manufacturing experience established over more than half a century will generate chemical reactions that direct the entire Nichii-Iko Group by means of a new wind blowing in from the outside, leading to even higher quality.

*1 **P.01** Nichii-Iko's New Quality Policy

*2 **P.13** Topic 1

Message from Top Management

The acquisition of business from Teva Takeda will be an opportunity for Nichi-Iko to advance further

Teva Takeda's Takayama Plant becoming a part of the Nichi-Iko Group will be a turning point for the Group, and we believe that it will also make significant contributions to reinforcing our revenue base. Until now we have engaged in active capital investment at the acquired plant, transformed productivity and profit structures in tangible forms to enhance on-site morale, and achieved a smooth integration. At the Takayama Plant, we similarly conducted capital investment to raise productivity with a clear understanding of its roles within the Group and intend to demonstrate synergy effects. Our expectations for this plant, reborn as the Nichi-Iko Gifu Plant in February 2021, are optimization of production throughout the Group and a shift to internal manufacturing. The Toyama Plant 1, the Group's main plant, currently produces numerous products and is under a considerable burden. We plan to optimize production through integration with the Gifu Plant, which is geographically close. In addition, production of antibiotics and anti-cancer drugs that is outsourced will be handled at the Gifu Plant and other

measures will be taken to increase the rate of internal manufacturing and reinforce our revenue base.

We are also putting our efforts into the establishment of systems for the stable supply of drugs, one of our core missions. At a recent conference of experts held by the Japanese Ministry of Health, Labour and Welfare, a proposal was made for the stable supply of drugs made from 551 ingredients. Nichi-Iko handles 141 of those ingredients. We intend to take responsibility for achieving continuous and stable supplies of drugs for which there are high levels of medical need such as antibacterial agents, and we are making progress with securing multiple suppliers of APIs and multiple manufacturing sites*. Teva Takeda's Takayama Plant has a specialized department to address this issue, and following integration, we will make use of their capabilities to increase the pace of establishing stable supply systems.

* **P.09** Nichi-Iko's Supply Chain Management

When business format transformation in the U.S. is complete, global market development will advance greatly

Global development is a major theme of the Long-term Vision. We are already active in the generic drug business in the U.S., Europe, and Asia, and of these, we are focusing particular efforts on expanding business in the U.S., which is a massive market^{*1}. We are currently strongly advancing business transformation in the U.S. with a focus on Sagent, which we acquired in 2016. Previous business model of Sagent was to procure generic drugs from India and China and sell them, but it is now transforming his business format to internally manufacturing generic drugs including biosimilars to reinforce cost competitiveness in the U.S. market. We have already acquired a Food and Drug Administration (FDA) certified pharmaceutical plant in Raleigh, North Carolina through Sagent. The plant, which has obtained approval to manufacture small-molecule drugs and biopharmaceuticals, produces injectables, and the Montreal Plant of Omega, a subsidiary of Sagent that produces small-molecule drugs, has also obtained FDA

approval. In addition, Sagent has acquired an equity stake in SterRx, which produces compound formulations^{*2} in accordance with FDA rules. The biosimilar Infliximab BS, which is being prepared for release in the U.S., is being developed with the aim of obtaining approval for an interchangeable product compatible with the first advanced original biopharmaceutical in the U.S., and we plan to develop biosimilars into a major business in the U.S. to capture this massive market.

We are still in the advance investment stage, but if we complete this business transformation and begin functioning as a manufacturer, market development will take a major step forward. We are confident that we can achieve significant results in the U.S. within the next year. Our policy will be to globally expand this success in the U.S. and accelerate the expansion of business in Europe and Asia.

^{*1} ^{*2} **P.34** Business Overview | Overseas Business: U.S. Market

Approaching patients even closer to become the pharmaceutical company selected in a changing society

For Nichi-Iko to achieve sustainable growth for the future, it is essential that we make further advances toward becoming a company that can approach patients and their families. To do this, we intend to reinforce systems and structures that can approach and make contact with patients and their families. One aspect of this is expanding and enhancing the Customer Support Center, which functions as a point of contact for product-related questions and inquiries, to increase opportunities for direct contact with the comments of patients and their families^{*1}. We are also boldly undertaking digital transformation (DX) as another means. One practical example currently underway is the business alliance^{*2} with MedPeer, Inc. We jointly launched a digital service that connects patients and their families with family clinics and dispensing pharmacies online, and the major aim of this too is directly approaching patients and their families. Operating this service will enable patients and their families to communicate online with physicians and pharmacists and can provide new value. We seek to obtain unfiltered opinions and comments from a community site operated by MedPeer that is limited to physicians and pharmacists and to develop and manufacture drugs that truly meet needs.

As a company involved in health and life, in addition to taking actions we can do as a pharmaceutical company, we are further promoting partnership agreements with local governments^{*3} nationwide with the aim of increasing opportunities for contact with communities and society so that we can extend healthy lifespans and normalize healthcare costs, contributing to solving the problems of society in the future. As online medication guidance and telemedicine become more common in the future, we may enter an era in which drugs are distributed through electronic commerce (EC). As conventional wisdom and practices are overturned, we will need to shorten the distance to patients and their families and be in a position to engage in direct dialogue so that we can become a pharmaceutical company that is chosen by society. I am confident that if we can stick to the patient-centric concept set forth in the Long-term Vision, always listen to feedback from patients and their families, and always respond to problems, we will remain a company needed by society.

^{*1} **P.62** Society | Information Provision ^{*2} **P.14** Topic 2

^{*3} **P.65** Society | Connecting with Communities

The seeds for growth have been thoroughly sown We are now about to enter the harvest period

Nichi-Iko prides itself on being the generic pharmaceutical company with the largest number of long-listed products with expired patents in the domestic pharmaceutical industry. This is because drug repositioning (a method of identifying new efficacy of approved drugs and developing them as drugs for other conditions) holds tremendous potential for creating drugs with new value. In fact, we handle a number of drugs that are effective in treating COVID-19, currently an extremely serious problem for society. In Japan, there are expectations that FUTHAN[®] (Nafamostat Mesilate) for injectables and DECADRON[®] Tablets (Dexamethasone), for which we have clinical data accumulated over many years, can be used as COVID-19 treatments^{*1}. In the U.S., the CAMELOT (CAMostat Efficacy vs. pLacebo for Outpatient Treatment of COVID-19) Project has been launched to conduct the phase II clinical trial of Camostat Mesilate, which is currently in phase II development as an orphan drug, as a COVID-19

treatment.^{*2} By employing this type of drug repositioning, we intend to make contributions to society that are unique to Nichi-Iko through our business.

Over the past several years, I have worked enthusiastically to sow the seeds for future growth through my own efforts and by inspiring Nichi-Iko as a whole. We are now about to enter the harvest period. We will secure reliable results and use them as sustenance to achieve the Long-term Vision, remaining a company that is needed by patients, their families, and society.

^{*1} **P.11** COVID-19 Initiatives

^{*2} **P.35** Business Overview | Overseas Business: U.S. Market



Nichi-Iko's Supply Chain Management

Nichi-Iko is aware that reinforcing supply chains from API procurement to production is an important management issues for fulfilling its social responsibility of maintaining stable supplies of drugs. The Company made every effort to resolve the shortage of cefazolin, a fundamental antibacterial agent essential in clinical settings, that occurred in early 2019, and is working to establish robust systems for stable supply.

Cefazolin Shortage Reaffirms the Need for Robust Supply Chains

The API for cefazolin sodium injection “Nichi-Iko,” a cephem antibiotic formulation, was purchased from two companies—Company A and Company B—in Italy for manufacturing, but starting at the end of 2018, lots of the API purchased on the Company A route that were contaminated by foreign substances increased rapidly. In addition, the Chinese manufacturer that was the world's only manufacturer of tetrazole acetic acid (TAA), one of the starting materials for cefazolin sodium API, suspended shipments under order of the authorities due to issues relating to environment regulations. As a result, Company B's stocks of TAA were depleted. Due to the intersection of these problem, supply of cefazolin sodium injection “Nichi-Iko” was unavoidably suspended in February 2019.



Cefazolin sodium injection “Nichi-Iko,” a cephem antibiotic formulation used by many healthcare institutions

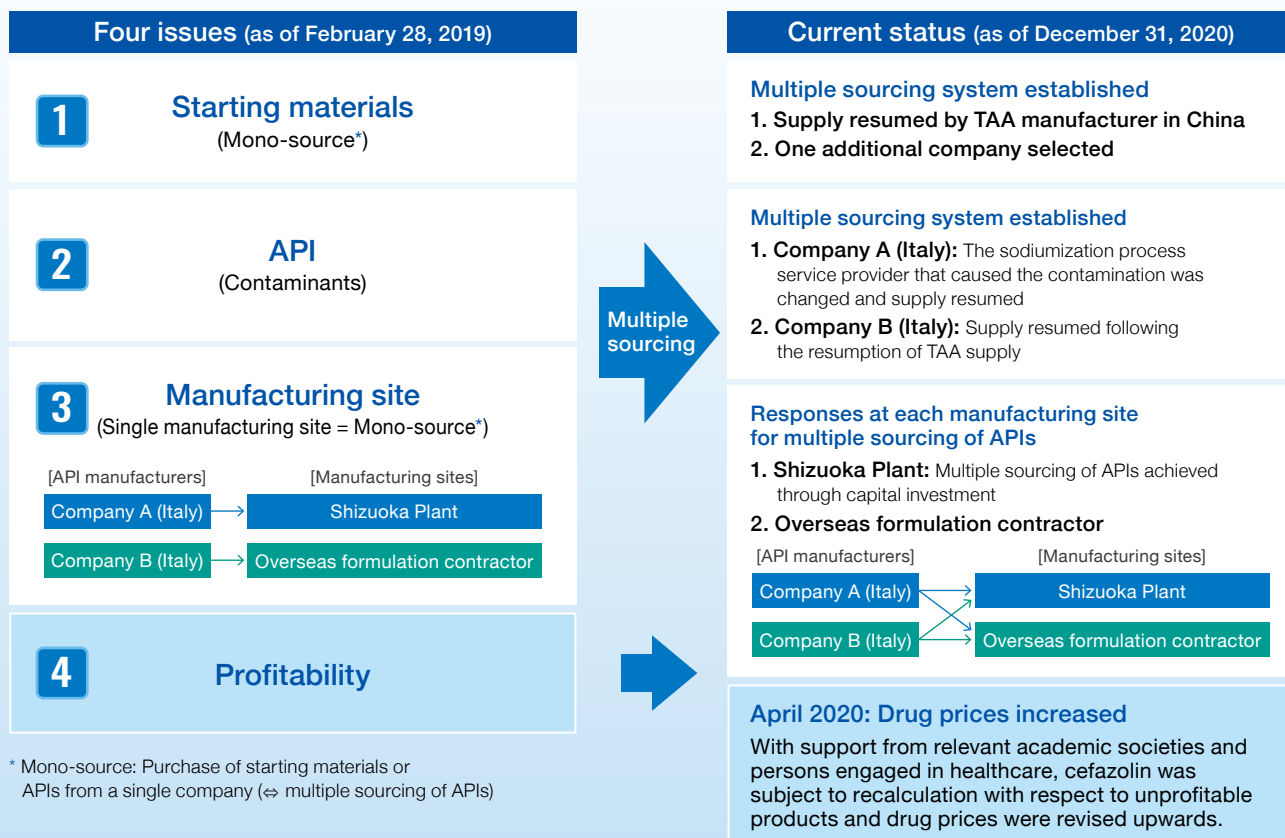
Establishment of Stable Supply System through Multiple Starting Material and API Procurement Routes and Multiple Formulation Manufacturing Sites, and Some Domestic Production

To eliminate supply instability, Nichi-Iko implemented the following four measures, began phased shipments in November 2019, and resumed normal shipments in October 2020.

1. Multiple sourcing of APIs

Supply of the formulation resumed on November 25, 2019 as a result of the resumption of API supply from the Company B route in Italy (see Figure 2), and on the Company A route in Italy (see Figure 2), resumption of API supply became possible by changing the sodiumization process service provider. Through these measures, a system for multiple sourcing of the APIs for the formulation was established.

Figure 1 Status of Measures to Establish a Stable Supply System



* Mono-source: Purchase of starting materials or APIs from a single company (⇔ multiple sourcing of APIs)

2. Establishment of formulation production system at multiple manufacturing sites including the Shizuoka Plant

By using the API from the Company B route, product was supplied through manufacturing by an overseas formulation contractor, and Nichii-Iko made capital investments at the Shizuoka Plant in order to start formulation production in Japan. As a result of these efforts, a production system at multiple manufacturing sites including the Shizuoka Plant was established.

3. Collaboration with overseas manufacturing sites for starting materials (TAA and others)

Until now, Nichii-Iko has made direct on-site visits to starting material manufacturers to confirm environmental measures and stable supply systems. Going forward, the Company will continue to share information with manufacturers, reinforce collaboration, and establish robust supply chains. The Company has selected one additional TAA manufacturer and has established a multiple sourcing system for starting materials as well.

4. Recalculation of unprofitable products

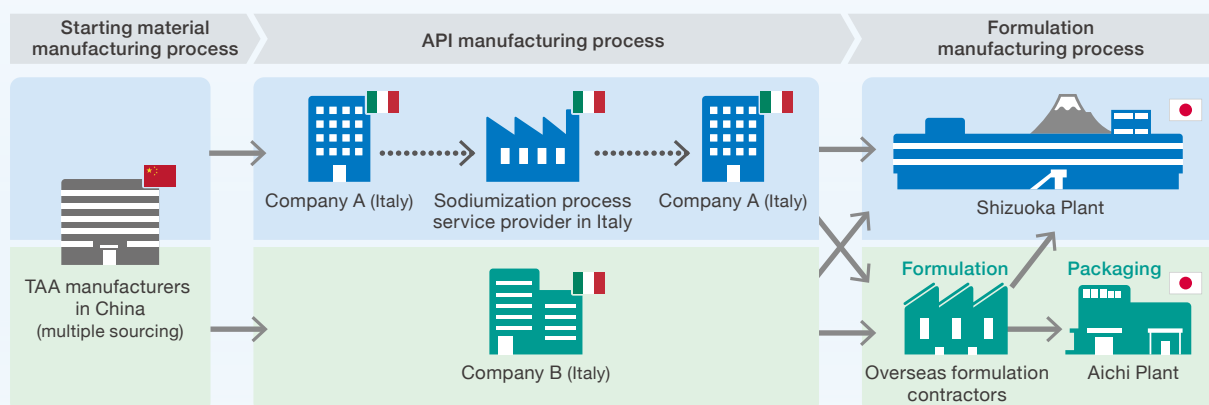
For the April 2020 drug price revisions, Nichii-Iko received support from relevant academic societies and persons involved in healthcare with respect to the importance of fundamental antibacterial agents that are crucial in healthcare and recalculation was performed regarding unprofitable products. With the aim of establishing even more stable supply systems, the Company made capital investments in its own plants in Japan and took measures to establish robust supply chains, and going forward, will make every effort to promote sales based on product value that will maintain manufacturing and sales in the future.

Discussions are advancing by means of a conference of experts concerning 551 ingredients of stably-secured pharmaceuticals. Cefazolin is included in the list as an ingredient, and there are a total of 141 ingredients listed that the Nichii-Iko Group manufactures and sells or trades. Based on the experience gained as a result of the cefazolin supply problem, the Group will take responsibility for continuous and stable supplies of these medically critical products.

Developments from the Occurrence of the Supply Problem to the Resumption of Shipments

End of 2018	Contaminants discovered in cefazolin API; supply of TAA starting material suspended <ul style="list-style-type: none"> • Lots of API with contamination from the Company A route in Italy increase suddenly • The world's sole manufacturer of TAA suspends shipments due to environmental regulations imposed by Chinese authorities
End of February 2019	Product shipment suspended <ul style="list-style-type: none"> • Following reports to and consultation with authorities and reports to academic societies, Nichii-Iko suspends product shipments
March 2019	TAA supply resumed <ul style="list-style-type: none"> • Shipments from the TAA manufacturer resume
September 2019	Capital investment in stable supply systems <ul style="list-style-type: none"> • Nichii-Iko invests in ¥1.5 billion in its Shizuoka Plant to add API manufacturing facilities • In addition to an overseas API formulation contractor, an integrated production system for formulation process was established in Japan
November 2019	Phased product shipments started <ul style="list-style-type: none"> • Phased shipments started with the highest priority on providing this formulation to patients and healthcare providers as quickly as possible
October 2020	Normal shipments resumed <ul style="list-style-type: none"> • As a result of these four undertakings, normal product shipments were resumed

Figure 2 Establishment of a Stable Supply System for Cefazolin



Feature

COVID-19 Initiatives

The COVID-19 (new coronavirus) pandemic that has been running rampant around the world since early 2020 is an urgent issue that humankind must overcome. Nichi-Iko has positioned COVID-19 countermeasures as a priority issue, and the Company is making every effort to address it.



Facing a Global Threat with a Strong Sense of Mission as a Pharmaceutical Company

As a generic pharmaceutical company, Nichi-Iko manufactures and sells more than 1,200 products. Among them are several products that are expected to be effective for treating COVID-19. Cooperating with clinical research on the development of drugs and establishing systems for the supply of those drugs to numerous patients are Nichi-Iko's missions as a pharmaceutical company. The Company is also implementing various COVID-19 countermeasures for employees and is taking action to prevent community spread of COVID-19.

FUTHAN® for Injectables, a Drug Candidate, Provided Free for Clinical Research in Japan and Overseas

Promising drug candidates for COVID-19 provided to clinical research in Japan and overseas

Nafamostat, a proteolytic enzyme inhibitor, is attracting attention as a promising candidate drug for COVID-19. Nafamostat has the potential to prevent SARS-CoV-2, the virus that causes COVID-19, from invading cells and may have anticoagulant effects to prevent exacerbation of symptoms due to the formation of blood clots in blood vessels. Clinical research by leading research institutions in Japan and overseas is underway. Nichi-Iko manufactures and sells nafamostat, a candidate drug for COVID-19, under the product name FUTHAN® for injectables.

In Japan, the University of Tokyo announced in March 2020 that it has identified an existing domestic drug that is expected to prevent COVID-19 infection. Special clinical research started in May 2020 at multiple facilities in Japan including the University of Tokyo Hospital. Overseas, the University of Oxford and the University of Edinburgh are conducting joint research on the therapeutic effects of nafamostat. Nichi-Iko has provided FUTHAN® to these projects.

In addition, Nichi-Iko is conducting research and development with the Institute of Medical Science of the University of Tokyo, RIKEN, and Daiichi Sankyo Co., Ltd. on a nafamostat inhalation formulation. As a manufacturer and seller, Nichi-Iko is providing clinical data accumulated over many years regarding intravenous drip infusion of FUTHAN® and supplying APIs.

As the manufacturer and seller of FUTHAN®, an original drug, Nichi-Iko plans to increase production of FUTHAN® in order to fulfill its supply responsibilities. The Company has invested approximately four billion yen in the Aichi Plant to increase freeze drying manufacturing facilities and will establish a structure capable of producing three million doses annually, with operations to commence at the end of 2021.



Nichi-Iko plans to increase production of FUTHAN®, which is expected to be an effective drug against COVID-19

Supply of DECADRON® Tablets, A COVID-19 Treatment

Nichi-Iko drug with extensive supply track record listed in medical guides as the second drug for COVID-19 in Japan

In July 2020, the Japanese Ministry of Health, Labour and Welfare included dexamethasone, an anti-inflammatory drug, in medical guides as the second COVID-19 therapeutic agent in Japan. Dexamethasone is a steroid used to treat asthma and pneumonia. Nichi-Iko manufactures and sells dexamethasone tablets under the product name DECADRON® Tablets. Research in the U.K. has confirmed that treatment with dexamethasone reduces the death rate among severely ill COVID-19 patients, and its use is also recommended in the U.S. Dexamethasone is already covered by insurance in Japan, and Nichi-Iko has an extensive supply track record. Continued demand is expected into the future, and the Company is working to respond with stable supplies.



Dexamethasone, which was listed in medical guides as the second COVID-19 drug in Japan

Development of COVID-19 Drugs by Sagent, a U.S. Subsidiary

Phase II clinical trial of camostat starts in U.S.

In October 2020, Sagent, a subsidiary in the U.S., took the lead in starting a phase II clinical trial intended to evaluate the efficacy and safety of Camostat in high-risk outpatients positive for COVID-19 (the CAMELOT Project). Test subject enrollment began in November 2020, and the project was scheduled for completion in early 2021. If a positive result is obtained from this trial, Sagent plans to apply for emergency use authorization (EUA). It is expected that Nichi-Iko's Shizuoka Plant will start supplying the drug to the U.S. government as well as state and local governments in parallel with the phase III clinical trial.

Details concerning the CAMELOT project

P.35 Business Overview | Overseas Business: U.S. Market



Camostat is planned to be manufactured at the Nichi-Iko Shizuoka Plant

Contributions to Local Communities

Raising public awareness of infection prevention through partnership agreement with local governments

Nichi-Iko has entered into partnership agreements with local governments around Japan with the aim of extending the healthy lifespans of citizens and normalize healthcare costs. As one part of these efforts, the Company is actively supporting COVID-19 countermeasures. The Company donated Pure Hand gel hand sanitizer and conducted courses on proper handwashing to prevent infection, raising awareness of COVID-19 and contributing to preventing its spread in the community.



A course on handwashing to prevent infection

Topic 1

Generic Drug Business Acquired from Teva Takeda

Nichi-Iko is undertaking a variety of initiatives with the aim of enhancing corporate value. The Company announced the acquisition of Teva Takeda Pharma Ltd.'s generic drug business and Takayama Plant in July 2020. Two Teva Takeda assets—production and quality control—will become sources of significant growth in the future.

Overview

Overcoming Problems, Enhancing Corporate Value

Optimizing production systems throughout the Nichi-Iko Group and reinforcing the earnings base are major management issues that the Group is currently facing. Nichi-Iko recently assumed the manufacturing and marketing approval of 486 generic drugs held by Teva Takeda, its Takayama Plant in Gifu Prefecture and the plant employees, and outsourcing agreements for products manufactured at the plant. The Nichi-Iko Group will work to leverage these new assets to the greatest extent possible, thereby optimizing operations even further and achieving quality on global levels, which will lead to stronger competitiveness. Nichi-Iko acquired the target business in February 2021, and the Teva Takeda Takayama Plant restarted as Nichi-Iko Gifu Plant. Nichi-Iko established the Nichi-Iko Gifu Plant Integration Promotion Office in August 2020 and is currently building new systems.



Overview of the Gifu Plant

- **Location:** Takayama City, Gifu Prefecture
- **Site area:** 118,599 m²
- **Building total floor area:** 119,282 m²
- **Production formulations:** Tablets and injectables (ampoules, vials, syringes, and bags)
- **Production results:** 2.7 billion tablets; 45.4 million injectable doses (FY 2019)
- **Production capacity:** 4.0 billion tablets; 110 million injectable doses
- **No. of employees:** 744 (as of June 30, 2020)
- **Functions:** Production, procurement, regulatory affairs, quality control, quality assurance
- **Features:**
 - Ability to manufacture specialized formulations (syringes and bags)
 - Ability to manufacture antibiotics and anti-cancer drugs
 - State-of-the-art production facilities (automation)
 - Expensive site allows for further expansion of production facilities

Two Key Objectives

The main objectives of this acquisition are optimizing Nichi-Iko Group production systems through internal manufacturing and other measures as well as reinforcing quality control systems. The Group will achieve further growth by accomplishing these two objectives.

1 Optimizing Group Production Systems through Internal Manufacturing and Other Measures

By leveraging the Teva Takeda Takayama Plant's four billion tablet production capacity and manufacturing facilities for special formulations including anti-cancer drugs, it will be possible to internally manufacture drugs that until now were outsourced. By integrating the APIs of overlapping drugs, consolidating manufacturing sites, and reviewing redundant products in the future, the Nichi-Iko Group will pursue thorough optimization of operations and maximize integration synergy effects.



A new manufacturing lineup will be added to the Group

2 Reinforcing Quality Control Systems

By acquiring this business, the Nichi-Iko Group will obtain a global-level quality control system and outstanding human resources. It will also be possible to introduce and use external expertise through the contract manufacturing business, and the Group's quality control systems will be further strengthened. In conjunction with the acquisition of this business, the Group's quality control departments will expand to some 600 employees.



Quality control systems will be reinforced through the integration of the two companies' culture

Business Alliance with MedPeer to Capture Demand in Health Tech Field

Society is about to undergo major changes as a result of digital transformation (DX). In response to these changes, Nichi-Iko too will create new businesses in the health tech field, contributing to advances in healthcare.

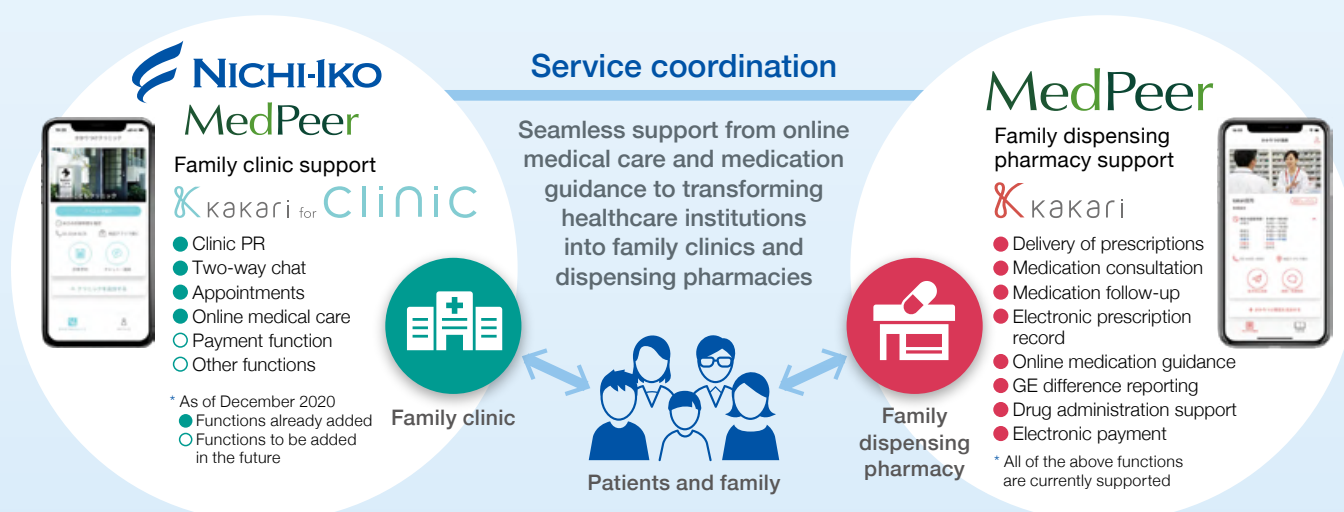
Overview

Solving Social Problems by Promoting DX

One of the fundamental strategies in Nichi-Iko's 8th Medium-term Management Plan is to continue our deeper pursuit of business arenas. A specific initiative to carry out this strategy was the formation of a strategic alliance with MedPeer, Inc. in November 2019 and joint sales promotion of "kakari," a family dispensing pharmacy support service. In September 2020, Nichi-Iko launched the "kakari for Clinic" joint business, a clinic support service that links patients and clinics. In conjunction with the recent global spread of COVID-19, new social issues in the healthcare field including a series of restrictions on consultations to prevent secondary infection have become clear. Nichi-Iko believes that the Company can contribute to solving these issues by making use of health tech including online medical care and online medication guidance in response to changes in the behavior of patients and their families. Through the business alliance with MedPeer, Nichi-Iko will promote the DX business centered on patients and their families and will generate new value for society to advance even further as a global comprehensive generic pharmaceutical company.

Connecting Patients and Their Families with Family Clinics and Dispensing Pharmacies

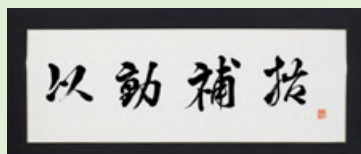
"kakari for Clinic" is a digital service that connects local clinics with patients and their families. It supports family clinics by facilitating communication through an app with a PR function that can directly distribute notices from clinics to patients, an appointment function that reduces waiting times and infection risks during consultations, a chat function for two-way communications between clinics and patients, and other functions. The services provided through joint business operations by Nichi-Iko, MedPeer, and Nichi-Med, a newly-established joint venture (owned 66% by Nichi-Iko and 34% by MedPeer). Provision of the online medical care function started in December 2020, and other functions will be rolled out in stages. In addition, by coordinating with "kakari," a family dispensing pharmacy support service with online medication guidance and other functions, it is possible to comprehensively link patients, clinics, and pharmacies to create a support platform that covers diagnosis to medication guidance. Through the DX business, Nichi-Iko seeks to bring innovation to the medical field and contribute to enhancing the quality of life of patients and their families.



Action Invites Opportunity: A History of Creation and Challenges

Nichi-Iko has achieved substantial growth through bold management adapted to social changes

Since its foundation in 1965, Nichi-Iko has focused management resources on promising markets, expanded and globally develop business through M&A, reinforced quality control systems for the benefit of patients, and taken other measures to continuously tackle the challenges of creating new value based on the spirit of “Action Invites Opportunity.”



“Action Invites Opportunity” means that...

Nothing can begin unless one takes action. Taking action makes it possible to see new opportunities. We believe Nichi-Iko is able to continue creating and taking on new challenges because our DNA is imbued with this belief that “action invites opportunity.”

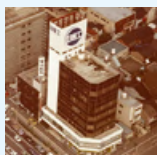
Jul. 1965

Shiro Tamura established Nihon Iyakuin Kogyo Co., Ltd. in Toyama City



Sep. 1974

Completed construction of head office building in Sogawa, Toyama City



Jan. 1987

Obtained approval for manufacture of SEDAPAIN injection, a central nervous system analgesic, as a new proprietary drug

Jun. 1994

Obtained approval for manufacture of UNICON tablets, a new drug to treat asthma, under foreign license



Feb. 2000

Yuichi Tamura appointed President and CEO

From 2000

Transfer of approval for long-listed products provided a breakthrough for enabling handling by wide-area wholesalers

Jun. 2005

Changed company name from Nihon Iyakuin Kogyo Co., Ltd. to Nichi-Iko Pharmaceutical Co., Ltd.



From 2005

Extended product lineups and increased supply capacity by acquiring stock in Maruko Pharmaceutical, Nihon-Gallen, Oriental Pharmaceutical, Teikoku Medix, and other companies

1995:
Withdrawal from
new drug development

Shift from
new drugs to
generic drugs

Focused management resources on generic drugs and implemented organizational and business reforms
Expanded performance in conjunction with rising recognition of generic drugs

Sales trend

1965 ∞ 1980

1985

1990

1995

2000

2005

Founding Period

Launch of Generic Drug Manufacturing and Sales;
Taking on the Challenge of New Drugs

Growth Period

Expansion of the generic drug business through M&A and business alliances

May 2010

Entered into a strategic alliance with Sanofi

Oct. 2010

Entered into a capital and business alliance with Aprogen of South Korea

APROGEN

Dec. 2010

Listed on the First Section of the Tokyo Stock Exchange

**2010–2018**

Expanded Toyama Plant 1; established 18.5 billion tablet production system

**2010**

Started operations at Pentagon Building

2013

Started operations at Pyramid Building

2018

Started operations at Obelisk Building

2014

Became first domestic generic pharmaceutical company to reach ¥100 billion in sales

Apr. 2014

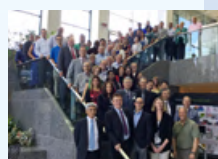
Acquired production subsidiary of Astellas Pharma (currently the Nichi-Iko Shizuoka Plant)

Jul. 2015

50th anniversary of Nichi-Iko's founding

**Aug. 2016**

Made Sagent Pharmaceuticals of the U.S. a wholly owned subsidiary

**Sep. 2017**

Obtained manufacturing and marketing approval in Japan for Nichi-Iko Infliximab BS for I.V. Infusion 100 mg

**New Quality Policy**

"Our Pledge of Trust and Confidence — Nichi-Iko Group Quality Policy" adopted on July 15, 2020, the 55th anniversary of the Company's founding

P.01 Nichi-Iko's New Quality Policy

Long-term Vision

Patient-centric Generic Pharmaceutical Company adopted as the Long-term Vision

P.19 Nichi-Iko's Long-Term Vision

Mar. 2018

Entered into a strategic alliance with Eisai

**Apr. 2019**

Elmed Eisai became a wholly owned subsidiary

Nov. 2019

Concluded business alliance with MedPeer

Feb. 2021

Generic drug business and Takayama Plant acquired from Teva Takeda

2021

Application for Infliximab BS to be filed in the U.S.



Global Growth Period

Investment in biosimilars for further growth

*1 Four-month fiscal year for the period ended March 2012 due to change in fiscal year end

*2 IFRS (International Financial Reporting Standards) applied starting in the fiscal year ended March 2018

The Value Creation Process

As a generic pharmaceutical company,
Nichi-Iko will contribute to solving social problems and
increase corporate value by advancing even further

Mission Statement

Inputs

Manufacturing Capital

- Production sites: **7** plants in Japan and **3** plants overseas
- Supply capacity: **18.5** billion tablets, the largest in Japan

Organization and Human Capital

- Number of employees (consolidated): **1,954** (as of March 31, 2020)
- Group companies: **4** companies in Japan and **5** companies overseas

Societal and Relationship Capital

- Collaboration with business partners
- Medical facility coverage rate: Hospitals **98.8**%; clinics **64.6**%; dispensing pharmacies **97.6**% (as of March 31, 2020)

Intellectual Capital

- Amount of R&D investment for development of biosimilars and small-molecule generic drugs: **¥33.0** billion (cumulative for the fiscal year ended March 31, 2020 through the fiscal year ending March 31, 2022)

Financial Capital

- Total assets: **¥336.8** billion (as of March 31, 2020)

Natural Capital

- Shift to LNG fuel
- Introduction of CO₂-free energy

Distribution & Sales

Logistics

Business Foundation

Action Invites Opportunity

P.15 Action Invites Opportunity:
A History of Creation
and Challenges

Nichi-Iko's strength is an established global-scale development, production, and sales value chain that boasts the largest number of generic drugs in the industry. Based on the clear Long-term Vision, the Company provides trust and confidence to stakeholders through the stable supply of premium quality drugs, and will contribute to solving various social problems while sustainably increasing corporate value by making further advances in the generic drug business.

We shall excel as the outstanding generic pharmaceutical company, making every effort to continue to serve and deliver our products needed by our patients and their families, pharmacists, doctors, distributors and other pharma companies around the world.



Long-term Vision

P.19 Nichi-Iko's Long-term Vision

Corporate Governance

P.45 Corporate Governance

People

P.59 Society | People

New Quality Policy

P.01 Nichi-Iko's New Quality Policy

Outcome Resolving social issues

Reduced burdens on patients
and their families

Longer healthy lifespans

Control of
the rising healthcare costs

Development of
COVID-19 drugs

Continued stable supply of
stably-secured pharmaceuticals*
including antibacterial agents

Reduced CO₂ emissions

* Stably-secured pharmaceuticals: Pharmaceuticals made from 551 ingredients proposed by 58 academic societies that are indispensable for medical treatment, are widely used, and must be stably secured.

Nichi-Iko's Long-term Vision

In 2020, on the occasion of the 55th anniversary of its founding, Nichi-Iko adopted a new Long-term Vision as a statement of the Company that it seeks to be.

Based on “Our Pledge of Trust and Confidence—Nichi-Iko Group Quality Policy,” which was announced earlier, we hope to achieve this vision through the efforts of all employees to carry out the six stated missions for supporting patients and their families around the world.

— Nichi-Iko's Long-term Vision —

Patient-centric Generic Pharmaceutical Company

**Supporting patients around the world
through the continuous supply of
needed drugs in accordance
with “Our Pledge of Trust and Confidence”**

**As a global comprehensive generic pharmaceutical company
that serves with compassion the patients suffering from illnesses
and their families, all Nichi-Iko employees will work together
to continue supplying drugs that provide trust and confidence
so that we can continue growing in the future.**

Building Structures for Trust and Confidence

■ Premium Quality

Make further advances in production and quality control and undertake continuous improvement measures to achieve quality at the world's highest levels.

■ Stable Supply

Pursue optimization of development, procurement, production, and logistics to maintain stable supplies of products.

■ Product Lineup

Expand the biosimilar and oncology fields to broadly meet the needs of society with an extensive product lineup.

■ Global Development

Supply the drugs that patients need in Japan, the U.S., Europe, and Asia.

■ New Value Creation

Leverage drug repositioning of prescription drugs that do not rely on patents to create new potential.

Provide needed products and information to patients through strategic alliances with business partners and the use of DX.

■ Unwavering Business Foundations

Establish stable financial foundations so that we can continue supporting patients.

Achieve sustainable growth as a business enterprise and fulfill our social responsibilities as a pharmaceutical company.

8th Medium-term Management Plan, “NEXUS∞”

The 8th Medium-term Management Plan, which is known as “NEXUS∞” and covers the period from April 2019 to March 2022, is currently underway. Nichi-Iko is carrying out four strategies to expand business, strengthen business foundations, undertake global operations, and fulfill its social responsibilities. Through these efforts, the Company is accelerating its development as a global comprehensive generic pharmaceutical company that undertakes business with a focus on patients and their families.

Theme of the 8th Medium-term Management Plan



Going Beyond with Infinite Power to Connect

**To Evolve as a Global Comprehensive
Generic Pharmaceutical Company**

Strategic Imperatives as a Global Comprehensive Generic Pharmaceutical Company

Strategy		Priorities	
1	Continue our deeper pursuit of business arenas	Business expansion	
<ul style="list-style-type: none">• Extend product lineups in biosimilars and anticancer generics, etc. to contribute to reducing the burden on patients and their families and to containing healthcare costs• Contribute to local communities through promotion of initiatives for a regional community-based integrated care system that provides comprehensive support and services• As an ethical pharmaceutical company, lead strategic alliances with business partners to benefit patients and their families			
Vision	Achieve broader coverage of therapeutic area as well as geographical regions with extensive loss-of-exclusivity (LOE) product lineups		
Progress	<ul style="list-style-type: none">• As a global comprehensive generic pharmaceutical company, we seek to make contributions to healthcare in areas other than the manufacture and sale of drugs, and have entered businesses such as online medical care and online medication guidance, areas that are expected to have increased demand in the future<ol style="list-style-type: none">1. Business alliance established with MedPeer and sales of “kakari” started in November 20192. Joint venture established and “kakari for Clinic” launched in September 2020• In November 2020, filed an application for approval of bevacizumab BS (an original biopharmaceutical sold under the brand name Avastin®), a new biosimilar, in collaboration with mAbxience Research		

Strategy

2

Relentless efforts for operational excellence

Priorities

Business foundation

- Develop and improve products that allow us to respond to the needs of patients and their families (customer feedback)
- Leverage our procurement and production capabilities as Japan's largest generic pharmaceutical company to drive cost reduction and internalize manufacturing
- Pursue synergies from integration with Elmed

Vision

Secure unwavering business foundation by optimizing the entire value chain

Progress

- Achieved cost-cutting synergy effects through the merger with Elmed
- Implemented cost-cutting programs including PMP8^{*1}
- Made product improvements from time to time using PENG^{*2}

^{*1} Profit Management Plan 8

Cost reduction measures across eight areas. Cumulative cost reductions of at least ¥15.0 billion are to be achieved over the three years of the plan.

^{*2} A post-marketing information collection system

Collects post-marketing product information and performs proprietary assessment and analysis. The system makes product improvements based on this information.

Strategy

3

Drive for a global standard of quality and competitive edge

Priorities

Global operation

- Expand the scale of business in the U.S. market in biosimilars, boost the compounding business and orphan drugs, in addition to Sagent Pharmaceuticals, Inc.'s current strength in generic injectables
- Expand the scale of Nichi-Iko brand products in Asia
- Promote global development readiness and expand product lineup to meet quality standards in each country
- Expand into new business arenas through proactive alliances

Vision

Deliver "premium quality" of Nichi-Iko products consistently to patients and their families around the world

Progress

- In the U.S. market, in addition to conducting business based on four pillars—generic drugs, compound formulations, biosimilars, and orphan drugs—launched the CAMELOT Project to develop COVID-19 treatments in November 2020
- Obtained approval from the FDA Thailand for anti-cancer drugs through collaboration by Sagent and Nichi-Iko (Thailand)
- Concluded a comprehensive business alliance agreement for the generic drug business in China with Eisai

Strategy

4

Be the most trusted life science company, driven by our ESG activities

Priorities

Social responsibility

- Adhere to and enhance governance and compliance systems that underpin a sound business foundation.
- Be proud of our involvement in health and human life as a pharmaceutical company, and actively engage in CSR activities.
- Continue working to reduce and improve the environmental impact of our business, one of our responsibilities to society.
- Strive to create employee-friendly environments by promoting more flexible work styles and offering diverse opportunities for employees to grow by maximizing their individual strengths and talents.

Vision

Earn the undisputed trust from patients and all our stakeholders to fulfill our social mission with full commitment to integrity and transparency

Progress

- Contributed to normalizing regional healthcare costs and extending healthy lifespans through generic drug educational programs, courses on hand sanitizing to prevent infection, and other measures under partnership agreements with local governments
- Switched use of kerosene as a fuel to more environmentally friendly LNG and took measures to reduce CO₂ emissions by 30% compared to the fiscal year ended March 31, 2019
- Provided Carboplatin Injection 450 mg "Nichi-Iko" free of charge to specified clinical research on triple negative breast cancer
- Provided FUTHAN[®] free of charge for COVID-19 drug research and development being conducted in Japan and overseas

Message from the Representative Director, EVP



We are focusing even more on quality control and stable supply and are committed to fulfilling “Our Pledge of Trust and Confidence” to all stakeholders

Takahiro Yoshikawa

Representative Director, EVP
Quality, Supply Chain, and BS Management

**Nichi-Iko supplies approximately 10% of drugs in Japan.
We carry out our Quality Policy with an awareness of our responsibility.**

Nichi-Iko's most important mission as a pharmaceutical company is the continuous supply of high-quality drugs for the benefit of patients and their families. To carry out this mission and achieve further development, it is essential that Nichi-Iko strengthen its quality control and stable supply systems, and we are aware that this is a key issue.

“Our Pledge of Trust and Confidence—Nichi-Iko Group Quality Policy,” which we announced on July 15, 2020, the anniversary of the Company's foundation, is a clear restatement of our strong understanding that without an attitude that emphasizes quality, there is no meaning in Nichi-Iko's existence. This Quality Policy establishes five Quality Action Guidelines for providing trust and confidence to all stakeholders, and the subject of each of these guidelines is “I.” These guidelines are not subjective perspectives of what we are pursuing as a pharmaceutical company, but rather, our declarations of the intent of each employee to protect and enhance quality. We will instill this policy and foster a mindset with

a strong awareness of quality throughout the Company while focusing efforts on developing human resources that have the skills necessary to reliably carry it out. We encourage participation in various trainings designed for all employees to acquire quality control knowledge and skills and will unsparingly and proactively invest in quality-related education to conduct these programs.

The rate of generic drug use in Japan is currently approaching 80% on a volume basis, and of that amount, Nichi-Iko has acquired about a 12% share of the market. This means that approximately 10% of the drugs taken in Japan are Nichi-Iko products. If quality-related issues were to occur, the impact on healthcare in Japan could be immeasurable. The responsibility that we bear is extremely momentous, and each one of us is fully aware of this weight. We have taken the Quality Policy to heart and put it into practice in our day-to-day work. Creating this type of corporate culture is part of the duties that I perform as the officer responsible for quality.

Understanding manufacturers from APIs to intermediates and building robust supply chains

We are also undertaking organizational restructuring to reinforce quality control even further. Previously, quality control was a part of the production structure, but in October 2018, we established the Quality Operations Division as an independent organization to concentrate authority relating to quality and reinforce management systems. In conjunction with this, we also bolstered checking functions, and in April 2020, we established the GMP Audit Office to perform specialized audits relating to quality. GMP (good management practices) are manufacturing and quality control standards for drugs specified by law. Through the rigorous audits conducted by the GMP Audit Office, we ensure strict compliance with rules that must never be deviated from as a pharmaceutical company.

In addition to strengthening quality control systems, creating systems for stable supply is also an important issue that Nichi-Iko must address with redoubled efforts. What is needed for the stable supply of drugs is the continuous maintenance of supply chains from procurement of raw materials to manufacturing while ensuring high quality without any breakdown of those supply chains. Currently, the APIs for most of the small-molecule generic drugs that are our main products are procured from overseas manufacturers, primarily in Europe, and we use our proprietary technologies to

formulate the drugs and supply them to the front lines of healthcare. These APIs are produced from substances known as intermediates that are generated through chemical reactions of compounds that serve as raw materials. Under current conditions, the manufacturers of intermediates are concentrated in China because of manufacturing costs and other reasons. This means that in order to maintain supply chains, we need to carefully monitor developments concerning not just the API manufacturers, but also the Chinese manufacturers of the intermediates used to produce the APIs. It is difficult for us to oversee and have influence on Chinese intermediate manufacturers with which we do not engage in direct transactions, but this too is an area in which we are active. Our procurement departments are staffed with human resources that have English and Chinese capabilities and deep understanding of pharmaceuticals, and they travel to local plants of key APIs and intermediates in China to confirm that manufacturing is performed under appropriate environments and according to proper procedures. They also directly check for any environmental risks that could necessitate a suspension of operations and provide guidance as necessary. We plan to expand and enhance these measures in the future and to thoroughly investigate and monitor supply chains for each pipeline.

Boldly tackling the challenges of biosimilars (biogenerics). Everything is for providing trust and confidence.

Nichi-Iko handles a number of fundamental drugs that are essential for healthcare such as antibacterial agents. Building supply chains necessary for the stable supply of these products requires extensive efforts and expenditure, but it is a responsibility that we absolutely must fulfill as a pharmaceutical company. Consequently, we will do everything that we possibly can to meet this responsibility. Moreover, quality control and stable supply of biosimilars, the market for which is expected to grow in the future, is also an important issue. We are now in a time when biopharmaceuticals account for more than half of the world's top 10 best-selling drugs in terms of sales revenues. The need of society for biosimilars is massive, and Nichi-Iko has already marketed two products and has a number more in the pipeline under development.




The development of biosimilars, however, can be an extremely difficult matter. Biopharmaceuticals have complex structures made up of multiple functional sites and have quality characteristics such as biological activity,

instability, and immunogenicity. For this reason, the development of biosimilars requires extensive data to show equivalence and homogeneity compared to the original biopharmaceuticals with respect to quality, safety, and efficacy, even if the APIs are manufactured using cell culture techniques and the formulations are manufactured from APIs. In addition, intellectual property rights including material patents, application patents, and manufacturing method patents are complex. This means that compared to the development of chemical synthesis generic drugs, acquisition of nonclinical and clinical testing data requires considerable time and investment. Despite this, we are undertaking these challenges to provide trust and confidence to patients, their families, and all stakeholders.

Quality control and stable supply initiatives do not have end goals. To be a company that is needed by society, pursuing quality control and stable supply is Nichi-Iko's mission, and I hope to undertake management with this as a source of pride.

Strengths of the Nichi-Iko Group

This section presents the Nichi-Iko Group's strength and ESG initiatives in the development and planning, API procurement, production, logistics, and distribution and sales processes that the Group carries out in the business of competitive generic drugs and biosimilars.

		 Development/ Planning	 API Procurement	 Production
		Quick, responsive development system leverages Group's collaborative strengths	Global procurement system delivers stable supply, high quality and low costs	High-efficiency, low-cost production system enhances Group profitability
Strengths/Features/Systems		<ul style="list-style-type: none"> Proactive investment in biosimilar development Joint development through in-Group collaboration 	<ul style="list-style-type: none"> Leveraging Group network for reliable procurement of high-quality, low-cost APIs from suppliers worldwide 	<ul style="list-style-type: none"> Efficient production via functional consolidation of 7 domestic and 3 overseas plants Manufacture of biosimilars at own plant (Raleigh)
		<ul style="list-style-type: none"> Reliability of quality data ensured via use of IT in quality control 		
		<ul style="list-style-type: none"> Quick response to national regulations (FDA rules, Pharmaceuticals and Medical Devices Law, GCP^{*1}, GMP^{*2}, GQP^{*3}, GVP^{*4}, GDP^{*5}, etc.) 		
	Japan	<ul style="list-style-type: none"> Development of formulations compatible with a wide range of dosage forms Enhanced ability to develop value-added formulations through the merger with Elmed Improvements to formulations that reflect customer feedback 	<ul style="list-style-type: none"> Price negotiations that leverage the benefits of volume Alliance with Eisai (use of Vizag, India plant) 	<ul style="list-style-type: none"> Low-cost production leveraging scale of 18.5 billion tablet supply system Streamlined capital investment through flexible use of production outsourcing Formulation technology through collaboration with development
	U.S.	<ul style="list-style-type: none"> Drug development and partner selection by highly experienced staff 	<ul style="list-style-type: none"> Direct connections with suppliers worldwide 	<ul style="list-style-type: none"> Strategic partnerships with CMOs^{*6} Low-cost production system at two company-owned plants in North America (Montreal and Raleigh)
	Asia			<ul style="list-style-type: none"> Products exported from Nichi-Iko plants in Japan Use of Sagent CMO partners
		<ul style="list-style-type: none"> Quick decision-making and execution by top management Proactive partnerships and alliances with other companies for further expansion 		
ESG		<ul style="list-style-type: none"> Proper management of chemical substances University of Toyama endowed lecture, "Drug Formulation Design" Development of formulations that meet the needs of patients and their families (OD tablets using Nichi-Iko proprietary soluble tablet[®] technology, jelly formulations, etc.) 	<ul style="list-style-type: none"> Securing multiple API sources Information gathering for sustainable procurement Periodic supplier inspections 	<ul style="list-style-type: none"> Environmentally friendly production equipment and packaging Occupational safety and health initiatives Rigorous compliance with manufacturing and quality control standards
		<ul style="list-style-type: none"> A governance structure that splits the supervisory and executive functions, with Executive Vice Presidents supervising all operations Strong sense of ethics and strict compliance as a life sciences company 		

*1 Good Clinical Practices (standards for performing clinical testing of drugs)

*2 Good Management Practices (standards for drug manufacturing and quality control)

*3 Good Quality Practices (standards for drug quality control methods)

*4 Good Vigilance Practices (standards for post-manufacturing/post-marketing safety management)

*5 Good Distribution Practices
(standards for proper distribution of drugs)



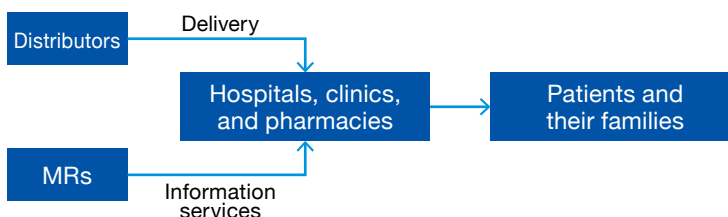
Logistics

Stable supply and delivery system makes effective use of outsourcing



Distribution/Sales

Efficient, highly value-added marketing and information system responsive to customer needs



- Speed of response to quality information

- Use of own distribution centers in Hokkaido, Toyama, East Japan and West Japan and a nationwide distribution network through wide-area drug wholesalers
- Efficient operation offering next-day supply to medical institutions nationwide

Distributors

MRs

Hospitals, clinics, and pharmacies

Patients and their families

- Strong cooperative relationships with wide-area drug wholesalers
- Efficient sales via a small number of elite MRs

- High medical facility coverage rate (between 97% and 98% of dispensing pharmacies and DPC hospitals⁷⁾)

- The largest number of products of any domestic pharmaceutical company
- Improvements to ease of swallowing, packaging and printing

- Management-oriented proposals from the Nichi-Iko Medical Practice Institute (MPI) and the Medical Practice Support team (MPS)
- Information collection via PENG (post-marketing information collection system) for drug improvements

- Strong relationships with the three major wholesalers (AmerisourceBergen / Cardinal Health / McKesson)

- Highly capable sales staff that have achieved the top 10 sales volume in the U.S. market for generic injectables
- Ability to negotiate with group purchasing organizations (GPO)

- Partnerships with local companies

- Supplying made-in-Japan products in response to need for high-quality drugs
- Partnerships with local companies to cover everything from local regulatory response to marketing
- Establishment of sales and marketing organization in Thailand

- Optimal allocation of human resources acquired through M&A (objective promotion based on ability)

- Distribution system based on business continuity plan (BCP)

- Stable supply of generic drugs to lower patient burden and healthcare costs
- Ongoing supply of products to meet societal demands

- Program "Koshi-juku" to develop future management class and other human resource development efforts

⁶ Abbreviation for Contract Manufacturing Organization, referring to a company that manufactures drugs under contract from a pharmaceutical company

⁷ Hospitals that use the DPC system, which determines the amounts of payments for healthcare costs per day of hospitalization based on diagnostic procedure combinations

Value Chain

The Nichi-Iko Group has established a value chain for developing, producing, and providing stable supplies of high-quality generic drugs. This section explains the roles of each division in the value chain and initiatives concerning the new Quality Policy.

Development & Planning Division



Toru Kogawa
Senior Vice President
Head of the Development
& Planning Division

Procurement Division



Atsushi Matsumoto
Senior Vice President
Head of the Procurement Division



Roles in the Value Chain

Developing Products that Help Patients and Contribute to Profitability

The role of the Development & Planning Division is to develop products that serve with compassion the patients suffering from illnesses and their families. To do this, everything starts with understanding the needs of patients and using information on the actual status of prescription usage in healthcare sites for product development. We are making unsparing efforts to accumulate the latest formulation technologies, intellectual property information, and so on and devoting all our energies to creating new value. The development of generic drugs also requires fostering an ability to predict profitability. We are reinforcing business foundations while giving due consideration to the proper balance with patient satisfaction.

New Quality Policy Initiatives

Becoming “Better Than the Best” by Reflecting Feedback from the Market in Products

Product development requires not only the activities for the creation of drugs that serve with compassion the patients suffering from illnesses and their families, but also coordination among departments responsible for production, quality control, sales and marketing, and so on in order to create the formulation technologies that will make stable supplies of products possible. We reflect in product development and manufacturing activities the information that we actively collect from inside and outside the Company and work to establish a business environment that emphasizes open communication and the visualization and early resolution of problems in order to pursue high quality at all times. For the Development & Planning Division, the Mission Statement and “Our Pledge of Trust and Confidence—Nichi-Iko Group Quality Policy” are two different aspects of the same thing for undertaking development activities, and we will continuously move forward so that we can achieve “better than the best” proposals through measures that give form to feedback from patients, their families, and individuals who work in healthcare.



Roles in the Value Chain

Building Robust Supply Chains for Stable Supply

The Procurement Division is responsible for processes from negotiating contracts to ordering and purchasing products from suppliers in Japan and overseas relating to effective ingredients (APIs) and additives used in drugs manufactured in-house and at contract plants, packaging materials necessary for product packaging, and drugs manufactured at contract plants. Production of raw materials for drugs is performed through a division of roles in countries around the world. To ensure stable supplies, we strive to understand the supply chains for each procured product and to build trusting relationships with suppliers and the manufacturing plants of their suppliers throughout the world.

New Quality Policy Initiatives

Sharing New Quality Policy with All Suppliers and Manufacturing Plants

It is essential that we cooperate with each supplier and manufacturing plant so that we can supply drugs in accordance with our Quality Policy. The Procurement Division will serve as a liaison to the suppliers that support the manufacture of our drugs, and we will notify suppliers and manufacturing plants regarding our Quality Policy through our day-to-day business dealings and seek their cooperation based on mutual understanding. Contributing to the stable supply of drugs to patients in accordance with our Quality Policy is also one of the important roles of the Procurement Division. Through procurement operations, we will conduct ordering and maintain inventories in accordance with our stable supply manual, share information on products that are experiencing supply issues with relevant divisions, and cooperate with suppliers and manufacturing plants to promptly resolve those issues.

Production Division



Masatoshi Takaishi

Senior Vice President
Stable Supply Management Officer
Head of the Production Division



Roles in the Value Chain

Building Production Systems that Satisfy Global Quality Standards

The Production Division formulates and manages production plans for product families with different dose forms at each site in accordance with sales plans and establishes and maintains stable supply systems. We also create and improve production lines, introduce manufacturing control systems, conduct a GMP education, and take various other measures to address physical and non-physical aspects so that global quality standards can be satisfied. With regard to the environment, we are contributing to the creation of a low-carbon and recycling-oriented society by switching to LNG fuel, investigating the introduction of renewable energy, and taking other measures as part of the Company's initiatives to address the SDGs.

New Quality Policy Initiatives

Raising Awareness of Compliance and Improving Quality with Original Systems

We will undertake manufacturing with self-awareness and a sense of responsibility and strive to foster a culture of quality and build trust so that our products can be taken with peace of mind by everyone from our immediate family members to patients throughout the world. To raise awareness concerning legal compliance, we will conduct educational programs on compliance with various laws and regulations online and using outside instructors and will raise the level of CAPA (corrective action and preventive action) at each plant to maintain and enhance quality. In addition, we collect data during manufacturing and reflected in manufacturing control systems to prevent human error, maintain electronic records, and ensure data integrity. We will take measures to ensure the handover and improvement of formulation technologies, promptly identify aspects of unstable supply, share information with relevant departments, and quickly take corrective action.

Quality Assurance & Pharmacovigilance Division



Hiroshi Shimazaki

Senior Vice President
Head of the Quality Assurance
& Pharmacovigilance Division



Roles in the Value Chain

Responding Appropriately to Laws and Regulations Relating to Drugs and Ensuring Quality

The main work of the Quality Assurance & Pharmacovigilance Division is responding to drug-related laws and regulations. In addition to quality assurance at each of our plants, we are also responsible for ensuring the quality of outsourced drugs and APIs and formulations manufactured overseas. We are also responsible for responding to quality information and requests from customers and collecting and analyzing safety information. We are responsible for complying with regulations necessary for ensuring reliability in each stage from drug development to obtaining approval, manufacturing, distribution, and sales and for ensuring the quality of drugs from their creation to supply to patients.

New Quality Policy Initiatives

Investigating and Confirming Our Own Plants and Sites around the World

Our Quality Policy is premised on the wish to approach each patient individually. We investigate and confirm our own plants as well as relevant sites around the world to ensure proper compliance with all regulations from the production of raw materials to the manufacture of drugs including GLP and GCP in relation to development, GMP in relation to manufacturing, GDP to ensure quality during the drug distribution process, and GPMSP and GPSP to ensure safety in the market so that every single tablet and capsule is properly taken by patients. As a company involved in pharmaceuticals, we will adopt a strict stance that prioritizes science-based ethics and morals. During the current COVID-19 pandemic, we will do our best in all activities and act in accordance with the new Quality Policy.

Value Chain

Quality Operations Division



Hiroaki Oribe

Senior Vice President
Head of the Quality
Operations Division



Roles in the Value Chain

Supplying Reliable and Safe Drugs through Rigorous Quality Control and Assurance

The Quality Operations Division comprises quality control departments, which strictly assess and control the quality of drug raw materials and products as well as the drug manufacturing environment through testing and inspections, and quality assurance departments, which perform management to ensure that the processes by which drugs are manufactured are always appropriate and ensures their quality as drugs. At each plant, these departments make appropriate determinations at all times as independent organizations from manufacturing departments and play important roles in the continuous supply of reliable and safe drugs.

New Quality Policy Initiatives

Pursuing Quality Management Systems with Outstanding Effectiveness

In accordance with the new Quality Policy, we aim to establish and continuously improve high-level quality systems in compliance with regulations in Japan as well as global regulatory requirements such as those of the FDA. To do this, it is necessary that all employees including managers take quality seriously, work together to maintain and raise quality, and individually sustain high levels of awareness regarding quality at all times. In the Quality Operations Division, it is important to continuously improve and accumulate knowledge concerning drug manufacturing at each plant and pass it along to employees through an ongoing and robust educational system. We will also actively undertake the introduction of IT systems with the aim of creating highly effective and efficient quality management systems.

Sales & Marketing Division



Osamu Mihara

Senior Vice President
Head of the Sales
& Marketing Division



Roles in the Value Chain

Providing Drugs to Patients with Efficacy and Safety Information

The Sales & Marketing Division collaborates with other divisions from its position in close proximity to those working in healthcare and is responsible for providing efficacy, safety, quality, and other information with high-quality drugs to healthcare institutions and patients at reasonable prices. The MRs who are responsible for information provide information relating to our products and gather information from healthcare sites to promote proper usage and lead to enhancement and improvement of products. Undertaking activities to create products that are even more convenient to use is also one of the important roles of the division.

New Quality Policy Initiatives

Promoting DX and Enhancing the Quality of Information Provision and Collection

To provide trust and confidence to patients and healthcare professionals, we will provide information necessary for the proper use of our products quickly and in a timely manner and responds even more promptly to information concerning side effects. We will also implement digital transformation (DX) to create systems that can thoroughly analyze needs and provide necessary information and will work to create information value as well as systems for the creation of information value. We will make greater efforts to gather information so that we can give form to feedback from healthcare sites and collaborate with other divisions to improve formulations with high added value. As a company involved in pharmaceuticals that are directly related to life, we value ethics and morals above all else, and we will comply thoroughly with guidelines on the provision of sales information, fair competition rules, and promotion codes.

Business Overview

Generic Drugs

Aiming for sustainable growth by seizing opportunities for growth, even in the “Post-80% Era”

Biosimilars

With its market presence already established, Nichi-Iko has a strong product pipeline in both Japan and the U.S.

Overseas Business | U.S. Market

Accelerating development in the North America market by enhancing Nichi-Iko's production capacity and establishing new business pillars

Overseas Business | Asia Market

Working toward market expansion with Thailand as the core base by focusing on anti-cancer drugs as well as the cardiovascular field



Business Overview | Generic Drugs

Aiming for sustainable growth by seizing opportunities for growth, even in the “Post-80% Era”

Nichi-Iko's Generic Drug Business

Market Scale

Although the domestic drug market in Japan has grown significantly from six trillion yen in 2000, it has remained almost flat over the past five years at a scale of more than 10 trillion yen on a drug price base (four-year CAGR -0.5%)* and the prescription drug market for the fiscal year ended March 31, 2020 was 10.6294 trillion yen. Included in that, the scale of the generic drug market was 1.4352 trillion yen (four-year CAGR +7.0%)* and the long-listed product market was 1.7750 trillion yen (four-year CAGR -8.2%)*.

* CAGR: Compound annual growth rate

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Market Environment

The Basic Policy on Economic and Fiscal Management and Reform 2017 resolved by the Japanese government set out a goal of a generic drug usage ratio of 80% by volume by September 2020. Based on preliminary figures, a usage ratio of approximately 78.3% as of September 30, 2020 was announced. Although this was a little under the goal of 80%, the replacement with generic drugs in the domestic drug market in Japan has increased greatly over the past 10 years.

Meanwhile, although there has been replacement of almost 80% in volume, it remains at a low level on a monetary base.

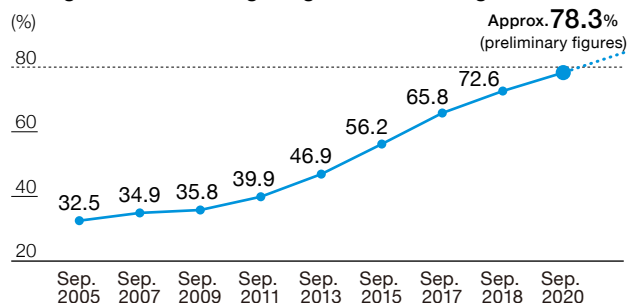
Improving the public finances for its medical insurance system is an urgent issue for Japan. Popularizing the use of generic drugs, for which prices are lower than for original drugs, reduces the burden on patients and contributes to improving public finances for medical insurance. Streamlined healthcare costs also create a type of circulation that allows more funding to go to new medical technology and innovative drugs and bringing them to patients. Therefore, the setting of new target values, including monetary targets, is required, instead of having the usage ratio of 80% by volume as the goal.

Drug Price System

In Japan's drug price system, in addition to the general price revision that takes place once every two years, an interim drug price revision is scheduled for April 2021.

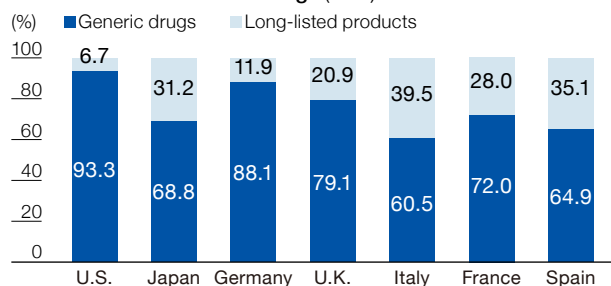
Recently, drug price revisions have occurred every year—at the general revision in April 2018, the revision associated with the consumption tax increase in October 2019, and the general revision in April 2020. Nichi-Iko's drug price revision rates are shown in the table on the right.

Changes in Generic Drug Usage Ratios and Targets

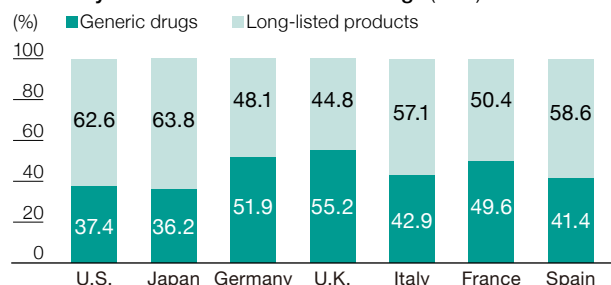


Source: Prepared based on materials disclosed by the Ministry of Health, Labour and Welfare

Volume Share of Generic Drugs (2019)

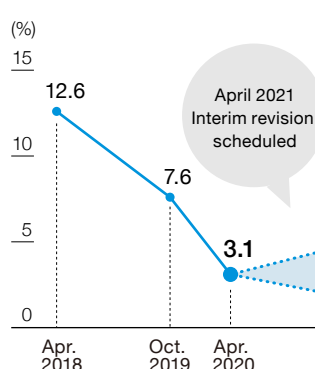


Monetary Amount Share of Generic Drugs (2019)

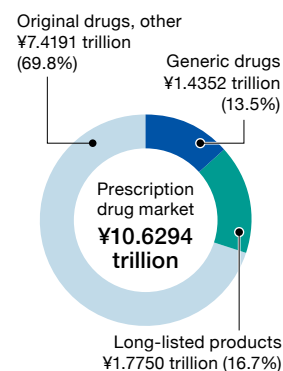


Source: March 2020 Survey Report on Roadmap for Promoting Use of Generic Drugs (Ministry of Health, Labour and Welfare)

Changes in Nichi-Iko's Drug Price Reduction Ratio



Prescription Drug Market (FY2019)



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Risks (Risks to Growth)

Yearly Drug Price Revisions

In Japan, drug prices have generally been revised every two years and the drug prices for many products have been reduced. In addition, beginning in April 2021, the government plans to conduct interim drug price revisions as well, resulting in annual revisions. An urgent challenge for the generic drug industry is how to increase profitability. The scale of Nichi-Iko's actual drug price revisions has been gradually decreasing. Prices were revised down 12.6% in April 2018, 7.6% in October 2019, and 3.1% in April 2020, compared to the same times in the previous years.

Reduction of Incentives to Encourage Usage of Generic Drugs

Having reached the deadline for the goal of 80% usage of generic drug in September 2020, it can be presumed that incentives to promote usage of generic drugs will decrease.



Opportunities (Factors for Growth)

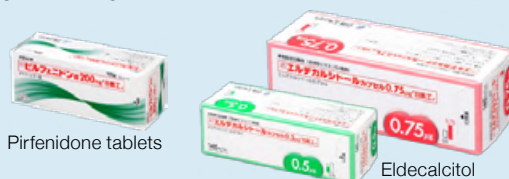
Expiry of Patents for Major Original Drugs

Expiry of patents for major original drugs will continue after the fiscal year ending March 31, 2021. The scale of the market for original drugs that Nichi-Iko will enter is expected to exceed 500 billion yen in the fiscal year ending March 31, 2021, and will continue at a level of 200 billion yen level for several years after that. This market entry will contribute to Nichi-Iko's sales and profits as well as its business performance for several years after the products are launched.

Number of Companies Entering the Market Is Declining

In the past, 20 to 30 generic pharmaceutical companies would enter the market for one generic drug. Thereafter, some of the non-specialized generic pharmaceutical companies withdrew from the market. Also, the number of companies entering the generic drug market has decreased recently because it has become a market environment in which developing drugs independently has become difficult due to the lowering of initial listed drug prices and annual drug price revisions.

There are two companies, including Nichi-Iko, marketing the generic drug eldecalcitol (Edirol®) which is listed in the Drug Price Standard as of June 2020, and Nichi-Iko alone entered the market for pirfenidone tablets (Pirespa®). The Company believes that, through creating this sort of situation, generic drugs can be marketed at appropriate prices.



Expanding the Lineup of Authorized Generics (AGs)

In December 2020, Nichi-Iko launched Pusofeki AG (Dellegra® combination tablets) and LoreAce AG (ComPlavin® combination tablets), adding two products to its lineup and bringing the total of Nichi-Iko's AGs to five products. Going forward, Nichi-Iko will work to build up its sales track record and expand its lineup of AGs in the market.



Wider Use of Drug Formularies

As drug formularies become more widely used by regions and medical institutions they are switching to economically advantageous generic drugs and will consider switching to generic drugs with the same efficacy as the original drugs. In addition, in selecting manufacturers, consideration will be given mainly to products of generic pharmaceutical companies that have a good track record in the market in terms of economic efficiency, quality, and stable supply and supply systems of a certain scale.

* Formulary: Guidelines for using drugs developed through comprehensive evaluation of efficacy, safety, and economic efficiency

Regional Differences in the Volume Share of Generic Drugs Dispensed

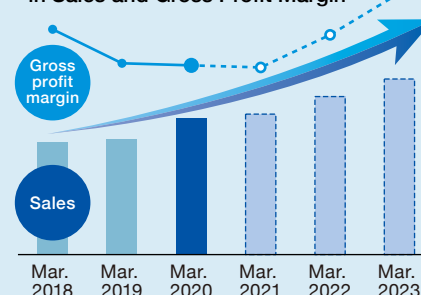
Regional differences in the volume share of generic drugs dispensed are regarded as a problem. It is considered necessary for local governments to have specified target values for solving that problem, and to normalize increased healthcare costs. Nichi-Iko will conduct generic drug educational activities with local governments with which it has comprehensive partnership agreements for normalization of increased healthcare costs, and will offer solutions to rising healthcare costs.

Sustainable Growth Is Possible, Even in the "Post-80% Era"

While there is currently no expectation of major growth in the volume of existing products, business performance of new products holds an important key to sustainable growth. While Nichi-Iko is looking out for opportunities provided by the expiry of patents for major original drugs, the development of generic drugs by smaller numbers of companies entering the market, and the market entry of AGs, the Company is committed to responding to formularies and generic drug educational activities in local governments with which it has partnership agreements.

Also, to increase profitability, Nichi-Iko will actively advance the bringing of internal manufacturing to Nichi-Iko Group plants and contract manufacturing of specialized formulations to the Gifu Plant. The Company considers that an 80% volume share is not the goal and there is a high possibility of sustainable growth, even in the "Post-80% Era."

Domestic (Nichi-Iko Segment) Trends in Sales and Gross Profit Margin



Business Overview | Biosimilars

With its market presence already established, Nichi-Iko has a strong product pipeline in both Japan and the U.S.

Nichi-Iko's Biosimilars Business

Biosimilars (biogenerics) are drugs equivalent to and with the same quality, safety, and efficacy as the original biopharmaceuticals. The initial prices of biosimilars are basically listed by multiplying the drug price of the original biopharmaceutical by 0.7. As biopharmaceuticals are expensive, biosimilars which are cheaper than the original biopharmaceuticals have a mission and role to play in reducing patients' own expenses, lowering purchasing costs of medical institutions, and reducing the financial burdens of governments. Nichi-Iko's current lineup of biosimilars and product pipeline are as follows.

Nichi-Iko's Lineup (Currently Marketed)

Active ingredients (original biopharmaceutical)	Market	Number of companies entering the biosimilars market	Development partner	Launched
Infliximab (Remicade®)	Japan	5	Aprogen (South Korea)	November 2017
Etanercept (Enbrel®)	Japan	4	Lupin (India)	November 2019



Infliximab BS

Nichi-Iko's Development Pipeline

Active ingredients (original biopharmaceutical)	Market	Market Scale	Number of companies entering the biosimilars market	Development partner	Preclinical	Phase I	Phase II	Application and approval
Infliximab (Remicade®)	U.S.	¥400 billion	3	Aprogen (South Korea)	Application planned for 2021			
Bevacizumab (Avastin®)	Japan	¥95 billion	2	mAbxience (Spain)	Application made in November 2020			

Deepening Collaboration with Partners While Actively Developing Biosimilars for Japan

In Nichi-Iko's biosimilars (biogenerics) business, starting with the capital and business alliance that the Company entered into in 2010 with Aprogen, a bioventure company in South Korea, it has advanced development from among Aprogen's abundant product pipeline.

Nichi-Iko's first biosimilar, Infliximab BS, received approval in Japan in September 2017 and was launched in November 2017. Clinical development has also been carried out in the U.S. Currently, phase III trials have been completed and the Company is aiming to file for approval in the U.S. in 2021. Etanercept BS, which was developed by the Indian company, Lupin, was introduced and marketing commenced in 2019. Also, the Company has received licensing of Bevacizumab BS from the Spanish company, mAbxience, and is advancing regulatory affairs procedures with the aim of launching the product in Japan in 2022.

This presence in the biosimilars market has been recognized and currently Nichi-Iko has received proposals from several partners for licensing and marketing alliance. As Nichi-Iko's development policy going forward, the Company intends to actively consider licensing and marketing alliance in the later stage of development for products for which there are few competitors and early market entry is possible.

Aiming for Approval of Infliximab BS as the First Interchangeable Product in the U.S.

Currently, Nichi-Iko is planning to file for interchangeability approval in the U.S. for Infliximab BS, which the Company is developing in the U.S. Interchangeable products are biosimilars that are interchangeable with the original biopharmaceuticals and for which equivalent clinical results have been obtained and demonstrated. In the FDA guidance, the replacement dosage of the interchangeable product with the original biopharmaceutical is required for risk assessment of efficacy and safety. Nichi-Iko has conducted clinical trials in accordance with the guidance and the Company believes that it has collected data that fully satisfies the requirements. As of September 2020, the FDA has not approved any interchangeable products, and the Company is proceeding with the development with the aim of obtaining the first approval of an interchangeable product in the U.S.

With regard to manufacturing, it is planned that the APIs will be supplied by Nichi-Iko's partner company, Aprogen, formulation will take place at the Raleigh Plant of its U.S. subsidiary, Sagent, and the products will then be shipped to markets. With regard to marketing, it is planned that the products will also be distributed through the sales network of Sagent, which is ranked among the top 10 across the U.S. in generic injectables.

U.S. Market

Accelerate development in North American market with in-house production and new business pillars

CEO Message

Maintaining connections with our customers throughout the pandemic

In the years since Sagent's founding in 2006, we have demonstrated the critical importance of customer engagement in all of our activities. PreventIV Measures®, the labeling used for our generic injectables, is color coded to help reduce the risk of errors in administration. When we first introduced this to the market, it was a groundbreaking innovation, lauded by customers and buying groups across the United States. We also rely on our highly experienced sales team to forge relationships with the teams at individual hospitals, key buying groups and wholesalers across the United States. We pride ourselves in standing ready to help make a difference in patient outcomes through the medicines we provide.

The opportunity to serve the broader community has never been clearer in the history of Sagent than during the current pandemic. Our experienced sales team has worked unceasingly to help fulfill the critical needs of our customers, seeking to supply our products that help in the fight against COVID-19, including propofol, to as many U.S. hotspots as possible. Our U.S.-based manufacturing sites, including our SterRx compounding facility, and our Canadian business, Omega, each produced and distributed substantial amounts of critical product into the U.S. and Canadian markets. The customer-first mentality used in the midst of the crisis is helping increase customer loyalty, which will help us continue to expand our 'base' sales as the pandemic eases.



Dr. Peter A. Kaemmerer
Sagent Pharmaceuticals, Inc.
CEO

At the same time, we continue to see great opportunities across not only our core generic business, but also in the other pillars of Sagent North American operation, including our compounding*, biosimilar and orphan drug endeavors. Our compounding business provides the ability to more rapidly address market shortages and clinical needs, helping customers better serve patients across the U.S. Our continued progress in both the biosimilar and orphan drug areas will establish new pillars of growth for the Sagent business, and will further demonstrate the breadth of our customer focused activities in the U.S. marketplace.

We are meeting the challenges that 2020 has brought forward – and are excited about our ability to continue driving quality and gaining trust as we move into 2021.

* Compounded products: Product formulations which have had the dosage form altered by a pharmacist by adjusting the concentration, eliminating additives, etc. in accordance with the needs of patients.



Product lineups with enhanced labeling, PreventIV Measures®

U.S. Market

Business / Competitive Environment

Meeting the needs of the expanding U.S. injectable market by increasing production capacity

The U.S. market for injectables continues to evolve. Over the past five years, several companies, including many that previously only served as contract manufacturers, have sought to enter the U.S. market. At the same time, we have seen, through the work done by the U.S. Food and Drug Administration (U.S. FDA), a continued increase in the number of new applications being approved by the agency. We have also seen the number of key U.S.-based buying groups continue to decline. Today, there are only three primary buying groups in the United States. The consolidation of purchasing power and the increase in market entrants have served to make the market increasingly competitive.

Even with these changes, the U.S. market continues to be plagued by ongoing product shortages. There were more than 200 different products reported as being in short supply throughout the United States in September 2020. While some shortages are due to the incredible needs placed on the health care system due to the pandemic, others arise due to the impacts of competition on the market.



Omega Montreal Plant, manufacturing site of products for the U.S.

These significant market changes heighten the importance of our newly acquired and approved North American manufacturing sites. Bringing more injectable production under our own control will enhance our ability to quickly react to market conditions – helping manage shortages and event-driven demand surges with ever greater speed.

COVID-19 Impact on Sagent

Strengthening product supply system to help patients

The pandemic has impacted many of the ways that we work and collaborate together. Throughout this difficult situation, however, the Sagent team has been able to come together, even when we were physically apart, to help those in need across both the United States and Canada.

Across the Sagent, SterRx and Omega businesses, we have seen a substantial surge in demand for products used to help treat COVID-19 related illnesses. At the onset of the pandemic, we saw record demand for every product that could help patients with the virus. Our sales and supply chain teams worked tirelessly, especially with individual hospitals, to ensure that product was able to reach many of the hardest hit areas in the first hot spots.



Propofol, COVID-19-related product

Even during the initial surge, we were planning how we would address potential additional waves of the virus. Our Canadian team rearranged their manufacturing schedule to produce several days of product used to support patients with serious medical issues arising from the virus. In the U.S., we have worked with our contract manufacturers to enhance supply of certain products over the remainder of the year, to be ready to help as the U.S. moves toward the autumn, and the normal flu season. While we hope the pandemic begins to abate, we stand ready to continue helping those in need.

CAMELOT Clinical Trial

Clinical trials for COVID-19 patients

The pace of experimentation with potential treatments for COVID-19, both vaccine and therapeutic based, has been staggering, and demonstrates the incredible role the pharmaceutical industry as a whole can play in improving outcomes for patients. One of the molecules that may help to eliminate the ability of the SARS-CoV-2 coronavirus to attach to human cells is Camostat Mesilate (Camostat). While Camostat has been marketed for other indications by Nichi-Iko in Japan for many years, it is not currently approved for use in the United States. In the autumn of 2020, Sagent initiated a U.S.-based Phase 2 clinical trial titled “CAMostat Efficacy vs. pLacebo for Outpatient Treatment of COVID-19” (CAMELOT) to determine the clinical efficacy of Camostat in ambulatory patients with confirmed COVID-19 and at least one risk factor. We expect the Phase 2 trial will be complete in early 2021.

Sagent Strengths

Highly experienced sales team and capability enhanced in-house manufacturing

From its beginning, Sagent has been a sales and customer focused organization. As we have grown, our sales teams have grown as well. Today, we have our original hospital-based sales team, with industry experience that rivals any of our competitors across the United States. Supporting this team is a group that interacts with the national players – group purchasing organizations and U.S.-based wholesale distributors, and teams that support the sales efforts for our specialty and compounded products. The critical relationships that these teams have across the United States provides us insights and opportunities that would otherwise be missed.

With the assistance of the Nichi-Iko team, we are evolving from a purely virtual organization to one that includes multi-site, multi-capability manufacturing. We completed an expansion of our Omega facility in 2019 that provides the ability to manufacture not only for the Canadian, but also for the U.S. market. During 2019, we also acquired our Raleigh facility – providing the overall Group with its first lyophilized manufacturing capability, as well as the ability to manufacture biologic, as well as small molecule, products. We anticipate manufacturing products from both sites for the Japanese market as well – demonstrating the opportunity for synergy afforded by our injectable manufacturing capacity.



FDA-compliant Omega facility in Montreal (Canada)

Update and Future of Compounding, Biosimilar, Orphan

Focus on compounding to address customer needs

Since Sagent became a Nichi-Iko Group Company, the business has evolved from a single pillar (generic injectables) to one with three additional pillars of growth – including compounding, biosimilars, and orphan drugs.

Each of these pillars will further stabilize the Sagent foundation, and enable us to help patients in new and exciting ways.



SterRx facility in Plattsburgh (New York)

Compounding

In July 2019, we acquired a majority share of SterRx LLC, a 503(b) compounding organization located in New York. With control over all aspects of the operation, we have substantially expanded SterRx's manufacturing capacity and footprint in the past year. During FY 2020, we launched six new compounded products into the market, and plan to launch an additional four products during FY 2021. We anticipate continuing to bring more compounded products into the market – enabling us to meet customer needs, address market shortages, and help patients across the United States.



Newly added BFS (Blow Fill Seal) line at SterRx facility

Biosimilars and orphan drug

One of the key aspects of the Sagent acquisition was to serve as the sales and marketing organization for our future biosimilar and orphan drug endeavors in the United States. On both fronts, we continue to advance our development efforts. On infliximab, which will be the first Nichi-Iko biosimilar to launch in the U.S. market, we completed the Phase 3 trial in early 2020. We will manufacture infliximab at our Raleigh facility, enhancing our control over the supply chain in our initial biosimilar. For our orphan drug, our Phase 2 trial will continue throughout the coming year. Both of these products will provide significant catalysts to the ongoing growth of the North American business.

U.S. Market

Generic Pipeline Update / Future

Expanding generic portfolio, investing in new products

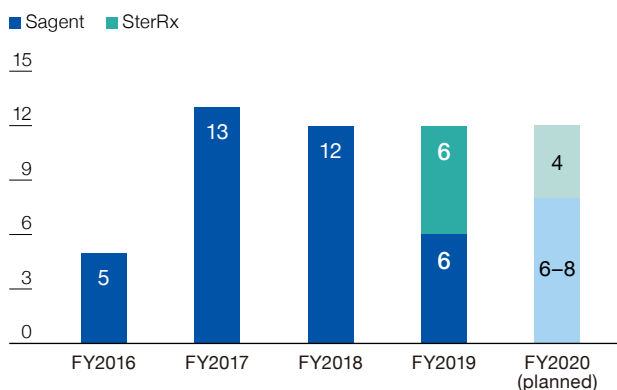
Over the past three years, we have launched a total of 31 products into the U.S. market, and have nearly 70 products, in more than 140 presentations, on market as of March 31, 2020. These products have included a mix of products launched at market formation, including fulvestrant, used to treat late-stage breast cancer, the introduction of new formulations to the market (differentiated size vial of daptomycin, reducing product waste), and late-to-market product entries. This mix of product introductions allows us to bring innovations into the market while also expanding the breadth and depth of our overall product portfolio.



Fulvestrant, launched at market formation

We view the continued expansion of our base generic business to be a crucial part of the future of Sagent. To that end, we are proactively investing in new product opportunities – some of which will be produced in our own Raleigh and Montreal facilities. Our expectation is to launch between six and eight generic products in the upcoming fiscal year. Long term, we are seeking to launch six to ten products annually. These new products will include more complex molecules and innovative formulations, as well as products that address gaps in our overall product portfolio.

Annual Product Launches



Update on Tech Transfer / In-House Production

Executing tech transfer to facilitate in-house manufacturing

The acquisition of the Raleigh facility and acceptance by FDA of the Montreal-based Omega facility in 2019 enabled us to begin the transition from a wholly outsourced manufacturing model to a more blended one. We anticipate that shifting manufacturing of multiple products from third party CMOs, usually in overseas markets, to supply from our own facilities will drive substantial benefits



in the medium term – enhancing consistency of supply, shortening the overall supply chain, and ultimately improving the profitability of our product portfolio.

Haloperidol, first in-house product to have launched from Omega

Today, these sites provide the ability to manufacture both liquid and lyophilized products to the U.S. market, and the Raleigh site is approved to manufacture both small molecule and biologic products. These capabilities provide us a solid performance base from which to build. Moving manufacturing for individual products between manufacturing sites is, however, a time intensive process. We are working through individual products in an expeditious manner, with several concurrent transfers underway at each site.

We are beginning to see results from the transfer program. We expect to file several products from the Omega and Raleigh sites during the current year. During 2020, we successfully launched our first product into the U.S. market from our Omega facility. This exciting accomplishment is only the first step – with many more product launches expected in the coming years. We also expect to file our first stand-alone ANDAs from the sites during 2021...showing the transformation of our development pipeline as well as our current product portfolio.



Raleigh (North Carolina) facility to manufacture infliximab for the U.S.

Asia Market

Working toward market expansion with Thailand as the core base by focusing on anti-cancer drugs as well as the cardiovascular field

Market Environment and Competitive Situation

Demand for high-quality generic drugs is increasing in line with changing demographics and development of healthcare infrastructure

The market in China, which is enormous, is growing. In the ASEAN market, medium-term developments include population growth and further aging. Progress is also expected in putting healthcare infrastructure in place, driven by an increase in medical institutions and the spread of insurance systems. These developments are projected to progressively increase drug needs going forward. In particular, in Thailand, market growth was stagnant from April to June in 2020 due to a reduction in medical consultations from the impact of COVID-19. However, looking ahead, recovery is expected over 2021 to an annual growth of between 5% and 9%, which was the rate prior to COVID-19. In Vietnam, recovery and growth in the drug market is expected, led by growth in the generic drug market. Government-run medical institutions in the region recommend the use of low-cost domestic generic drugs, but at the same time, there is increasing demand for high-quality generic drugs. Also, among privately-run hospitals, there has been an increase in the number of hospitals emphasizing profitability in conjunction with an accelerating shift to group-run hospitals, and the number of hospitals using both original drugs and high-quality generic drugs has increased.

subsidiary in Thailand, Nichi-Iko (Thailand) Co., Ltd., ahead of other Japanese generic pharmaceutical companies. Since then, it has rolled out drugs equal to the high quality available in Japan, primarily in the cardiovascular field. In 2020, the Nichi-Iko Group company, Sagent, worked to introduce its FDA-approved cancer drug, Vinorelbine, which has received approval from the FDA Thailand. In addition to Nichi-Iko (Thailand) taking a new step forward in the anti-cancer drug market as a strategic field, Sagent will out-license other anti-cancer drugs to the Thai market. Also, in January 2020, Nichi-Iko (Thailand) commenced marketing of all its products aimed at the whole of the Thai market. Its employees visit medical institution users directly and provide timely product information. By responding carefully to the needs of local medical institutions and patients through measures such as adding information to press through pack (PTP) sheets, it has built relationships of trust with medical institutions and has steadily increased the number of medical institutions using its products. The knowledge and expertise Nichi-Iko has accumulated through many years of experience in filing regulatory affairs applications for generic drugs and building business alliances in Asia with Thailand as a hub and through the marketing activities of its own company in Thailand is also a major strength.

Nichi-Iko's Strengths

Accumulating expertise on regulatory affairs applications, business alliances, and marketing activities in Asia

In January 2014, Nichi-Iko established its own sales



Anti-cancer drug, Vinorelbine



Information added to PTP sheets



Takashi Kashiwagi
Senior Vice President
Head of the
Corporate Strategy
& Planning Division

Message from the Head of the Corporate Strategy & Planning Division

We will continue to file new applications in the Asia market and accelerate market development

Using Nichi-Iko (Thailand) Co., Ltd., which is expanding its business in Thailand, as an ASEAN business hub, Nichi-Iko is working to expand its business to Vietnam, Malaysia, Singapore, the Philippines, and Hong Kong.

Our policy in Thailand for the fiscal year ending March 31, 2021 is to expand the Nichi-Iko brand in the cardiovascular field, and we are currently moving forward with marketing by Nichi-Iko (Thailand) of five ingredients in seven products. In 2020, we started a new challenge in the Thai anti-cancer drug market through Vinorelbine, the anti-cancer drug of our U.S. subsidiary, Sagent. We have made applications for approval of other Sagent anti-cancer drugs to the FDA Thailand, and will further enhance our activities in the hospital market. In addition, we are currently marketing eight ingredients in Hong Kong.

In terms of future business expansion, we have filed applications which are in the process of approval for three ingredients in Thailand, 14 ingredients in Vietnam, and two ingredients in our horizontal rollout in Asia. Also, in fiscal 2020, we plan to file new applications for two ingredients in Thailand and one ingredient in Vietnam, as well as one ingredient in Singapore and Malaysia as part of our horizontal rollout in Asia. Nichi-Iko is moving steadily forward on three fronts—expansion of business and sales in the cardiovascular and anti-cancer fields in Thailand; synergies with the hospital market via Sagent anti-cancer drugs; and strategies for expansion to the countries of Asia—and will achieve further growth in this way.

Message from the Executive Vice President of Strategy



Noboru Inasaka
Executive Vice President
Strategy

**The profit enhancement plan is progressing steadily.
We will make further improvements from synergies achieved
through business acquisitions.**

Results for the Fiscal Year Ended March 31, 2020

There were two drug price revisions, in October and March, making this a challenging fiscal year. Elmed became a subsidiary, and with the addition of its sales revenue, we planned on achieving consolidated sales of 200 billion yen, but we were short by 10 billion yen.

As a result, in comparison to our plan for 8.5 billion yen in operating profit, core operating profit was 8.0 billion yen, and operating profit was 2.9 billion yen, a shortfall of 5.6 billion yen. A lack of sales was a factor, but the three main factors of not achieving our target were as follows.

- a) Loss on the sale of Trastuzumab development assets in Japan: 1.5 billion yen;
- b) Impairment losses of Sagent development assets in the U.S.: 1.9 billion yen; and
- c) Provisions for return and disposal expenses for products recalled in April 2020: 1.6 billion yen.

The total of these three factors is 5.0 billion yen.

Both a) and b) are the result of reassessment of assets under development in Japan and the U.S. (Sagent) and their sale or revaluation.

On the other hand, the reporting locations on the statement of profit and loss are different, and as a result this is not included in operating profit, but we reported gains on sale and valuation gains of 6.4 billion yen obtained through the sale of shares of affiliates, and this amount is included in profit before tax as other income. By way of reference, the details are as follows.

- Gain on the sale of some Aprogen shares: 3.6 billion yen
- Gain on the valuation of Aprogen shares: 2.4 billion yen
- Gain on the low-cost purchase of shares of SterRx, a subsidiary of Sagent: 0.4 billion yen

Among the loss items, with respect to c) the recall of products, we have implemented multiple product recalls since the start of the fiscal year ending March 31, 2021. We apologize for the tremendous inconvenience caused to users.

I believe that when the Takayama Plant to be acquired in February 2021 under our agreement with Teva Takeda is added to the Nichi-Iko Group, it will be important to re-optimize and reestablish Nichi-Iko's production and quality control systems.

Plan for the Fiscal Year Ending March 2021

In the financial results for the second quarter ended September 30, 2020, we announced severe financial results with lower revenues and profits.

During this fiscal year, sales prices were lowered twice as a result of the drug price revisions implemented in October 2019 and April 2020. In addition, we implemented multiple voluntary product recalls during the first fiscal half even while controls were imposed on medical treatment and sales activities were restricted in response to the COVID-19 pandemic, and as a result, we were unable to conduct effective promotional activities.

In the second fiscal half, we will need to calmly focus on promotional activities and must achieve our targets.

Cash Flows

Cash flows during the fiscal year ended March 31, 2020 included 18.5 billion yen from operating activities and 18.2 billion yen used in investing activities. The basic policy on investment is to conduct investment within the scope of free cash flows, but the level of borrowings is also an issue of finance, and it is necessary to consider the maximization of free cash flows while keeping in mind debt repayment.

In the second quarter ended September 30, 2020, however, free cash flows were minus 7.8 billion yen. With respect to cash flow from operating activities, the decrease in profit before tax is one factor, and we consider this to be a special period since debt payments were 8.3 billion yen higher than in the same period of the previous fiscal year.

Future Investment

Under the G1 pricing rule (phased review of long-listed products), long-listed products and generic drugs are treated as drugs under the same expired patents, and drug prices for both are set the same. In addition, when these products are subject to annual drug price revisions, it is an important issue for both early manufacturers and subsequent manufacturers to consider how to achieve stable supplies of these drugs.

We are constantly thinking about the roles that the Company must fulfill, and in cases where we determine that fulfilling those roles is an obligation of the Company and is necessary, we may prepare suitable funds to an appropriate extent and reorganize business.

We plan to acquire the Teva Takeda Takayama Plant, but we are hopeful that it will not have a significant impact on the Company's capital procurement.

Total Shareholder Return

Total shareholder return (TSR) is presented in the securities report as an indicator of share price performance.

TSR also indicates the corresponding value (57.0%) compared to the Company's share price in recent years. We apologize to shareholders and believe that efforts to increase corporate value are urgently needed.

Goodwill and intangible assets are sources of future profit, but they may also be subject to impairment and are acquired using borrowings, and this is a feature that can be seen on the Company's balance sheet. This is reflected in profit levels as well as share prices, and TSR is indicated on that time axis. It is necessary to present the results of these assets in the form of profit at the earliest possible time, but additional time will be necessary.

KPIs to Be Achieved as an Officer Under the Medium-term Management Plan

The Medium-term Management Plan provides for a profit enhancement plan with cumulative profits of 15.0 billion yen over three fiscal years, and steady progress is being made toward achieving that plan. During this fiscal year, however, we have implemented recalls of multiple products. We apologize to patients, healthcare institutions, and wholesalers for the inconvenience we have caused.

I believe that it goes without saying that what we need to achieve when customers use Nichi-Iko drugs is prioritizing the provision of trust and confidence over all else.

Synergies through Business Acquisition

Following the acquisition of Elmed in April 2019, we will also acquire a portion of Teva Takeda's generic drug business and its Takayama Plant in February 2021. As a result, we will gain many new products, users, and a new manufacturing site and human resources. Prescription drugs are covered by the health insurance program and are purchased at official prices (drug prices), which means that we are unable to independently set sale prices. Considering that sale prices may decrease in the future due to annual drug price revisions, it may be said that this is a challenging business.

Under these circumstances, as a generic pharmaceutical company, users and drug licenses are key assets for the Company. What Nichi-Iko gains through M&A is not limited to products that it does not possess, and even in cases where there is some overlap with Nichi-Iko's existing products, the gains include a heightened awareness of Nichi-Iko among users, and in some instances manufacturing sites, APIs, manufacturing methods and costs are different and official prices can be different. This enables us to make choices that are optimal for future quality and profits that will be generated.

The Nichi-Iko Group will take this opportunity to rebuild its quality control systems, optimize production systems, and optimize the allocation of internally manufactured products and outsourced products at each plant.

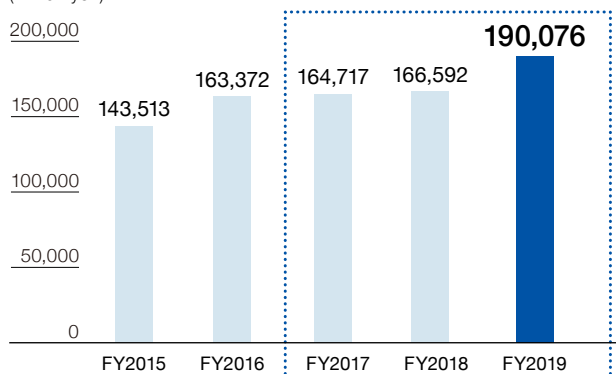
Within the Nichi-Iko product lineup, half of the products are manufactured within the Group and half are outsourced products manufactured outside the Group or are products handled by the Group. Compared to other generic pharmaceutical companies, which manufacture 80% to 90% of their products internally, the low percentage of the Nichi-Iko Group's internally manufactured products is a characteristic of the Group. We will examine optimal reallocation while focusing on this point.

Financial and Non-financial Highlights

IFRS applied starting in the fiscal year ended March 31, 2018

Revenue

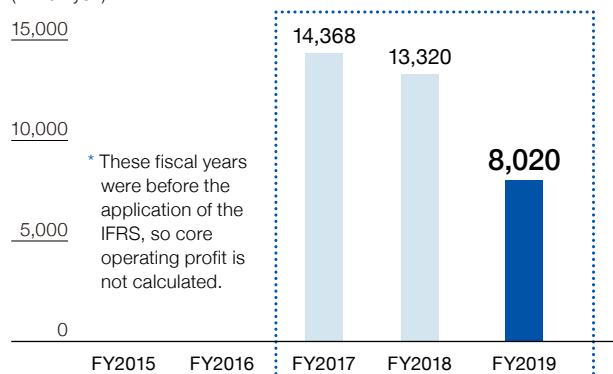
(million yen)



The integration of Elmed in the Group contributed to the increase in sales, and consolidated financial results for the fiscal year ended March 31, 2020 were up significantly, with sales revenue reaching a record high. Nichi-Iko had the highest sales among all Japanese generic pharmaceutical companies.

Core Operating Profit

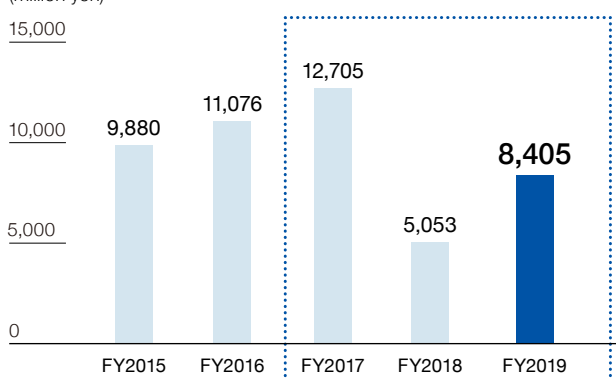
(million yen)



Temporary losses occurred including impairment losses in business in the U.S., expenses for voluntary recalls, and loss on the sale of Trastuzumab BS in conjunction with a change of biosimilar development policy, and as a result, profit was down in the fiscal year ended March 31, 2020.

Amount of Capital Investment

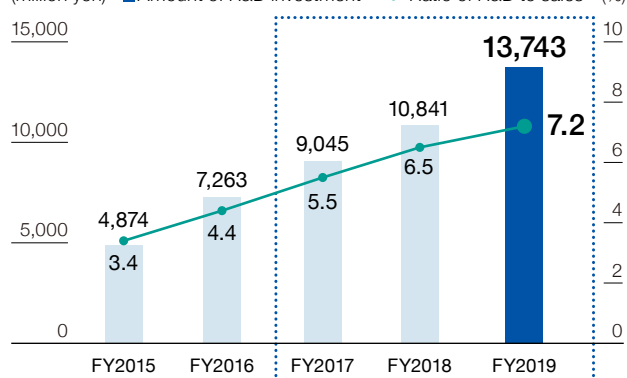
(million yen)



A total of 8,405 million yen in capital investment was made to increase production capacity and reduce costs through internal manufacturing. Of that amount, approximately 3,000 million yen was applied to increasing manufacturing facilities for freeze-dried formulations at the Aichi Plant.

Amount of R&D Investment / Ratio of R&D to Sales

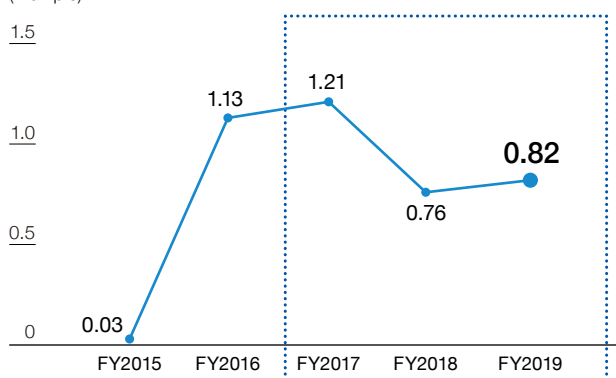
(million yen) ■ Amount of R&D investment ◆ Ratio of R&D to sales (%)



Work on applying for approval of Infliximab BS is proceeding with the aim of a market release in the U.S. at an early stage and clinical trials necessary for application have been completed.

Net D/E Ratio

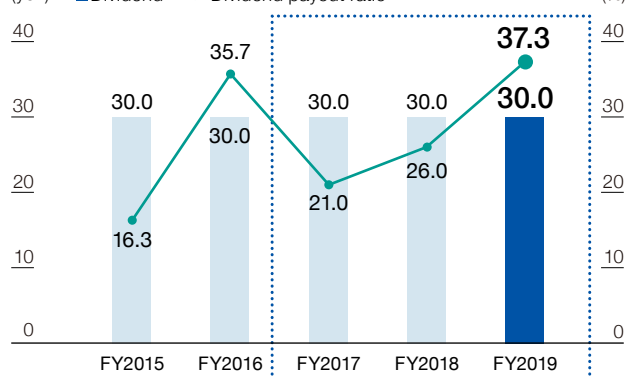
(multiple)



The net D/E ratio in the fiscal year ended March 31, 2020 was 0.82. We plan to maintain the net D/E ratio at approximately 1.0 throughout the 8th Medium-term Management Plan.

Dividend/Dividend Payout Ratio

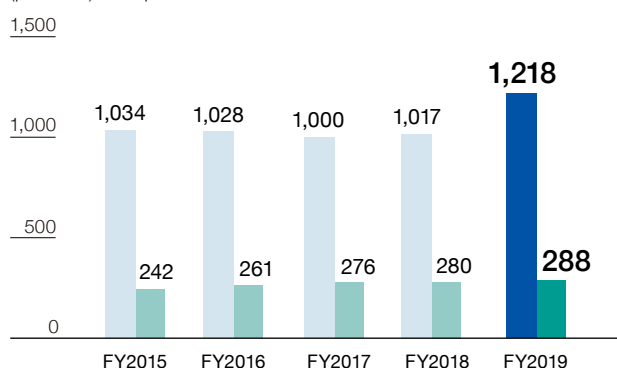
(yen) ■ Dividend ◆ Dividend payout ratio (%)



The annual per-share dividend for the fiscal year ended March 31, 2020 was set at 30 yen (a dividend payout ratio of 37.3%). A dividend payout ratio between 25–30% is planned for the period of the 8th Medium-term Management Plan.

Number of Products

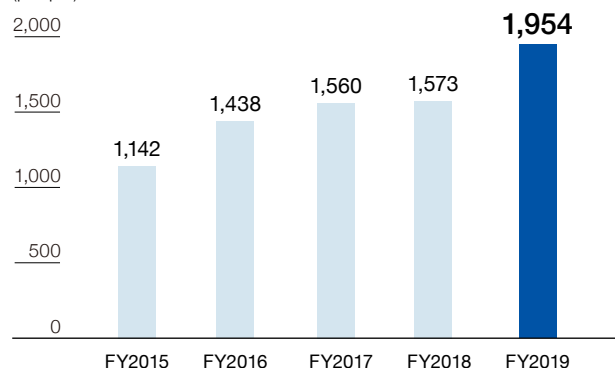
(products) ■ Japan ■ Overseas



The number of products increased in the fiscal year ended March 31, 2020 as a result of the integration of Elmed in Japan and the market launch of new products by the Sagent Group. The total numbers of products were 1,218 in Japan and 288 overseas.

Number of Employees (Consolidated)

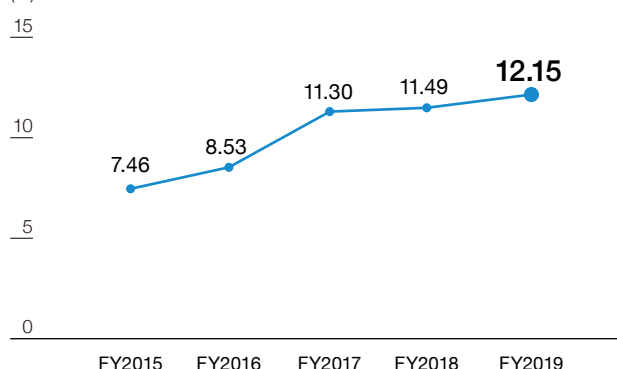
(people)



In the fiscal year ended March 31, 2020, Elmed was integrated and SterRx, a U.S. subsidiary, was added to the Group. As a result, the Group had a total of 1,954 employees in Japan and overseas.

Ratio of Female Managers (Non-consolidated)

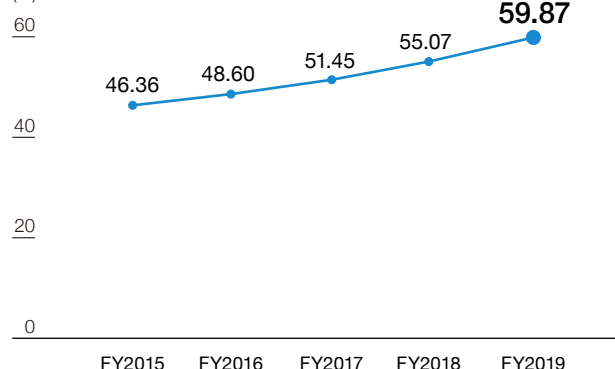
(%)



The ratio of female managers in the fiscal year ended March 31, 2020 increased to 12.15%. Nichi-Iko is working to establish and enhance workplace environments and systems that are friendly to women with the aim of raising this ratio further.

Annual Paid Leave Utilization Rate (Non-consolidated)

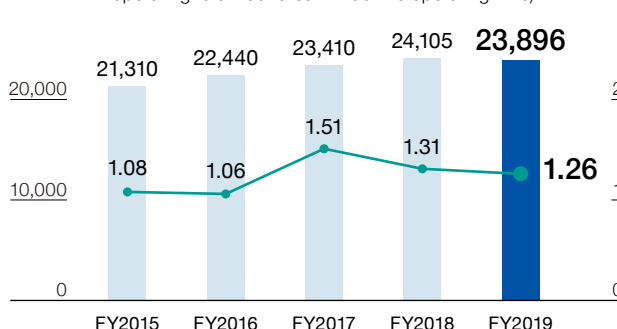
(%)



The rate of paid leave taken has risen each year and was 59.87% in the fiscal year ended March 31, 2020. Nichi-Iko uses an internal system for systematically taking leave to encourage employees to take advantage of their paid leave and will continue to promote the use of paid leave to enhance the work-life balance of employees.

Energy Use / Base Units (7 Domestic Plants)

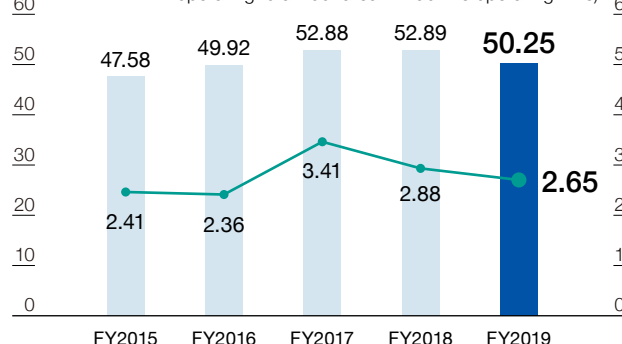
(kl) ■ Energy use (crude oil equivalent) ■ Base units (crude oil equivalent / operating total floor area × machine operating time)



As a result of measures to conserve energy including updating facilities to high-efficiency equipment and changing to equipment operating methods with low energy loss, energy use in the fiscal year ended March 31, 2020 was down compared to the previous year and base units improved.

CO₂ Emissions / Base Units (7 Domestic Plants)

(thousand tons of CO₂) ■ CO₂ Emissions ■ Base units (CO₂ Emissions / operating total floor area × machine operating time)



CO₂ emissions fell and base units improved in conjunction with the decrease in energy use. Nichi-Iko will continue energy conservation measures and consider the introduction of renewable energy in the future with the aim of further reducing emissions and improving base units.

CSR/ESG: Message from the Deputy President



Kenji Akane

Deputy President
CSR, ESG, and Business Creation

Nichi-Iko will achieve sustainable growth and raise corporate value through measures that emphasize ESG that Nichi-Iko can implement because of its unique status

Contributing to solutions to social problems based on knowledge acquired as a pharmaceutical company

Consideration for the environment, society, and governance (ESG) is essential for the long-term growth of a company, and stakeholders require sustainable growth by both society and the Nichi-Iko Group. As a pharmaceutical company, Nichi-Iko will strategically address social issues and work to solve them through its business and actively undertake ESG initiatives in order to meet this need.

Environment

Nichi-Iko will mitigate environmental burdens arising from business activities by switching to LNG fuel to reduce CO₂ and through other measures

The Company is aware that environmental problems including climate change are major issues that can have a significant impact on sustainable development of society and its business continuity.

Nichi-Iko's environmental initiatives include creating environmental management systems in accordance with ISO 14001 and Nichi-Iko is continuously taking action to mitigate and improve environmental burdens occurring in conjunction with its business activities.

In October 2020, Nichi-Iko switched from using

kerosene as a fuel to LNG at the Toyama Plant 1 and installed a new LNG storage tank. In conjunction with this, starting in April 2021, the Company plans to start using electric power generated from renewable energy (hydroelectric power) that does not produce any CO₂ during generation. By doing so, we aim to cut CO₂ emissions from the Toyama Plant 1, which is a key plant, by 30%.

Nichi-Iko implements 3R activities (reduce, reuse, recycle) with regard to waste generated in business activities and is working to reduce the amount of waste produced as well as the environmental burdens from incineration and landfill disposal of waste. As one part of these activities, the Company has set a target of zero emissions, which requires that the final landfill disposal rate of waste generated from all plants be no more than 1%, and is taking measures to recycle waste.

Going forward, Nichi-Iko will continue to implement various measures that emphasize the environment in order to achieve sustainable growth and increase corporate value.

Social

Nichi-Iko donates drugs to clinical research and has entered into comprehensive partnership agreements with local governments

Societal expectations towards Nichi-Iko as a generic pharmaceutical company are high, and the Company

must respond with an unwavering sense of mission.

Nichi-Iko provides drugs free of charge to clinical research being conducted in Japan and overseas for developing new treatments. In August 2019, the Company provided Carboplatin Injection 450 mg “Nichi-Iko” free of charge for specified clinical research on triple negative breast cancer, and in 2020, the Company provided FUTHAN® for injectables free of charge to the University of Tokyo Hospital, the University of Oxford and University of Edinburgh in the United Kingdom, which are conducting specified clinical research on COVID-19 drugs.

Nichi-Iko has been entering into partnership agreements with local governments since August 2019 to address social and regional issues. As of December 31, 2020, the Company has entered into agreements with 22 local governments in nine prefectures. Nichi-Iko plans to expand this program even further in the future, contributing to the development of healthy local communities.

Nichi-Iko was formed by the integration of a many different companies until now. As a result, the Company has assembled a diverse workforce. Nichi-Iko is working to create systems that enable each individual to demonstrate their maximum capabilities, and is putting its energies into promoting diversity and inclusion. Nichi-Iko also engages in global recruiting that includes foreign nationals including foreign students as well as persons who have graduated from high school or university overseas.

Under the 8th Medium-term Management Plan, the Company set a target for the ratio of female managers of at least 15% in the fiscal year ending March 31, 2022 (the ratio as of March 31, 2020 was 12.2%) with the goal of creating society where women can fully demonstrate their individuality and potential. Nichi-Iko's initiatives regarding work style reforms and achieving a good work-life balance include the establishment and improvement of workplace environments and systems that facilitate work by women and acquisition of “Kurumin” and “L-boshi” (three-star) certification from the Ministry of Health, Labour and Welfare.

Governance

Nichi-Iko is reinforcing governance systems including making the transition to a Company with an Audit and Supervisory Committee

Nichi-Iko seeks improvement of corporate value over the medium to long term by creating corporate governance systems that emphasize the balance between supervision and execution while maintaining management transparency and soundness.

At the 56th Ordinary General Meeting of Shareholders held in June 2020, Nichi-Iko changed to a company with an audit and supervisory committee with the aim of enhancing corporate governance systems and further reinforcing supervisory functions by making members of the Audit and Supervisory Committee, which is responsible for auditing the execution of duties by the directors, members of the Board of Directors.

The Board of Directors currently comprises five internal directors and six independent directors, a majority of the total. Thus, the Board already meets global standards for

the number of independent directors. In addition, the Board of Directors includes diverse members, as indicated in the descriptions of the “Main Area of Specialization and Background” of the independent directors. The Independent Officers’ Meeting, which is made up of the six independent directors, engages in active discussions from a variety of perspectives.

Moreover, the Company regard the corporate governance structure to be a matter of utmost importance from the perspective of achieving sound business management and winning the trust and confidence of shareholders and investors.

For this reason, Nichi-Iko put particular efforts into compliance measures. The Company reinforced structures by making the Compliance Committee, which had been a subsidiary organization of the Risk Management Committee, an independent organization, and President and CEO Tamura personally oversees compliance.

Business Creation

Nichi-Iko is creating new business in the DX field through an alliance with MedPeer

To “continue Nichi-Iko's deeper pursuit of business arenas,” the fundamental strategy of the 8th Medium-term Management Plan, as an ethical pharmaceutical company, Nichi-Iko is leading strategic alliances with business partners to benefit patients and their families. The Company began collaborating with MedPeer in May 2020. This is the Company's first business alliance with a non-pharmaceutical company. NichiMed Co., Ltd. was established in September 2020 through joint investment and plans to expand business by connecting with patients by providing apps relating to family pharmacies and family clinics.

It is precisely because Nichi-Iko is involved in health and life that it seeks to engage in activities that contribute to society. The company will continue to broadly provide the knowledge and expertise that it has acquired as a pharmaceutical company to serve patients and their families with compassion so that it can solve social issues and achieve sustainable growth.

TOPICS

ESG/SDG Assessment-based Financing by Sumitomo Mitsui Banking Corp.

In May 2020, Nichi-Iko raised capital through ESG/SDG assessment-based financing with the aim of analyzing the current status of ESG/SDG initiatives. Sumitomo Mitsui Banking Corporation and Japan Research Institute, Limited evaluated the reduction in CO₂ emissions by switching to LNG fuel, responses to regional comprehensive care systems and contributions to community healthcare through comprehensive partnerships agreement with local governments, the target for the proportion of female managers, and consideration for diversity.

Corporate Governance

Basic Approach

The principles of corporate governance at the Nichi-Iko Group call for strict compliance with the law, raising awareness of the importance of management transparency and a strong sense of corporate ethics, and ensuring accurate decision-making and swift execution.

Nichi-Iko recognizes that enhancing and strengthening governance is a top priority for management.

Nichi-Iko is currently enhancing an internal control system that will strengthen its corporate governance structure.

As a pharmaceutical company, Nichi-Iko is also working to improve its audit system, and increasing its efforts with respect to developing, maintaining and improving corporate ethics, compliance, internal controls and risk management.

Corporate Governance Structure

The Company regards the corporate governance structure to be a matter of utmost importance from the perspective of achieving sound business management and winning the trust and confidence of shareholders and investors. A resolution was adopted at the 56th Ordinary General Meeting of Shareholders held in June 2020 to transition Nichi-Iko to a company with an audit and supervisory committee with the objective of enhancing corporate governance systems and reinforcing supervisory functions of the directors by making members of the Audit and Supervisory Committee, which is responsible for auditing the execution of duties by the directors, members of the Board of Directors.

• Board of Directors

The Board of Directors comprises 11 board members (10 men and one woman) including six independent directors and is structured to allow for in-depth discussion of management strategy and decision-making based thereon.

To conduct management that is highly responsive to changing times and requirements, the Board of Directors meets at least once a month to deliberate and make decisions regarding basic management policies and strategies.

• Audit and Supervisory Committee

The Audit and Supervisory Committee is made up of three directors including two independent directors, and the chair is determined by resolution of the Committee. Selected as members of the Committee are individuals who possess extensive experience and skills as well as the necessary financial, accounting, and tax knowledge. One member serves full-time to enhance the effectiveness of audits, and the Company established an Audit and Supervisory Committee Administrative Office and staffed it with specialized assistant auditors that have extensive experience to establish a suitable audit environment.

• Independent Officers' Meeting

The Company adopted Rules for the Independent Officers' Meeting and established an Independent Officers' Meeting comprising all six independent directors to function as a forum for the independent officers. A lead independent officer is selected by mutual vote, and meetings are held, in principle, biannually.

Through these meetings, the independent directors share information and exchange ideas, based on which each works to form an opinion. They strive to provide appropriate advice from an independent, objective perspective, thereby enhancing the effectiveness of management supervision.

• Management Meeting

In principle, the Management Meeting, which is attendant by internal directors and vice presidents, meets weekly to report on, discuss, and make decisions concerning the execution of important matters. The Management Meeting aims to foster among all members in attendance a shared awareness of issues and problems and a spirit of solidarity in their execution. By doing so, and by enabling appropriate management judgment and rapid issuance of instructions, the Management Meeting works to enhance the transparency and soundness of overall operations and to give rise to efficiency and flexibility.

Nichi-Iko's Corporate Governance Initiatives

Directors 11

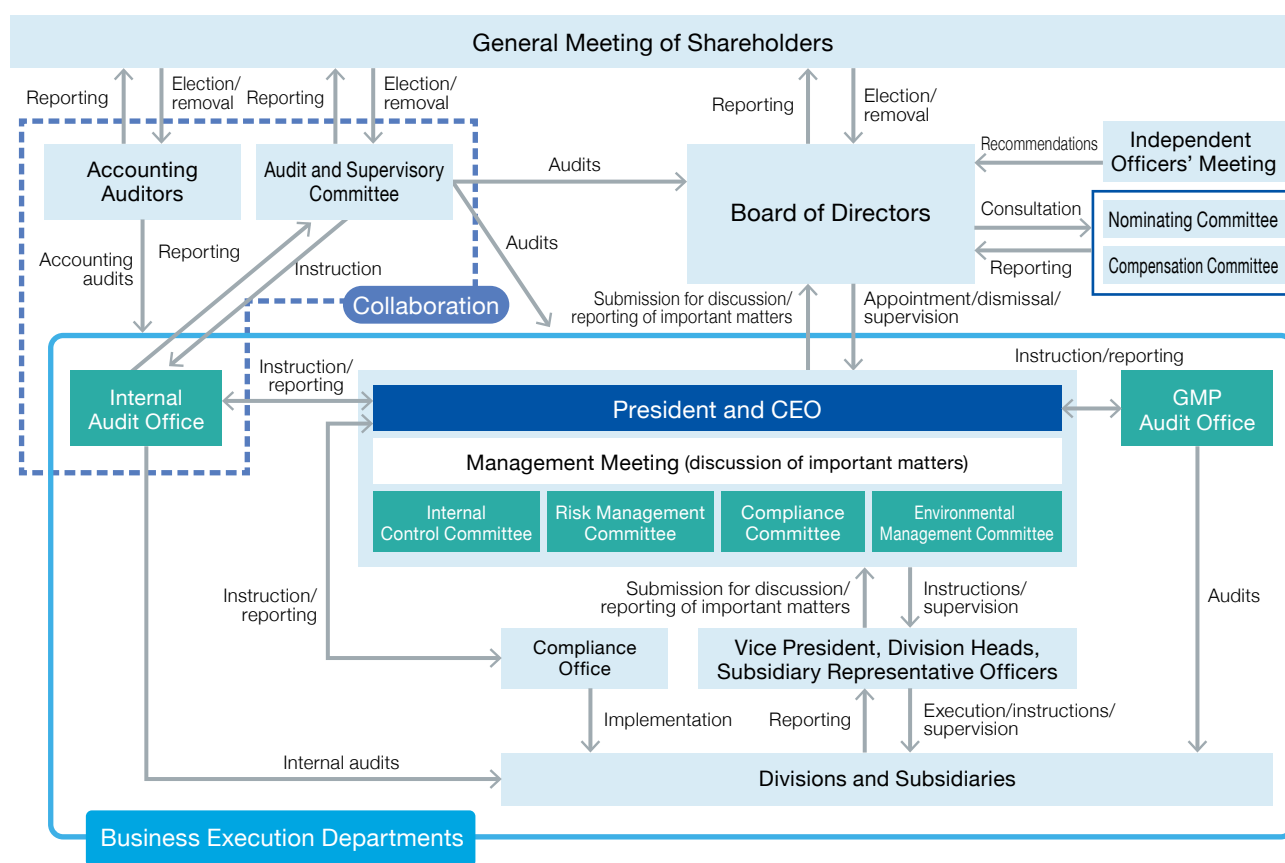
Internal
Directors
5

Independent
Directors
6

(of which three are Audit
and Supervisory Committee members)

- Board of Directors effectiveness evaluations conducted since 2018
- Nominating and Compensation committees established in February 2019
- Roles of directors and vice presidents split in May 2019
- Environmental Management Committee established in November 2019
- GMP Audit Office established in April 2020
- Anti-takeover measures discontinued in May 2020
- Transition to a company with an audit and supervisory committee made in June 2020

Corporate Governance Structure



- **Internal Control Committee**

The Internal Control Committee is charged with putting in place systems to ensure the Group's discussions, information sharing, and communication of instructions and requests regarding internal controls are handled efficiently. When needed, it also offers guidance regarding measures to improve internal controls, as well as support and advice for implementing those measures.

- **Risk Management Committee**

Based on fundamental risk management policies, the Risk Management Committee creates risk management systems and processes to address risks that could affect the advancement and growth of Group operations and impact corporate value. By identifying risks that could materially affect management, and by implementing appropriate countermeasures, the Committee works to ensure ongoing, stable development of the Company's business.

- **Compliance Committee**

The Compliance Committee is responsible for understanding, analyzing and working to implement countermeasures regarding compliance issues Group-wide, establishing rules and guidelines and conducting training. At the same time, the Compliance Committee works to acquire information under internal reporting system regulations. It investigates reports, finalizes measures to prevent recurrence based on discussions with individual business execution departments, and issues instructions on and supervises those measures.

- **Environmental Management Committee**

The Environmental Management Committee implements Group-wide measures relating to environmental preservation and sets environmental policies and targets. It collaborates with

business execution departments and provides recommendations, instructions, and supervision concerning conservation of resources and reduction of environmental impact in conjunction with business activities.

- **GMP Audit Office**

The GMP Audit Office was established as an independent organization under the direct authority of the President and CEO with the aim of reinforcing compliance concerning manufacturing control and quality control (GMP) of drugs and other products at Nichi-Iko Group plants. The Office conducts audits at each plant to identify risks of deviation from GMP, immediately reports to the President and CEO and the Board of Directors, issues recommendations on correction of deviations, and provides guidance and support for implementation of those corrective measures. It also plans and conducts GMP education and training and takes measures to raise GMP compliance levels in the Nichi-Iko Group.

- **Internal Audit Office**

The Internal Audit Office conducts internal audits within the Nichi-Iko Group under the direction of the President and CEO and the Audit and Supervisory Committee. It reports the results to the Internal Control Committee and responsible persons in the relevant departments, and when necessary, the Internal Control Committee provides guidance on corrective measures regarding internal controls and offers support and advice on their implementation. The Internal Audit Office also assesses the effectiveness of internal controls and provides instructions and advice on remediation of any deficient assessment results. It also reports, including reports on remediation, to the President and CEO, Audit and Supervisory Committee, and Internal Control Committee.

Corporate Governance

Nominating Committee and Compensation Committee

In February 2019, the Company established a Nominating Committee and a Compensation Committee to serve as voluntary advisory bodies to the Board of Directors with the aim of enhancing and reinforcing corporate governance even further. The majority of members of both committees are independent directors.

The Nominating Committee is responsible for deliberating the election of executive vice presidents, and the selection and removal of the President and CEO and executive vice presidents, and making recommendations to the Board of Directors.

The Compensation Committee is responsible for deliberations regarding policies, compensation amounts and other details regarding decisions about director compensation, and making recommendations to the Board of Directors.

Separation of Executive Vice Presidents and Vice Presidents

The Company has split its directors and vice presidents to further clarify the management and supervisory functions of the directors and the operational function of the vice presidents. From the perspective of specialization, directors each have responsibility for different management issues. By providing cross-divisional and cross-organizational supervision and guidance, they work to resolve issues and enable the Board of Directors to make the best possible decisions.

Independent Director

The Company's independent directors are the president of a chamber of commerce and industry, a university professor, an attorney, a medical doctor, and a certified public accountant and tax accountant, all of whom possess high levels of expertise and impartiality. This composition was determined with due consideration to the balance of knowledge, experience, and skills.

Nichi-Iko has established a set of standards for judging the neutrality of its independent directors based on standards set forth by the Tokyo Stock Exchange.

Analysis and Assessment of the Effectiveness of the Board of Directors

The Company recognizes there is a gap between its vision for the roles and responsibilities of the Board of Directors as set forth in our basic approach to corporate governance, and the current status of the Board of Directors. To further enhance the effectiveness of the Board of Directors and to understand issues warranting further consideration, in April 2020 the Company conducted a survey of all of its directors and Audit & Supervisory Board members (at the time).

- 1) Composition of the Board of Directors
- 2) Operation of the Board of Directors
- 3) Agenda of the Board of Directors
- 4) Structure for Supporting the Board of Directors

In June 2020, Nichi-Iko conducted a dialogue with the Board of Directors based on the results of an analysis of the 43 items in the survey. As a result, Nichi-Iko confirmed that the effectiveness of the Board of Directors is being ensured.

Although improvements have been made with regard to prior explanations according to the backgrounds of independent directors and selection of report items based on their importance, which was identified as an area with room for improvement in the assessment for the previous fiscal year, the Company has confirmed that it should continue to work on these issues and there is room for improvement concerning deliberations on risk management and compliance.

Based on the results of this effectiveness assessment, Nichi-Iko will work to enhance discussions and improve effectiveness, allowing the Board of Directors to ensure a greater degree of effectiveness.

Note that an overview of the results of this assessment of the effectiveness of the Board of Directors has been published and is available at the website below:
<http://nichiiko-ir.irbridge.com/en/Vision/CorporateGovernance.html>

Main Areas of Specialization and Backgrounds of Independent Directors and Board of Directors Attendance Rates

Name	Main Career, etc.	Main Area of Specialization and Background					Board of Directors	
		Corporate management	Pharmaceutical sciences	Law	Medicine	Finance and accounting	Attendance in the fiscal year ended March 31, 2030 (No. of meetings attended/ No. of meetings held)	Attendance rate
Shigeo Takagi Independent Director	Chairman of the Toyama Chamber of Commerce and Industry Supreme Advisor, The Hokuriku Bank, Ltd.	●					12/13	92.3%
Hideki Sakai Independent Director	Dean, Faculty of Pharmacy and Pharmaceutical Sciences of the University of Toyama		●				13/13	100.0%
Hajime Imamura Independent Director	Attorney at law			●			13/13	100.0%
Kyoko Tanebe Independent Director	Medical Doctor, Toyama Prefectural Assembly Member				●		12/13	92.3%
Hitoshi Hori Independent Director Audit and Supervisory Committee Member	Certified Public Accountant, Tax Accountant					●	13/13	100.0%
Kou Sato Independent Director Audit and Supervisory Committee Member	Certified Public Accountant, Tax Accountant					●	13/13	100.0%

Audit Structure of the Audit and Supervisory Committee

The Audit and Supervisory Committee holds regular meetings with the President and CEO and exchanges opinions with the accounting auditors and Internal Audit Office to enhance audit structures. The Committee strives to improve the audit environment by engaging in close communications with the Internal Audit Office, provides instructions and cooperation to the Internal Audit Office in accordance with audit policies and plans, and conducts investigations of the Company's business and financial status.

The full-time member of the Audit and Supervisory Committee attends the weekly Management Meeting and other important meetings and audits the execution of business by the directors by examining important documents relating to decision-making and so on and reporting to the monthly Audit and Supervisory Committee meetings. This member also reports to the Audit and Supervisory Committee the results of interviews of Nichi-Iko Group directors and employees to monitor internal control systems throughout the Group as a whole.

Policies Regarding Election and Removal of Officers

The election and removal of executive management is conducted based on a comprehensive assessment of individuals with extensive experience and knowledge who can contribute to sustainable Company growth and medium- to long-term improvement in corporate value.

In nominating candidates for director, Nichi-Iko is careful to consider its business as a whole, working to ensure a balance across management, operations, production, development, medical and pharmacological science, finance and accounting, legal affairs and auditing and other areas.

The election of directors is deliberated by the Nominating Committee, which makes recommendations to the Board of Directors. After a decision by the Board of Directors, the nominees are elected via a vote of the General Meeting of Shareholders.

In the event a director engages in misconduct or other acts that damage the reputation of the Company, or is found lacking in aptitude as an officer, the individual can be removed via a vote of the General Meeting of Shareholders, following deliberation by the Nominating Committee and recommendation to the Board of Directors, which will then decide to recommend the individual's resignation. Note that a description of individual candidates for directors and Audit & Supervisory Board Members is included in the General Meeting of Shareholders convocation notice.

Officer Compensation

Basic policies on determination of director compensation are as follows:

- i) Compensation should support the realization of the corporate mission.
- ii) Compensation is designed to recruit and retain outstanding human resources.

iii) Compensation is designed to reflect the Company's medium-term management strategy and to provide motivation for growth over the medium to long term.

iv) Compensation includes mechanisms to curtail the emphasis on short-term oriented perspectives and impropriety.

v) Compensation is designed to be transparent, fair, and reasonable from the perspective of accountability to stakeholders including shareholders and employees, and compensation decisions are made through appropriate processes that ensure this.

The Company's officer compensation is made up of base compensation and performance-linked compensation. Compensation levels are set taking into consideration comparisons with other companies in the same industry or of the same size in Japan and overseas as well as the Company's financial status.

Payment is made through a combination of cash compensation and stock-based compensation provided through stock options.

The Compensation Committee is responsible for deliberating on policies concerning the determination of compensation as well as the amounts of compensation for directors and executive management. The Committee makes its recommendations to the Board of Directors, which then decides compensation.

Discontinuation of Anti-takeover Measures

The Company discontinued and eliminated the Countermeasures against Large-scale Purchases of Company Share Certificates, etc. (Anti-takeover Measures) in May 2020.

The Company first submitted a proposal on anti-takeover measures to the 43rd Ordinary General Meeting of Shareholders held in February 2008 as a part of its initiatives to secure and enhance corporate value as well as the shared interests of shareholders. The proposal was approved by the shareholders, and the measures have been implemented continuously since then.

However, the Company has monitored the opinions of shareholders including institutional investors in Japan and overseas and changes in the external environment such as developments concerning anti-takeover measures and the spread of corporate governance codes, and based on the results of careful and repeated investigation of the necessity of continuation of this plan, the Company decided to discontinue it.

Even after the discontinuation of anti-takeover measures, in cases where proposals for large-scale purchases of the Company's shares are made, the Company will continue to gather information necessary for shareholders to make decisions, engage in timely and appropriate disclosures, strive to secure adequate time for investigation by shareholders, and take other appropriate measures to the extent permitted by the Financial Instruments and Exchange Act, Companies Act, and other applicable laws and regulations to secure and enhance corporate value as well as the shared interests of shareholders.

Risk Management

Risk Management Framework

As the basis of its risk management structure, Nichi-Iko has established risk management regulations as well as a Risk Management Committee chaired by the President and CEO, with members comprised of directors, division heads, and others. Based on its fundamental risk management policies, Nichi-Iko works to address risks that might affect the advancement and growth of the Group operations and its corporate value. This includes identifying risks that have a material impact on management via the creation of a risk management structure and a series of risk management processes, referring the matter to the Management Meeting as necessary, and implementing appropriate countermeasures to ensure the continued, stable growth

of the business.

The Company periodically examines anticipated risks by analyzing the internal and external environments, assesses the frequency, degree of impact, vulnerability, and so on for each risk, identifies those risks that affect the Group, and identifies and selects risks that will have substantial impact on management. The Company undertakes risk management to minimize the losses incurred by the Nichi-Iko Group and society in the event that a risk occurs by identifying responses to risks at those times and issues, formulating specific countermeasures against those risks, and verifying and reviewing the status of progress and so on.

Business Continuity Plans (BCP)

The Company has formulated a Business Continuity Plan (BCP) to prepare for the occurrence of a disaster, accident, or other emergency situation.

In the event of a disaster, accident or other emergency, Nichi-Iko will: (1) ensure the safety of employees and their families, and work to protect human lives and avoid injuries; (2) devise measures to avoid or reduce risks in order to minimize damage to company offices, facilities, equipment and other business assets; and (3) develop countermeasures and means to continue business,




ensure product inventory and maintain product deliveries, and work toward an early recovery in the event of an interruption in business due to the occurrence of a disaster, in order to ensure the stable supply of product.

To accomplish this, the Company created a BCP manual along with a disaster handbook that employees can keep with them at all times. The Company also conducts regular emergency response training at all business sites.

Business and Other Risks

The main risks that the Nichi-Iko Group has identified and selected are described below.

Based on an awareness of the locations of these risks, the Group is making maximum efforts to create structures for preventing risk occurrence and responding to unexpected circumstances.

Risk Item	Risk Overview
 Characteristics of Generic Drugs and Competition	Generic drugs are "drugs placed on the market after the patents on the initially developed 'original drugs' have expired." Upon the expiration of patents on the original drugs, many generic pharmaceutical companies may enter the markets, causing prices to fall due to increased competition. As a result, the Group's earnings may decline and its business performance may be adversely affected.
 Changes in Healthcare Systems	The manufacturing and marketing of prescription drugs are regulated in each stage of development, production, distribution and administration to patients by a variety of approval and licensing requirements as well as by monitoring systems. These healthcare systems include structures that are leading to the widespread use of generic drugs, but depending on the particulars of changes to these systems, the Group's business performance may be adversely affected.
 Revision of National Health Insurance Drug Prices	Until now, drug prices have generally been revised every two years, and prices for many products have been reduced. Starting in April 2021, the government plans to conduct interim drug price revisions as well, resulting in annual revisions. Depending on the scale of price reductions resulting from these revisions, the Group's business performance may be affected due to lower profitability.

Risk Item	Risk Overview
 Regulatory Control	<p>In the event of a violation of laws and regulations governing the approval and licensing of drug manufacturing and marketing, regulatory agencies could impose penalties on the Company including a suspension of business operations or cancellation of licenses and approvals. No cause for such cancellation of licenses or approvals has arisen to date. Should such an event occur, however, the business activities and performance of the Group may be affected.</p>
 Entry of Original Drug and Foreign Drug Manufacturers	<p>The expansion of the generic drug market is likely to continue. In conjunction with this, if an original drug manufacturer in Japan or an international pharmaceutical company enters the Japanese generic drug market or if a company markets an authorized generic prior to patent expiration, competition in the generic drug industry could intensify, which in turn could cause a decrease in profitability and have an impact on the Group's business performance.</p>
 Litigation Risks	<p>If an original drug manufacturer initiates patent litigation based on the nature of a generic drug or if it is not possible to completely prevent infringement of the Nichi-Iko Group's intellectual property by a third party, the Group's business performance could be affected. If regulatory authorities commence legal proceedings or initiate litigation concerning a violation of laws and regulations with respect to the Group's business activities, the Group's business performance or financial status could be affected.</p>
 Overseas Development	<p>The Nichi-Iko Group undertakes production and sales activities globally, and when doing so, it faces country risks including regulatory controls, political instability, and uncertainty in business environments. If faced with these types of risks, the Group's business performance could be affected.</p>
 Product Recalls, Suspension of Sales	<p>Generic drugs typically entail extremely small risks of unknown serious adverse events. However, should new, unforeseen adverse events occur or in the case of concerns regarding product safety or quality such as contamination of products with impurities or failure of products standards to satisfy approval criteria, the Company may be forced to recall products and suspend sales, which could affect the Group's business performance.</p>
 Risks Related to Slowdown or Delays in Production due to Disasters, etc.	<p>Should operations at a production site cease due to the occurrence of an earthquake, tsunami, fire or other disaster, or due to technical, regulatory or other issues, this could, depending on the product, bring supply to a halt, in turn affecting the Group's performance. In addition, because certain important raw materials are supplied by specific suppliers, the Group's performance could be affected in the event deliveries are halted due to a disaster or for some other reason.</p>
 Environmental Risks	<p>The Nichi-Iko Group complies with environmental laws and regulations concerning the atmosphere, water quality, noise, vibration, odors, soil contamination, land subsidence, waste, and so on. If, however, environmental improvement expenses are incurred or compensation must be paid to nearby areas or if new capital investment and the like is necessary as a result of amendment of relevant laws and regulations or the occurrence of environmental contamination or other such incidents, the Group's business performance or financial status could be affected.</p>
 R&D Risks	<p>The Nichi-Iko Group engages in careful and active investment in development of generic drugs, biosimilars, and orphan drugs. Compared to generic drug development, the development of biosimilars in particular requires longer development periods and greater expense. If delays in development or unexpected increases in development costs occur for any reason, the Group could incur development cost impairment losses and so on, and this in turn could have an effect on the Group's business performance.</p>
 Risks Relating to Financial Markets and Exchange Rates	<p>The Nichi-Iko Group holds shares of its business partners and other companies and is susceptible to effects from changes in share prices. In addition, the Group has interest-bearing debts and could be affected by changes in interest rates. Furthermore, the Group has overseas consolidated subsidiaries, and amounts reported in foreign currencies in the financial statements of those subsidiaries are translated into Japanese yen on the consolidated financial statements, and therefore, the Group is susceptible to effects from changes in exchange rates. Such changes in financial markets and exchange rates could have an effect on the Group's business performance and financial status.</p>
 Information Management Risks	<p>The Nichi-Iko Group uses various information systems, and unauthorized access to or cyberattacks against those systems could result in the suspension of system operation or the leak of confidential information outside the Group. If such information were leaked, liability to pay compensatory damages, administrative disposition, harm to social reputation, and other outcomes could affect the Group's business performance.</p>
 Outsourcing Risks	<p>The Nichi-Iko Group engages in outsourcing of various operations to companies outside the Group. If problems occur in conducting those operations and there are impediments to the supply of products and services or if an incident involving the leak of important information such as customer information, unlawful conduct, improper conduct, or a scandal occurs, the Group's business activities and business performance could be affected.</p>
 Risks Relating to COVID-19	<p>If Nichi-Iko Group officers or employees become infected with COVID-19 and it becomes difficult to effectively conduct business activities such as a partial suspension of operations, the Group's business performance and business development could be affected. Furthermore, impacts on procurement of raw materials or purchased products or restrictions on medical consultations of patients due to the protraction or further expansion of the global COVID-19 pandemic could affect the business performance of the Group.</p>

Introduction to Officers



1 Yuichi Tamura

President and CEO
Compliance

2 Takahiro Yoshikawa

Representative Director, EVP
Quality, Supply Chain,
and BS Management

3 Kenji Akane

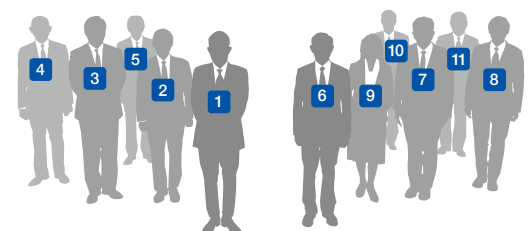
Deputy President
CSR, ESG,
and Business Creation

4 Noboru Inasaka

Executive Vice President
Strategy

5 Toshinori Kongoji

Director and Audit and
Supervisory Committee Member





6 Shigeo Takagi

Independent Director

7 Hideki Sakai

Independent Director

8 Hajime Imamura

Independent Director

9 Kyoko Tanebe

Independent Director

10 Hitoshi Hori

Independent Director and Audit
and Supervisory
Committee Member

11 Kou Sato

Independent Director and Audit
and Supervisory
Committee Member

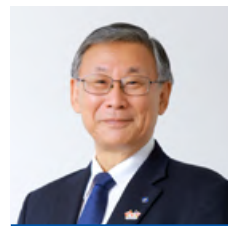
Introduction to Officers

Directors (as of October 1, 2020)



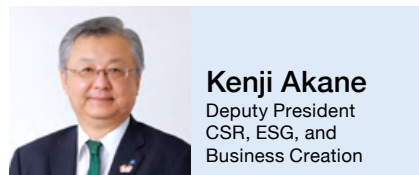
Yuichi Tamura
President and CEO
Compliance

Apr. 1989 Joined the Company
Feb. 1990 Executive Vice President, Director of Corporate Strategy & Planning Office
Feb. 1992 Executive Vice President, Sales & Marketing Division, and Director of Corporate Strategy & Planning Office and Tokyo Management Department
Feb. 1994 Representative Director, Executive Vice President, Responsible for Sales & Marketing Division and Corporate Strategy & Planning Office
Feb. 2000 President and CEO (present position)



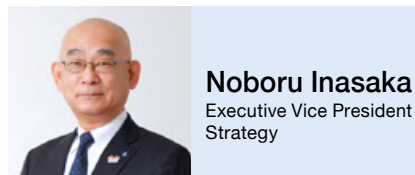
Takahiro Yoshikawa
Representative Director, EVP
Quality, Supply Chain,
and BS Management

Oct. 2010 Joined the Company
Vice President, Deputy Head of the Distribution Stabilization Promotion Division
Dec. 2010 Senior Vice President, Head of the Planning Division
Dec. 2011 Senior Vice President, Head of the Development & Planning Division
Jun. 2013 Executive Vice President, Head of the Development & Planning Division
Apr. 2016 Executive Vice President, Head of the Procurement Division
May 2019 Executive Vice President, Supply Chain, and BS Management
Apr. 2020 Representative Director, Supply Chain, and BS Management
May 2020 Representative Director, EVP, Supply Chain, and BS Management
Jul. 2020 Representative Director, EVP
Quality, Supply Chain, and BS Management (present position)



Kenji Akane
Deputy President
CSR, ESG, and
Business Creation

Jun. 2005 General Manager, Finance and Public Funds Department of The Hokuriku Bank, Ltd.
Sep. 2006 Joined the Company, Director of General Affairs
Dec. 2006 Vice President, Director of General Affairs
Dec. 2008 Vice President, Head of the Administrative Division and Director, Finance Department
Feb. 2009 Executive Vice President, Head of the Administrative Division and Director, Finance Department
Feb. 2011 Executive Vice President, Head of the Administrative Division
Dec. 2011 Executive Vice President, Overall Management and Internal Audit Group of the Company
Apr. 2017 Executive Vice President, President Office and Compliance & Internal Auditors Office
Apr. 2018 Deputy President and Vice President Compliance & Internal Auditors Office
May 2019 Deputy President
CSR, ESG, and Business Creation (present position)



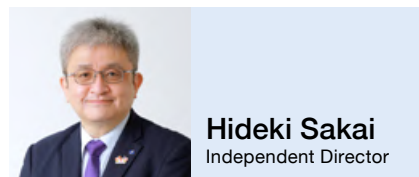
Noboru Inasaka
Executive Vice President
Strategy

Mar. 1978 Joined the Company
Dec. 2001 Director of Operation Department
Dec. 2005 Representative Board Member of Oriental Pharmaceutical Co., Ltd. (secondment)
Jan. 2008 Vice President, Director of Operation
Dec. 2008 Vice President, Deputy Head of the Sales & Marketing Division and Director of Operation
May 2009 Senior Vice President, Director of Purchasing
Dec. 2009 Senior Vice President, Director of Finance
Dec. 2011 Senior Vice President, Head of the Administrative Division
Jun. 2014 Executive Vice President, Head of the Administrative Division
Apr. 2018 Executive Vice President, Director of Head of the Administrative Division
May 2019 Executive Vice President, Strategy (present position)



Shigeo Takagi
Independent Director

Apr. 1971 Joined The Hokuriku Bank, Ltd.
Jun. 1998 Board Member of The Hokuriku Bank, Ltd.
Jun. 2002 Representative Executive and President of The Hokuriku Bank, Ltd.
Sep. 2003 Representative Executive and President of Hokugin Financial Group, Inc. (present Hokuhoku Financial Group, Inc.)
Feb. 2011 Independent Director of the Company (present position)
Jun. 2013 Special Advisor of The Hokuriku Bank, Ltd.
Nov. 2013 Chairman of the Toyama Chamber of Commerce and Industry (present position)
Jul. 2016 Supreme Advisor of The Hokuriku Bank, Ltd. (present position)



Hideki Sakai
Independent Director

Apr. 1992 Research Fellowship for Young Scientists of Japan Society for the Promotion of Science
Aug. 1992 Research Associate, Faculty of Pharmaceutical Sciences of Toyama Medical and Pharmaceutical University
Sep. 1996 Long-term Staff Researcher of Ministry of Education
May 1998 Associate Professor, Faculty of Pharmaceutical Sciences of Toyama Medical and Pharmaceutical University
Feb. 2005 Professor, Faculty of Pharmaceutical Science of Toyama Medical and Pharmaceutical University
Oct. 2005 Professor, School of Pharmacy and Pharmaceutical Sciences of the University of Toyama
Apr. 2006 Professor, Graduate School of Medicine and Pharmaceutical Sciences (Pharmacy) of the University of Toyama
Oct. 2013 Associate Dean, School of Pharmacy and Pharmaceutical Sciences, University of Toyama
Jun. 2014 Independent Director of the Company (present position)
Apr. 2018 Dean, Graduate School of Medicine and Pharmaceutical Sciences for Research, University of Toyama
Dean, School of Pharmacy and Pharmaceutical Sciences of the University of Toyama (present position)
Oct. 2019 Professor, Faculty of Pharmaceutical Sciences, Academic Assembly of the University of Toyama (present position)
Dean, Faculty of Pharmaceutical Sciences, Academic Assembly of the University of Toyama (present position)



Hajime Imamura
Independent Director

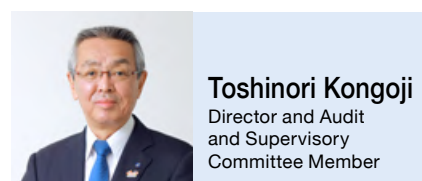
Apr. 1984 Registered with the Toyama-ken Bar Association (present position)
Feb. 1994 Auditor of the Company (currently Audit & Supervisory Board Member (Independent))
Jan. 1998 Established Imamura Law Office
Representative of Imamura Law Office (present position)
Jun. 2017 Resigned as Audit & Supervisory Board Member (Independent) of the Company
Independent Director of the Company (present position)



Kyoko Tanebe
Independent Director

Jun. 1990 Clinical Fellow, Toyama Medical and Pharmaceutical University Hospital
Feb. 1991 Medical Doctor, Department of Obstetrics and Gynecology, of Aikku Hospital, Imperial Gift Foundation Boshi-Aiiku-Kai
Apr. 1998 Research Associate, Department of Obstetrics and Gynecology of Toyama Medical and Pharmaceutical University
Jul. 2006 President of Women's Clinic We! Toyama, Touseikai Medical Corporation
Jun. 2018 Independent Director of the Company (present position)
Jan. 2019 Representative of Women's Clinic We! Toyama, Touseikai Medical Corporation (present position)
Apr. 2019 Toyama Prefectural Assembly Member (present position)

Audit and Supervisory Committee Members (as of October 1, 2020)



Toshinori Kongoji
Director and Audit
and Supervisory
Committee Member

May 1971 Joined the Company
Jan. 1998 Director of Finance
Dec. 2001 Vice President, Director of Finance
Feb. 2004 Executive Vice President, Director of Finance
Oct. 2009 Executive Vice President, the Sales & Marketing Division
Jun. 2010 Executive Vice President, Head of the Sales & Marketing Division
Jun. 2014 Representative Director and Executive Vice President
Officer Responsible for the Sales & Marketing Division and Head of the Sales & Marketing Division
Apr. 2018 Executive Vice President
Executive Vice President of Elmed Eisai Co., Ltd. (secondment)
Apr. 2019 Executive Vice President, Compliance & Internal Auditors Office
Jun. 2019 Audit & Supervisory Board Member
Jun. 2020 Director and Audit and Supervisory Committee Member (present position)



Hitoshi Hori
Independent Director
Audit and Supervisory
Committee Member

Aug. 1982 Registered as Certified Public Accountant (present position)
Sep. 1985 Registered as Tax Accountant (present position)
Aug. 2002 Established Hori Tax Accountant Corporation
Representative of Hori Tax Accountant Corporation (present position)
Feb. 2005 Audit & Supervisory Board Member (Independent) of the Company
Jun. 2020 Nichi-Iko Audit and Supervisory Committee Member (present position)



Kou Sato
Independent Director
Audit and Supervisory
Committee Member

Oct. 1975 Joined Fuso Audit Corporation
Mar. 1979 Registered as Certified Public Accountant (present position)
Aug. 1997 Representative of Chuo Audit Corporation
Aug. 2007 Representative of KPMG AZSA and Co., KPMG AZSA LLC.
Jun. 2012 Resigned from KPMG AZSA LLC.
Jul. 2012 General Manager of Certified Public Accountant Sato Kou Office, Kou Sato CPA Office (present position)
Sep. 2012 Registered as Tax Accountant (present position)
Jun. 2014 Audit & Supervisory Board Member (Independent) of the Company
Jun. 2020 Nichi-Iko Audit and Supervisory Committee Member (present position)

Operating Officers (as of October 21, 2020)



Takashi Kashiwagi
Senior Vice President
Head of the Corporate
Strategy & Planning Division



Hiroshi Shimazaki
Senior Vice President
Head of the Quality Assurance
& Pharmacovigilance Division



Toru Kogawa
Senior Vice President
Head of the Development
& Planning Division



Hiroaki Oribe
Senior Vice President
Head of the Quality
Operations Division



Osamu Mihara
Senior Vice President
Head of the Sales & Marketing Division



Masatoshi Takaishi
Senior Vice President
Head of the Production
Division



Shuji Ishida
Senior Vice President
Head of the
Administrative Division



Atsushi Matsumoto
Senior Vice President
Head of the Procurement
Division



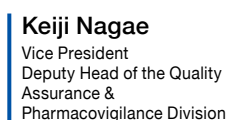
Tetsuo Kadozaki
Senior Vice President
Director, Integration
Promotion Office of
Nichi-Iko Gifu Plant



Susumu Kanda
Senior Vice President
Director, Office of the
President



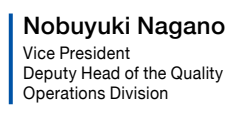
Ken-ichi Takayama
Vice President
Deputy Head of the
Corporate Strategy & Planning Division



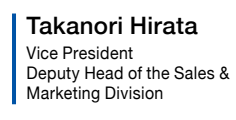
Keiji Nagae
Vice President
Deputy Head of the Quality Assurance & Pharmacovigilance Division



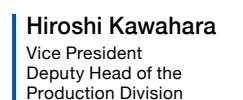
Atsushi Kosugi
Vice President
Deputy Head of the
Development & Planning Division



Nobuyuki Nagano
Vice President
Deputy Head of the Quality Operations Division



Takanori Hirata
Vice President
Deputy Head of the Sales & Marketing Division



Hiroshi Kawahara
Vice President
Deputy Head of the
Production Division



Yoichi Arakawa
Vice President
Deputy Head of the
Administrative Division



Xiaoqian Chen
Vice President
Deputy Head of the
Procurement Division

Round-Table Discussion by Independent Directors

Independent directors increase the Nichi-Iko Group's corporate value by supervising management from various perspectives, based on our respective expertise

Nichi-Iko established a new Quality Policy in 2020 and is pursuing further growth on the global stage as a generic pharmaceutical company that serves with compassion the patients suffering from illnesses. In this discussion, four independent directors of Nichi-Iko spoke about Nichi-Iko's initiatives in that regard from perspectives such as corporate governance and management issues.



Shigeo Takagi
Independent Director

Hideki Sakai
Independent Director

Hideki Sakai
Independent Director

Kyoko Tanebe
Independent Director

Lively Discussion Takes Place from Various Perspectives in an Open Atmosphere Where Opinions Are Stated Freely

Takagi Nichi-Iko's independent directors are a highly varied group of people. I myself, in my role in the Board of Directors, utilize my experience of the banking industry gained as a banker over many years in the past. I support Nichi-Iko's management by always pointing out strains that occur in relation to corporate growth, and on the financial side, doubts that I have about financing and investment efficiency or the business strategies.

Sakai To Nichi-Iko, as a pharmaceutical company, the most important matters are the quality, efficacy, and safety of its drugs. Based on my specialized knowledge of pharmaceutical sciences gained from working as an academic in a university faculty of pharmaceutical sciences for over 25 years, I verify whether quality, efficacy, and safety are properly assured in the series of processes from research and development to production, and state my opinions to the Board of Directors.

Imamura Based on my experience as a practicing lawyer, I carry out the function of checking whether there

are any compliance problems in the various decision-making processes of Nichi-Iko. I consider that another aspect of my role is to take action to minimize damage in the event that an emergency occurs.

Tanebe I am a practicing medical doctor. I believe it is my responsibility to ensure that on-site expectations of medical policies announced by the government are reflected in the management of Nichi-Iko. Also, based on my experience as a long-serving member of a specialist committee of the Council for Gender Equality of the Cabinet Office, I would like to be involved in enhancing ESG initiatives such as promoting diversity through the participation of women.

Takagi Due to the inclusion of these independent directors with diverse backgrounds in the Board of Directors, lively discussions take place at each meeting of the Board. It is certainly not a "sleeping board" that is just for receiving explanations and approving matters for resolution and reports.

Tanebe The Board of Directors of Nichi-Iko truly has an open atmosphere where people can speak freely. There is a close relationship between colleagues within the Board, and we can point out matters that we think are wrong

without reserve.

Imamura The atmosphere in the Board of Directors has changed greatly compared with the past. I was formerly an Audit & Supervisory Board Member of the Company and the Board of Directors generally received certain reports from management and approved them and there were practically no negative opinions. However, currently, the number of independent directors has increased and they make expert remarks from a variety of different standpoints, which always generates enthusiasm in the Board.

Sakai Naturally, I speak actively on matters relating to my own field of expertise and by asking the opinions of other independent directors I am also able to give opinions to management from different perspectives, and I think this helps to stimulate discussions. Furthermore, suggestions that we make are always received sincerely by President and CEO Tamura, who is the Chairman of the Board, and are reflected in the agenda for the next meeting, and actually incorporated and implemented. I feel that we are running a highly effective Board of Directors.

Increase the Level of All Employees' Risk and Compliance Responsiveness

Takagi To Nichi-Iko at present, one of the issues for increasing corporate value is enhancing the governance system.

Imamura In 2020, Nichi-Iko changed from being a Company with a Board of Company Auditors to a Company with an Audit and Supervisory Committee, and I believe this was a great step forward for strengthening the governance system. A board of company auditors can give opinions to management but does not have management voting rights. By changing to a Company with an Audit and Supervisory Committee and enabling persons with voting rights to carry out audits, there is greater weight placed on the process leading up to resolutions, and I think this helps to strengthen governance.

Tanebe Currently, the Nichi-Iko Board of Directors is comprised of five directors who have been promoted from inside the Company and six independent directors, which I think is a good balance. As there is a high ratio of independent directors and it is not known in advance what questions each of them will raise, this always makes the full-time directors nervous and this is shown by their level of preparation. Maintaining transparency in the Board in this way is important in governance. I think it will still take time to see the effects of changing to a Company with an Audit and Supervisory Committee, but I am very much looking forward to Nichi-Iko being improved and transformed by the new structure.

Sakai Enhancing risk management is also an important theme for improving corporate governance. To date, Nichi-Iko has achieved major growth while conducting M&As but that also involves the difficult aspect of

integrating the cultures and climates of different companies. I believe Nichi-Iko tries to utilize any risk management ideas and methods that should be followed in the internal affairs of the companies subject to the mergers, but to spread ways of thinking and structures created by combining their respective good points to all employees may be extremely difficult. To avoid risk management problems occurring, it is necessary to extend them companywide through measures such as employee education and standardized systems, and I think those initiatives should be progressively strengthened.

Tanebe Outcomes are the main things that can be checked by the Board of Directors. We may not be able to see the processes that led to those outcomes. Even when risks surface, there are cases where we have to make judgments only by outcomes. However, we consider ideas in the process of determining why those situations happened, conduct interviews about the situations on-site, and check whether there have been any systems errors. Ideally, I would like to commit to personally going to sites and creating a climate in which each employee does not overlook even small emerging risks, but as that would be quite difficult from the position of an independent director, I hope to be able to contribute by working appropriately toward realizing such a climate.

Takagi Risk management and compliance will keep evolving in accordance with social conditions, and we need to increase the level of employees' risk and compliance responsiveness. In order to avoid overlooking even small emerging risks, as mentioned by Ms. Tanebe, we must keep working to raise the level of that responsiveness. At the same time, for the independent directors to make our own appropriate management judgments, I believe we have to always keep up with the latest information about market and government trends and the like, and increase our sensitivity to risk and compliance.

Imamura Ms. Tanebe has spoken about the Board of Directors only being able to check outcomes, but I think that for appropriate decision-making it is important that diverse views from persons on-site are reflected at the stage prior to matters being brought up for discussion at the Board. Currently at Nichi-Iko meetings of committees related to risk management and compliance, including the Risk Management Committee, Compliance Committee, Internal Control Committee, and Environmental Management Committee, are held regularly and I attend those meetings and make various suggestions from the standpoint of an independent director. As reporting matters from among those discussions are brought up at the Board of Directors, if the discussions which form the groundwork are energized, it will naturally also enhance the discussions at the Board of Directors. I believe my role is to further stimulate these committee discussions, and I will make even greater efforts in that regard.

Round-Table Discussion by Independent Directors

The New Quality Policy Was Also Influenced by Independent Directors' Opinions. It Is Important for All Employees to Consider "Premium Quality."

Takagi In July 2020, the Company announced its new Quality Policy, "Nichi-Iko's Pledge of Trust and Confidence (Nichi-Iko Group Quality Policy)." To date, Nichi-Iko's business operations were based on providing "premium quality," but as Mr. Sakai mentioned previously, while the scale of the organization is being expanded through M&As, unfortunately quality awareness has not necessarily penetrated to every corner of on-site operations. Although most of the employees' efforts toward quality achieve a perfect score of 100 points, if just one person has scored 0 points, Nichi-Iko will be considered to have achieved 0 points as a company. This new Quality Policy reflects that situation and is recognized as an expression of its strong determination to improve quality in all its companies.

Imamura In the manufacturing of drugs, if just one person makes a mistake in the process, trust in Nichi-Iko as a company will be lost straightaway. Therefore, in accordance with the new Quality Policy, each and every employee must comply unconditionally with the laws and regulations in relation to drugs. To take the lead in that regard, at each meeting of the Board of Directors the President and CEO reads out Nichi-Iko's Mission Statement followed by the whole of the Quality Policy. Also, at the Management Meeting, after the reading of the Mission Statement by the President and CEO, all the members who are present read out the Quality Policy together. By reading it out together regularly instead of reading it to themselves, members try to properly entrench an accurate awareness of the content, and this approach is highly regarded.

Sakai The independent directors also participated in formulation of part of the Quality Policy. In the Quality Policy statements, there is a section that says "...as a generic pharmaceutical company that serves with compassion the patients suffering from illnesses..." but the expression "serves with compassion the patients suffering from illnesses" was not included at the draft stage. However, during the Board of Directors' discussions for determining the policy, Mr. Takagi and I



suggested that we should be even more aware of patients suffering from illnesses as a pharmaceutical company, and on consideration by the Chairman of the Board (the President and CEO), the expression was added. With compassion for the patients while considering the hardships and worries of patients and their families, we must work wholeheartedly to deliver drugs to the world. The expression reflects Nichi-Iko's strong desire to always conduct its business with a firm focus on patients.

Takagi Nichi-Iko must take responsibility for supplying drugs, and unwavering quality is an essential prerequisite for that. This Quality Policy constitutes management's re-acknowledgement that it is the mission of Nichi-Iko to further improve quality and then fulfill its responsibility to supply drugs. As independent directors, we must firmly support this mission.

Sakai I think there are two types of "going beyond" that are valued by Nichi-Iko under the leadership of President and CEO Tamura. One of them is "surpassing." Nichi-Iko's "premium quality" may be interpreted in a variety of ways including surpassing current quality levels and also all employees surpassing themselves. Actually, to enable each employee to understand "premium quality" and reflect it in their respective duties, each branch and department conducts initiatives for considering the meaning of "premium quality." Another type of "going beyond" is "overcoming." It can be interpreted as meaning overcoming drug patent and technology barriers and the like for development, planning, and production of drugs and also overcoming difficult work problems (barriers) faced by employees. Through "surpassing" and "overcoming," I am confident that the quality of Nichi-Iko's drugs and all its employees will increase more and more going forward.

Tanebe Nichi-Iko is a company that brings many people together but "standards" differ among people.

"Standards" refers to values, so to speak, and by measuring things according to various standards, hidden quality risks are also revealed. The Company must utilize the diverse values within the organization while also placing importance on small standards that have been overlooked to date. I believe that the new Quality Policy shows the commitment of Nichi-Iko's top management to making sincere efforts in that regard. This will also help to promote diversity, and I would definitely like to support it.



Nichi-Iko Has Chosen the Right Path. Enhancing ESG Will Also Increase Competitiveness.

Takagi Nichi-Iko's Board of Directors deals with management with constant awareness of medium- to long-term issues. The biggest issue faced by the Company going forward is the progressive declining and aging of Japan's population. Due to the declining population, markets will contract and the pressure to reduce healthcare costs due to the progressive aging of society will increase, curbing drug prices and impacting profits. In that sort of market, M&As are necessary to expand the scale of the business and it is also essential to develop overseas markets. The acquisition of Sagent in the United States is part of this strategy, and I believe the path Nichi-Iko has chosen is the right one.

Sakai I am very much looking forward to the future development of the overseas business. Nichi-Iko Group employees as well as the independent directors wear an original badge featuring the Japanese, U.S., and Canadian flags. This precisely symbolizes the Nichi-Iko Group's global development. In the United States, Nichi-Iko manufactures biological and small-molecule injectables at the Raleigh Plant of Sagent, which has passed the strict regulations of the U.S. Food and Drug Administration (FDA) and it has also enhanced the production of compound drug formulations at the Sagent subsidiary, SterRx. Meanwhile, it manufactures small-molecule injectables at the Omega Montreal Plant in Canada and is proud of their high competitiveness. Markets are also being developed in Asia, mainly through the local subsidiary, Nichi-Iko (Thailand) Co., Ltd.

Takagi What supports this business expansion is Nichi-Iko's people. Even though the organization is expanded and improved by M&As, this does not necessarily mean that the right people are allocated to the appropriate places. To fully demonstrate the hidden potential of all employees and help to raise the overall level at Nichi-Iko, human resource development and appropriate placement are extremely important. I think there should be unstinting investment in people.

Tanebe I am looking forward to the further development of Nichi-Iko in the future but to ensure that development greater emphasis should be placed on ESG. As part of



that, I would like to make efforts with a focus on the social area in which Japanese companies are weak. Specifically, I would like to further advance the participation of women and make Nichi-Iko into an organization composed of diverse people. Emphasizing diversity and respecting a variety of opinions will help to control risks, improve the quality of drugs, and enhance stable supply. Also, at Nichi-Iko, the appointment of female managers has increased at headquarters, plants and other locations but the ratio of female managers at companies operating in Toyama Prefecture, the location of the Nichi-Iko headquarters, is low compared to the ratio at companies nationwide, and I would like to change that to a situation in which Nichi-Iko is a leader. The opportunities for women's active participation in society are increasing, and if the time that men have for housework and child-rearing is increased, it will lead to vitalization and sustainable development of local communities. First of all, arrangement of an environment within the Company in which women can participate actively in management positions and selection of female directors from within the Company is my ultimate mission. I think that diversity is also important for expanding the business globally, and I would like to contribute to enhancing Nichi-Iko's competitiveness through social initiatives.

Imamura As Ms. Tanebe has said, in Europe and the United States it is recognized that diversity is directly linked to corporate competitiveness. In particular, it is strongly considered that if the proportion of women is not increased, organizations will not change, and last year the "30% Club" was also started in Japan. There are activities being carried out to create a sound gender balance by increasing the proportion of women holding executive positions in companies, and they have spread globally in recent years. Also in ESG investment, there is a trend toward excluding companies that have not achieved appropriate gender balance as targets for investment, and this is now an inevitable theme in the context of whether companies will survive.

Takagi Nichi-Iko is a company that still has hidden potential for significant growth. As an independent director, I give my opinions frankly so as to draw out that potential, and I hope to be able to contribute to enhancing the Company's corporate value.



Society | People

The people that support Nichi-Iko's business are the Company's most valuable asset. The Company is putting efforts into creating rewarding, pleasant workplaces and developing individual abilities.

Creating a Rewarding Organization

Nichi-Iko formulated the Human Resource Development Policy and has distributed it to all employees with the aim of fostering human resources. As persons involved in pharmaceuticals, each employee has the pride and responsibility to serve with compassion patients suffering from illnesses and to ensure that each tablet delivered each day brings happiness to patients and their families. Nichi-Iko believes that creating rewarding and pleasant workplaces and skill development support policies that focus on individual employees so that the Company can contribute to people around the world as a generic pharmaceutical company is among the main pillars of its business.

Nichi-Iko's Human Resource Development Policy

- Create structures for developing people who will bring a global management perspective to their roles
- Create the Nichi-Iko People Platform
 - Enhance the enthusiasm and sense of fulfillment of all employees
- Reinforce the high-priority points of human resource development
 - Link reinforcement of the operation of the performance appraisal system and appraiser training

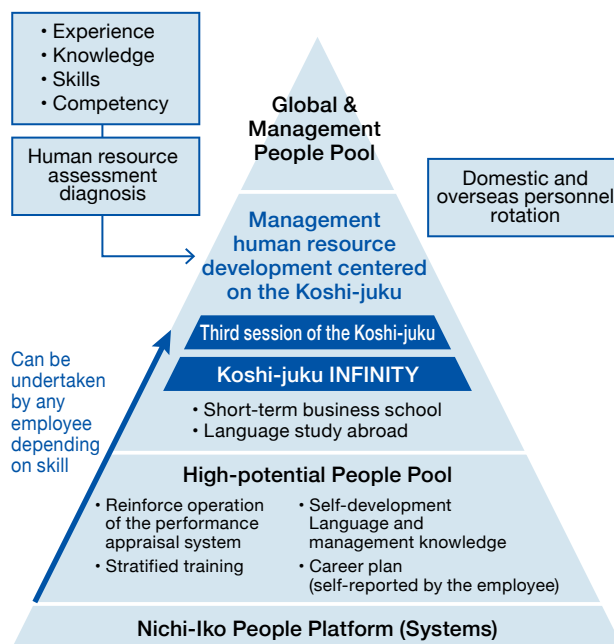
The Human Resource Development Policy focuses on fostering people who bring a global management perspective to their roles. To achieve this, the Company believes that the priority issues are creating paths for each and every employee to make the most of their capabilities and find self-fulfillment and creating rewarding workplaces. To put it another way, taking the career plans of employees seriously while reinforcing the operation of the performance appraisal system to ensure fairness will lead to growth. At the foundation of these systems, the Company built the Nichi-Iko People Platform. This platform supports the systems that enable employees from new hires to next-generation managers to establish paths for working with enthusiasm and vigor and achieving growth.

People Platform systems use performance appraisal histories of organization members and so on in the day-to-day fostering of human resources from a management perspective. From the employee's perspective, individual employees declare their career plans and communicate with organization heads to clarify their self-fulfillment goals. The performance appraisal system operates on top of these systems as a program that leads to employee growth. In addition, records of interviews between organization heads and employees, work experience, qualifications and skills,

records of training and self-development, and other human resource information are collected as assets.

In this way, the Company is reinforcing the foundations that seamlessly support growth of all people from new employees to those who bring a global management perspective to their roles.

Overview of the Nichi-Iko People Platform



Human Resource Development Initiatives (Education and Training)

1. Handing Down Nichi-Iko's DNA

The Company focuses its efforts on developing the next generation of executive management by recruiting ambitious young employees for a management development program called "Koshi-juku."



The keynote address by the President and CEO at the third session of the Koshi-juku (October 2020)

Handing down Nichi-Iko's DNA is a major objective, and the program is a valued opportunity for exposure to the thinking of top management through direct dialogue with the

President and CEO. As a forum for honing the background and qualities needed to perform one's work from a management perspective, participants are broadly recruited, mainly from management levels. This fiscal year, the Company held the third session of the Koshi-juku. To deepen the ambitions fostered by the Koshi-juku, individuals who completed the program are selected to attend short-term business school. Through interaction with people from other companies, they are expected to enhance their management skills while learning about strategy development, project management, and so on.

The Company also launched Koshi-juku INFINITY. This program is designed to foster the next generation of managers who will lead Nichi-Iko. They research the formulation of the next Medium-term Management Plan with the aim of making Nichi-Iko into the leading global comprehensive generic pharmaceutical company, using the Nichi-Iko's Long-term Vision and the 8th Medium-term Management Plan "NEXUS∞" as compasses.

2. Stratified Training

Stratified training is planned and conducted by using curricula tailored to the individual's position, from introductory training for new employees to management training for the heads of organizations.



New employee training (for employees hired in fiscal 2020): The photo shows the headquarters meeting site. In consideration of employee safety, the training was conducted at sites nationwide using videoconferencing (October 2020).

The role of organizational heads in human resource development has grown increasingly important. The Company believes that on-the-job training (OJT), where employees learn by performing work at the worksite, is the most important opportunity for human resource development. The Company focuses on OJT and conduct company-wide, interdisciplinary management training for organization heads that is unique to Nichi-Iko on the topic of reinforcing support for member growth through operation of the performance appraisal system and interviews with employees. By implementing both this training and the People Platform, the Company supports the growth of people. The Company has also introduced a curriculum that considers the importance of diversity management with a focus on empowering women. Training is currently conducted

primarily online, but efficient group training will be resumed at an appropriate time.

Introductory training for new employees is designed to get new hires excited about taking their first steps as working adults and focuses primarily on mastering basic business skills. Following assignment, employees are supported by a mentoring program and OJT. In addition, company-wide, interdisciplinary stratified training is planned and conducted with emphasis on milestones.

3. Functional Training

Within functional training, the Company places the highest priority on "Our Pledge of Trust and Confidence—Nichi-Iko Group Quality Policy" and conducts training on good manufacturing practices (GMP; standards for manufacturing and quality control of drugs and other products). In addition, functional training includes ongoing training for the medical representatives (MRs) who bring a sense of pride and responsibility to their work on the front lines as well as follow-up training for junior MRs.

4. Self-development

Nichi-Iko uses the term *ikuji* (self-education), and is working to expand and enhance programs that support self-initiated education and self-development. Language ability is the first step toward playing a global role. The Company provides opportunities for all employees to take the TOEIC exam, established award programs and programs that support self-improvement of language ability, and have tied these into the overseas language study program. In addition, the Company has established programs that support the acquisition of basic managerial knowledge and has created an environment that enables employees to engage in self-development based on their own awareness of career formation.

Training Systems

Executive level	Third session of the Koshi-juku
	Koshi-juku INFINITY
	Training for organization heads
	Manager training
Stratified training	Dispatched to short-term business school
	Team leader training
	Leader training
	Junior employee annual training / Junior MR training
Functional training	New employee introductory training
	GMP training
	MR introductory training and follow-up training
Self-development	Division head training
	TOEIC and language study abroad programs
E-learning	Self-development support (language and management fundamentals)
	Compliance training, etc.

Society | People (Diversity & Inclusion)

Nichi-Iko is working to promote diversity and inclusion to nurture an environment in which each unique individual can exert his or her full potential, to create innovation, and to ensure sustainable corporate growth.

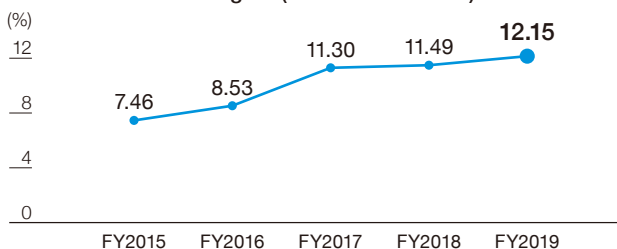
Promoting an Active Role for Female Employees

We have formulated an action plan based on the “Act on Promotion of Women’s Participation and Advancement in the Workplace,” which was enacted in 2016. We establish and select role models for female employees, and communicate those examples within the Company. Under the 8th Medium-term Management Plan, “NEXUS∞,” we have set a



target for the ratio of female managers of 15% or more, with the goal of creating a society in which women can fully exert their individuality and potential.

Ratio of Female Managers (Non-consolidated)



Promoting Employment of Disabled Persons

Nichi-Iko is working to establish environments and operations where able-bodied employees and disabled employees can work together in the same workplace and actively recruiting disabled individuals to promote diversity.

Employment of Non-Japanese Employees

Nichi-Iko actively implements global hiring by recruiting non-Japanese employees with a focus on international students who studied in Japan and hiring persons who graduated from high schools and universities outside of Japan. These employees are currently active in a variety of areas including the development and procurement departments.

Workstyle Reforms

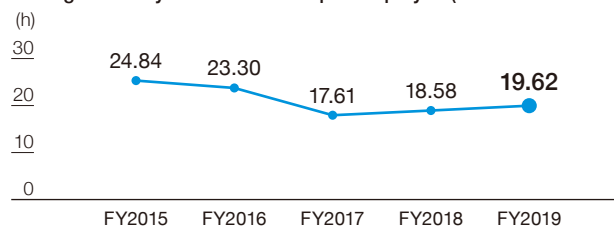
Nichi-Iko seeks to direct employee awareness of performing their jobs toward higher productivity and enhancement of corporate capabilities while achieving a good work-life balance.

The Company also allows employees to work from home and are implementing staggered working hours and otherwise diversifying workstyles as COVID-19 infection prevention measures. In addition, the Company is developing and expanding IT infrastructure to support remote work.

[Main Initiatives]

- Flextime system
- Remote work, staggered work hour
- Utilization of accumulated paid leave (personal illness or injury, infertility treatment, childcare, caregiving, nursing)
- Promotion of increases in the annual paid leave utilization rate (the target is at least 70%)
- Promotion of systematic utilization of accumulated paid leave (scheduled leave program)
- Visualization of working hours (attendance management system improvements, PC log confirmation system)
- Super-flex (no core hours)
- Bone marrow donor leave program

Average Monthly Overtime Hours per Employee (Non-consolidated)



Supporting a Balance Between Work, Child-rearing, and Caregiving

We have carried out a variety of measures based on the “Act on Advancement of Measures to Support Raising Next-Generation Children” and have also put in place and expanded programs that go beyond legally required standards.

[Main Initiatives]

- 30% of basic monthly salary paid during childcare leave.
- Eligible age of children under the program for working shorter hours during childcare expanded to children through the third grade of elementary school.
- Use of accumulated paid leave program expanded to include family caregiving.
- The program for shorter working hours during caregiving can be started and stopped in a number of times within a three-year use period.

Number of Employees Taking Childcare Leave (Non-consolidated)

	FY2015	FY2016	FY2017	FY2018	FY2019
Male	1	0	2	1	4
Female	8	7	9	10	26
Total	9	7	11	11	30

“Kurumin”

A certification system based on the Act on Advancement of Measures to Support Raising Next-Generation Children. Nichi-Iko has been certified by the Ministry of Health, Labour and Welfare as a “child-rearing support company” under the Kurumin system.



“L-boshi” (three-star)

The Ministry of Health, Labour and Welfare has granted Nichi-Iko the third level of certification, recognizing excellent efforts based on the Act on Promotion of Women’s Participation and Advancement in the Workplace.



Nichi-Iko's Information Provision Structure

At Nichi-Iko, about 300 MRs provide information about drug efficacy, safety and other aspects of proper use to medical institutions nationwide, complying with the Promotion Code and the Guidelines for Prescription Drug Marketing Information Provision Activities. They also work to gather information on drug adverse reaction and quality, and promote proper drug usage. Further, our MRs engage in value-added activities, including providing healthcare workers with information on our products as well as information on healthcare administration and management. Our Medical Practice Support (MPS) team plays a central role in our information provision system. The team currently consists of "MPS consultants" certified by the Japan Association of Healthcare Management Consultants and those qualified in-house as "MPS advisers." We encourage all MRs to obtain these qualifications, and conduct explanatory meetings and provide information regarding healthcare administration and generic drugs.



MRs disseminate and gather information

Customer Support Center Functions Expanded

The Nichi-Iko Customer Support Center serves as a point of contact for product-related questions and consultations. It handles inquiries and requests for materials by phone and works to support efforts to collect and provide information. The content of the calls is conveyed to the MR in charge in an effort to provide a seamless flow of information between the Customer Support Center, the MRs in charge and the medical facilities.

As indicated in the Nichi-Iko's Long-term Vision, the Company believes it is essential to evolve into a company that serves the patients suffering from illnesses and their families with compassion, and hopes to build structures that will enable it to have direct contact with patients and their families. As one part of this effort, the Company expanded and enhanced the functions of the Customer Support Center, which serves as a point of contact for product-related questions and consultations, thereby increasing opportunities to gain feedback from patients and their families.



Customer Support Center TEL: +81-120-517-215

8:30 a.m. to 6:30 p.m. (JST)
(except weekends, holidays and
when the Company is closed for business)

Provision of Information Using DX

Since the declaration of a state of emergency in April 2020, the frequency of detailing has decreased in conjunction with the voluntary curtailment of face-to-face marketing activities, but Nichi-Iko has actively supplemented remote detailing by email and telephone with Web conferencing using an online conferencing system. At this time, detailing is returning to pre-COVID-19 levels, and the Company believes that the establishment of new systems for the provision of information are taking root.

The Company also created a dedicated page on swallowing food on the physician-only community website of MedPeer, one of its business partners, and offers online seminars conducted by specialist physicians on MedPeer Channel, an on-demand distribution program. To respond to needs in the new-normal era, the Company will continue its efforts to facilitate the provision of information using non-face-to-face means.



The Food Swallowing Navi
on the MedPeer dedicated page

Society | Health and Safety

About Health and Safety

The Nichi-Iko Group puts the safety and health of its employees first, engaging in health and safety activities aimed at a goal of zero disasters. From the time employees are hired, they are offered regular health and safety training, and health dialogues are conducted by public health nurses during morning meetings and at other times as part of the Group's efforts to enhance employee awareness of safety and health issues while keeping in mind responses to the COVID-19 pandemic. At the monthly meetings of the Safety and Health Committee, reports are made on departments with large amounts of overtime and efforts are made to verify the underlying causes and take other measures to prevent long working hours. The Committee receives reports on safety and health issues and makes improvements where necessary. With respect to mental health, the Group conducts annual stress tests, which are required by law, and uses the results to improve work environments and help employees become aware of their own stress circumstances.

The production departments conduct safety patrols and risk and safety assessments, a mechanism for minimizing as much as possible the risk of equipment-related and other injuries. In the event of an industrial accident, following an on-site investigation and a probe of the cause, a report covering industrial accidents occurring at all plants is submitted to the Management Meeting. The Company then takes measures to prevent recurrence by identifying problems to ensure that similar accidents do not occur.

Once a month, we use our internal network to publish reports available for viewing by all employees, including our "Health Newsletter," and "Safe Driving Report." The Health Newsletter offers content related to health including mental health issues. The Safe Driving Report provides information on precautions while operating automobiles and bicycles, contributing to employee safety and health.



As result of taking these safety and health related measures, all business sites had zero industrial accidents* in 2019, the second consecutive accident-free year.

* Sites with no fatalities or injuries caused by industrial accidents that resulted in absence from work of one day or more or the loss of a body part or the functioning thereof.

Occurrence of Industrial Accidents

	January–December 2017	January–December 2018	January–December 2019
Industrial accident frequency rate	0.34	0	0
Industrial accident severity rate	0.001	0	0

Frequency rate: Number of fatalities and injuries resulting from industrial accidents per one million actual working hours. An indicator of the frequency of an industrial accident.

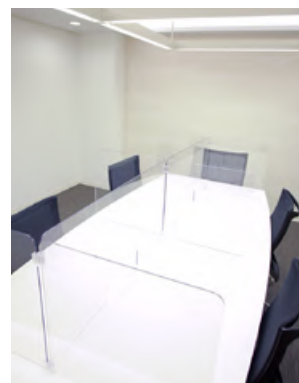
Severity rate: Total number of lost workdays per 1,000 actual working hours. An indicator of the severity of an industrial accident.

Responses to Disasters, Infection, etc.

Nichi-Iko has formulated a Business Continuity Plan (BCP) to prepare for every type of disaster and constantly collect new information and review the plan as needed to ensure that the optimal BCP is maintained at all times. We have also deployed a safety verification system and conduct regular safety verification training. In the event of an actual earthquake or other disaster, we have built a mechanism that uses the safety verification system and our emergency contact network to confirm the status of our employees, their families and their homes, and our plants and offices, to provide flash reports to upper management, and to implement countermeasures as necessary. The Company has also deployed stockpiles of emergency goods at all business sites to prepare for a potential disaster.

To respond to COVID-19, the Company promptly convened an Emergency Countermeasures Committee, investigated flexible responses tailored to the changing conditions, and implemented a variety of countermeasures.

Responses to COVID-19



- Thorough practicing of social distancing including separation of work locations
- Introduction of thermography at the headquarters and plants and installation of ozone generators in each room of business sites
- Installation of acrylic panels to prevent dispersion of droplets in offices, conference room, meeting rooms, etc.
- Provision of hand sanitizer at various locations in business sites and distribution to all employees
- Curtailment of group meeting and promotion of the introduction of digital tools

5S Activities

Nichi-Iko actively undertakes 5S (sort, set in order, shine, standardize, and sustain) activities. Achieving high quality and eliminating waste are the pillars of the workplace, and their significance is in promoting improvement of the workplace by implementing measures, creating an environment where employees can work more efficiently, and creating more added value in work.

The Company appoints 5S promotion personnel in all departments, uses 5S check sheets, and receives reports to confirm the status in all departments and at all sites and promote implementation.

Compliance Promotion Structures

At Nichi-Iko, the President and CEO oversees compliance, and rigorous compliance is practiced throughout in all Group companies as a precondition for all business activities.

The Company established the Nichi-Iko Group Charter of Corporate Conduct, respect human rights, whether in Japan or other countries, comply in good faith with laws and regulations, international rules, principles of good faith, and internal rules, and act with high ethical standards and good sense as its underlying principle.

The Company also established the Standards of Conduct for Officers and Employees of the Nichi-Iko Group and the Nichi-Iko Group Compliance Regulations. These set forth standards of conduct for officers and employees to act in accordance with laws, regulations, and the articles of incorporation.

With the aim of engaging in fair and good-faith management in compliance with laws and regulations, the Company established as a management structure the Compliance Committee chaired by the President and CEO and with directors, the heads of each division, and others as members. The Committee identifies and analyzes cross-sectional compliance issues within the Nichi-Iko Group and implements countermeasures to establish and maintain compliance structures.

Compliance Initiatives

To instill an awareness of compliance in the Nichi-Iko Group, the Group prepared and distributed to all officers and employee a handbook that includes the Mission Statement, "Our Pledge of Trust and Confidence—Nichi-Iko Group Quality Policy," the Nichi-Iko Group Charter of Corporate Conduct, the Standards of Conduct for Officers and Employees of the Nichi-Iko Group, and other information.

The Company also conducts annual compliance training for officers and employees, periodically issues materials of compliance education, and takes other measures to raise awareness of compliance.



Internal Reporting Systems

Nichi-Iko established points of contact for internal reports at the Compliance Office and an external law firm. The Company strives to prevent and correct conduct in violation of laws and regulations by organizations or individuals within the Nichi-Iko Group by accepting reports and consultations from employees and others and responding appropriately.

Number of Reports (Including Consultations)

Category	FY2018	FY2019	FY2020 (April to September)
Number	1	2	2

Measures to Eliminate Anti-social Forces

Based on the Guidelines for Companies to Prevent Damage from Anti-social Forces, Nichi-Iko has established Rules for

Dealing with Anti-social Forces and works to ensure familiarity with these rules company-wide.

Measures for Fair Trade and Appropriate Provision of Sales Information

The Nichi-Iko Group established the Nichi-Iko Code of Practice (COP) covering all interactions by officers and employees with researchers, medical professionals, patient organizations, distributors, and others based on the International Federation of Pharmaceutical Manufacturers & Associations COP and the Japan Generic Medicines Association COP. The Company has informed all officers and employees about the COP including detailed rules regarding lecture fees, manuscript writing fees, and other matters.

The Company also participates in the Fair Trade Council of the Ethical Pharmaceutical Drugs Marketing Industry as an operating committee corporate member and engages in exchanges of information with other companies and informs Group officers and employees regarding revision and operation of the Council's Fair Competition Code, its commentaries, and so on.

In accordance with enforcement of the Guidelines for Prescription Drug Marketing Information Provision Activities, the Company established an oversight department to monitor information provision activities and to examine and provide oversight and guidance on materials used. The Company strives to conduct proper sales information provision activities by periodically reporting to the Examination and Supervision Committee, which includes outside members, obtaining advice, and taking other measures. In conjunction with this, the Company established complaint desk, and in cases where information on improper information provision activities is received from outside, the facts are confirmed and corrective action is taken.

Transparency in Corporate Activities and Relationships with Medical Institutions

Close cooperation with medical institutions and medical professions is essential for the Nichi-Iko Group, and the Group believes that it is important to obtain broad understanding of the fact that the Group undertakes corporate activities based on high ethical standards by ensuring transparency.

The Nichi-Iko Group complies with the Transparency Guideline for the Relation between Corporate Activities and Medical Institutions of the Japan Generic Medicines Association. The Company adopted the Guidelines on Transparency based on a full understanding of, and reflecting, the intent and objectives of the Clinical Trials Act, which came into effect in April 2018. The Guidelines are posted on the Company's website as conduct standards for the Nichi-Iko Group. In accordance with the Guidelines, each fiscal year the Company discloses on its website and other media information on payments and the provision of funds to medical institutions and others (conflict of interest information) following the financial settlement for the relevant fiscal year.

Society | Connecting with Communities

Coexisting with communities, supporting a brighter future for children, and contributing to creating a healthier, more abundant society

Each employee thinks about what he or she can do to extend people's healthy life spans, normalize increases in healthcare costs, and support a brighter future for children, and as "ONE NICHI-IKO" that has awareness and the ability to take action, Nichi-Iko will work to remain a generic pharmaceutical company that serves with compassion patients suffering from illnesses and to contribute to the sustainable development of society.

Open Innovation "University of Toyama Innovation in Medicine"

As part of its CSR activities, Nichi-Iko supports university research and educational activities. The Company believes that through such support, the development of outstanding human resources and the creation of innovative research results at universities will lead to broad social development.

The Company donated an endowed lecture in Drug Formulation Design at the University of Toyama (for the five years from April 2015 to March 2020) and donated to the University of Toyama Immunobiology Lecture Fund (from April 2007 to March 2019).

The endowed lecture in drug formulation design will be continued for an additional five years starting in April 2020.

At the Faculty of Pharmacy and Pharmaceutical Sciences, University of Toyama, these funds are used to improve the level of education and research in formulation technology; to further advance the level of formulation technology among pharmaceutical companies in Toyama Prefecture; and to dramatically improve the level of knowledge and technology regarding drug formulation among graduates of the University of Toyama.

Provision of Drugs to Specified Clinical Research

In August 2019, Nichi-Iko provided Carboplatin Injection 450 mg "Nichi-Iko" free of charge for clinical research on triple negative breast cancer being conducted at the Breast and Endocrine Surgery Department of Kobe University Hospital.

Triple negative breast cancer accounts for about 10% to 15% of all breast cancers, often occurs in young patients, and exhibits high rates of malignancy. Hormone therapy and anti-HER2 therapy are not expected to be effective, and only anti-cancer drugs are selected from the initial stages. However, recurrence rates are high in patients that do not respect to anti-cancer drugs, and the likelihood of death from

metastasis remains high. As a result, the most promising therapy is to treat the patient with anti-cancer drugs before or after surgery to reduce recurrence, and there are high expectations for specified clinical research involving post-operative administration of Carboplatin.



A certificate of appreciation from the Fukuro no Kai, a triple negative breast cancer patient's organization

Support for The Eye mate Inc.

As part of our social contribution program, since the 40th anniversary of our founding in July 2005, we have



continuously supported the guide dog training program run by The Eye mate Inc. We positioned it as an anniversary program after carefully

considering what we could do for those with physical disabilities that cannot be overcome with drugs.

Specifically, the Company placed donation boxes at the Nichi-Iko headquarters, the Tokyo headquarters, plants, branches, and Group companies. Medical institutions that endorse the Company's purpose have also installed donation boxes.

Support for Music and Sports

Nichi-Iko has been a special sponsor of Taro Hakase's concert tour since 2012, the year following this world-renowned violinist's composition of "WITH ONE WISH" shortly after the Great East Japan Earthquake, to encourage the victims of the disaster with a theme of Nichi-Iko leaping into the future, supporting them with its creativity. "WITH ONE WISH" has been adopted as the Company song.

Soccer coach Yu Nakajima (holder of an official C-class license from the Japan Football Association), with whom the Company has a contract, provides soccer instruction to children throughout Toyama Prefecture.

This program was postponed in 2020 due to the COVID-19 pandemic, but the Company supported the Icchan Relay Marathon, Toyama Marathon, and other events. The Company also held the Nichi-Iko Boys/Girls PK Tournament and other programs, and continue to actively support sports.



The 2019 Icchan Relay Marathon (June 2019)



The 2019 Toyama Marathon (October 2019)



The Nichi-Iko Boys/Girls PK Tournament (August 2019)

Partnership Agreements with Local Governments

As a company involved in people's health and lives, the Nichi-Iko Group actively enters into partnership agreements with local governments and seeks with the objective of engaging in social contribution activities that it is able to do precisely because of its status as a pharmaceutical company. To date, the Group has concluded agreements with 22 local governments in nine prefectures (as of December 2020).

The Group provides the knowledge and expertise that it has gained as a generic pharmaceutical company that serves with compassion patients and their families to support the health of individuals, prevent disease, avoid serious illness, and otherwise contribute to the development of healthy local communities.

Specific measures include courses for local residents on preventing infection, information concerning proper handwashing and disinfection, and how to take drugs conducted at various facilities. In conjunction with these programs, the Group also donated Pure Hand gel sanitizer.



Mascots collected from partner communities



An exercise class for seniors Himi City



A course of preventing infection by washing and disinfecting the hands held in Namerikawa City

Central Toyama City and the Tateyama Mountain Range, a series of 3,000-meter range peaks

Environmental Policy and Management



Nichi-Iko's Approach to the Environment

Nichi-Iko established an Environmental Management Committee (chaired by the director in charge of CSR and ESG) to undertake voluntary environmental preservation measures, set environmental policies and targets, and take action to achieve them.

In accordance with the principles of the Nichi-Iko Group Charter of Corporate Conduct and the Standards of Conduct for Officers and Employees of the Nichi-Iko Group, the Company actively takes measures to conserve resources and reduce environmental burdens resulting from business activities through the practice of environmental management. By improving the E (environmental aspects) of ESG through these efforts, the Company is promoting the Sustainable Development Goals (SDGs) and reinforcing its sustainability.

In addition, the Company has established environmental management systems compliant with the ISO 14001 standard at its manufacturing sites in Japan, made a self-declaration of conformance* in June 2017, and has maintained compliant since then.

* The process of building an environmental management system by one's own organization in accordance with the official method stated in the ISO 14001 standard, auditing it to verify compliance with the international standards of ISO on the Company's own responsibility, and declaring compliance.



PLAN: Formulating Plans

- Environmental aspects
- Duty of compliance
- Targets, action plan

CHECK: Inspection and Corrective Action

- Monitoring, measurement, analysis, and assessment
- Nonconformities and corrective action
- Recordkeeping
- Internal audits

DO: Implementation and Operation

- Resources, competencies, education and training, and awareness
- Communication
- Documentation management
- Operation management
- Preparation for and response to emergencies

ACT: Management Review

- Periodic review of environmental activities
- Progress management of review items

Environmental Principles

Nichi-Iko is aware of the importance of environmental preservation on the community and global scale, and the Company established the following guidelines to pursue the formation of a society in harmony with the environment in all of its activities related to the manufacture of its drugs.

Code of Conduct

- (1) We will strive to maintain and improve healthy environments, prevent contamination, and preserve the environments at our business sites through our production and environmental activities.

- (2) We will set environmental targets based on (i) to (iv) below and take action to achieve them

- (i) We will properly manage the chemical substances we use.
- (ii) We will reduce our environmental impacts on the air and water quality.
- (iii) We will promote the 3Rs (reduce, reuse, recycle) to reduce waste subject to final disposal.
- (iv) We will promote the conservation of resources and energy.

- (3) We will fulfill our duty to comply with environmental laws and regulations and respect related social demands.

- (4) We will continuously improve EMS* in order to enhance environmental performance

- We will maintain this policy as documented information.
- We will convey this policy to employees at our business sites and all persons who work at those business sites.
- We will make this policy available to all interested persons.

* Environmental Management System

Climate Change (Reduction in CO₂ Emissions)

Fuel Switched from Kerosene to LNG

The fuel used at the Toyama Plant 1 will be switched from kerosene to more environmentally friendly LNG. In conjunction with this change, the existing on-site kerosene boilers will be switched to high-efficiency gas boilers. Preparations are underway to complete construction and start operation in the fiscal year ending March 31, 2021.

In addition, Nichi-Iko plans to promote the use of renewable energy (see section below), and in total, the Company is seeking to reduce CO₂ emissions from the Toyama Plant 1, a key Nichi-Iko plant, by approximately 30%.



A total of 18 gas boilers will be installed

LNG storage tanks
(Two tanks with capacity of 100 kL each)

Measures for the Rationalization of Energy Use

In addition to these measures at the Toyama Plant 1, the Company is taking energy-conservation measures that contribute to the rationalization of energy use at other sites in Japan including improving facility operation and updating facilities to the latest versions.

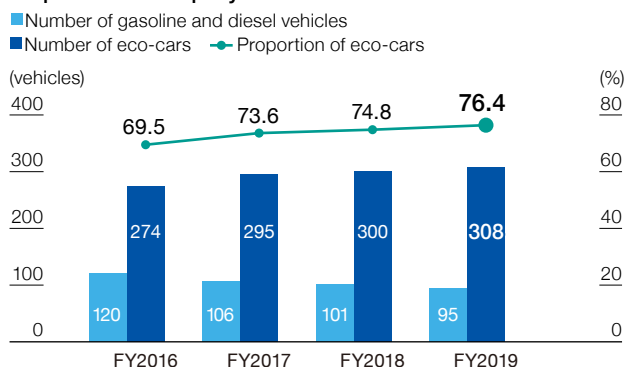


Toyama Plant 1

Introduction of Eco-cars

The Company is introducing hybrid vehicles, which have outstanding fuel efficiency, for use as commercial vehicles. In the future, the Company plans to introduce electric vehicles, which do not emit any CO₂ during operation.

Proportion of Company-owned Eco-cars



Renewable Energy

Purchase of CO₂-free Electric Power

From the perspective of preventing global warming, Nichi-Iko plans to start using electricity derived from renewable energy sources (hydroelectric power) that do not emit CO₂ during power generation at the Toyama Plant 1 starting in April 2021.

Biodiversity

Beautification Activities

Nichi-Iko conducts periodic beautification activities in the vicinity of plants and strive to preserve local environments.

Green Purchasing of Supplies (Stationery, etc.)

Green purchasing refers to the purchase of goods with small environmental impact from businesses that endeavored to minimize their environmental impact while considering the need to purchase those goods. The Company promotes green purchasing activities for supplies used internally (stationery and other goods).

- **Purchasing results in the fiscal year ended March 31, 2020:** Approximately 13 million yen



Status of Beautification Activities

Activities are conducted every month as a part of ISO environmental programs at the Toyama Plant 1 (shown in the photo), Shizuoka Plant, and other sites.

Environmental Initiatives

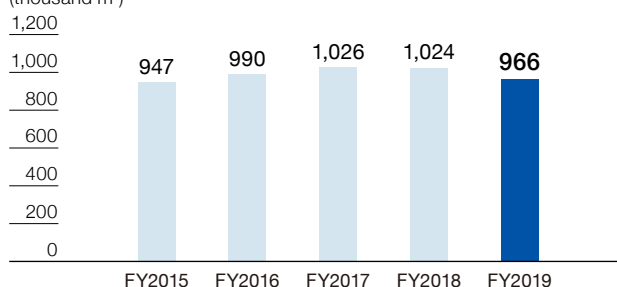
Water Resources

Nichi-Iko takes in surface water, industrial water, and subterranean water for use in business activities at manufacturing plants. Water is a shared, precious community resource, and it must be used effectively. The Company is working to reuse water resources and reduce the amount of water used through measures such as reuse of thermal water discharges released from production processes and recirculation of cooling water.

The Company is currently constructing new manufacturing buildings and expanding facilities at multiple plants, and expects that water resource input volumes will increase in conjunction with the operation of those facilities. To address this, the Company will work to reuse water resources and reduce the amount of water used by reusing thermal water discharges released in production processes, recirculating cooling water, and other measures.

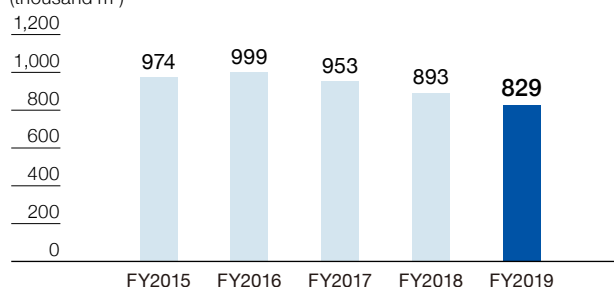
Water Resource Input

(thousand m³)



Total Wastewater

(thousand m³)



Measures at the Aichi Plant

Construction of a System for Reuse of Thermal Water Discharges (Use in Boiler Water Supply System)

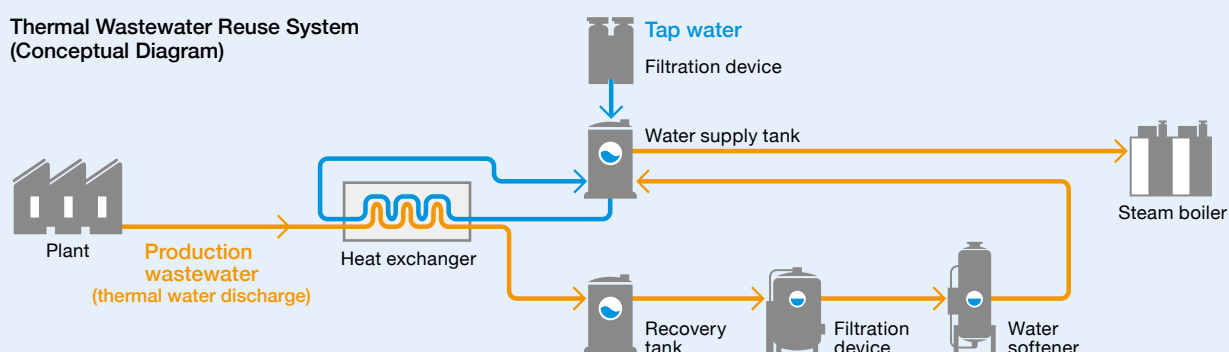
At the Aichi Plant, Nichi-Iko plans to build a system that will make use of the thermal energy in high-temperature water discharges released from production processes to heat boiler supply water. This measure is expected to reduce fuel consumption and CO₂ emissions.

In addition, the system will purify production wastewater and connect to on-site supply systems for reuse, and not only will recovery and use of thermal energy be possible, the water resource input volume will decrease. The Company is currently making preparations with the aim of completing construction and starting operation in the fiscal year ending March 31, 2021.



Aichi Plant

Thermal Wastewater Reuse System (Conceptual Diagram)

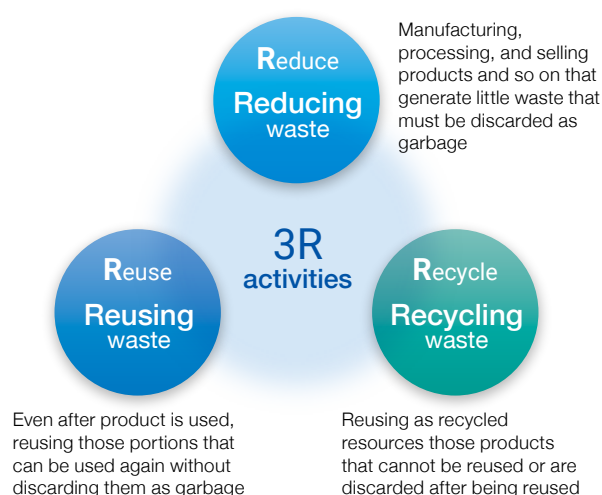


Waste / Recycling

3R Activities for Waste

Nichi-Iko conducts 3R activities to address the waste generated in its business activities.

3R is derived from the initial letters of reduce, reuse, and recycle. The meanings are described below.



3R activities are measures intended to minimize garbage as much as possible, reduce adverse environmental impacts from incineration or landfill disposal of garbage as much as possible, and create a recycling-oriented society by effectively and repeatedly using the earth's limited resources through the three Rs described above.

At manufacturing plants, the Company is also working to reduce waste disposal costs through recycling in conjunction with the sale for value of plastic waste (raw material containers and so on) and recovering and recycling glass bottles (reagent bottles).



Raw material containers that can be recycled

Confirmation of Transportation and Processing of Waste

The Company periodically confirms the status of compliance with laws and regulations, contractual

performance, acquisitions of permits and approvals, and actual disposal conditions by waste carriers, processing companies, and final disposal companies with which the Company is already conducting business by means of documents and on-site visits. In addition, when the Company starts business with new service providers, it performs similar confirmations.



Confirming processing at a processing site



Waste material after compaction (styrene form)

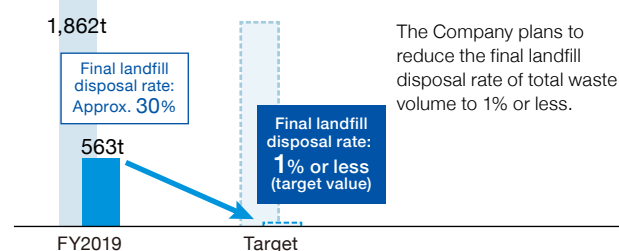
Zero Emissions

In the fiscal year ended March 31, 2020, Nichi-Iko plants generated 1,862 tons of waste, of which 563 tons was finally disposed of in landfills. Thus, the final landfill disposal rate* was approximately 30%. The Company defines zero emissions as a final landfill disposal rate of 1% or less and has set a new target of reducing the final landfill disposal rate of all manufacturing plants to 1% or less. Diligent measures are currently underway at each manufacturing plant to recycle waste with the objective of reducing environmental impact.

* Final landfill disposal rate = (Final landfill general and industrial waste disposal volume) ÷ (Total waste volume) × 100

Zero Emissions Target

■ Total waste volume ■ Final landfill waste disposal volume



The Company plans to reduce the final landfill disposal rate of total waste volume to 1% or less.

Main types of waste to be recycled

Waste plastic, waste glass, sludge

Measures at the Shizuoka Plant | Zero Emissions Achieved Ahead of Other Plants

At the Shizuoka Plant, advances were made in waste recycling and zero emissions was achieved ahead of all other plants (result in the fiscal year ended March 31, 2020: 0.23%). In the future, measures undertaken at the Shizuoka Plant will be deployed at other plants to promote recycling throughout the Company.

Going forward, the Company will promote recycling, strive to reuse waste, and conduct comprehensive management of waste with the aim of achieving a recycling-oriented society.



Shizuoka Plant

Environmental Initiatives

Chemical Substances

Nichi-Iko appropriately manages specified chemical substances used in business activities in compliance with the PRTR system*.

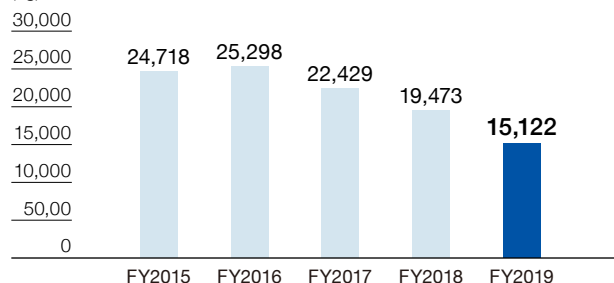
Responses to the PRTR system in the fiscal year ended March 31, 2020 included reporting on the volumes of specified chemical substances transferred and released at the Toyama Plant 1.

- **Subject substance:** Acetonitrile
- **Volume released in the fiscal year ended March 31, 2020:** 6,082 kg

The Company will continue its efforts to manage volumes handle and released in the future.

* The PRTR system: Under this system, businesses provide notice to the national government of the amounts of chemical substances suspected of being harmful that are released or transferred out of business sites, and the national government tabulates and publishes the release and transfer volume data.

Total Specified Chemical Substance Releases and Transfers (kg)

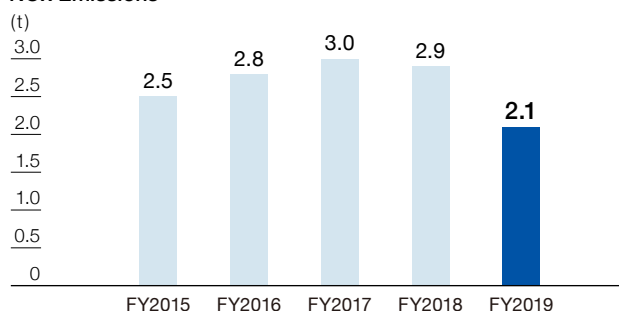


Atmospheric Pollutants

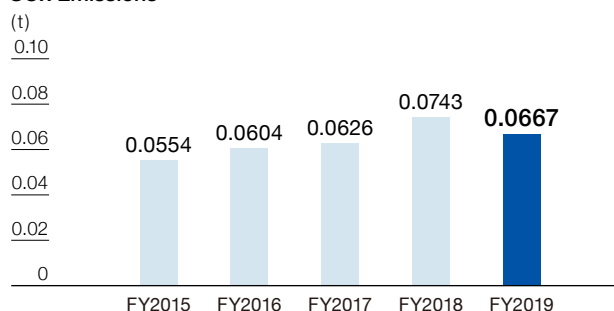
Nichi-Iko takes measures at manufacturing plants to maintain gas emissions from the stable operation of boilers to within environmental standards criteria and periodically take gas measurements to confirm that the environmental standards are satisfied.

With the switch from kerosene, which is currently in use, to clean LNG at the Toyama Plant 1, reductions in emissions of NOx (nitrous oxides) and SOx (sulfur oxides) will be reduced.

NOx Emissions



SOx Emissions



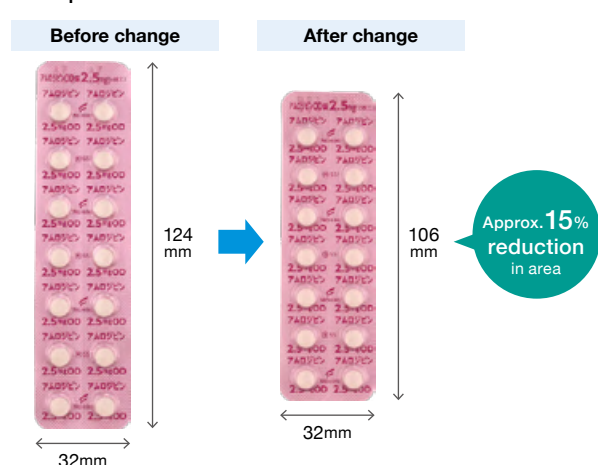
Measures for Environment-conscious Products

In the case of formulations packaged in PTP, Nichi-Iko is working to effectively use resources and reduce waste PTP sheets by reducing the sizes of the sheets and making them thinner. The Company is currently adopting the smaller and thinner PTP sheets in stages for those newly-released formulations packaged in PTP for which they are appropriate.

The Company will continue to adopt the sheets for newly-released products in the future and are looking into adoption for previously-released products as well.

The Company is also looking into the use of environment-conscious materials in the packaging and containers of its products with the aim of reducing environmental burdens.

Example of Smaller PTP Sheet Size



Achievements of Creating Value

- Financial Summary
- Consolidated Financial Statements

Financial Summary

	Nov. 2010	Nov. 2011	Mar. 2012	Mar. 2013
Financial Highlights				
Performance (actual results on a consolidated basis)				
Revenue	64,352	77,740	26,998	93,926
(Of which, the Nichi-Iko Group ^{*1})				
(Of which, the Sagent Group)				
Operating profit	7,097	7,492	2,139	8,229
(Of which, the Nichi-Iko Group ^{*1})				
(Of which, the Sagent Group)				
Core operating profit				
(Of which, the Nichi-Iko Group ^{*1})				
(Of which, the Sagent Group)				
Profit attributable to owners of parent	3,865	3,908	1,330	5,129
Financial Position				
Total assets	65,575	82,786	88,455	102,921
Net assets	26,099	44,593	45,528	48,810
Cash flow				
Cash flow from operating activities	2,747	1,371	3,627	9,770
Cash flow from investing activities	-5,409	-9,504	-1,594	-7,192
Cash flow from financing activities	2,826	10,645	-126	-3,294
Financial and management indices				
Amount of capital investment	4,079	5,318	1,666	10,709
Amount of R&D investment	2,006	2,065	783	3,250
Depreciation expenses	2,857	4,201	1,458	4,592
Net D/E ratio (multiple)	0.66	0.27	0.29	0.30
Ratio of total equity attributable to owners of parent	39.8%	53.9%	51.5%	47.4%
Return on equity (ROE) attributable to owners of parent	17.2%	11.1%	3.0%	10.9%
Dividend payout ratio	26.1%	31.5%	32.5%	25.0%
Total shareholder return (TSR)	124.1%	75.4%	79.8%	94.5%
Stock price at end of period (yen)	2,930	1,724	1,819	2,140
Per share information				
Basic earnings per share (EPS) (yen)	122.50	101.54	32.92	128.14
Per share equity attributable to owners of parent (BPS) (yen)	805.62	1,123.82	1,144.65	1,236.93
Dividend per share (yen)	32.00	32.00	10.70	32.00

* JGAAP applied through the fiscal year ended March 31, 2017; IFRS applied thereafter.

*1 The Nichi-Iko Group excluding the Sagent Group (consolidated companies of Sagent) from its consolidated basis.

(million yen)

JGAAP				IFRS		
Mar. 2014	Mar. 2015	Mar. 2016	Mar. 2017	Mar. 2018	Mar. 2019	Mar. 2020
103,622	127,021	143,513	163,372	164,717	166,592	190,076
			151,224	128,659	131,076	154,912
			12,148	36,058	35,515	35,163
7,383	9,619	12,910	8,554	10,301	8,223	2,873
			8,181	12,035	11,370	3,780
			372	-1,733	-3,147	-907
				14,368	13,320	8,020
				12,074	11,745	6,980
				2,294	1,575	1,040
4,588	6,592	11,031	4,788	8,070	6,864	5,133
129,130	139,834	161,128	270,890	278,364	306,838	336,819
66,195	74,487	82,597	87,580	87,542	116,323	117,170
5,546	21,179	7,097	3,951	18,925	23,811	18,450
-9,826	-14,647	-3,485	-81,754	-15,896	-24,983	-18,228
20,676	-14,146	10,626	64,620	3,206	24,803	1,002
4,586	5,949	9,880	11,076	12,705	5,053	8,405
4,441	4,984	4,874	7,263	9,045	10,841	13,743
5,797	4,784	4,913	6,591	8,659	9,401	11,871
0.12	0.05	0.03	1.13	1.21	0.76	0.82
51.2%	53.2%	50.4%	32.2%	31.4%	37.9%	34.4%
8.0%	9.4%	14.1%	5.6%	9.5%	6.7%	4.4%
27.0%	24.1%	16.3%	35.7%	21.0%	26.0%	37.3%
72.8%	122.8%	116.9%	82.3%	81.2%	73.8%	73.4%
1,590	2,768	2,596	1,731	1,675	1,468	1,427
104.75	110.26	184.45	84.09	143.19	115.46	80.42
1,112.19	1,246.36	1,377.53	1,552.67	1,550.65	1,825.00	1,811.50
28.30	26.60	30.00	30.00	30.00	30.00	30.00

Consolidated Financial Statements

Consolidated Statement of Financial Position

(million yen)

		Prior consolidated fiscal year (March 31, 2019)	Current consolidated fiscal year (March 31, 2020)
Assets			
Current Assets	Cash and cash equivalents	42,093	42,944
	Trade and other receivables	30,035	39,923
	Inventories	66,783	78,127
	Income taxes receivable	72	—
	Other financial assets	447	425
	Other current assets	3,290	3,287
	Total current assets	142,722	164,708
Non-current Assets	Property, plant and equipment	55,710	59,201
	Goodwill	42,892	44,322
	Intangible assets	46,721	56,607
	Investments accounted for using equity method	12,993	2,066
	Other financial assets	5,724	7,925
	Deferred tax assets	9	10
	Other non-current assets	64	1,975
	Total non-current assets	164,115	172,110
Total Assets		306,838	336,819

(million yen)

		Prior consolidated fiscal year (March 31, 2019)	Current consolidated fiscal year (March 31, 2020)
Liabilities and Equity			
Liabilities	Current liabilities		
	Trade and other payables	44,172	61,750
	Borrowings	37,435	46,747
	Other financial liabilities	956	1,722
	Income taxes payable	74	214
	Refund liabilities	2,196	3,270
	Contract liabilities	116	116
	Other current liabilities	6,884	8,868
	Total current liabilities	91,837	122,690
	Non-current liabilities		
	Borrowings	90,739	87,045
	Other financial liabilities	1,589	2,257
	Retirement benefit liability	173	945
	Provisions	57	81
	Refund liabilities	75	95
	Contract liabilities	865	748
	Deferred tax liabilities	3,329	4,521
	Other non-current liabilities	1,847	1,262
	Total non-current liabilities	98,677	96,958
	Total liabilities	190,514	219,648
Equity	Share capital	23,360	23,360
	Capital surplus	21,896	21,896
	Other equity financial instruments	9,918	9,918
	Treasury shares	-2,893	-2,562
	Retained earnings	55,016	57,365
	Other components of equity	9,025	5,848
	Total equity attributable to owners of parent	116,323	115,826
	Non-controlling interests	0	1,343
	Total equity	116,323	117,170
Total Liabilities and Equity		306,838	336,819

Consolidated Financial Statements

Consolidated Statement of Income

(million yen)

	Prior consolidated fiscal year (April 1, 2018 to March 31, 2019)	Current consolidated fiscal year (April 1, 2019 to March 31, 2020)
Revenue	166,592	190,076
Cost of sales	133,434	152,756
Gross profit	33,157	37,319
Selling, general and administrative expenses	22,504	25,614
R&D expenses	3,503	4,261
Other operating profit	1,528	303
Other operating expenses	455	4,873
Operating profit	8,223	2,873
Finance income	192	111
Finance expenses	890	1,809
Other profit	—	6,426
Other expenses	—	185
Gain (loss) on investments accounted for using equity method	1,377	-19
Profit before tax	8,903	7,396
Income tax expense	2,039	2,479
Profit	6,864	4,917
Profit attributable to:		
Owners of parent	6,864	5,133
Non-controlling interests	0	-216
Profit	6,864	4,917
Earnings per share		
Basic earnings per share (yen)	115.46	80.42
Diluted earnings per share (yen)	114.04	80.14

Consolidated Statement of Comprehensive Income

(million yen)

	Prior consolidated fiscal year (April 1, 2018 to March 31, 2019)	Current consolidated fiscal year (April 1, 2019 to March 31, 2020)
Profit	6,864	4,917
Other comprehensive income		
Items that will not be reclassified to gain or loss		
Financial assets measured at fair value through other comprehensive income	537	-1,010
Re-measurement of defined benefit plans	162	-419
Share of other comprehensive income of investments accounted for using equity method	-350	-11
Total of items that will not be reclassified to gain or loss	349	-1,440
Items that may be reclassified to gain or loss		
Exchange differences on translation of foreign operations	2,990	-1,254
Share of other comprehensive income of investments accounted for using equity method	-71	-53
Total of items that may be reclassified to gain or loss	2,919	-1,307
Other comprehensive income (net of tax)	3,268	-2,748
Comprehensive income	10,132	2,169
Comprehensive income attributable to:		
Owners of parent	10,132	1,664
Non-controlling interests	0	504
Comprehensive income	10,132	2,169

Consolidated Statement of Cash Flows

(million yen)

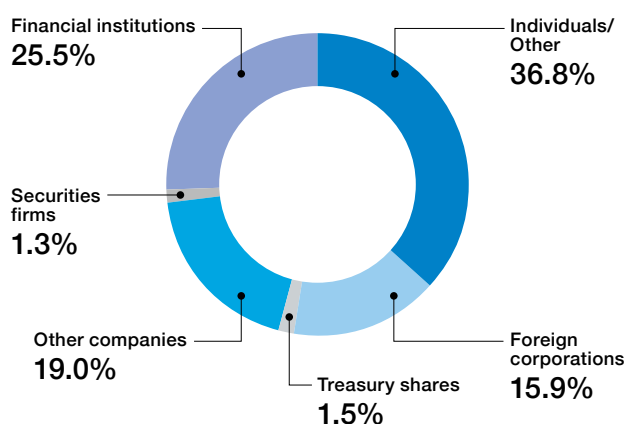
		Prior consolidated fiscal year (April 1, 2018 to March 31, 2019)	Current consolidated fiscal year (April 1, 2019 to March 31, 2020)
Cash flow from operating activities	Profit before tax	8,903	7,396
	Depreciation and amortization	9,401	11,871
	Impairment loss	4,730	1,961
	Loss (gain) on sale and retirement of property, plant, and equipment and intangible assets	108	1,163
	Interest and dividend income	-56	-111
	Interest expenses	650	677
	Share of loss (gain) of investments accounted for using equity method	-1,377	19
	Loss (gain) on sale of shares of affiliates	—	-3,611
	Loss (gain) on valuation of investment securities	—	-2,389
	Decrease (increase) in trade and other receivables	1,599	1,800
	Decrease (increase) in inventories	8,085	-5,821
	Increase (decrease) in trade and other payables	-3,837	6,602
	Increase (decrease) in provisions	-1,042	982
	Other	-363	-586
	Subtotal	26,800	19,955
	Dividends received	86	106
	Interest received	23	58
	Interest paid	-663	-671
	Income taxes paid	-2,443	-1,229
	Income tax refund	7	229
	Cash flow from operating activities	23,811	18,450
Cash flow from investing activities	Purchase of property, plant and equipment	-7,440	-6,799
	Purchase of intangible assets	-7,338	-11,750
	Purchase of investments	-998	-8
	Payments for acquisition of investments accounted for using equity method	-5,678	—
	Proceeds from sale of investments accounted for using equity method	—	3,200
	Proceeds from sale and redemption of investments	—	3,279
	Collection of loans receivable	598	112
	Proceeds from reversal of international interests	999	—
	Business transfer expenditure	-4,957	—
	Payments for acquisition of subsidiaries	—	-6,341
	Other	-168	78
	Cash flow from investing activities	-24,983	-18,228
Cash flow from financing activities	Net increase (decrease) in short-term borrowings	-2,123	7,758
	Proceeds from long-term borrowings	16,700	5,674
	Repayments of long-term borrowings	-7,920	-8,571
	Proceeds from issuance of new shares	6,724	—
	Proceeds from sale of treasury shares	4,143	225
	Repayments of finance lease obligations	-943	—
	Repayments of lease obligations	—	-1,679
	Proceeds from issuance of other equity financial instruments	9,918	—
	Dividends paid	-1,734	-1,915
	Distributions to owners of other equity financial instruments	—	-464
	Other	39	-23
	Cash flow from financing activities	24,803	1,002
Effect of exchange rate changes on cash and cash equivalents		-66	-373
Net increase (decrease) in cash and cash equivalents		23,564	850
Cash and cash equivalents at beginning of period		18,529	42,093
Cash and cash equivalents at end of period		42,093	42,944

Company Information (As of March 31, 2020)

Company Name	Nichi-Iko Pharmaceutical Co., Ltd.
Headquarters	1-6-21 Sogawa, Toyama City, Toyama Prefecture, 930-8583 Japan
Tokyo Headquarters	1-5-4 Nihonbashi-Honcho, Chuo-ku, Tokyo, 103-0023 Japan
Established	July 15, 1965
Share Capital	23,360 million yen
Affiliated Banks	The Hokuriku Bank, Ltd.; Sumitomo Mitsui Banking Corporation; Sumitomo Mitsui Trust Bank, Limited; MUFG Bank, Ltd.; Development Bank of Japan Inc.
End of Fiscal Year	March
Listing Stock Exchange	Tokyo Stock Exchange First Section
Business Activities	Manufacture, sale, import/export, etc. of drugs, quasi-drugs, and various other types of pharmaceutical products A total of 1,226 products including drugs for cardiovascular, digestive, respiratory, and central and peripheral nervous systems
Employees	1,954 (consolidated)
R&D Sites	Global Development and Quality Control Center (Namerikawa City, Toyama Prefecture)
Production Sites	Hokkaido Plant (Kitahiroshima City, Hokkaido); Yamagata Plant (Tendo City, Yamagata Prefecture); Saitama Plant (Saitama City, Saitama Prefecture); Toyama Plant 1/Toyama Plant 2 (Namerikawa City, Toyama Prefecture); Shizuoka Plant (Fuji City, Shizuoka Prefecture); Aichi Plant (Kasugai City, Aichi Prefecture); Omega/Montreal Plant (Canada); Sagent/Raleigh Plant (U.S.); SterRx/Plattsburgh Plant (U.S.)
Distribution Centers	Hokkaido Distribution Center (Kitahiroshima City, Hokkaido); Nichi-Iko Distribution Center (Namerikawa City, Toyama Prefecture); East Japan Distribution Center (Kuki City, Saitama Prefecture); West Japan Distribution Center (Kobe City, Hyogo Prefecture)
Sales Offices	Sapporo Branch; Sendai Branch; Kanto Branch; Tokyo 1st Branch; Tokyo 2nd Branch; Nagoya Branch; Keiji-Hokuriku Branch; Osaka Branch; Hiroshima Branch; Fukuoka Branch
Group Companies	<p>Japan Elmed Co., Ltd. (Toyama City, Toyama Prefecture) Yakuhan Pharmaceutical Co., Ltd. (Kitahiroshima City, Hokkaido) EMI Inc. (Osaka City, Osaka Prefecture) Nichi-Iko Osaka Co., Ltd. (Higashiosaka City, Osaka Prefecture)</p> <p>Overseas Sagent Pharmaceuticals, Inc. (Chicago, U.S.) Omega Laboratories, Ltd. (Montreal, Canada) SterRx LLC. (New York, U.S.) NIXS Corporation (Kansas City, U.S.) Nichi-Iko (Thailand) Co., Ltd. (Bangkok, Thailand)</p>

Securities code	4541
Listed stock exchange	Tokyo Stock Exchange First Section
Trading unit	100 shares
Number of authorized shares	93,500,000
Number of shares issued	65,162,652
Number of shareholders	34,690

Distribution of stock ownership by shareholder



Major Shareholders

Name	Address	Number of Shares Held (thousands)	Shareholding Ratio (%)
TAMURA Co., Ltd.	1-5-24 Sogawa, Toyama City, Toyama Prefecture	4,552	7.09
The Hokuriku Bank, Ltd.	1-2-26 Tsutsumicho-dori, Toyama City, Toyama Prefecture	2,831	4.41
The Master Trust Bank of Japan, Ltd. (Trust Account)	2-11-3 Hamamatsucho, Minato-ku, Tokyo	2,582	4.02
Japan Trustee Services Bank, Ltd. (Trust Account No. 9)	1-8-11 Harumi, Chuo-ku, Tokyo	2,499	3.89
Taku Co., Ltd.	1-5-24 Sogawa, Toyama City, Toyama Prefecture	2,122	3.31
Japan Trustee Services Bank, Ltd. (Trust Account)	1-8-11 Harumi, Chuo-ku, Tokyo	1,813	2.82
Yuichi Tamura	Toyama City, Toyama Prefecture	1,790	2.79
Nipro Corporation	3-9-3 Honjo-Nishi, Kita-ku, Osaka City, Osaka Prefecture	1,321	2.06
JPMC GOLDMAN SACHS TRUST JASDEC LENDING ACCOUNT	GOLDMAN SACHS AND CO, 180 MAIDEN LANE, 37/90TH FLOOR, NEW YORK, NY 10038 U.S.A.	1,208	1.88
Japan Trustee Services Bank, Ltd. (Trust Account No. 5)	1-8-11 Harumi, Chuo-ku, Tokyo	1,152	1.80

* Shareholding ratios are calculated after deducting treasury shares (954,517 shares).

* Taku Co., Ltd. is a wholly-owned subsidiary of TAMURA Co., Ltd.

* Of the above number of shares held, the number involving trust operations is as follows:

The Master Trust Bank of Japan, Ltd. (Trust Account) 2,582,000	Japan Trustee Services Bank, Ltd. (Trust Account) 2,499,000
Japan Trustee Services Bank, Ltd. (Trust Account) 1,813,000	Japan Trustee Services Bank, Ltd. (Trust Account No. 5) 1,152,000



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