Nichi-Iko Pharmaceutical Co., Ltd.

Nichi-Iko Group

Integrated Report

2019

Year ended March 31, 2019

Nichi-Iko Pharmaceutical Co., Ltd.

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The Nichi-Iko Group works to provide premium quality exceeding what is possible today by constantly creating new products, taking on challenges and remaining excited about our business. We will continue to evolve so that we can deliver that premium quality to patients and their families around the world.

Mission Statement

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.

Contents

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, 2018 through March 31, 2019
(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.

About Premium Quality

The Nichi-Iko Group believes that the creativity and efforts of each individual employee are important, and under the slogan "Premium Quality," all of our employees constantly work to exceed what is possible today.

At a Glance

Number of products
1,019 products
(As of March 31, 2019)

Amount of R&D investment
10.8 billion yen
(Fiscal year ended March 2019)

The leader
in domestic sales among generic drug manufacturers

Development of biosimilars
with an eye to markets in Japan, the U.S. and Europe

Stable supply system
18.5 billion tablets
(Established in the fiscal year ended March 2018)

Products used by
over 97%
of hospitals and dispensing pharmacies
(Fiscal year ended March 2019)

Characteristics of Generic Drugs
Generic drugs contain the same active ingredients as the original drugs. Because they can be developed in a shorter time and for less cost compared to original drugs, in most cases generic drugs are cheaper. Formulations can also be devised to improve ease of swallowing and other characteristics.

Market Background
- As part of Japan's efforts to control healthcare costs, policy calls for giving generic drugs an 80% share of the market by volume by September 2020, and market growth is expected.
- In principle, drug prices are revised (lowered) once every two years. Drug price revisions are scheduled for October 2019 in conjunction with a hike in the consumption tax.
- The generic drug market in the U.S. is characterized by its large scale compared to Japan and intense competition.

Offices (Japan)
- ❶ Headquarters (Toyama-shi, Toyama Prefecture)
- ❷ Tokyo Headquarters (Chuo-ku, Tokyo)

R&D Sites
- ❸ Global Development and Quality Control Center (Namerikawa-shi, Toyama Prefecture)

Production Sites
- ❹ Hokkaido Plant (Kitahiroshima-shi, Hokkaido)
- ❺ Yamagata Plant (Tendo-shi, Yamagata Prefecture)
- ❻ Saitama Plant (Saitama-shi, Saitama Prefecture)
- ❼ Shizuoka Plant (Fuji-shi, Shizuoka Prefecture)
- ❽ Aichi Plant (Kasugai-shi, Aichi Prefecture)
- ❾ Toyama Plant 1 (Namerikawa-shi, Toyama Prefecture)
- ❿ Toyama Plant 2 (Namerikawa-shi, Toyama Prefecture)

Distribution Centers
- ⓫ Hokkaido Distribution Center (Kitahiroshima-shi, Hokkaido)
- ⓬ Nichi-Iko Distribution Center (Namerikawa-shi, Toyama Prefecture)
- ⓭ East Japan Distribution Center (Kuki-shi, Saitama Prefecture)
- ⓮ West Japan Distribution Center (Kobe-shi, Hyogo Prefecture)

Sales Offices
- ⓯ Sapporo Branch (Kitahiroshima-shi, Hokkaido)
- ⓰ Sendai Branch (Sendai-shi, Miyagi Prefecture)
- ⓱ Kanto Branch (Saitama-shi, Saitama Prefecture)
- ⓲ Tokyo 1st Branch (Chuo-ku, Tokyo)
- ⓳ Tokyo 2nd Branch (Saitama-shi, Saitama Prefecture)
- ⓴ Nagoya Branch (Nagoya-shi, Aichi Prefecture)
- ㉑ Keiji-Hokuriku Branch (Kyoto-shi, Kyoto Prefecture)
- ㉒ Osaka Branch (Osaka-shi, Osaka Prefecture)
- ㉓ Hiroshima Branch (Hiroshima-shi, Hiroshima Prefecture)
- ㉔ Fukuoka Branch (Fukuoka-shi, Fukuoka Prefecture)

Domestic Group Companies
- ㉕ Elmed Co., Ltd. (Toyama-shi, Toyama Prefecture)
- ㉖ Yakuhan Pharmaceutical Co., Ltd. (Kitahiroshima-shi, Hokkaido)
- ㉗ EMI Inc. (Osaka-shi, Osaka Prefecture)
- ㉘ Nichi-Iko Osaka Co., Ltd. (Higashiosaka-shi, Osaka Prefecture)

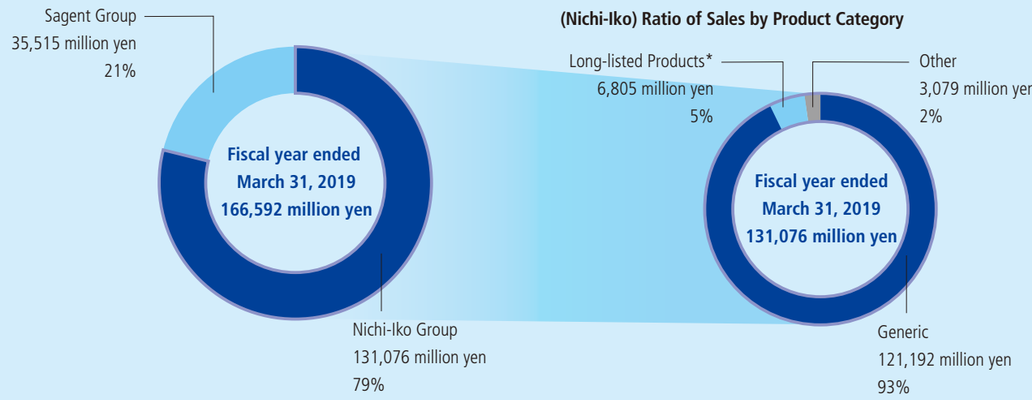
Development of the U.S. Market: Transforming the Sagent Business Model
- ☑ Infliximab BS (biosimilar) Phase III patient administration completed and data analysis underway in preparation for FDA application
- ☑ Orphan drug clinical testing (Phase II) underway in preparation for application
- ☑ Acquired FDA-certified Raleigh manufacturing site to bring production of biosimilars and generic injectables in-house.
- ☑ Omega Montreal manufacturing site acquired FDA certification (August 2019)
- ☑ Invested in SterRx, entering the compound business

Offices (Overseas)

Production Sites
- Ⓐ Omega/Montreal Plant (Montreal, Canada)
- Ⓑ Sagent/Raleigh Plant (Raleigh, U.S.)
- Ⓒ SterRx/Plattsburgh Plant (New York, U.S.)

Overseas Group Companies
- Ⓓ Sagent Pharmaceuticals, Inc. (Chicago, U.S.)
- Ⓔ Omega Laboratories, Ltd. (Montreal, Canada)
- Ⓕ SterRx (New York, U.S.)
- Ⓖ NIXS Corporation (Kansas City, U.S.)
- Ⓗ Nichi-Iko (Thailand) Co., Ltd. (Bangkok, Thailand)

Ratio of Sales by Segment



(Nichi-Iko) Ratio of Sales by Product Category

*Original drugs with generic equivalents

Action Invites Opportunity: A History of Creation and Challenges

"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."

Founding Period

Founded as a manufacturer of generic drugs.
Attempts at and withdrawal from new drug development

Growth Period

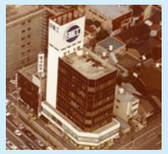
Expansion of the generic drug business through M&A and business alliances; investment in biosimilars

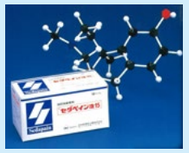
Launch of Generic Drug Manufacturing and Sales; Taking on the Challenge of New Drugs

Jul. 1965 Shiro Tamura established Nihon Iyakuhin Kogyo Co., Ltd. in Toyama City
Jun. 1967 Completed construction of plant to produce pharmaceutical tablets and powders in Toyama City
Jun. 1970 Completed construction of Namerikawa Plant in Namerikawa City
Mar. 1972 Completed construction of Research Institute on Toyama Plant premises
Sep. 1974 Completed construction of head office building in Sogawa, Toyama City
Jul. 1980 Listed on the Second Section of the Nagoya Stock Exchange
Nov. 1981 Listed on the Second Section of the Osaka Stock Exchange
Mar. 1983 Completed construction of new GLP-compliant Research Institute adjacent to the Namerikawa Plant
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

1995: Withdrawal from new drug development

May 1996 Completed construction of GMP-compliant injection plant in Namerikawa City




Feb. 2000 Yuichi Tamura appointed President and CEO
Jun. 2005 Company name changed from Nihon Iyakuhin Kogyo Co., Ltd. to Nichi-Iko Pharmaceutical Co., Ltd.
Dec. 2010 Listed on the First Section of the Tokyo Stock Exchange

Formulation of Medium-term Management Plan

Jul. 2000 1st Medium-term Management Plan, "Presence No. 1" (December 2000 through November 2003)
Jan. 2003 2nd Medium-term Management Plan, "Nexstage No. 1" (December 2003 through November 2005)
Apr. 2005 3rd Medium-term Management Plan, "Trend 43" (December 2005 through November 2007)
Jan. 2007 4th Medium-term Management Plan, "Pentagon 2009" (December 2007 through November 2009)
Jan. 2009 5th Medium-term Management Plan, "Honeycomb 2012" (December 2009 through March 2012)
Mar. 2012 6th Medium-term Management Plan, "Pyramid" (April 2012 through March 2016)
May 2016 7th Medium-term Management Plan, "Obelisk" (April 2016 through March 2019)
May 2019 8th Medium-term Management Plan, "NEXUS∞" (April 2019 through March 2022)

Nichi-Iko's Three Growth Strategies

❶ Expand Domestic Generic Drug Business

Strengthen relationships with wide-area drug wholesalers and expand business through partnerships with new drug manufacturers

(1) Strengthening of relationships with wide-area drug wholesalers
From 2000 Transfer of approval for long-listed products provides a breakthrough for enabling handling by wide-area wholesalers
From 2005 Acquisition of stock in Maruko Pharmaceutical, Nihon-Gallen, Oriental Pharmaceutical, Teikoku Medix and others

(2) Expansion of business through partnerships
From 2010 Strategic alliance with Sanofi (Transfer of sales of long-listed products, launch of Japan's first authorized generic)
From 2018 Strategic alliance with Eisai Co., Ltd.


Strategic alliance with Eisai

❷ Ensure a Stable Supply System

Use of M&A to acquire plants and expand supply capacity

From 2005 Supply capacity expanded through acquisition of plants owned by Maruko Pharmaceutical, Oriental Pharmaceutical and Teikoku Medix
Apr. 2014 Acquired Fuji Plant of Astellas Pharma Group manufacturing subsidiary and began business as the Nichi-Iko Pharma Tech Shizuoka Plant

❸ Invest in Biosimilars for Future Growth

Invested in biosimilars with the goal of early development of this growth field

Oct. 2010 Entered into a capital and business alliance with Aprogen Inc. of South Korea (development) APROGEN
Oct. 2013 Entered into a capital alliance with Binex of South Korea (manufacturing) BINEX
Aug. 2016 Made Sagent Pharmaceuticals, Inc. of the U.S. a wholly owned subsidiary (sales in the U.S.) SAGENT Pharmaceuticals
Sep. 2017 Obtained manufacturing and marketing approval in Japan for Nichi-Iko Infliximab BS for I.V. Infusion 100 mg
Feb. 2019 Sagent acquired manufacturing site for injectables
2021 Infliximab BS scheduled to go to market in the U.S.

* Fiscal year closing was November through the fiscal year ended November 2011; changed to March closing beginning with the fiscal year ended March 2012
*1 Four-month fiscal year for the period ended March 2012 due to change in fiscal year end
*2 IFRS applied beginning with the fiscal year ended March 2018

The Value Creation Process

INPUT

Financial Capital

- Cash generated by expansion of scale and ongoing cost reductions
- Overseas sales From 35.5 billion yen to 60.0 billion yen
  (Planned, for fiscal years ending March 31, 2020 through March 31, 2022)
- Efforts to reduce Company-wide costs More than 15.0 billion yen (cumulative)
  (Planned, for fiscal years ending March 31, 2020 through March 31, 2022)

Organization and Human Capital

- Cohesive organizational structure through quick decision-making
- Number of employees (consolidated) 1,573 (as of March 31, 2019)
- Structure for promoting women's participation and advancement
  Ratio of women in management (non-consolidated) From 11.5% to 15% or greater
  (Planned, for fiscal years ending March 31, 2020 through March 31, 2022)
  2 female officers (1 Independent Director, 1 Vice President)
- Employment ratio of those with disabilities From 2.2% to 2.5% or greater
  (Planned, for fiscal years ending March 31, 2020 through March 31, 2022)

Societal and Relationship Capital

- Medical facility coverage rate Hospitals 98.4% Clinics 62.5% Dispensing Pharmacies 97.3%
- Ratio of sales by sales channel
  Wholesale channel 84.4% Reseller channel 6.3% Others 9.3%
- Number of products 1,019 products (as of March 31, 2019)
- Strategic alliance with Sanofi
- Strategic alliance with Eisai

Intellectual Capital

- Amount of R&D investment
  33.0 billion yen
  (Cumulative, planned, for fiscal years ending March 31, 2020 through March 31, 2022)
- Formulation of two biosimilars
- Planned product R&D
  In Japan: 71 products
  (Planned, for fiscal years ending March 31, 2020 through March 31, 2022)
  Sagent: 16 to 24 products
  (Planned, for fiscal years ending March 31, 2020 through March 31, 2021)

Manufacturing Capital

- Supply capacity 18.5 billion tablets, the largest in Japan
- Number of production plants 7 in Japan, 3 overseas
- Amount of capital investment 19.0 billion yen
  (Cumulative, planned, for fiscal years ending March 31, 2020 through March 31, 2022)
- Percentage of APIs from multiple sources 70% of Company products
  (Planned, for fiscal years ending March 31, 2020 through March 31, 2022)

Natural Capital

- Promotion of energy savings, CO_2 countermeasures

Strategic allocation of resources ➡P15
8th Medium-term Management Plan, "NEXUS∞"

Mission Statement

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.

Value Chain

OUTPUT

Outcome:

Resolving social issues

- Stable supply of low-cost, high-quality drugs
- Reduced social security costs
- Reduced burden on patients and their families
- Efforts toward the regional community-based integrated care system
- Efforts to reduce CO_2 emissions

SUSTAINABLE DEVELOPMENT GOALS

Business Foundation

Management Structure
Corporate Governance ➡P37

Corporate Culture
People ➡P51

Quality Control
Quality ➡P49

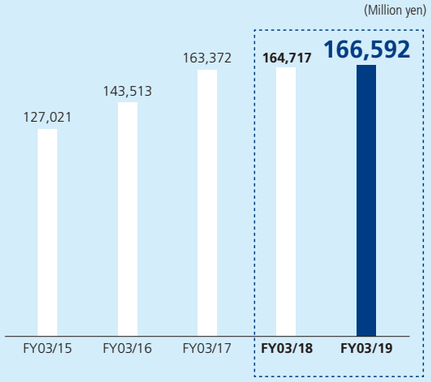
External Environment

Volume share of generic drugs in domestic market to exceed 80%	Worsening earnings environment with annual drug price revisions	Government promotion of the regional community-based integrated care system
Advancement of rapid aging in Japan	Expectations for overseas market development	Expectations for widespread use of biosimilars

Financial and Non-financial Highlights

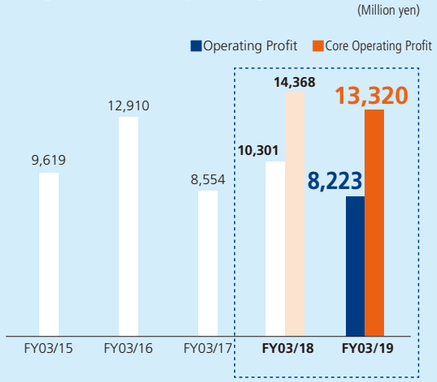
* IFRS applied starting in the fiscal year ended March 31, 2018

Revenue*



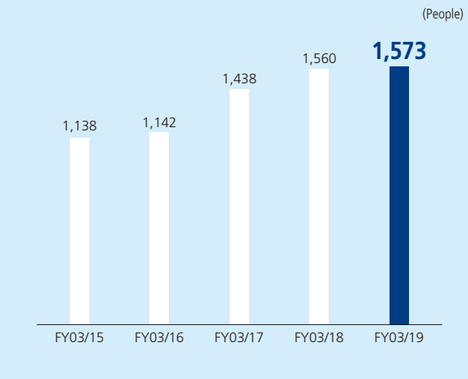
Though a drop in prices due to the April 2018 drug price revisions had an impact, an increase in domestic generic drug sales volume contributed to higher revenue.

Operating Profit/Core Operating Profit*



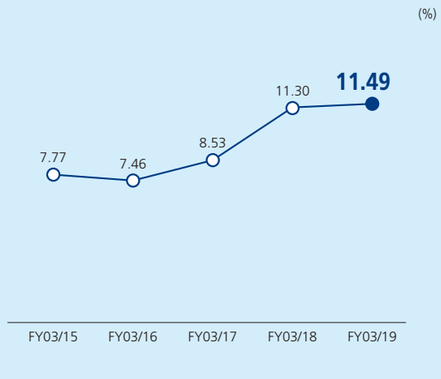
Profits were lower year on year due to the impact of drug price revisions. Due to impairment losses in the U.S., operating profit was 8.2 billion yen against core operating profit of 13.3 billion yen.

Number of Employees (Consolidated)



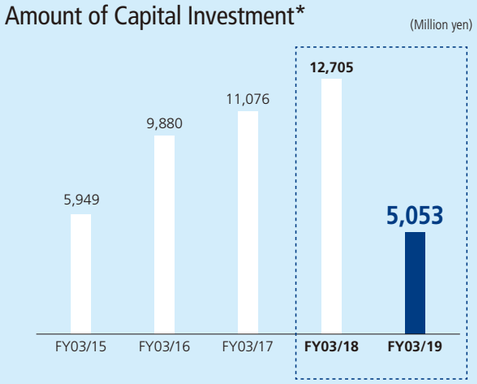
U.S. subsidiary Sagent joined the Group in the fiscal year ended March 31, 2017, bringing the number of employees to 1,573 for the fiscal year ended March 31, 2019.

Ratio of Female Managers (Non-consolidated)



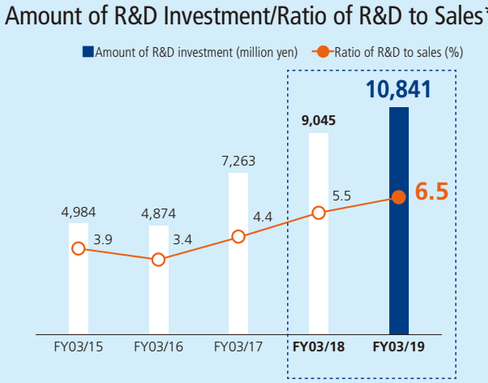
The ratio of female managers has steadily increased over the past several years. We are working to establish a workplace environment that is friendly to women to further promote the active participation of women and increase this ratio further.

Amount of Capital Investment*



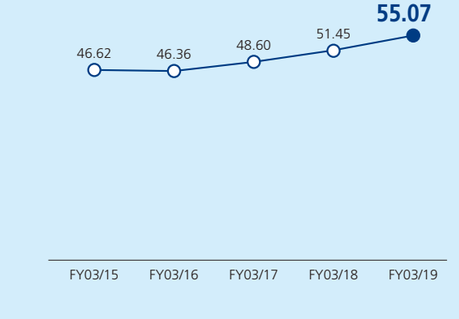
Capital investment in building an 18.5 billion tablets supply system was completed in the fiscal year ended March 31, 2018, putting in place a stable supply system to meet further growth in demand for generic drugs.

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



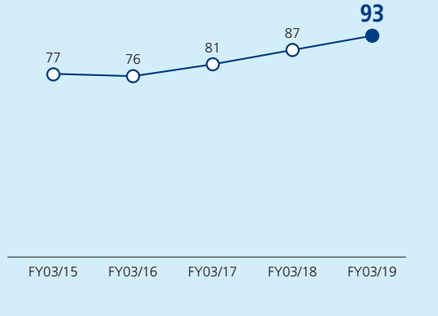
Infliximab BS in final stages of Phase III in preparation for launch in U.S. We will continue to move forward with global R&D in generic drugs and biosimilars.

Ratio of Annual Paid Leave Taken (Non-consolidated)



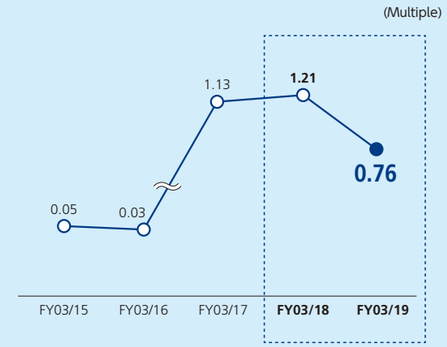
The rate of paid leave taken has risen each year, and was 55.07% in the fiscal year ended March 31, 2019. We will continue our efforts to advance work-style reforms, including taking of paid leave and reduction of overtime hours.

Post-retirement Rehiring Ratio (Non-consolidated)



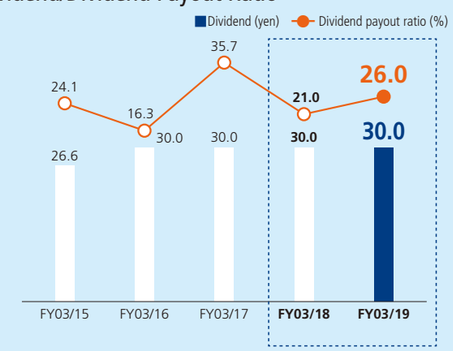
The Company has introduced a rehiring system aimed at allowing retirees with a strong desire to work to utilize their own experience and contribute to the Company. The rehiring ratio was 93% in the fiscal year ended March 31, 2019.

Net D/E Ratio*



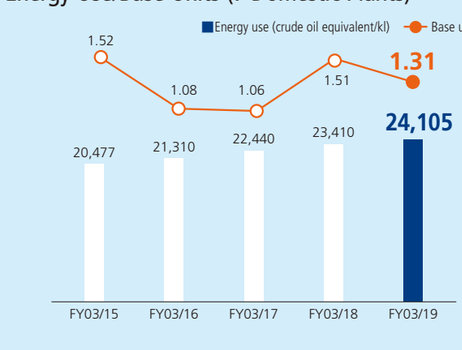
Funds raised via exercise of stock warrants, bringing the D/E ratio to 0.76 as of March 31, 2019. The Company plans to maintain a D/E ratio of about 1.0 for the period of its 8th Medium-term Management Plan.

Dividend/Dividend Payout Ratio*



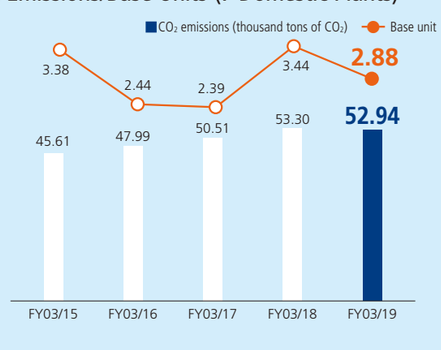
Annual per-share dividend for the fiscal year ended March 31, 2019 was set at 30 yen (a dividend payout ratio of 26.0%). A dividend payout ratio between 25-30% is planned for the period of the 8th Medium-term Management Plan.

Energy Use/Base Units (7 Domestic Plants)



With the December 2017 completion of the Obelisk Building at Toyama Plant 1, the Company saw an increase in energy use, but by working to improve productivity, we were able to contribute to a reduction in base units.

CO_2 Emissions/Base Units (7 Domestic Plants)



Efforts to improve productivity contributed to a reduction in base units.

We will contribute to society by evolving into a global comprehensive generic pharmaceutical company, working on behalf of patients worldwide and the families that support them.

President and CEO
Yuichi Tamura

The Aspirations Behind Our Mission Statement

Continue to reliably provide drugs to the patients, their families and the healthcare professionals who need them. That is the mission of a pharmaceutical company. Still, to fulfill that mission as conditions surrounding generic pharmaceutical companies change significantly requires ceaseless creativity and challenges. We continue to take the lead in these challenges, not only in product development, but in developing sales channels and in M&A, in order to deliver Nichi-Iko generic drugs to patients worldwide. This is our goal.

The Generic Drug Industry Faces a Turning Point

Founded in 1965, Nichi-Iko expanded from the manufacture and sale of generic drugs into the development of new drugs, but later shifted direction to focus exclusively on manufacturing generic drugs. Since the 2000s, thanks in part to the rising momentum behind the push to encourage the use of generic drugs, we have steadily grown in size. In the fiscal year ended March 31, 2014, we became the first generic pharmaceutical company in Japan to reach sales of 100 billion yen (JGAAP).

Business conditions for the domestic drug industry today are increasingly difficult, with the government instituting a variety of cost control policies aimed at reducing mounting healthcare costs. While the ratio of generic drug use in the drug market as a whole now approaches 80% on a volume basis, profitability in the generic drug industry is also expected to fall as a result of annual drug price revisions.

In Europe and America, the share of the amount spent on generic drugs is larger than what it currently is in Japan. Eventually, we believe Japan will also begin evaluating the impact not only of seeking to reduce healthcare costs by increasing the usage of generic drugs, but also by making changes where generics do not yet exist. In this case, it is expected that there will be a further push to switch to generic drugs that have the same efficacy. Given these circumstances, we believe that the domestic generic drug market has the potential to expand and grow further.

In other words, the domestic drug market is facing a major turning point, and what may have an even bigger impact than drug price revisions designed to maintain the universal healthcare system will be changes in patient therapeutic behavior. The current healthcare regime, based on hospital inpatient and outpatient care, will change as home-based care advances. To respond to progress in developing regional comprehensive care systems, the shape of care will also shift to one centered on internet-based home care and medication counseling. We also believe drug formularies (guidelines for using drugs that are most effective and economical for the patients) will become more widely used, partly in an effort to standardize drugs used by region. The question is how we incorporate these trends in our own products. I believe this will be a key point in the development of our business going forward.

Achievements and Issues with "Obelisk," the 7th Medium-term Management Plan

First, "ability to grow market share." The plan established a target of "15% share of the domestic market." As of the fiscal year ended March 31, 2019, that share was 11%, but with the post-merger integration of the Elmed Co., Ltd. subsidiary, it is now 14%. That share will expand further in the fiscal year ending March 31, 2020, and we expect to reach our target of 15%.

Next, "supply capacity." As a result of aggressive capital investment, including the start of operations at the new "Obelisk Building" at Toyama Plant 1, we have put in place "a structure capable of supplying our target of 18.5 billion tablets."

Finally, "development capabilities." We succeeded in "entering the U.S. and the market for biosimilars," two of the goals we set for expanding into new therapeutic areas and regions. First, through our 2016 acquisition of Sagent Pharmaceuticals, Inc., with its strength in injectables, we acquired a platform for marketing biosimilars in a new region. We also succeeded in entering a new therapeutic area with the 2017 launch in Japan of Infliximab BS, the Company's first biosimilar. These moves have enabled us to establish a foundation for the future.

8th Medium-term Management Plan "NEXUS∞"

The 8th Medium-term Management Plan is called "NEXUS∞." "NEXUS" carries the meaning of "tying together" or "connecting." This word reflects Nichi-Iko's aspirations for this medium-term plan: to respond to vastly shifting changes in business conditions by building a solid foundation for growth, collaborating globally across all areas including procurement, production, sales, and R&D, and expanding into new therapeutic areas. Our theme for "NEXUS∞," "Better than the Best" also incorporates the sense of "continuing to take on challenges in order to go beyond the status quo."

Building a value chain through global cooperation and alliances, Nichi-Iko will bring new collaborative capabilities to the table as we evolve into a global comprehensive generic pharmaceutical company.

Following is a description of the key points behind the four strategic imperatives we will employ to accomplish this.

The first strategy is to continue our deeper pursuit of business arenas (where to play). To contribute to reducing the burden on patients and their families and healthcare costs, we will work to expand our product pipeline by developing biosimilars, anticancer and other complex generic drugs. We will also work to enhance our presence in the market. To further address the development of regional comprehensive care systems, we will engage in strategic alliances with a wide range of partners, including new drug and generic pharmaceutical companies, pharmacies, wholesalers and nursing care providers, etc.

Our second strategy is to build an unshakeable business foundation by optimizing the entire value chain. "Operations" in this case refers to the entire series of processes, from raw material procurement to formulation. Consolidating dispersed operations will also deliver advantages in terms of cost. We will also utilize our procurement and production capabilities as Japan's largest generic pharmaceutical company, leveraging economies of scale to achieve further cost reductions.

As we think about operational excellence, however, it is also essential that we maintain quality and a stable supply. In 2019, a problem arose triggered by the inclusion of foreign matter in a source ingredient, leading to an outage of specific products and causing significant concern for patients and others. Based on lessons learned from this incident, we will endeavor to establish a system for ensuring even greater supply stability, working further to develop multiple channels for purchasing raw materials.

Our third strategy is to deliver a global standard of quality and competitive edge. In the U.S., this will involve a multifaceted approach to expanding the scale of our business in biosimilars, the compound business and orphan drugs, in addition to Sagent Pharmaceuticals, Inc.'s current strength in generic injectables for hospitals. In Asia, Nichi-Iko will move forward with efforts to include possible entry into the Chinese market, in addition to the four countries where our products are currently available.

As we expand our business into new countries and regions, the immediate issue will be to ensure we first obtain U.S. Food and Drug Administration (FDA) approval. While FDA standards for product approval differ significantly from those of Japan and other Asian regions, they are highly compatible with the standards of countries outside Asia, and represent a so-called "world standard." For that reason, we believe obtaining FDA approval will provide a major stepping-stone to entering markets in the U.S. and elsewhere.

Lastly, our fourth strategy is to become the most trusted life science company, driven by our ESG activities. These community-focused activities will include our ongoing contributions to society through sports, and going forward, we also plan to engage in activities unique to us as a pharmaceutical company, including those involving health and human life. For instance, we are working to provide off-patent drugs to patients battling difficult-to-cure breast cancer.

Our efforts to strengthen governance have included abolishing the practice of having Executive Vice Presidents serve concurrently as Vice Presidents. By separating responsibility for business execution, we have clarified responsibility for management issues, while building an environment that allows for cross-organizational supervision.

We also consider our various people-related policies to be an important part of our ESG activities. In addition to our efforts to facilitate people exchanges with our overseas subsidiaries and to optimize gender ratios, in 2017 we launched a program called "Koshi-juku," which is aimed at developing management personnel.

Numerical Targets Under "NEXUS∞"

Numerical targets for the fiscal year ending March 31, 2022 are based on reference figures as of the end of March 2019, and include five key performance indicators (KPIs): "Ex-Japan sales"; "cost reductions through Profit Management Plan 8 (PMP8)"; "dividend payout ratio"; "ratio of female managers"; and "multiple sourcing of APIs."

Our metric for ex-Japan sales is 1.7 times more than the reference figure, or 60 billion yen. This is based on expectation that sales in the U.S. will increase significantly, centered primarily on our expansion into biosimilars–the result of a successful three-year effort to build a business base there–and that we will gain approval in five Southeast Asian countries. This is an explicit reflection of our policy of making these efforts the driver of the Company's overseas growth.

We also aim to achieve cost reductions amounting to a cumulative 15 billion yen. We are engaged in a wide-ranging variety of cost reduction efforts, including optimizing operations through collaboration in and outside of Japan, as well as the integration of Elmed products.

We will continue to maintain our dividend payout ratio at a level between 25% and 30%.

Many women play an active role in the Company, and our goal is to raise the ratio of female managers from the current 11.5% (non-consolidated) to 15% or greater. In May 2019, we appointed the Company's first non-Japanese female Vice Presidents. This is a trend we will push going forward.

We will also raise the ratio of multi-sourced active pharmaceutical ingredients (APIs), or the percentage of in-house products whose APIs are procured from multiple sources, from the current 45% to 70%. This will bring even greater stability to our supply system, and we believe that selecting less-expensive sources will lead to cost reductions.

Alliance with Eisai Co., Ltd.

In conjunction with our alliance with Eisai Co., Ltd., in April 2019 the Company acquired all of the shares of Eisai's wholly-owned subsidiary Elmed Eisai Co., Ltd., and subsequently launched the business as "Elmed Co., Ltd."

Elmed Co., Ltd. already had strong development capabilities in the area of value-added generic drugs. We believe that by utilizing Nichi-Iko's facilities, Elmed's development staff will be able to develop products with an even higher profit margin.

As efforts to develop a regional community-based integrated care system move forward, we hope to combine the unique qualities of Eisai–a manufacturer of new drugs with particular strengths in the areas of dementia and oncology–with our own, advancing into businesses that we could not develop alone.

"Premium Quality"

"Premium quality" reflects the Nichi-Iko's policy of "going beyond high quality to achieve something even greater." This is not to say we have established any specific standards for what constitutes premium quality. What is important is the attitude that each person brings to thinking about and pursuing premium quality. Nor is this slogan limited to our development and manufacturing divisions. We would like to see all of our employees pursue "premium quality" in their own work. I consider the phrase "premium quality" to mean "exceeding what is possible today by constantly creating new products, taking on challenges and remaining excited about our business."

Message to Stakeholders

I have given an overview of Nichi-Iko's approach from a variety of angles. At the root is a simple concept: that an ethical pharmaceutical company must put "patients–and the families that support them–first." As long as its efforts remain focused on these two groups, a pharmaceutical company will in due course become an indispensable presence in society. I believe that aiming to become such a company, one that delivers products in response to real needs, will lead to sustainable growth.

8th Medium-term Management Plan, "NEXUS∞"

Review of the Previous Medium-term Management Plan

In the midst of a challenging social and market environment, in August 2016–the first year of "Obelisk," our 7th Medium-term Management Plan–we acquired Sagent Pharmaceuticals, Inc., establishing a base in the U.S. and successfully marking our global launch. In September 2017, we also acquired approval for Infliximab BS, launching sales in November and building a base for expansion in a new field and territory.

Additionally, in March 2018 we entered into a strategic alliance agreement with Eisai Co., Ltd. aimed at transforming our business model. This served as a bridge to a new stage driven by collaboration with business partners, and in April 2019, we made Elmed Eisai Co., Ltd. a wholly-owned subsidiary.

Review of "Obelisk," the 7th Medium-term Management Plan

Expansion	Production	Development
FY03/19 14% share by value of the generic drug market (Nichi-Iko 11% Elmed Eisai Co., Ltd. 3%) Elmed Co., Ltd. becomes a wholly-owned subsidiary	January 2018 New Obelisk Building began operation 18.5 billion-tablet supply system	November 2017 Infliximab BS launched in Japan August 2016 Acquired Sagent Pharmaceuticals, Inc. and entered into the U.S.
To be achieved in FY03/20	**Achieved**	**Both achieved**
Establish a 15% share of the domestic generic drug market	**Establish supply system for 18.5 billion premium quality tablets**	**Entered the biosimilars and the U.S. market**

Key Topics During the Period

FY03/17	Jul. 2016	Concluded agreement to acquire Sagent Pharmaceuticals, Inc.
FY03/18	Sep. 2017	Obtained manufacturing and marketing approval in Japan for Infliximab BS for I.V. Infusion 100 mg "Nichi-Iko"
	Nov. 2017	Launched Infliximab BS for I.V. Infusion 100 mg "Nichi-Iko"
	Dec. 2017	Construction of new Obelisk Building completed at the Toyama Plant
	Jan. 2018	Business alliance with Lloyd Laboratories, Inc. and InnoGen Pharmaceuticals, Inc. (Philippines)
	Mar. 2018	Concluded strategic alliance agreement with Eisai Co., Ltd. for a capital and business alliance
FY03/19	Jun. 2018	Concluded licensing agreement for Etanercept BS "Nichi-Iko"
	Jul. 2018	Business alliance with Sunward Pharmaceutical Pte Ltd (Singapore)
	Feb. 2019	Sagent Pharmaceuticals, Inc. acquired the Raleigh manufacturing site
	Mar. 2019	Obtained manufacturing and marketing approval for Kyowa Pharmaceutical Industry Co., Ltd.'s Etanercept BS "Nichi-Iko"

Business Performance

(Million yen)

	JGAAP	IFRS	
	FY03/17	FY03/18	FY03/19
Sales revenue	163,372	164,717	166,592
Operating profit	8,554	10,301	8,223
Net Profit	4,788	8,070	6,864
Capital investment	11,076	12,705	5,053
R&D investment	7,263	9,045	10,841
Depreciation expenses	6,591	8,659	9,401

The environment surrounding the Company is changing significantly.

Environment surrounding the domestic generic drug market

Political/Economic

- Volume share of generic drugs in domestic market to exceed 80%
- Domestic profitability will continue to drop with annual drug price revisions
- Government promoting development of a regional Community-based integrated care system

Society

- Demands for a stable supply, advanced quality control and provision of information
- Handling of relevant laws, regulations and industry standards, which change from day to day (guidelines on providing sales information, review of joint development of generic drugs)
- Expectations for preventive and preemptive medicine comprehensive care system

Market Trends

- Expectations for biosimilars
- Diverse competitors
  (Rise of generic drug makers affiliated with wholesalers and pharmacies; aggressive moves by new pharma companies into authorized generics (AGs); companies from different sectors coming into the market)
- Only pharmaceutical companies capable of supplying a certain volume of competitive generic drugs will stay in the market

Given this environment, the Company aims to become a global comprehensive generic pharmaceutical company needed by the world's patients and their families. We have developed "NEXUS∞," our new Medium-term Management Plan, to further our evolution into "a global comprehensive generic pharmaceutical company," and will engage in addressing our priorities.

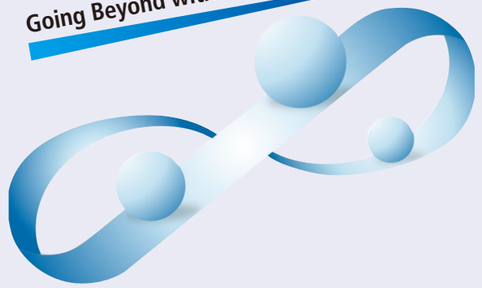
To a new stage

Vision

Theme of the 8th Medium-term Management Plan

Better than the Best

Going Beyond with Infinite Power to Connect



To Evolve as a Global Comprehensive Generic Pharmaceutical Company

Numerical Targets

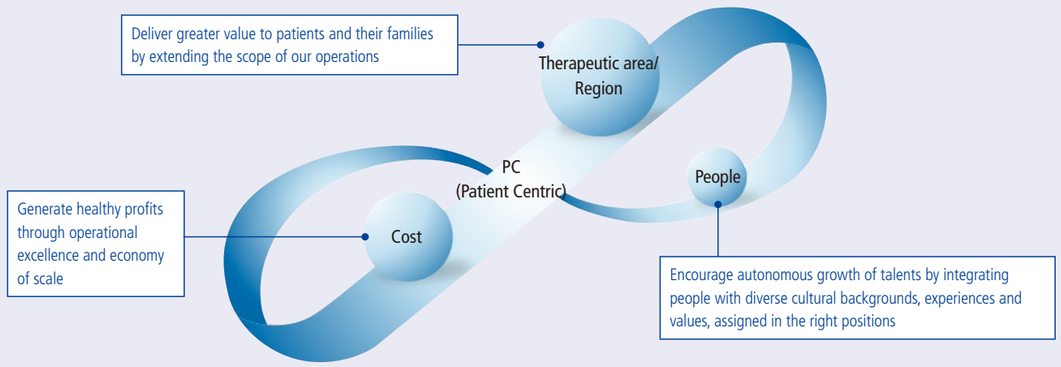
Numerical Targets	Reference figure (end of March 2019)	Targets (end of March 2022)
Ex-Japan sales	35.5 billion yen	60 billion yen
Cost reductions through PMP8*	—	Over 15 billion yen (cumulative)
Dividend payout ratio	25%–30%	Maintain the same level
Ratio of female managers (non-consolidated)	11.5%	15% or greater
Ratio of multiple sourcing of APIs	45% of in-house products	70% of in-house products

Maintain net D/E ratio at about 1.0 times (0.8 times in FY03/19)
Cumulative total of 33 billion yen for R&D and 19 billion yen for capital investment forecasted by the end of March 2022
*Profit Management Plan 8, cost reduction measures the Company is advancing during the term of "NEXUS∞," the 8th Medium-term Management Plan.

Key Performance Indicators (KPIs)

- Ex-Japan sales: Accelerating overseas growth and advancing globalization.
- Cost reductions through PMP8: Will work to stabilize business base by achieving a low-cost operation.
- Dividend payout ratio: Solid execution of strategic imperatives will ensure dividend payout ratio to be maintained at current levels.
- Ratio of female managers (non-consolidated): The Company's first female Independent Director appointed in June 2018. In May 2019, the Company also appointed its first non-Japanese female Vice President.
- Ratio of multiple sourced APIs: To continue offering a reassuring choice for patients, their families and healthcare professionals, we believe nothing is more important than efforts to ensure a stable supply.

Synergy at the Core of Growth



"Better than the Best." Continuing to take on new challenges under the theme of "Going Beyond with Infinite Power to Connect," Nichi-Iko will maximize the three synergies (therapeutic area/region, cost, people) through collaboration, expansion and growth with our business partners. By pursuing business centered on patients and their families, we will further our evolution into a **"global comprehensive generic pharmaceutical company."**

We are moving forward with four strategic imperatives to achieve this vision of a global comprehensive generic pharmaceutical company, driven by "creation" and "challenge."

Strategic Imperatives as a Global Comprehensive Generic Pharmaceutical Company

Strategic Imperative 1

Continue our deeper pursuit of business arenas

Priorities: Business expansion

- 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.

Strategic Imperative 2

Relentless efforts for operational excellence

Priorities: Business foundation

- Product development and improvement efforts 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 Co., Ltd.

Broader coverage of therapeutic area as well as geographical regions with extensive Loss-of-exclusivity (LOE) product lineups

Secure unwavering business foundation by optimizing the entire value chain

Ultimate Goals

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

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

Strategic Imperative 3

Deliver 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.

Strategic Imperative 4

Become 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.

Our goal is to improve corporate value by working to maximize profits in each division and through an appropriate level of growth investment.

Role as Executive Vice President of Strategy

As the person in charge of profit, I supervise each division's activities from the perspective of maximizing profits. In overseeing assets, I analyze assessments of tangible and intangible fixed assets, while giving special consideration to ways of converting operating assets–particularly inventory–into cash. As of May 2019, Nichi-Iko has abolished its practice of having Executive Vice Presidents serve concurrently as Vice Presidents. I believe the role of Executive Vice President is to take advantage of this freedom from being tied to any specific division, and to encourage collaboration between multiple divisions.

FY03/19 Results and Outlook for FY03/20

The fiscal year ended March 31, 2019 began with a drop in sales prices with the April 2019 National Health Insurance revision of drug prices. Sales volume rose only about 10% year on year. Normally this number would represent a passing grade, but considering the drug price revisions, it falls short of our expectations. On the other hand, we did see a certain level of success with cost reductions.

While the impairment losses were extremely regrettable, they were based on a review of specific products, and did not impact the overall value of the Sagent Group.

Two more rounds of drug price revisions have been unofficially announced that will have an impact on results for the fiscal year ending March 31, 2020. While we expect the outlook to be tough, our response will center on further cost reduction measures, including the effect of the integration with Elmed. In the U.S., we will also move forward with applying for approval of Infliximab BS and with transfer of production to the Raleigh, North Carolina manufacturing site. The fiscal year will thus focus on solidifying our foundations for the future.

Current Problems and Measures to Address Them

One issue is an objective assessment of our levels of borrowing. This, however, is something I think we need to allow, at least to a certain extent. Given the major changes taking place in the pharmaceutical drug industry, including generics, funding is essential to moving the business forward during this period. We will continue to raise funds as appropriate while keeping an eye on changes in interest rates.

Another issue is product strength. While Nichi-Iko has focused on developing biosimilars in recent years, I do not think we should be satisfied with our current lineup of products.

That said, some biosimilars are placed at a disadvantage in terms of their economic merits under Japan's current system for capping high medical expenses. The industry shares a common awareness that it is only a matter of time before steps are taken to address this situation. I am positive this aspect of our product lineup will change in the near future. We need to prepare by steadily building a system for the manufacture and sale of biosimilars.

KPIs to Be Achieved by the Executive Vice President of Strategy Under the Medium-term Plan

Five numerical KPIs have been established under NEXUS∞ through the end of March 2022. As the Director of Strategy, I am directly committed to and will work to achieve three of these: Ex-Japan sales, cost reductions through PMP8, and dividend payout ratio.

An important factor in achieving our goal of Ex-Japan sales of 60 billion yen will be the rollout of biosimilars in the U.S. We have already completed Phase III patient trials there, and are now conducting a quantitative and qualitative analysis of the data. Going forward, we will move ahead with the transfer of technology to the Raleigh, North Carolina manufacturing site we acquired, working to build a production structure capable of handling our business expansion in the U.S.

A key point in achieving a cumulative 15 billion yen in cost reductions will be cost-cutting measures involving the integration of Elmed. For outsourced products, we aim to reduce manufacturing costs by working with partners to reevaluate outsourcing, including possibly bringing production in-house.

As for dividend payout ratio, we will continue to maintain it at the current level, between 25% and 30%. We will actively pursue capital investment and M&A to ensure we capture every opportunity for further growth, but will maintain our dividend payout ratio.

Cash Management and Cash Flow

Our basic investment policy is to invest within the scope of free cash flow. While the cash conversion cycle is important, we do not intend to improve inventory turnover simply by posting numerical targets due to the nature of the pharmaceutical manufacturing business placing great importance on stable supply. We will consider the balance between process lead times and supply and demand, reviewing and setting optimal inventory levels for each product.

Post-merger Integration with Elmed Subsidiary

Only the Reliability Assurance Department has been left at Elmed, to maintain its licenses; nearly all other personnel have been integrated into Nichi-Iko's sales and other divisions. The current head of our sales division is from Elmed. Other individuals from Elmed who are working with us include multiple branch managers and our heads of development planning and human resource development. I think our culture makes us particularly suited to this kind of deeper integration.

Traditionally, Elmed has also outsourced its manufacturing. The cost synergies from moving that manufacturing in-house at Nichi-Iko can be very significant. Our policy will be to negotiate with existing suppliers while making solid progress with optimizing cost reductions.

Dialogue with Investors

As head of IR, I regularly visit and engage in dialogue with our investors. I also look forward to these visits as an opportunity for a useful exchange of opinions. On many occasions, that feedback can of course be tough. Still, I believe we should listen to our investors and examine ourselves, while also offering a good-faith explanation of our vision for the future of Nichi-Iko and its business.

Business Overview

Value Chain

The Nichi-Iko Group has established a framework for developing, producing and providing a stable supply of high-quality generic drugs. This section outlines our value chain through descriptions of the roles of each division and through messages from our Executive Vice Presidents and division heads.

We are working to achieve an even more stable supply system by focusing on the management and operation of our entire supply chain.

Executive Vice President
Procurement and Biosimilar
Takahiro Yoshikawa

My role is to supervise management of our supply chain, ensuring a stable supply and lower costs by securing multiple sources of optimal APIs for all Nichi-Iko Group products–whether products in development or those already on the market, and including our own and outsourced products as well as third-party products. Another crucial responsibility for us as a generic drug manufacturer is to have an understanding of the manufacturers that produce the API starting materials and important intermediates and their production status.

Proactive collaboration within the Group also allows for a sophisticated response to environmental and quality issues and to regulatory changes in each country.

Regarding biosimilars, we are engaged in a global search for a product pipeline to follow Infliximab BS and Etanercept BS. We are also currently transferring technology to our Raleigh Plant to enable in-house manufacture of the final dosage form of Infliximab BS. Issues for the near term include managing that process to deliver a stable supply and low-cost production.

Executive Vice President
Operational Excellence
Hiroshi Kawagishi

Our motto is to "Provide a stable supply of premium quality products." My responsibility as head of Operational Excellence is to supervise business operations across the entire value chain, while exercising good judgement from a management perspective.

While premium quality implies delivering safe, reliable, stable quality, we also aim to improve the capabilities of each of our employees with the goal of creating an organization with a strong sense of responsibility, confident in its ability to supply the market, which is the cornerstone of manufacturing.

With regards to stable supply, we have built an optimized production system while keeping a constant eye on both sales and inventory. Still, we were made keenly aware of our responsibility as a generic drug manufacturer when, in 2019, a problem arose triggered by the inclusion of foreign matter in a source ingredient, leading to an outage of specific products. Based on this experience, we are now conducting ongoing self-assessments regarding multiple sourcing of APIs and securing of manufacturing sites for risk preparedness, as well as stable supply, part of our efforts to build an even stronger stable supply system.

Role of Each Division in the Value Chain: Messages from Division Heads

	Development & Planning Division (Development/ Planning → API Procurement)	Procurement Division (Development/ Planning → API Procurement → Production)
	 Senior Vice President Head of the Development & Planning Division **Tetsuo Kadozaki**	 Senior Vice President Head of the Procurement Division **Atsushi Matsumoto**
I Role of Each Division	The role of our division is the development of generic drugs. Our work involves formulation design, including intellectual property research, as well as conducting various tests and handling the new formulation application process through final approval. We also conduct process development to ensure stability in actual production, then transfer the technology to the Production Division. Once a formulation has been launched, we are also responsible for making improvements to further enhance quality, and for adding APIs to ensure stable supply and reduce costs.	We are responsible for purchasing APIs, additives and other secondary ingredients and packaging materials required to manufacture drugs, as well as drugs we outsource for manufacturing and other drugs we handle. Our role is to acquire the raw materials needed to manufacture and market all of the Company's products, and to acquire them from reliable sources at competitive prices.
II Roles, Issues and Initiatives Under the New Medium-term Management Plan	An important role of the Development & Planning Division is to obtain approval for generic drugs in the shortest time possible while also adding new value, developing commercially viable formulations. In addition, under the new Medium-term Management Plan, we are working to achieve the following two goals: 1. To advance globalization, we are working to promote a development structure that meets quality standards in countries around the world, primarily the U.S., and to expand our product lineup. 2. To ensure stable supply and reduce costs, the Company has set a target of 70% for multiple sourcing of APIs. The Development & Planning Division works closely with other divisions to advance work in testing and reviewing formulations of candidate APIs for multiple sourcing, and in manufacturing samples for evaluation.	One of the quantitative targets of our Medium-term Management Plan is to achieve 70% for multiple sourcing of APIs. This is important in terms of a stable supply, and our work in this area primarily involves proposing candidate APIs for multiple sourcing and gathering information. Adopting a new API requires a variety of considerations, and as such is an issue that our division, and the entire Company, works together to address. Our division also recognizes its leading role in achieving the medium-term quantitative target of 15 billion yen in cost reductions, and we are working to reduce costs across all items we purchase. We are also actively engaged in cost-cutting measures that leverage the synergies of our integration with Elmed to optimize costs by product. Given the importance of a stable supply in the current environment, we are moving forward with appropriate supply chain risk management, from API to final formulation.
III Pursuit of "Premium Quality"	In the Development & Planning Division, which develops our generic drugs, our goal is "quality that goes beyond the status quo." The pursuit of "premium quality" means ensuring better quality and adding new value to do this, it is important that we conduct a detailed analysis of the original drug and identify areas where there is room for improvement. Deepening our understanding of original drugs will enable us to develop generic drugs with added value, including ease of swallowing and improved stability, identification and packaging.	The Procurement Division underpins the foundations of Nichi-Iko's "premium quality" in generic drugs. For example, in the development of orally disintegrating tablets (OD tablets), which add value to original drugs by making them easier to swallow, we procured the necessary raw materials and collected information on outsourcers, etc., contributing both to development and production. By quickly obtaining the right ingredients, materials and information, we contribute to the Development and Production Divisions and, eventually, to the patient. This is how the Procurement Division defines the pursuit of "premium quality."
IV Commitment to Low Cost	APIs account for the majority of the cost of generic drugs. Controlling API purchase prices can contribute significantly to reducing costs. Specifically, that effort involves promoting multiple sourcing of APIs. Use of multiple APIs makes it possible review prices between both suppliers. We believe this effort will contribute to fulfilling our mission as a generic drug company–to ensure a stable supply–and the role our division plays is crucial as we work toward our target of 70% for multiple sourcing of APIs.	We consider ways to reduce costs, as we work to fulfill our responsibilities as a manufacturer to quality, stable supply and compliance. Most important in that effort is that we gain an understanding of the entire supply chain through direct dialogue with manufacturers in and outside Japan, determine reasonable costs, and negotiate with suppliers. The diversification of suppliers that comes with multiple sourcing–one of the metrics of our Medium-term Management Plan–will also contribute to reducing costs.

API Procurement → Production

Production Division

Senior Vice President
Head of the Production Division
Masatoshi Takaishi

I Role of Each Division

The Production Division formulates and manages production plans at existing sites, and is responsible for establishing and maintaining a stable supply system and for improving production efficiency. Considering how to manufacture at low cost while maintaining quality is also an important part of our work.

II Roles, Issues and Initiatives Under the New Medium-term Management Plan

While delivering "premium quality" on a stable and continuous basis is one of our major roles, a more immediate issue is handling global quality standards. At sites in Japan scheduled to manufacture products for export, we are working to put in place production lines compliant with FDA standards and build a quality system. Along with efforts to achieve a low-cost operation, we are also actively moving forward with initiatives to improve production efficiency and contribute to stable supply. These include building a predictive maintenance system for our equipment and researching possible deployment of IT and IoT tools. Other efforts include work to achieve a low-carbon, recycling-oriented society, and to maintain and improve our regional and working environments.

III Pursuit of "Premium Quality"

Bringing a drug to market requires approval from the Ministry of Health, Labour and Welfare. Safe, secure, stable quality are of course our responsibility.

For the Production Division, "premium quality" means never being satisfied, but continuing to evolve toward a higher goal. In pursuing "premium quality" on a daily basis, everyone involved in production thinks and acts for themselves, working to give voice to patients around the world and ensuring that Nichi-Iko is the choice for generics among doctors, pharmacists and others in the pharmaceutical industry.

IV Commitment to Low Cost

The business of manufacturing generic drugs can gain significant advantages by growing in scale. To maximize these advantages, we will work to build a more efficient production system and improve capacity utilization rates. Doing so will require developing human resources familiar with formulating efficient production plans and manufacturing systems. In addition, we will work to develop the predictive maintenance and other systems mentioned above. We also plan to be proactive in suggesting capital investments that take into account future cost reductions.

Development/Planning → API Procurement → Production → Logistics → Distribution/Sales

Quality Assurance & Pharmacovigilance Division

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

I Role of Each Division

Our work consists primarily of handling drug-related 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. The division is also in charge of responding to safety data and requests from medical professionals, and for collecting and analyzing information on safety.

II Roles, Issues and Initiatives Under the New Medium-term Management Plan

At our 7th Medium-term Management Plan, we worked on shortening the time required to respond to requests for information on quality; in the new Medium-term Management Plan, we hope to shorten that time from 20 days to 14 days.

Envisioning situations where quick approvals are needed, we also plan to develop personnel who can be entrusted with handling the screening process and negotiations with the authorities. We will also work to put in place a system for managing and supervising biosimilars and other new products.

III Pursuit of "Premium Quality"

We do not believe that "premium quality" means the excessive pursuit of purity in terms of impurity content. Rather, our understanding of "premium quality" is that it is a matter of understanding and controlling what is behind the various elements involved. To do that, it is essential that we visit the API manufacturers to understand their processes and collect information on a day-to-day basis. It is also important that when outsourced manufacturers of our formulations make changes to their processes, they do so under our control. Ensuring quality and a stable supply requires a strong approach.

IV Commitment to Low Cost

Quality assurance operations in pursuit of "premium quality" do not always align with cost reduction policies. Still, we believe that depending on how the work is done, our Division has the potential to reduce costs. For example, costs can be controlled by introducing technology in the form of ITC-based inspections of overseas manufacturing plants, and through cooperating to share the contents of those inspections with other manufacturers. We plan to consider such cost-cutting measures even as we protect the true work of the Quality Assurance & Pharmacovigilance Division.

API Procurement → Production → Logistics → Distribution/Sales

Quality Operations Division

Senior Vice President
Head of the Quality Operations Division
Tomoaki Tamura

I Role of Each Division

We are responsible for checking quality for each process across all products at our domestic plants, from delivery of raw materials to product shipping. Because we play a very important role in drug manufacturing, we have been split off from the Production Division and work as an independent entity.

II Roles, Issues and Initiatives Under the New Medium-term Management Plan

One of our major initiatives is to advance the use of IT in managing GMP (Good Manufacturing Practice: standards for managing the manufacturing and quality of drugs and quasi-drugs), part of our efforts to strengthen quality assurance in line with global standards. This includes digitizing data that was previously processed by hand with the goal of preventing manufacturing record errors and alterations, as well as manpower savings through the use of automated input from analytical instruments. At the same time, we aim to gain approval for the manufacture and sale of products for the U.S. by putting in place a quality system compliant with FDA regulations.

Another issue is the quality control for those products outsourced by Elmed–which was recently made a subsidiary–production of which is scheduled to be brought in-house. We will work to build a management system, including restructuring of products where in sourcing will result in duplication.

III Pursuit of "Premium Quality"

Since our operations involve quality issues, we share our vision of "premium quality" with the entire division, and ask that each of our employees engage in their own pursuit of "premium quality." We respect and encourage individual decision-making, even in matters not directly related to product quality–for instance, improving one's English ability in order to be effective in an increasingly global environment. We are the final bulwark prior to a product going to market, and as such we contribute to "premium quality" by judging matters rigorously in terms of compliance.

IV Commitment to Low Cost

Given the nature of quality control operations, we do not often take the initiative in proposing cost-cutting measures involving production. That said, we do occasionally work on reducing tests costs by taking advantage of economies of scale in production. For example, product sampling tests are basically conducted in units of one lot; by increasing the quantity produced per lot, we can reduce the overall number of times a test is conducted. We will continue to engage in such efforts in response to changes in our production system.

Logistics → Distribution/Sales

Sales & Marketing Division

Senior Vice President
Head of the Sales & Marketing Division
Akihito Tsuge

I Role of Each Division

As the division closest to users of our products, we work with other divisions to deliver high-quality products and information to medical facilities and patients. We also support the activities of MRs (medical representatives) who are responsible for providing that information.

II Roles, Issues and Initiatives Under the New Medium-term Management Plan

We also contribute to maximizing the potential of the three synergies–people, therapeutic area/region and cost–that are at the core of our new Medium-term Management Plan, premised on achieving our sales targets.

With regards to human resources, we will work to strengthen our sales capabilities through the merger with Elmed, and to improve productivity. In addition to an increase in MRs, other departments–including the dispensing pharmacy, regional oncology hospital, and distribution promotion departments--will also increase staff and develop more efficient, effective sales activities. In terms of areas and regions, we will work with Eisai to maintain and expand our existing customer base with the goal of contributing to regional collaboration and comprehensive care. Cost-related measures will include a cost- and profit-conscious approach to developing product strategies.

III Pursuit of "Premium Quality"

From the sales and marketing perspective, we believe the pursuit of "premium quality" means working to ensure our high-quality products are supplemented by information that responds to the needs of patients and medical professionals. Drugs only demonstrate their value when information on the medicinal effects of the ingredients, dosing methods and amounts, safety and interaction with other drugs is delivered accurately. Information is provided in adherence with guidelines regarding information provision.

IV Commitment to Low Cost

Our large number of products is one of our Company's strengths, but it also means we must deal with a vast amount of information. We are working to develop a system for ensuring we can efficiently provide the information for our customers. Making sure the marketing plans, demand forecasts and other information we develop is even more accurate also leads to cost reductions for production, procurement and other divisions. We will thus contribute to cost-cutting company-wide by striving to enhance the accuracy of our information.

Strengths of the Nichi-Iko Group

Premium Quality

Development & Planning
Quick, responsive development system leverages Group's collaborative strengths

API Procurement
Global procurement system delivers stable supply, high quality and low costs

Production
High-efficiency, low-cost production system enhances Group profitability

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

Strengths/Features/Systems

Development & Planning

- Proactive investment in biosimilar development
- Joint development through in-Group collaboration

API Procurement

- Leveraging Group network for reliable procurement of high-quality, low-cost APIs from suppliers worldwide

Production

- Efficient production via functional consolidation of 7 domestic and 3 overseas plants
- Manufacture of biosimilars at own plant (Raleigh)

Logistics

Distribution & Sales

- Reliability of quality data ensured via use of IT in quality control
- Quick response to national regulations (FDA rules, Pharmaceuticals and Medical Devices Law, GCP*1, GMP*2, GQP*3, GVP*4, GDP*5, etc.)
- Speed of response to quality information

Japan

- 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

- Price negotiations that leverage the benefits of volume
- Alliance with Eisai (use of Vizag, India plant)

- 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

- 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

- 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 hospitals*7)
- The largest number of products of any domestic drug manufacturer
- 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 PENGE (post-marketing information collection system) for drug improvements

U.S.

- Drug development and partner selection by highly experienced staff

- Direct connections with suppliers worldwide

- Strategic partnerships with CMOs*6
- Low-cost production system at two company-owned plants in North America (Montreal and Raleigh)

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

- Highly capable sales staff that have achieved the No. 4 spot in sales volume in the U.S. market for generic injectables
- Ability to negotiate with group purchasing organizations (GPO)

- More efficient operations and optimal allocation of resources through use of outsourcing

Asia

- Products exported from Nichi-Iko plants in Japan
- Use of Sagent CMO partners

- 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
- Own sales and marketing organization in Thailand

- Quick decision-making and execution by top management
- Proactive partnerships and alliances with other companies for further expansion
- Optimal allocation of human resources acquired through M&A (objective promotion based on ability)

ESG

- 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.)

- Securing multiple API sources
- Information gathering for sustainable procurement
- Periodic supplier inspections

- Environmentally friendly production equipment and packaging
- Occupational safety and health initiatives
- Rigorous compliance with manufacturing and quality control standards

- 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

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

*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 drug distribution)
*6 Acronym for Contract Manufacturing Organization, referring to companies consigned to manufacture drugs for drug companies
*7 Hospitals incorporating the DPC system, which determines the amount of medical costs paid per day of hospitalization based on diagnostic procedure combinations

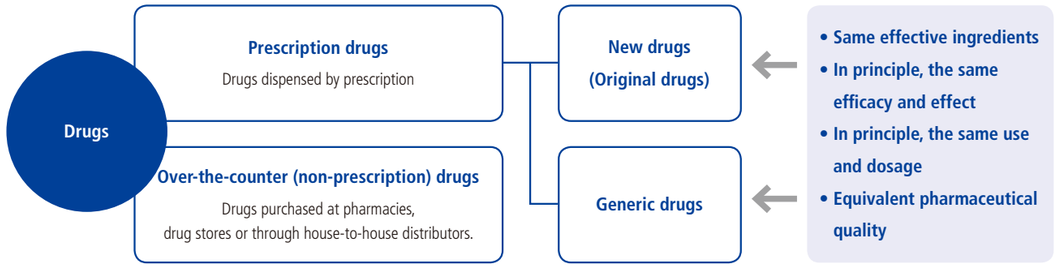
Business Overview

Generic Drugs

About Generic Drugs

Generic drugs are developed to inherit the same superior action as originally developed new drugs. Generic drugs contain the same active ingredients, in the same amounts, as their originator (new drug) counterparts, and in principle have the same effect. Nichi-Iko works to ensure its products are easy to swallow by making numerous changes and improvements. This means there may be slight differences from the originator drug in terms of color, shape and taste.

To dispel any patient concerns and enable patients to share a sense of reliability and ease regarding generic drugs, Nichi-Iko is active in disclosing accurate, detailed data about its products.



Generic Drug Features and Market Environment

Improving the finances of 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 health care expenses also allow more funding to go to new medical technology and new drugs.

Generics are launched after the launch of the originally developed drug and after its patents and reexamination period have expired (about 20 years later).

Over the long course of development of a generic drug, a great deal of data is obtained in the market about the original drug, including side effects and other information. Major developments take place in the equipment needed to develop and manufacture the drugs, making it possible to produce them using new manufacturing methods. Generics are thus not only expected to have an effect equal to the original drug, but their preparation can be reworked in a variety of ways.

Changes in the Generic Drug Market Environment

2007
- June

Basic Policy on Economic and Fiscal Management and Reform 2007 (the "Basic Policies 2007") calls for raising the share (on a volume basis) of generic drugs as a percentage of all drugs to 30% or more by 2012
- October

Ministry of Health, Labour and Welfare establishes the "Action Program for the Promotion of the Safe Use of Generic Drugs"

2013
- April

Ministry of Health, Labour and Welfare establishes the "Road Map for Further Promotion of the Use of Generic Drugs"
"Target to raise the volume share of generic drugs to 60% or greater by the end of March 2018"

2015
- June

Basic Policy on Economic and Fiscal Management and Reform 2015 (the "Basic Policies 2015") calls for raising the volume share of generic drugs to 70% or greater by 2017, and to 80% or greater as quickly as possible between 2018 and 2020

2017
- June

Basic Policy on Economic and Fiscal Management and Reform 2017 (the "Basic Policies 2017") calls for raising the volume share of generic drugs to 80% by September 2020, and for considering further measures to encourage their use in order to achieve that goal as quickly as possible.

Public health care costs have been on the rise in Japan in recent years, and in the government's "Basic Policy on Economic and Fiscal Management and Reform 2017," it was announced that measures would be considered to further encourage the use of generics to as quickly as possible achieve the goal of a generic drug usage ratio of 80% by September 2020. The government also announced plans to enhance measures to support research and development into biopharmaceuticals and biosimilars, and the amounts they would contribute to optimizing medical care expenditures, as well as a goal to double the number of biosimilar products by the end of fiscal 2020. This indicates the government's expectations for the role of generic drugs in controlling medical care expenditures and the speed with which they can be launched, and the importance of biosimilars (biogenerics).

Positioning in the Japanese Market

Nichi-Iko is one of the tops in domestic sales among generic drug manufacturers, and a leading company with the country's largest supply capacity. We are unique for our broad product structure and for the relatively high share we hold among wide-area drug wholesalers in comparison with other main generic drug manufacturers.

Characteristics of Nichi-Iko Generic Drugs

We are constantly thinking about what we can do for patients and their families. We work to devise formulations from a patient's perspective, and to improve usability for medical personnel.

Specifically, we have made dosage forms smaller to make them easier to swallow, and have replaced capsule forms with pills. Laser and inkjet printing are used to improve visibility, and use double-sided cross printing to ensure pills can be identified even when split. We also offer package dispensing, with packages delivered to the patient just as they were when they left the manufacturer.

In the belief that generics drugs are even more essential in the realm of high-priced drugs, we are also focusing resources on developing biosimilars of anti-cancer drugs.

By providing even more patients with our high-quality, cost-effective generic drugs, we are doing our part to reduce the burden on patients and to reduce public health care costs.

A deep lineup of **1,019** products, making us Japan's No. 1 pharmaceutical company

Our products are used by over **97%** of hospitals and dispensing pharmacies nationwide

A medicine for every disease × **To every medical institution**

Future Strategy and Product Launch Strategy

Nichi-Iko believes that the most important thing it can do on behalf of patients and their families is to provide a stable supply of products. At the same time, while new therapeutic drugs in recent years can be highly effective, many of them are also very expensive. Looking at trends in global drug development, there is a shift from small-molecule to macromolecular drugs, and biopharmaceuticals are becoming mainstream.

Given this environment, we believe the Company's mission is to bring high-priced drugs such as anti-cancer agents and biopharmaceuticals to market as generics and biosimilars. This in turn will contribute to reducing the burden on patients and help lower medical expenditures.

With a target share for generic drugs of 80%, the market for generic drugs in Japan is expected to grow for the time being. While volume may continue to expand even after that 80% target has been reached, at the same time the earnings environment is expected to worsen due to annual drug price revisions. This is why we believe that, while we are in the midst of a market expansion, generic drug manufacturers need to anticipate the future at this stage and consider consolidating, scaling up and expanding overseas.

Change in Global 10 Top-selling Products

2001

	Product Name	Primary Efficacy, etc.	Manufacturer	Sales (Million dollars)
1	Zocor (Lipovas)	Cholesterol-lowering drug	Merck	6,670
2	Lipitor	Cholesterol-lowering drug	Pfizer	6,449
3	Omeprazole/Prilosec	Anti-ulcer drug/PPI	AstraZeneca	5,684
4	Norvasc	Blood pressure lowering Ca antagonist	Pfizer	3,582
5	Mevalotin/Pravachol	Cholesterol-lowering drug	Sankyo/BMS	3,509
6	Procrit/Eprex	Renal anemia	J&J	3,430
7	Takepron	Anti-ulcer drug/PPI	Takeda Pharmaceutical/TAP	3,212
8	Claritin/D	Antihistamine	Schering-Plough	3,159
9	Celebrex	COX-2 inhibitor	Pharmacia	3,114
10	Zyprexa	Schizophrenia	Eli Lilly	3,087

2016

	Product Name	Primary Efficacy, etc.	Manufacturer	Sales (Million dollars)
1	Humira	Rheumatoid arthritis	AbbVie/Eisai	16,515
2	Enbrel	Rheumatoid arthritis	Amgen/Pfizer/Takeda	9,248
3	Harvoni	Chronic hepatitis C	Gilead Sciences	9,081
4	Remicade	Rheumatoid arthritis	J&J/Merck/Mitsubishi Tanabe Pharma	8,070
5	Rituxan	Non-Hodgkin's lymphoma	Roche	7,432
6	Revlimid	Multiple myeloma	Celgene	6,974
7	Avastin	Colon and rectal cancer	Roche/Chugai Pharmaceutical	6,885
8	Herceptin	Breast cancer	Roche/Chugai Pharmaceutical	6,884
9	Lantus	Diabetes	Sanofi	6,322
10	Prevnar	Pneumococcus	Pfizer	6,034

* ■ indicates biopharmaceutical
Source: Prepared by the Ministry of Health, Labour and Welfare based on *Pharma Future 2002 No. 136*, Cegedim Strategic Data Uto Brain Division and *Evaluate Pharma*, Evaluate Ltd.

Business Overview

Biosimilars

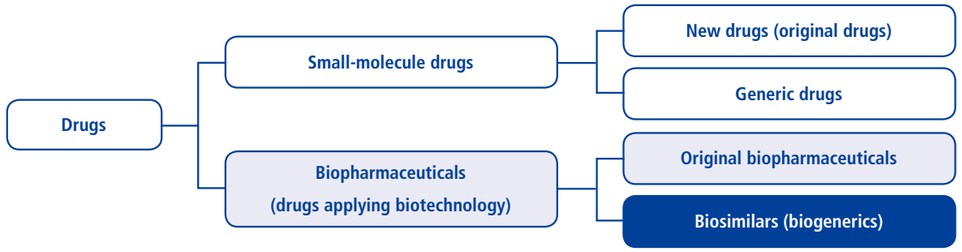
About Biosimilars (Biogenerics)

Biosimilars are drugs that have the same quality, safety and effectiveness as original biopharmaceuticals already approved in Japan as new drugs. Biosimilars, also known as biogenerics, are launched after the original biopharmaceutical's patent period and reexamination period have expired.

In Japan, guidelines have been published to ensure the quality, safety and effectiveness of biogenerics (Pharmaceutical and Food Safety Notification No. 0304007 dated March 4, 2009), and development takes place based on those guidelines.

In general, the active ingredients in generic drugs have a smaller molecular weight, and their structures are relatively simple. This makes it easy to demonstrate that their active ingredients are the same as the original drugs. Once biological equivalence with the original drug has been proven, the generic version is approved based on the safety and effectiveness of the original drug. Meanwhile, the active ingredients in biosimilars have a large molecular weight and extremely complex structures, making it difficult to demonstrate sameness. This is why it is necessary to demonstrate that a biosimilar is equivalent to and homogeneous with the original biopharmaceutical in terms of quality, safety and effectiveness. Development of biosimilars thus involves numerous tests, including clinical tests, just as in the case of new drugs.

Prices for original biopharmaceuticals are generally quite high, and this is why biosimilars that are equivalent to and have the same properties as the originals are likely to play an even larger role going forward.



	Generic drugs	Biosimilars (biogenerics)
Definitions	A drug with the same active ingredients, administration routes, usage and dosage, and efficacy and effectiveness as the original drug.	A drug equivalent to and with the same quality, safety and effectiveness as the original biopharmaceutical.
Product characteristics	Small-molecule compound	Macromolecule compound
	Stable	Requires reworking to achieve stability
	Easy to demonstrate equivalency	Molecular structure is complex, making it difficult to demonstrate equivalency. Manufacturer needs to demonstrate that products are equivalent and homogeneous.
Manufacturing	Manufactured through chemical synthesis	Manufacturing using cell culture techniques
Development requirements	Bioequivalence testing (Waived for intravenous administration)	• Research and develop proprietary cell line and cell bank • Compare equivalency and homogeneity of quality characteristics (special analysis of active ingredients and impurities, bioactivity, higher order structure, peptide map, etc.). • Compare pharmacological action and verify safety through non-clinical testing • Compare equivalency and homogeneity and verify safety through clinical testing (including pharmacokinetic (PK) or pharmacodynamics (PD) testing, or through PK/PD tests, efficacy tests and immunogenicity tests). • Post-marketing surveys (noting problems with immunogenicity, etc.)

Development Pipeline

	Preclinical	Phase I (Phase I clinical trials)*2	Phase III (Phase III clinical trials)*3	Application and approval
Infliximab BS*1 (Japan)	**Launched in Japan**			
Infliximab BS (U.S.)	**Phase III of interchangeability*4 study patient administration completed and data analysis underway in the U.S.**			
Etanercept BS (Japan)	**Approved in March 2019 (launching a year later, succession planned)**			
Trastuzumab BS (Japan, U.S., EU)	**Phase I begun in the U.S.**			

Collaboration with Partners in the Biosimilar Business

Development of Infliximab (original name: Remicade®), Trastuzumab (original name: Herceptin®) and other biosimilars requires culturing cells and then extracting their active ingredients. We have thus invested in and entered a capital and business alliance with Aprogen, a bio-venture company in South Korea which has the cells required.

With regard to production, in October 2013 we entered into an equity partnership with Binex of South Korea and have outsourced manufacturing of products for Japan.

To maximize the value of Nichi-Iko's first biosimilar, Infliximab BS for I.V. Drip Infusion 100 mg (Nichi-Iko), we conducted a joint promotion with Zeria Pharmaceutical Co., Ltd., which has its strength in the gastroenterology sector. We also entered into a sales licensing agreement with Ayumi Pharmaceutical Corporation, which specializes in the anti-rheumatoid field. Sales in Japan were launched in November 2017.

Based on a licensing agreement we entered into in June 2018 with Kyowa Pharmaceutical Industry Co., Ltd.–the Japan subsidiary of Lupin, the Indian company that developed Etanercept BS–in March 2019, Kyowa Pharmaceutical Industry Co., Ltd. obtained approval for the manufacture and sale of the Etanercept BS hypodermic syringe and pen (Nichi-Iko) and Nichi-Iko is now preparing to launch sales.

Overseas Rollout of Biosimilars

In October 2016, we began Phase III clinical testing in the U.S. involving a biosimilar for the anti-rheumatoid drug Remicade®. We plan to file for approval of interchangeability in 2020. Clinical development in the U.S. is now being led by Sagent in an effort to speed approval, with the goal of obtaining approval in 2021. Phase I clinical testing involving a biosimilar for Herceptin®, an anti-cancer drug, has also begun in the U.S.

*1 Short for "biosimilar"
*2 The candidate drug is administered to a small number of healthy people, a test intended primarily to study safety and the action of the active ingredients in the body (pharmacokinetics). The test is basically designed to provide material for determining whether to proceed to Phase II, and is not primarily intended to determine therapeutic effectiveness.
*3 Based on usage and dosage determined following Phase II, this large-scale test is intended to validate the therapeutic safety and effectiveness of the drug in a large population of patients whose disease status is such that the drug promises to be effective.
*4 Meaning that the drug is interchangeable with the original biopharmaceutical, and the pharmacist can dispense a biosimilar at his/her own discretion without the approval of the dispensing physician.

Overseas Business

America

Market Environment and Competitive Situation

At about 56 billion dollars, the U.S. market for generic drugs is by far the largest in the world, and the most dynamic. That also makes it the world's most challenging market, but that environment represents the chance for enormous success for players entering the market.

Development of biosimilars, or generic versions of biopharmaceuticals, is also increasingly active, and demand is expected to grow going forward.

Intense competition is already spreading in the U.S. market among both domestic and foreign companies. Market shakeouts also occur with remarkable speed, meaning that only companies that develop products that accurately capture market needs will survive.

Strengths of the Nichi-Iko Group

Sagent combines the differing business cultures of Japan and the U.S., something we leverage as a strength. The Nichi-Iko Group's management, with its long-term perspective, nurtures a sense of trust that is welcomed by the market. Meanwhile, a U.S.-style sense of speed and flexibility drives the creation of many new business opportunities.

Our strong manufacturing capabilities can be seen as another strength. In addition to the seven production sites in Japan, Sagent also has a subsidiary in Canada which manufactures products for that country. We are also preparing to begin manufacturing products for the U.S. from our Canadian subsidiary. In addition, at the end of February 2019, we acquired a manufacturing site for injectables in Raleigh, North Carolina, and are building a system that can support a more than adequate supply of products for the U.S.

Message from the CEO of Sagent

Leveraging Our Strengths to Establish a Base for Sales in the U.S. Market

Located in Chicago, Illinois, Sagent was founded in 2006 and in 2016 became a Nichi-Iko Group company. Our greatest strength as a seller of generic injectables is our sales structure. We have earned a strong reputation in the industry for our service quality, driven by our cross-organizational team.

As mentioned above, many companies from around the world have entered the U.S. generic drug market. Even in those conditions, I believe Nichi-Iko, which develops a wide variety of products–including orphan drugs and biosimilars–has sufficient competitive strength to succeed. Our next goal is to leverage our strengths and establish a sales platform for orphan drugs and biosimilars in the U.S. market. At the same time, we will expand our business in the market for common generic injectables, continuing our growth as a company.

Acquiring and developing personnel is an important part of achieving this objective. Companies that attract good people find business proceeds smoothly, naturally generating profits. I believe one of the duties of the corporate leader is to acquire talented personnel, and build an environment in which they can continue playing an active role over a long period of time. This is why we devote so many resources to human resource-related policies, building a suitable system for evaluations and offering attractive career options. We have also taken on several staff from Nichi-Iko. Having employees of different cultural backgrounds work together provides a major stimulus, and leads to the revitalization of our own personnel.

In addition to its sound approach to management, Nichi-Iko has the kind of strong leadership unique to an owner-led company. Building on our unshakeable relationship with Nichi-Iko, Sagent will continue moving forward toward its goal of becoming a one-billion-dollar company.

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

Career Summary

November 2016: Present position
2011 to 2016 President and CEO, DKSH Japan K.K.
2006 to 2011 Board Member, Landesbank Baden Wuerttemberg

Asia

Market Environment and Competitive Situation

China, the largest market for drugs in Asia, is seeing solid growth. In the ASEAN market, medium-term developments include demographic changes, such as population growth and further aging. Progress is also expected in putting health care infrastructure in place, driven by an increase in medical institutions and the spread of insurance systems.

In Thailand, where relative progress has been made in health care infrastructure and universal insurance systems, annual growth is expected to be between 5% and 9%, but the country is on its way to becoming a highly mature market. Meanwhile, in Vietnam the growth of the generic drug market is expected to lead high market growth (between 10% and 11% annually). The market for ASEAN as whole is expected to grow at an annual rate of 8% by 2022.

Government-run medical institutions in the region recommend the use of low-cost, domestic generic drugs, but at the same time, patients demand high-quality generic products. Among privately-run hospitals, recent years have seen an increase in the number of hospitals emphasizing profitability in conjunction with the shift to group-run facilities. Hospitals using both original drugs and high-quality generic products have increased.

Strengths of the Nichi-Iko Group

In January 2014, Nichi-Iko established its own sales subsidiary in Thailand, Nichi-Iko (Thailand) Co., Ltd., ahead of other Japanese generic drug manufacturers. To date, our close collaboration with FDA Thailand has enabled us to roll out sales of drugs equal to the high quality available in Japan, primarily in the cardiovascular field. We have made solid progress in expanding our trust relationships with medical institutions there. The knowledge and expertise we have accumulated through our many years of experience in filing generic drug applications and building business alliances in Asia with Thailand as a hub is also a major strength.

We will continue to exploit these strengths of the Nichi-Iko Group going forward, working with Sagent of the Nichi-Iko Group to deploy its U.S. FDA-approved cancer drugs in Asia.

Message from the Head of the Corporate Strategy & Planning Division

Nichi-Iko's Business Strategy in Asia

Through its subsidiary Nichi-Iko (Thailand) Co., Ltd., Nichi-Iko is working to expand its business in Thailand and to use Thailand as an ASEAN business hub for expanding to Vietnam, Malaysia, Singapore and the Philippines.

In Thailand, we currently sell four ingredients in six product formulations. Our policy for the fiscal year ending March 31, 2020, is to expand sales and profits by capturing the hospital market, and we are advancing a strategy of selling into the cardiovascular field.

We will also file new applications for products from Sagent, expanding into the cancer field and preparing to make the most of synergies in the hospital market.

Further, in terms of future business expansion, we will be filing new applications this fiscal year for Nichi-Iko products, including two ingredients in Thailand and eight in Vietnam. We also plan to file new applications for five ingredients in Singapore, Malaysia and the Philippines as part of our horizontal rollout in Asia. We are moving steadily forward on all three fronts: Expansion of business and sales in Thailand; synergies with the hospital market via Sagent products; and a horizontal rollout across the countries of Asia.

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

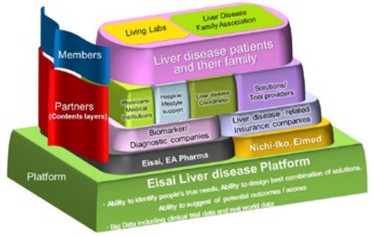
Feature

Strategic Alliance with Eisai

On March 28, 2018, a strategic alliance was concluded between Nichi-Iko and Eisai Co., Ltd. to expand the generic drug business, facilitate growth and increase the revenues of both companies by fully utilizing the assets and strengths of both companies and maximizing synergies.

Creation and Promotion of Area Ecosystems*

With its broad spectrum of generic drugs, Nichi-Iko will join Eisai as a partner, providing content to the area ecosystem Eisai is pushing forward with. By doing so, we believe we can enhance that ecosystem in areas in which Eisai specializes, including dementia and liver disease, while further contributing to patients and their families in regional healthcare.



Conceptual diagram of Eisai's liver disease ecosystem (example)

Utilizing High-quality, Competitively Priced APIs

As we move toward our goal of "premium quality" and execute PMP8, we look forward to making maximum use of Eisai's plant in Vizag, India and its R&D, manufacturing, quality control, audit and other functions to supply APIs that are outstanding in terms of price, quality and supply stability. In developing new formulations, we can also utilize Eisai's API development capabilities and manufacturing technology to further improve efficiency and ensure a successful application and approval process.

Eisai Vizag India Plant

Collaboration in Marketing Activities

We will cooperate with Eisai in providing generic drugs under Eisai's "Integrated Package Strategies" aimed at contributing to home and regional healthcare. Based on real-world data, we will select from among our lineup of more than 1,000 products those which can deliver value when packaged with Eisai Group products and IT tools. Eisai will promote these integrated packages in the areas of liver disease, breast cancer, epilepsy, brain tumors and strokes, dementia, rheumatoid arthritis, constipation and others.

On April 1, 2019, Eisai also began co-promotion of five products (four ingredients) marketed by Nichi-Iko.

18 ingredients

Providing Information under the Integrated Package Strategies

Six areas covered

(1) Liver, (2) breast cancer,
(3) epilepsy, brain tumor and stroke,
(4) dementia, (5) rheumatoid arthritis and
(6) constipation, etc.

4 ingredients

Co-promotion

We are conducting co-promotion aimed at the expansion of new generic drug products in focus areas.
Future expansion is also being considered.

Coordinated activities between Nichi-Iko and Eisai (Basic activities)

* An ecosystem built on a platform centered on the ability to draw out patients' true needs, to design solutions and to propose outcomes and access based on medical data, including clinical tests and real world data. A variety of content is then built on this platform to deliver drugs and other solutions needed by patients and other stakeholders.

Launch of Elmed Co., Ltd.

On April 1, 2019, Nichi-Iko acquired all of the shares of Elmed Eisai. At the same time, we changed the name to Elmed Co., Ltd., taking advantage of a name familiar to and well-established among patients and healthcare professionals. Elmed continues to manufacture and market value-added generic drugs as a member of the Nichi-Iko Group.

As the business environment for the generic pharmaceutical business undergoes significant changes, efforts will be made to transform the business model for generic pharmaceuticals and strengthen business foundation by combining the strengths of the two companies such as Nichi-Iko's abundant product lineup and supply capacity and Elmed's value-added formulation technology, increasing market share and also reducing costs through the expansion of scale.

Synergies from collaboration with Elmed

Field/Region

Carrying on the proprietary value-added formulation technologies accumulated by Elmed, including the soluble tablets developed for patients with difficulty swallowing, we aim to further increase market share by incorporating those technologies in an effort to differentiate our products.

People

By optimally allocating Elmed personnel throughout the Nichi-Iko Group, we will incorporate new ways of thinking and reinvigorate our existing organization, while merging the best parts of both companies to create a new corporate culture.

Cost

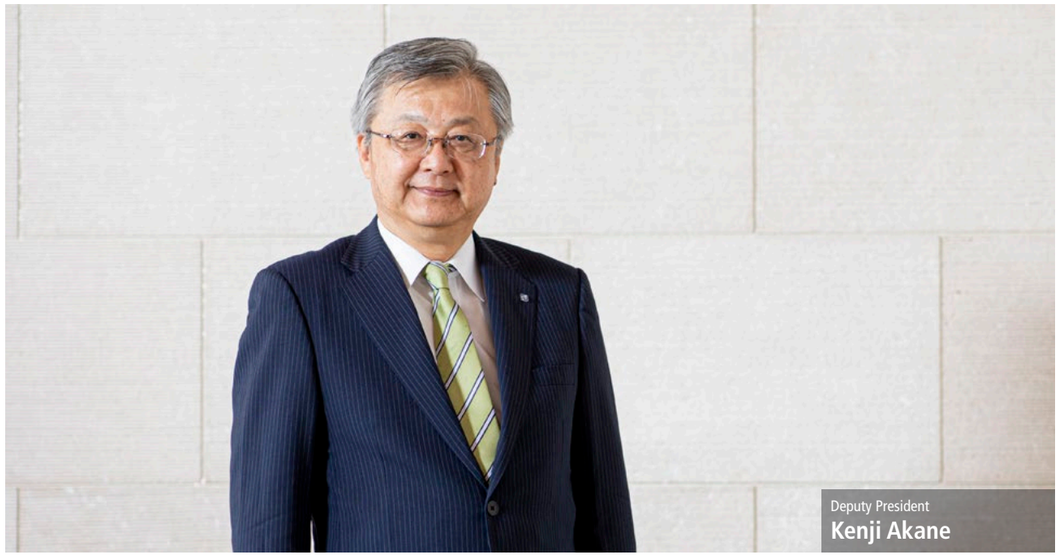
We will promote development cost synergies by unifying redundant items in product development as well as cost synergies leveraging the benefits of scale through increased volume, with the aim of maximizing profit by strengthening efforts aimed at optimizing APIs, improving production efficiency and improving administrative efficiency.

(Reference)
About Eisai Co., Ltd.
Eisai's corporate philosophy is "human health care (hhc)," putting the emotions of patients and their families first and contributing to improving the benefits provided to them. The company has a global network of R&D, production and sales facilities, and approximately 10,000 employees worldwide are engaged in the creation and provision of innovative new drugs in areas with high levels of unmet medical needs centered on neurology and oncology, which the company positions as important strategic areas. Eisai is also actively engaged in coordinating with key stakeholders to improve access to pharmaceuticals in developing and emerging countries.
See https://www.eisai.co.jp for detailed information on Eisai Co., Ltd.

CSR/ESG

Sustainability at Nichi-Iko

CSR/ESG: Message from Deputy President



Engaging in CSR and ESG Across the Organization

As Nichi-Iko has grown, so has the weight of the responsibility we bear to society. As we aim to become a global comprehensive generic pharmaceutical company, it is particularly important that our CSR and ESG initiatives are achieved at world-class levels. ESG-related targets in our basic strategy under NEXUS∞ are an indication of that commitment. My role is to build an organization-wide system for implementation by restructuring the efforts that, to date, have been carried out by our individual divisions.

Many CSR and ESG-related measures involve multiple divisions. The abolishment of the practice of having Executive Vice Presidents serve concurrently as Vice Presidents should allow our Executive Vice Presidents to supervise across divisions according to their individual roles, putting in place a structure for communicating radially, in a sense.

Environmental Activities

Currently, the Production Division is working to reduce energy and water use and wastewater emissions, emissions of specified chemical substances and the amount of waste generated. That being said, achieving a proper balance between company growth and expansion and our impact on the environment is not an issue that should be pursued by the Production Division alone. We have thus established reduction targets for elements not directly related to production–use of gasoline in company vehicles, for instance, or use of paper–and the company as a whole is working to achieve those targets.

Community Activities

As part of contributing to the community, we hold professional sports tournaments, open the soccer field on our company grounds to the public, and offer support for sports events in which employees of local companies and their families can participate. We also conduct fund-raising activities for areas affected by earthquakes in East Japan and Kumamoto.

In a sense, the business of manufacturing generic drugs itself makes a significant contribution to society. Nichi-Iko's goal is to continue contributing through our business, while engaging in CSR activities unique to us as a pharmaceutical company.

Efforts to Achieve Diversity

Currently, one of our four Independent Directors is a woman. We are working to improve diversity in other ways as well, including appointing a female non-Japanese national as Vice President.

We also aim to raise the ratio of women in management positions from the current 11.49% to 15% by the end of March 2022.

Recognizing that respect for human rights is a social responsibility we must fulfill as a company, we will work to nurture greater human rights awareness through a steady process of employee training.

We have grown as a company by welcoming a wide range of people with each M&A we complete. We will continue to advance a variety of measures based on Nichi-Iko's inherent respect for diversity.

Governance

In addition to our sequential response to the Corporate Governance Code, we recently launched Compensation and Nominating committees, further enhancing transparency and fairness.

Our Independent Directors, who represent about 44% of all Executive Vice Presidents, comprise experts in fields such as pharmacology, medicine, management and the law. We are also working to build an appropriate governance structure by having Audit & Supervisory Board Members (Independent) in accounting and taxation, and by asking a Tokyo law firm to act as general counsel.

Responding to Society's Expectations

We believe our mission as a generic drug manufacturer is to address the needs of patients and their families in terms of both quality and price. This is also reflected in our philosophy of "premium quality," the pursuit of quality in every component of our business. Seen from the vantage point of CSR and ESG, the most important element of premium quality is to ensure that society's definition of common sense is aligned with our own. We will remain keenly alert to the needs of patients, their families and society as a whole, as we work to advance these cross-divisional initiatives.

CSR Basic Policy

Nichi-Iko is engaged in the following initiatives based on the concept of "coexisting with our communities, supporting a brighter future for our children, and contributing to creating a healthier, more abundant society."

Contributing to Society through Our Business

Our lineup of approximately 1,000 products makes us the No.1 pharmaceutical company in Japan. We have also established a sales network that encompasses more than 97% of hospitals and dispensing pharmacies nationwide. By maximizing these advantages to offer broad access to our high-quality, cost-effective generic drugs, we are doing our part to reduce the burden on patients and to reduce national healthcare expenditures.

Giving Shape to Customer Feedback

To enhance ease of swallowing, convenience and safety, we listen to customer requests and strive to develop and improve product formulations from a variety of aspects, including container structure and package designs.

We not only ensure equivalency with original drugs, but also develop products that offer improved convenience for "patients and their families."

Sample improvements

- Improved ease of oral administration (improved the flavor of jelly formulations, molded tablets, OD tablets, etc.)
- Formulation change from capsules to tablets; additional standards
- Improved identification (printed tablets; inverted printing on both sides)
- Improved packaging and labeling (to prevent broken bottles, etc.)

CLOSE UP

Changing Tablets and Powders to One-dose Stick-type Jelly Formulations

Designed to improve oral administration (issues of taste and texture) and convenience (portability, etc.)

AIRPUSH JELLY® AIRPUSH JELLY is a registered trademark of Nichi-Iko Pharmaceutical Co., Ltd.

AIRPUSH JELLY is a one-dose, stick-type jelly that can be easily administered with just a light push on the air pocket incorporated in the package design.

Hold with the jelly end up | Open from cut end | Lightly squeeze the air pocket

Corporate Governance

Corporate Governance Initiatives

Features of Corporate Governance at Nichi-Iko Co., Ltd.

- **4 of 9 Executive Vice Presidents are Independent Directors**
- **2 of 4 Audit & Supervisory Board Members are Audit & Supervisory Board Members (Independent)**
- **Board of Directors effectiveness evaluations conducted since 2018**
- **Nominating and Compensation committees established in February 2019**
- **Roles of Executive Vice Presidents and Vice Presidents split in May 2019**

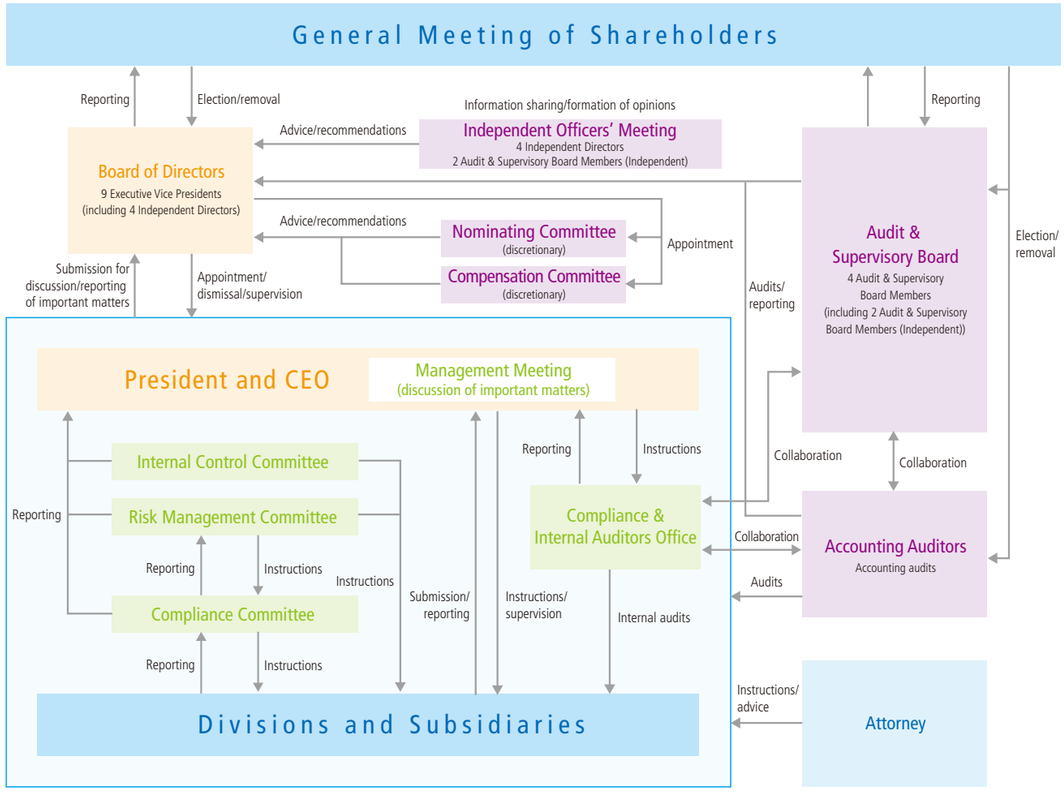
Basic Approach

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. We recognize that enhancing and strengthening governance is a top priority for management.

We are currently developing an internal control system that will strengthen our corporate governance structure.

As a pharmaceutical company, we are also working to improve our audit system, and increasing our efforts with respect to developing, maintaining and improving corporate ethics, compliance, internal controls and risk management.

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 trainings. At the same time, the Compliance Committee works to acquire information under internal reporting system regulations. It investigates the reports, finalizes measures to prevent recurrence based on discussions with individual business divisions, and enforces implementation of those measures on a Company-wide level. It also reports to the Risk Management Committee, the President and CEO as well as the Board of Directors.

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.

The structure currently in place has been adopted, because it has been judged the most appropriate for the strengthening of corporate governance as a system that provides the internal control unit with valuable recommendations. These come through the enhanced supervisory functions of highly Independent Directors and audit functions provided by Audit & Supervisory Board Members (Independent), via mutual cooperation between those responsible for internal audits, audits by Audit & Supervisory Board Members and accounting audits.

- **Board of Directors**

The Board of Directors is comprised of nine Executive Vice Presidents, including four 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 & Supervisory Board**

The Audit & Supervisory Board is comprised of two Audit & Supervisory Board Members and two Audit & Supervisory Board Members (Independent). Audit & Supervisory Board Members are present at meetings of the Board of Directors and other important meetings. While ensuring neutrality, they provide appropriate audits of overall management, specifically through opinion statements on the lawfulness and appropriateness of business execution.

To ensure mutual collaboration with the internal audit group and the accounting auditors, the Audit & Supervisory Board holds trilateral meetings at regular intervals, exchanges information and provides the internal control unit with recommendations as needed as a pharmaceutical company regarding development, maintenance and operation of corporate ethics, compliance, risk management and internal controls.

- **Management Meeting**

A Management Meeting comprising Executive Vice Presidents, Audit & Supervisory Board Members as well as Vice Presidents and others is held, in principle, weekly. Participants report on, discuss, and make decisions regarding important issues and their execution. 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.

- **Independent Directors/Audit & Supervisory Board Members (Independent)**

The Company's Independent Director is comprised of a president of the Chamber of Commerce and Industry, a university professor, an attorney and a medical doctor, all with a high degree of expertise and impartiality. We also elect Audit & Supervisory Board Members (Independent), including certified public accountants and tax accountants, with a high degree of expertise, with full consideration given to a balance among knowledge, experience and ability.

We have established a set of standards for judging the neutrality of our Independent Directors based on standards set forth by the Tokyo Stock Exchange.

Independent Officers' Meeting

The Company has established "rules for the independent officers' meeting," and an "independent officers' meeting" comprising all Independent Directors (4 people) and Audit & Supervisory Board Members (Independent) (2 people). A lead independent officer is selected by mutual vote, and meetings are held, in principle, biannually.

Through these meetings, the independent outside officers 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.

Establishment of Nominating and Compensation Committees

On February 12, 2019, the Company established a Nominating Committee and a Compensation Committee to serve as an optional advisory body to the Board of Directors. These committees are comprised of a majority of independent outside officers.

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 Executive Vice President compensation, and making recommendations to the Board of Directors.

Separation of Executive Vice Presidents and Vice Presidents

The Company has split its Executive Vice Presidents and Vice Presidents to further clarify the management and supervisory functions of the Executive Vice Presidents and the operational function of the Vice Presidents. From the perspective of specialization, Executive Vice Presidents 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.

Analysis and Assessment of the Effectiveness of the Board of Directors

The Company recognizes there is a gap between our 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, between April and May of 2019 we conducted a survey of all of our Executive Vice Presidents and Audit & Supervisory Board Members.

Major Survey Items

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 2019, we conducted a dialogue with the Board of Directors based on the results of an analysis of the 42 items in the survey. As a result, we confirmed that the effectiveness of the Board of Directors is being ensured.

At the same time, we also recognized that there is room for improvement in terms of providing more complete briefing of important matters in advance, which will further enhance the effectiveness of the Board of Directors and enable the Executive Vice Presidents to form fuller discussions during their meetings. Based on the results of this effectiveness assessment, we 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/ja/CorporateGovernance.html

Executive Vice President Training

To ensure Executive Vice Presidents and Audit & Supervisory Board Members can fulfill their expected roles and responsibilities appropriately, the Company is active in providing opportunities to hold in-house trainings and attend outside seminars, under its policy of encouraging Executive Vice Presidents and Audit & Supervisory Board Members to collect new information related to current affairs and medicine as well as on regulatory amendments and other issues, and to acquire knowledge in their respective areas of responsibility.

Board of Directors Attendance Rate (Independent Directors, Audit & Supervisory Board Members (Independent))

The Board of Directors convened 14 times in the fiscal year ended March 31, 2019. In addition, written resolutions were conducted three times. Attendance rates at Board of Directors meetings are as shown below.

			Board of Directors Attendance Rates
Shigeo Takagi	Independent Director	Independent	92.9%
Hideki Sakai	Independent Director	Independent	100%
Hajime Imamura	Independent Director	Independent	100%
Kyoko Tanebe	Independent Director	Independent	100%
Hitoshi Hori	Audit & Supervisory Board Member (Independent)	Independent	100%
Kou Sato	Audit & Supervisory Board Member (Independent)	Independent	100%

Status of Internal Audits and Audit & Supervisory Board Member Audits

Internal audits of the Group are conducted by the Company's Compliance & Internal Auditors Office, which reports its findings to the Internal Control Committee and individuals in charge in each division. When necessary, the Internal Control Committee offers guidance regarding measures to improve internal controls, as well as support and advice for implementing those measures. The Compliance & Internal Auditors Office also assesses the effectiveness of internal controls. If deficiencies are found as a result, they will make recommendations regarding corrections, reporting both their findings and the results of those corrections to the Board of Directors.

The Audit & Supervisory Board Members work to communicate with Executive Vice Presidents, the Compliance & Internal Auditors Office, employees and others, collect information and put in place an audit environment in compliance with standards for Audit & Supervisory Board Members audits established by the Audit & Supervisory Board and in accordance with audit policies and division of duties.

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 Executive Vice Presidents or Audit & Supervisory Board Members, we are careful to consider our 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 Executive Vice Presidents and Audit & Supervisory Board Members is deliberated by the Nominating Committee established in February 2019, 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 an Executive Vice President or Audit & Supervisory Board Member 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 Executive Vice Presidents and Audit & Supervisory Board Members is included in the General Meeting of Shareholders convocation notice.

Policies Regarding the Election and Removal of Vice Presidents

The election and removal of individual Vice Presidents is determined by the Board of Directors following deliberation by the Nominating Committee established in February 2019. The Committee makes its recommendations to the Board of Directors, which then makes its decision based on comprehensive consideration of the individual's character, knowledge, abilities and other factors.

Officer Compensation

Basic policy for determining executive management and Executive Vice President compensation is that it comprises basic compensation, performance-linked compensation, and compensation based on an evaluation of business execution from a medium- to long-term perspective and of the individual's abilities.

The Compensation Committee established in February 2019 is responsible for deliberating policies for determining compensation as well as the amount of compensation for executive management and Executive Vice Presidents. The Committee makes its recommendations to the Board of Directors, which then decides compensation.

CEO Succession Planning

The Board of Directors determines a successor to the Company's Chief Executive Officer based on advice and recommendations from the Nominating Committee. Given the Company's management philosophy and specific management strategies, a successor is selected and decided upon based on whether the individual has the necessary knowledge, insight and leadership in terms of his/her credentials and track record, and whether the individual is capable of contributing to the Company's performance and leading its growth based on management policy.

The Company has also established a management development program aimed at junior employees, with the goal of developing the next generation of management candidates called "Koshi-juku."

Anti-takeover Measures

Because we are a public company, our shareholders and investors are free to trade our share certificates, etc. Therefore as a rule, we do not disallow large-scale purchases of Company shares certificates, etc.

That said, some unilateral, large-scale purchases of Company share certificates, etc. can result in shareholders being essentially forced to sell their shares without adequate information. They may not ensure sufficient time for our Board of Directors to propose alternatives, and may not acknowledge our desire to conduct management in a sincere and reasonable fashion. In that sense, some large-scale purchases of share certificates, etc. could seriously undermine our corporate value, and by extension the joint interests of our shareholders.

At the 53rd Ordinary General Meeting of Shareholders held on June 16, 2017, our shareholders thus approved the "Countermeasures Against Large-Scale Purchases of Company Share Certificates, etc. (Anti-takeover Measures)," which were deployed that same day. They are designed as part of an effort to secure and enhance corporate value and by extension the joint interests of our shareholders by preventing abusive takeover attempts against the Company.

Under these anti-takeover measures, actions that fall under either I) or II) below, or similar actions (excluding, however, those already approved by the Company's Board of Directors) or attempts at such actions may trigger countermeasures based on those takeover defense measures.

I) A purchase of share certificates, etc. for which the Company is the issuer, and which would result in the holder owning a total of 20% or more.
II) A purchase of share certificates, etc. for which the Company is the issuer, and in which share certificates, etc. involving a tender offer, along with share certificates, etc. held by persons with a special relationship with the tender offeror, total 20% or more.

Basic Approach to Eliminating Anti-social Forces

Based on the "Guidelines for Companies to Prevent Damage from Anti-social Forces," the Company has established "Rules for Dealing with Anti-social Forces," and works to ensure familiarity with these policies company-wide.

Management Team

Board Members (as of June 21, 2019)

President and CEO
Yuichi Tamura

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 Board Member, Executive Vice President, Responsible for Sales & Marketing Division and Corporate Strategy & Planning Office
Feb. 2000	President & CEO (present position)

Deputy President
Kenji Akane

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, Responsible for Compliance & Internal Auditors Office
May 2019	Deputy President (present position)

Executive Vice President
Strategy
Noboru Inasaka

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 and 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)

Executive Vice President
Procurement and Biosimilar
Takahiro Yoshikawa

Apr. 1975	Joined SUMITOMO CORPORATION
Apr. 2005	Senior Officer, General Manager of the Life Science Division of SUMITOMO CORPORATION
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 and Planning Division
Jun. 2013	Executive Vice President, Head of the Development and Planning Division
Apr. 2016	Executive Vice President, Head of the Procurement Division
May 2019	Executive Vice President, Procurement and Biosimilar (present position)

Executive Vice President
Operational Excellence
Hiroshi Kawagishi

Apr. 1979	Joined the Company
Dec. 2003	Director of Production Department 1, Namerikawa Plant of the Company
Dec. 2005	Plant Manager, Director of Production Department 1, Namerikawa Plant
Dec. 2010	Vice President, Production Division, Plant Manager and Director of Production Department 1, Namerikawa Plant
Feb. 2013	Vice President, Deputy Head of the Production Division, Plant Manager, Toyama Plant
Jun. 2014	Vice President, Director of the Production Management Office, Nichi-Iko Pharma Tech Co., Ltd. (secondment)
Apr. 2015	Senior Vice President, Head of the Production Division
May 2019	Senior Vice President, Operational Excellence
Jun. 2019	Executive Vice President, Operational Excellence (present position)

Independent Director
(Chairman of the Toyama Chamber of Commerce and Industry)
Shigeo Takagi

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)

Independent Director
(Dean, Faculty of Pharmacy and Pharmaceutical Sciences of the University of Toyama)
Hideki Sakai

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

Independent Director
(Attorney at law)
Hajime Imamura

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)

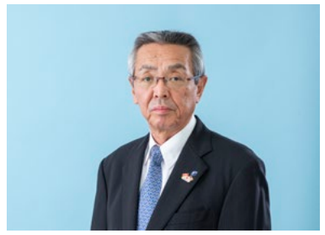
Independent Director
(Medical Doctor, Toyama Prefectural Assembly Member)
Kyoko Tanebe

Jun. 1990	Clinical Fellow, Toyama Medical and Pharmaceutical University Hospital
Feb. 1991	Medical Doctor, Department of Obstetrics and Gynecology, of Aiiku 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 & Supervisory Board Members (as of June 21, 2019)

Audit & Supervisory Board Member
Toru Ishise

Apr. 1980 Joined the Company
Dec. 2009 Vice President, Deputy Head of the Production Division
Dec. 2011 Senior Vice President, Head of the Production Division
Jun. 2012 Senior Vice President, Head of the Quality Assurance & Pharmacovigilance Division
Mar. 2014 Director of Nichi-Iko Fuji Plant Establishment Preparation Office
Apr. 2014 Representative Board Member and Plant Manager, Nichi-Iko Pharma Tech Co., Ltd. (secondment)
Apr. 2015 Senior Vice President, Deputy Management of the Quality Assurance & Pharmacovigilance Division and the Production Division
Apr. 2016 Senior Vice President, Head of the Development and Planning Division
Apr. 2018 Compliance & Internal Auditors Office
Jun. 2018 Audit & Supervisory Board Member (present position)



Audit & Supervisory Board Member
Toshinori Kongoji

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 and Marketing Division
Jun. 2010 Executive Vice President, Head of the Sales and Marketing Division
Apr. 2017 Executive Vice President, Sales and Marketing Division
Apr. 2018 Executive Vice President
Apr. 2018 Executive Vice President of ELMED EISAI Co., Ltd. (secondment)
Apr. 2019 Executive Vice President, Compliance & Internal Auditors Office
Jun. 2019 Audit & Supervisory Board Member (present position)

Audit & Supervisory Board Member (Independent)
(Certified Public Accountant, Tax Accountant)
Hitoshi Hori

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 (present position)

Audit & Supervisory Board Member (Independent)
(Certified Public Accountant, Tax Accountant)
Kou Sato

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 (present position)

Operating Officers (as of June 21, 2019)

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

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

Senior Vice President
Head of the Development & Planning Division
Tetsuo Kadozaki

Senior Vice President
Head of the Quality Operations Division
Tomoaki Tamura

Senior Vice President
Head of the Sales & Marketing Division
Akihito Tsuge

Senior Vice President
Head of the Production Division
Masatoshi Takaishi

Senior Vice President
Head of the Administrative Division
Shuji Ishida

Senior Vice President
Head of the Procurement Division
Atsushi Matsumoto

Senior Vice President
Head of the Biosimilar Development Office
Kenji Matsuyama

Vice President
President Office
Mitsuyuki Azuma

Vice President
Development & Planning Division
Toru Kogawa

Vice President
Deputy Head of the Administrative Division
Yoichi Arakawa

Vice President
Deputy Head of the Quality Assurance & Pharmacovigilance Division
Takao Ban

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

Vice President
Deputy Head of the Procurement Division
Xiaoqian Chen

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

Vice President
Deputy Head of the Production Division
Hiroaki Oribe

Independent Director

Shigeo Takagi

Chairman of the Toyama Chamber of Commerce and Industry
Supreme Advisor, The Hokuriku Bank, Ltd.
Independent Director, Hokuriku Electric Power Company
Audit & Supervisory Board Member (Independent), Seiren Co., Ltd.
Audit & Supervisory Board Member (Independent), Kawada Technologies, Inc.

I believe the role of the Independent Director is to lend indirect support to a company's challenges. Given my background in financial institutions, I strive to determine–in the case of M&As, for example–whether cost-performance ratios and synergies have undergone specific, numerical validation. I also focus on overseas expansion from the perspective of cash flow.

Expectations for the generic drug industry have grown as health care costs have risen in recent years. Responding to those expectations will, I think, require expanding the number of products in addition to improving quality and providing a stable supply. Nichi-Iko should continue taking on fields, such as biosimilars (biogenerics), that have yet to penetrate the market.

Japan can be seen as an advanced nation facing problems of an aging population. Nichi-Iko can contribute to the world by leveraging its expertise as a pharmaceutical company working in such an environment. In that sense, as well, I look forward to further global growth of the Company.

Nichi-Iko's greatest strength is that it has both an unchanging attitude toward providing "premium quality" and "shall excel around the world," and a flexibility that is unafraid of change. The Company should press ahead prudently with policies that are right for the times, including expanding its operations and investing in developing personnel responsible for improving quality. It should also focus further on its ongoing diversity efforts. That will be the key to long-term growth.

While Nichi-Iko works to contribute to society in many ways, in the long term, I think its biggest contribution will be the growth of its primary business. I hope to continue supporting that effort going forward.

Hideki Sakai

Professor, Graduate School of Medicine and Pharmaceutical Sciences of the University of Toyama
Dean, Graduate School of Medicine and Pharmaceutical Sciences for Research, University of Toyama
Dean, Faculty of Pharmacy and Pharmaceutical Sciences of the University of Toyama

Nichi-Iko's mission statement says, "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." To continue achieving this mission, it must, under the strong leadership of its President and CEO, Yuichi Tamura, constantly provide society with drugs that offer both high quality and high added value.

I accepted the post of Independent Director, because of how impressed I was by President and CEO Tamura's passion for and sincere approach to drugs. Nichi-Iko's policy is to create for patients as many varieties of "premium quality" generic products as possible. Creating such variety requires extraordinary ingenuity, perseverance and effort. I have over 25 years of experience as an academic in the pharmaceutical sciences. Based on the specialized knowledge of the pharmaceutical sciences I have acquired over the years, I hope to contribute to further improvements in Nichi-Iko's drug formulation technology and product quality.

Nichi-Iko is also focused on development of biosimilars. Generally, prices for original biopharmaceuticals are quite high compared to small-molecule drugs. Nichi-Iko's efforts to create biosimilars not only benefit patients, but also will lead to a major contribution toward reducing health care costs.

While the Company currently leads the domestic market in generic drugs, I am confident that going forward, it will become–as its mission statement offers–one of the most respected, well-established companies in the world in both generic products and biosimilars.

Hajime Imamura

Representative of Imamura Law Office
Attorney at law
Independent Director, TANAKA SEIMITSU KOGYO CO., LTD.

Based on my 35 years of experience as a practicing lawyer, I work to provide advice and recommendations with an emphasis primarily on problems involving internal controls and compliance.

The corporate governance code revised in 2018 now requires companies to deal appropriately with sustainability, including social and environmental problems. Companies should also ensure that their non-financial information is highly useful. Their disclosures regarding governance and social and environmental problems (so-called ESG components) must provide useful information. This is an indication of changing trends in the way corporate activity is evaluated. While this trend may strengthen going forward, it is not likely to be reversed. I believe efforts to address this issue will lead to medium- to long-term improvements in corporate value, and I would like to keep an eye on this issue from that perspective.

Nichi-Iko already has a significant presence in Japan as a generic pharmaceutical company. Going forward, they are expected to provide appropriate products to meet the needs of a global market as well.

I look forward to seeing Nichi-Iko grow to be recognized as an indispensable presence in society. As part of that effort, I will work to fulfill my role as Independent Director.

Kyoko Tanebe

Committee Member of the Expert Panel of Priority Policy, Council for Gender Equality Bureau of the Cabinet Office
Executive Director of Toyama Medical Association (public interest incorporated association)
Executive Director, Japan Association of Obstetricians and Gynecologists
Representative of Women's Clinic We! Toyama
Toyama Prefectural Assembly Member

As a practicing medical doctor, I make recommendations based on looking ahead to the future of medical policy and healthcare needs. Having also been in charge of ethical screening of clinical research and investigations into malpractice at medical organizations, I believe one of my duties is also to leverage that experience to monitor and supervise business from the point of view of risk management and human error prevention. For many years, I have also worked as a member of a specialist committee of the Cabinet Council for Gender Equality. This includes involvement in creating and evaluating key policies aimed at diversity and inclusion, and at achieving a society in which women can play an active role. Given this experience, I would like to be involved in diversity promotion, harassment prevention and other people strategies, as well as ESG-related risk controls.

Promoting diversity is an important issue for a company hoping to expand globally. Nichi-Iko should work to create an organization in which diverse people, including women, non-Japanese, minorities and others play an active role. This will also lead to improvement in its presence as an advanced company. I also believe the company should contribute to a more stable international situation by working to make contributions based on sustainable development goals, not only in Japan but also in countries around the world.

Nichi-Iko is based in a region where population decline is advancing. I believe there is significant value in companies like Nichi-Iko expanding globally while engaging in people strategies centered on diversity. I look forward to Nichi-Iko building a leading industry presence as a company undaunted by population decline.

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 Executive Vice Presidents, heads of each department and others. Based on our fundamental risk management policies, we work to address risks that might affect the advancement and growth of the Group operations and our 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, and implementing appropriate countermeasures to ensure the continued, stable growth of the business.

Divisions in charge of internal audits, compliance, risk management and other areas are also required to report regularly to our Audit & Supervisory Board Members regarding the status of our subsidiaries.

Regulations and other structures governing management of the risk of losses at subsidiaries are as noted below.

I) Subsidiaries are required to conduct risk management under the Nichi-Iko Group Risk Management Regulations, which set forth the Group's risk management policies. This ensures that risks are managed comprehensively across the Group.
II) Nichi-Iko operates a Risk Management Committee that serves as the entity in charge of risk management for the Group, and which deliberates issues and countermeasures involving the implementation of Group risk management.

Compliance

As the basis for its compliance structure, Nichi-Iko has established the Nichi-Iko Group Charter of Corporate Conduct, standards of conduct for officers and employees of the Nichi-Iko Group, and the Nichi-Iko Group compliance regulations. These serve as a code of conduct for ensuring compliance with laws, regulations and our corporate by laws. The spirit of the Charter and code of conduct is regularly invoked by the President and CEO as a means of enforcing legal compliance as a precondition for all corporate activity. In order to give tangible shape to these objectives, an Internal Control committee has been established, chaired by the President and CEO and comprised of members including Executive Vice Presidents, head of each department and others, for the purpose of promoting the development, maintenance and improvement of internal control systems. In addition, a Compliance Committee has been established for the purpose of developing and maintaining compliance structure.

The Compliance Committee is chaired by the Executive Vice President in charge of CSR and ESG. The committee identifies cross-sectional compliance issues at the Group level, conducts analyses and works to implement countermeasures, as well as engaging in the formulation of rules and guidelines and conducting training.

Divisions and subsidiaries must promptly report to the Compliance Committee in the event compliance-related issues are discovered. At the same time, the Compliance Committee works to acquire information under internal reporting system regulations. It investigates the content, finalizes measures to prevent recurrence based on discussions with individual business divisions, and enforces implementation of those measures on a Company-wide level. It also issues reports to the Risk Management Committee, the President and CEO as well as the Board of Directors.

Information is exchanged at regular meetings comprised of the Executive Vice President in charge of CSR and ESG, the Audit & Supervisory Board, the Compliance & Internal Auditors Office and the Accounting Auditors. The results of those discussions are reported to the Compliance Committee.

Nichi-Iko applies rigorous rules against anti-social Forces and other organizations that threaten civic order and security. As a defense against baseless or unlawful demands, we maintain a close collaboration with dedicated external organizations including law enforcement, attorneys and others and take systematic countermeasures.

Compliance and Risk-taking

An Internal Control Committee has been established for the purpose of developing, maintaining and improving internal control systems. Our risk management structure is based on established Group risk management regulations, and we have also installed a Risk Management Committee. The Risk Management Committee works to address risks that might affect the advancement and growth of the Group operations and our 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, and implementing appropriate countermeasures to ensure the continued, stable growth of the business.

A Compliance Committee has also been established as a means of enforcing legal compliance as a precondition for all corporate activity, and works to develop and maintain our compliance systems.

Business Continuity Plans (BCP)

The Company has formulated a Business Continuity Plan (BCP) to address procedures in the event of a disaster, accident or other emergency situation.

In case 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, we have created a BCP manual along with a disaster handbook that all employees carry with them. We also conduct regular emergency response training at all of our business sites.

Business and Other Risks

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 the Healthcare System	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 requirement as well as by monitoring systems. Further changes in the healthcare system may affect the business performance of the Group.
Entry of Original Drug and Foreign Drug Manufacturers	The expansion of the generic drug market is likely to continue. In conjunction with this outlook, original drug manufacturers in Japan as well as international pharmaceutical companies may actively seek entry into the Japanese generic drug market. This is likely to force even more intense competition on the generic drug industry, and may affect our business performance.
Revision of National Health Insurance Drug Prices	In Japan, drug prices are generally revised every two years, but beginning in April 2021, the government plans to enact drug price revisions in interim years as well, resulting in annual revisions. Additional drug price revisions are also scheduled to coincide with the raising of the consumption tax in October 2019. Depending on the size of price reductions resulting from these revisions, the Group's business performance may be affected.
Patent Litigation	Due to the nature of generic drugs, the manufacturer of the original drug may initiate patent litigation. Such litigation, should it occur, may affect the business performance of the Group.
Regulatory Control	In the event of a violation of laws and regulations governing the approval and licensing of drug manufacturing and marketing, regulatory agencies could impose a penalty on us, including 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.
Suspension of Product Sales and Recalls	Generic drugs typically entail an extremely small risk of serious adverse events. Should new, unforeseen adverse events arise, or in the event of accidents involving contamination of products with impurities, we may be forced to suspend sales and recall the products, which could affect the Group's performance.
Risks Related to Capital and Business Alliances	In addition to product marketing and joint development of generic drugs, the Group is engaged in capital and business alliances with other companies in the development of biosimilars and other products. If circumstances should lead to a change in or cancellation of such alliance partnerships, this could affect the Group's performance.
Risks Related to Slowdown or Delays in Production due to Disasters, etc.	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.
Risks Related to Development of Biosimilars	Compared to generic drug development, the development of biosimilars requires longer development periods and greater expense. The Group's performance could be affected in the event circumstances result in development delays or an unexpected increase in development costs.
Risks Related to Sales of Authorized Generics* by Other Companies	In the event an affiliate or other company associated with an original drug manufacturer markets an authorized generic prior to patent expiration, that company could monopolize market share, which in turn could affect the Group's performance.
Risks Related to M&A	We expect that the acquisition of subsidiaries through M&A will contribute significantly to the Group's performance going forward. That said, should such acquisitions perform below initial assumptions due to changing business conditions or for other reasons, this could lead to impairment of goodwill or other treatment, which in turn could affect the Group's performance and financial position.
Risks Related to Stock Dilution	Nichi-Iko has adopted a stock option program, under which stock warrants are granted to the Company's Executive Vice Presidents, employees and others. The exercise of these warrants could dilute the Company's per-share price.

* Drugs marketed as generics by different manufacturers who have been granted marketing rights by the original drug manufacturer.

Society

Quality Control

About Product Quality

Nichi-Iko drug products are nurtured through a process of planning, design, development, manufacturing, marketing and distribution. We have built a system of continuous improvement to ensure we deliver generic drugs of the finest quality and highest safety to the patients who use them and their families.

Quality in Planning and Design	We work to understand the needs of patients and medical professionals, and to quickly gather information in response to those needs.
Quality in Development and Manufacturing	We develop high-quality products based on scientific grounds, and manufacture them in compliance with PIC/S*1 GMP.
Quality in Marketing and Distribution	In compliance with marketing information provision guidelines and GDP, we ensure a stable supply.

Quality Assurance Structure

To comply with our quality policies and the "Standards for Quality Assurance for Drugs, Quasi-drugs, Cosmetics and Medical Devices" (GQP) as set forth by ordinance of the Ministry of Health, Labour and Welfare, the Quality Operations Division independent of the Production Division conducts quality control tests, and along with the Toyama Site QA Department, which ensures manufacturing and quality controls, conducts rigorous checks of product quality.

Further, we offer products of outstanding quality by having quality assurance units responsible for manufacturing and marketing operations ensure that each plant is conducting manufacturing and quality controls appropriately.

Ensuring a High Degree of Safety

While drugs may demonstrate efficacy, they may also invite the risk of adverse events. Information on the safety and efficacy of products following their launch is essential to reducing that risk and ensuring the proper use of drugs.

At Nichi-Iko, the Safety Assurance Department collects this safety information post-marketing. Following correct and objective evaluation and analysis, the information is reflected in package insert and provided to medical professionals via our MRs (responsible for drug information) and the internet, part of a variety of measures we take as needed.

Quality Policy

The Nichi-Iko Group complies with all drug-related laws and regulation. We make every effort to understand the expectations of our patients and their families, pharmacists, doctors, distributors and other pharma companies around the world, and we promise to deliver our products to respond to their expectations.

While the Nichi-Iko Group is compliant with drug GMP and GQP, we are also working to quickly build the systems required by "the Pharmaceutical Quality System "called for by the ICH*2. On behalf of the Nichi-Iko Group, I am committed to keeping this promise.

We have established quality targets, including those listed below, and I will personally review the results and determine the degree to which they have been achieved.

1. We will work to ensure that everyone within the organization is familiar with regulatory compliance, based on the ethics and morals of "drugs."
2. We will work to have a complete understanding of user expectations, needs and grievances, and to reflect that understanding in improvements to existing products and the development of new ones.
3. We will centralize management of quality information from "drug" development to production to marketing, and engage in continuous corrective and preventive measures.
4. Ahead of decisions by our manufacturing outsourcers and API suppliers, we are conducting rigorous evaluations and audits of operational performance capabilities and supply suitability and capacity, and will monitor their status on an ongoing basis.
5. We will completely ensure technology and information regarding quality are handed down, and bring commitment to our efforts to maintain and improve quality.
6. I will directly review every report involving quality assurance and will make appropriate judgements regarding matters including investment of management resources.

May 1, 2010 **Yuichi Tamura**, President and CEO

*1 The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme, which serves as an international standard for GMP
*2 The abbreviation for International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

Society

Information Provision

Nichi-Iko's Information Provision Structure

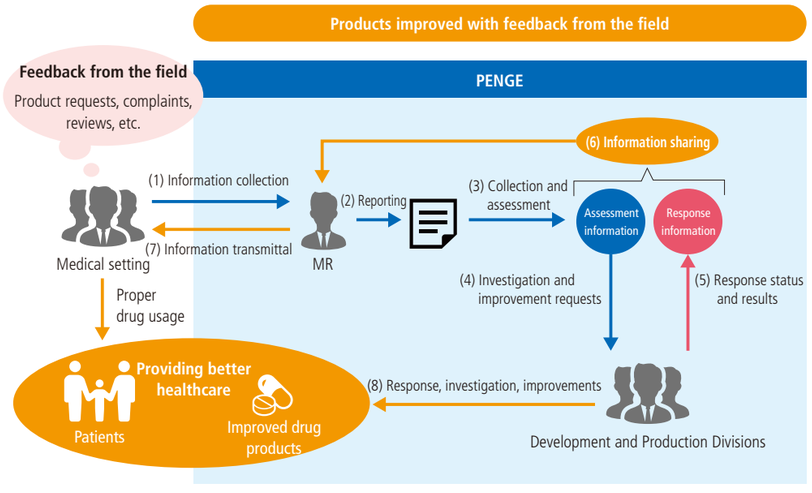
At Nichi-Iko, about 360 MRs provide information about drug efficacy, safety and other aspects of proper use to medical institutions nationwide, complying with the Promotion Code and the Guidelines for Prescription Drug Marketing Information Provision Activities. They also work to gather information on 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. The number of explanatory meetings held is increasing, with growth especially high in years when medical fees are revised.

PENGE (Post-marketing Information Collection System)

Nichi-Iko has employed PENGE, a system for post-marketing drug evolution, to ensure that all of our MRs collect information in the field on product and improvement needs, and that this information leads to product improvements and drug development. The name PENGE is an acronym for Product Evolution of Nichi-Iko's GEneric drugs, and the system is designed to evolve improved products that meet the needs of a medical setting.



Collect and perform proprietary assessment and analysis of post-marketing product information. PENGE was built as a system for adding product improvements based on this information.

Establishment of a Customer Support Center

Nichi-Iko has established a Customer Support Center which serves as a point of contact for product-related questions and advice. It handles inquiries and requests for materials by phone, and works to support efforts to 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.

Customer Support Center

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

Information is promptly distributed and provided via the information page for healthcare professionals on the Nichi-Iko website, where information of use to healthcare professionals is posted. Our product information search allows users to search and view package inserts, information on proper use, photos of formulations and other data.

Society

People

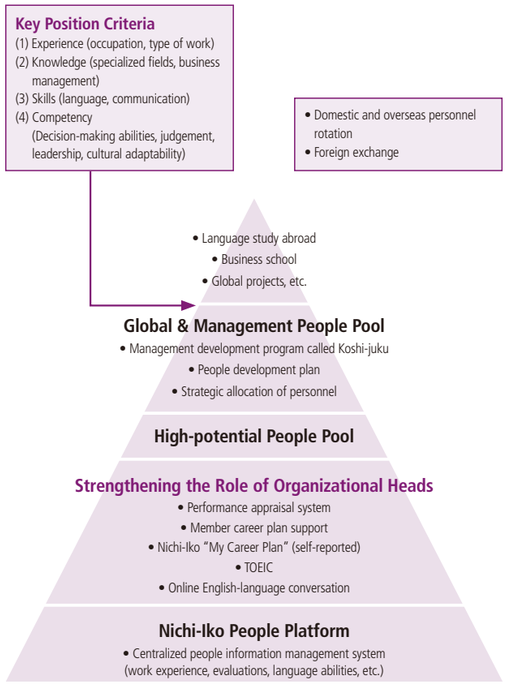
The people that support our business are Nichi-Iko's most valuable asset. We are working to create rewarding, pleasant workplaces and to develop individual abilities.

Creating a Rewarding Organization

In the midst of a continuing decline in Japan's work-age population, in April 2019 the government enacted a workstyle reform law, marking a significant change in ideas about "employment" and "work." In response to this societal shift, and to bring us closer to our goal of becoming a dominant global generic pharmaceutical company, in April 2019 we established a new Human Resource Development Department. This will consolidate all of our various people development efforts to date for the Nichi-Iko Group as a whole.

To make the leap forward to becoming a global comprehensive generic pharmaceutical company, we will strengthen our structure for developing a succession of people who will bring a global management perspective to their roles. The most important thing is that we prepare a path for each and every employee to make the most of their capabilities and find self-fulfillment. We are thus beginning work on designing the Nichi-Iko People Platform as a system for ensuring we take all of our employees' career plans seriously.

Overview of the Nichi-Iko People Platform



Human Resource Development Initiatives

Education and Training

Language ability is the first step toward playing a global role. Nichi-Iko opens the door for all employees to take the TOEIC exam, establishing award programs and programs that support self-improvement, and tying these into its overseas language study program.

We also focus our efforts on developing the next generation of executive management, recruiting ambitious young employees for the management development program called "Koshi-juku" we have created. While the program is designed to provide the learning, knowledge, skills and qualifications needed to act from a management perspective, more than anything it offers an opportunity for exposure to the thinking of top management through direct dialogue.

Stratified training is conducted by using a curriculum tailored to the individual's position, from introductory training for new employees to training for the heads of organizations.

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. Once they have been assigned to and take their first steps in their new positions, we support them further with mentoring programs and on-the-job training.

The role of organizational heads in people development has grown increasingly important. We conduct training for the heads of organizations across the Company to ensure that members gathered in an organization can exercise unlimited collaborative power and go beyond the status quo.

As a company whose business involves human life, our 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.

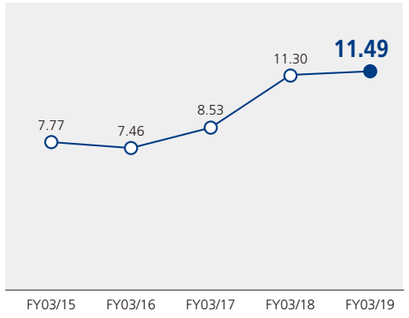
Diversity and Work-Life Balance

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

(1) 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) (%)



(2) Supporting a Balance Between Work, Child-rearing and Caregiving

We have carried out a variety of measures based on the "Act on Measures to Support the Development of the Next Generation," putting in place and working to expand programs that go beyond legally required standards.

- 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.
- Under the program for working shorter hours during caregiving, employees can now divide accumulated leave indefinitely, rather than within three years from start.

Number of Employees Taking Childcare Leave (Non-consolidated)

(People)

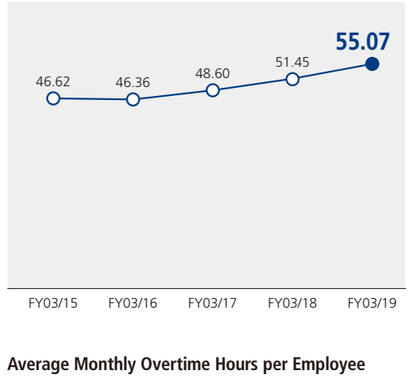
	FY03/15	FY03/16	FY03/17	FY03/18	FY03/19
Male	0	1	0	2	1
Female	8	8	7	9	10
Total	8	9	7	11	11

(3) Reducing Work Hours; Offering Flexible Schedules

We are working to change how employees approach and perform their jobs, offering a new approach to working hours that results in greater productivity.

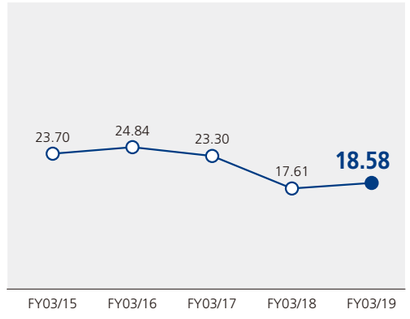
- Flextime system
- "Super-flex" (no core hours)
- Donor leave program
- Utilization of accumulated paid leave (personal illness or injury, infertility treatment, childcare, caregiving, nursing)
- Encouraging systematic utilization of accumulated paid leave (scheduled leave program)
- Visualization of working hours (attendance management system improvements, PC log confirmation)

Annual Paid Leave Utilization Rate (Non-consolidated) (%)



Average Monthly Overtime Hours per Employee (Non-consolidated)

(h)



(4) Promoting Employment of Persons with Disabilities

We are working to draft and execute comprehensive measures to actively support the participation of people with disabilities.

(5) Hiring of Non-Japanese Employees

We are advancing efforts toward "global hiring," focused on hiring of non-Japanese employees–primarily international students–and students who have graduated from high school and college outside of Japan. These employees are active in a variety of areas, including the Development and Procurement divisions.

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 short, 5-minute seminars by public health nurses are also held during our morning meetings and at other times, part of our efforts to enhance employee awareness of safety and health issues. Our Safety and Health Committee meets monthly to report on safety and health deficiencies and other matters and to conduct improvements where necessary. The Safety and Health Committee reports on departments with large amounts of overtime, working to verify the underlying causes and otherwise prevent long working hours. In terms of mental health, the Company conducts annual stress tests, which we are required to do under the law.

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 is filed covering industrial accidents occurring at all plants. Each plant then works to prevent a recurrence by identifying problems to ensure a similar accident does not occur.

Once a month, we use our internal network to publish reports available for viewing by all employees, including our "Health Newsletter," "Safe Driving Report" and "BCP Communique." The "Health Newsletter" offers content related to health, including mental health issues. "The Safe Driving Report" provides precautions about operating automobiles and bicycles, while "the BCP Communique" includes information on how to respond to earthquakes, typhoons, torrential rains and other disasters, and lists information on disasters that actually occurred. These publications are designed to benefit the safety and health of our employees.

As a result of the key safety and health initiatives noted above, our industrial accident frequency rate (number of deaths and injuries resulting from industrial accidents per one million actual working hours) was 0.34 in the one year between January and December 2017. Our severity rate (total number of lost work days per 1,000 actual working hours), an indication of the severity of such accidents, was 0.001 in the one year between January and December 2017. In the one year between January and December 2018, our accident frequency rate and severity rate were both zero, as no industrial accidents occurred that resulted in a shutdown of one day or more, or the loss of a body part or the functioning thereof.

To prepare for every kind of disaster, we have established a Business Continuity Plan (BCP), and are constantly collecting new information and reviewing the plan as needed to ensure we maintain the best possible BCP any time. 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, and to provide flash reports to upper management. We have also deployed stockpiles of emergency goods to prepare for a possible disaster.

Safety and Health Education: Publishing the "Health Newsletter"

Once a month we publish our "Health Newsletter." We carefully select a theme for each issue based on current needs and provide a variety of health information. The newsletter plays an important role in disseminating health-related information. We sometimes receive requests from employees about specific subjects, as well as many responses indicating that employees are learning from and enjoying the publication.

Conducting Health Education

During the morning meetings at our plants and headquarters, we hold "5-minute Seminars" on topics such as dealing with heatstroke, offering information our employees need to manage their health. This effort is aimed at increasing health awareness and employees' self-management skills. To address mental health issues, we also hold "Self Care Training" for all employees, as well as "Line Care Training" etc. aimed at supervisors. Through these efforts, we take care to prevent, quickly discover and promptly deal with mental health problems.

Society

Connecting with Communities

Open Innovation "University of Toyama Innovation in Medicine"

As part of our CSR activities, the Company supports university research and educational activities in the belief that the results of such research can lead to the wider development of society.

At the University of Toyama, we have donated an endowed lecture in "Drug Formulation Design" (for the five years between April 2015 and March 2020), as well as donating to "the University of Toyama Immunobiology Lecture Fund" (three years between April 2016 and March 2019).

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.

* Certain results were achieved through "the University of Toyama Immunobiology Lecture Fund" in FY03/18, and in "the Drug Formulation Design lecture" in FY03/19.

Key Social Contributions

• 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, we placed a donation box at the Nichi-Iko Toyama headquarters, the Tokyo headquarters, our plants, branches, and group companies. Medical institutions that endorse the Company's purpose have also installed donation boxes.

Practice walk with an Eyemate guide dog

• Support for Music and Sports

Since 2008, we have held an LPGA tour at Yatsuo Country Club in Toyama City, Toyama Prefecture, the location of our headquarters, in the hope of creating a gateway for young female golfers to "go challenge the world." Employees participate as volunteer staff during the tournament.

We have 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 an image of Nichi-Iko leaping into the future, supporting them with its creativity.

• Other Support Activities

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.

Nichi-Iko Presents: "Deliver the Goalkeeper"

Since 2012, we offer support to junior high schools in Toyama Prefecture who request it for training of future goalkeepers hoping to be active nationwide and around the world. Goalkeeper coaching is provided twice a month for four hours on the field or in the gymnasium etc. at each school. Of the schools we have guided, some have gone on to win their regional tournaments, and even moved on to the Toyama prefectural junior high school tournament.

Nichi-Iko Presents: "Kids Enjoy Soccer"

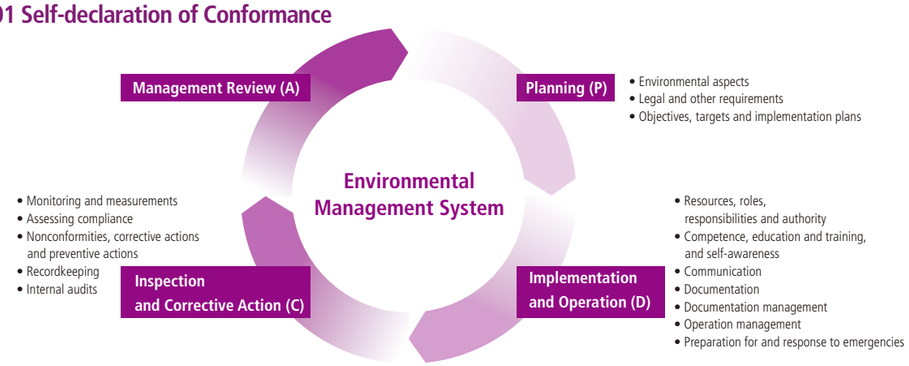
We have hosted this activity since April 2014 on the soccer field within the premises of Toyama Plant with the aim of providing a place where preschoolers living in the Namerikawa area of Toyama Prefecture can kick the ball and run around as much as they want. We hope this activity provides preschoolers who have vast potential with good encounters and stimulus through soccer.

Nichi-Iko Boys/Girls PK Tournament

We have opened the field within our Shizuoka Plant since 2014 to hold this tournament each August to support many local residents, from children to adults, in living healthy lives. We have also opened the multi-purpose green space within Toyama Plant since August 2017 to hold this tournament.

Environmental Initiatives

ISO 14001 Self-declaration of Conformance



The Company has built an environmental management system in accordance with the ISO 14001 standard, and in June 2017 made a self-declaration of conformance.*

* 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.

Basic Principles

The Nichi-Iko Group recognizes that initiatives to address environmental issues are a part of its social responsibility, and will continue to promote initiatives to reduce and improve the environmental impact of its business activities.

* Our goal is to maintain harmony with the natural environment, while contributing to people's healthy lives.

Code of Conduct

1. We will conduct environment-friendly production in all processes from manufacturing to disposal in an effort to prevent global warming and realize the formation of a recycling-oriented society.
   (1) We will properly manage the chemical substances we use.
   (2) We will reduce our environmental load on the air and water.
   (3) We will promote the 3Rs (reduce, reuse, recycle) while thoroughly conducting waste management.
   (4) We will promote the conservation of resources and energy.
2. We will make efforts toward sustainable environmental improvement while taking thorough measures to prevent any impact on the local environment even in times of accidents and emergencies.
3. We will comply with environmental laws and regulations, agreements and requirements which the organization has decided to accept, and will also make efforts to improve environmental management by setting voluntary control standards.
4. We will continuously improve our environmental management system by setting the environmental impact of business activities in our environmental objectives and targets, promoting such initiatives in a planned manner, and regularly conducting reviews.
5. We will promote social contribution activities and communication with local communities.
6. We will familiarize all persons who work at or work for the organization with this environmental policy.
7. We will distribute or disclose this environmental policy upon request from within or outside the Company.


Environment seminar


Environment Committee


Wastewater treatment education

Applicable Standards and Scope of Self-declaration of Conformance

Applicable standards: JIS Q 14001:2004, ISO 14001:2004

* Considering conforming to ISO 14001:2015

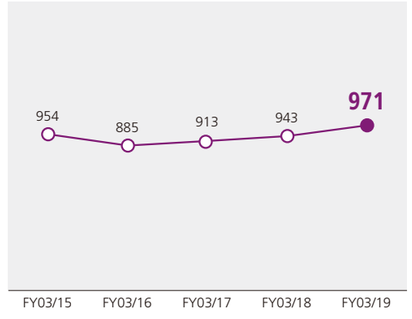
Scope of application: the Nichi-Iko Group's seven domestic plants (Hokkaido, Yamagata, Saitama, Aichi, Shizuoka, Toyama 1, Toyama 2)

Status of Internal Environmental Audits

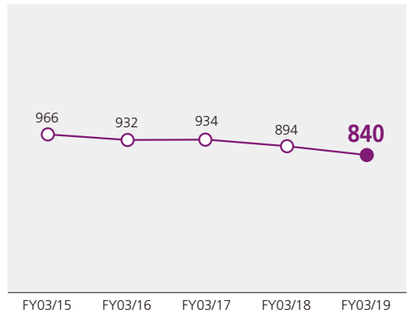
To prevent the cessation of activities, in our environmental management system we conduct internal environmental audits through mutual audits by accepting auditors from other plants.

Environmental Data (7 Domestic Plants)

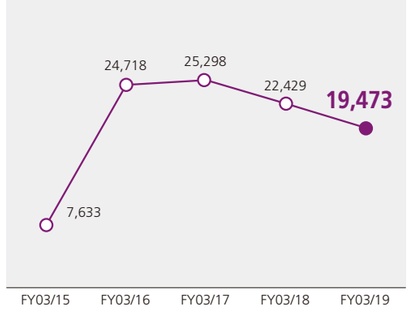
Water resource input (clean water, industrial water) (thousand m³)



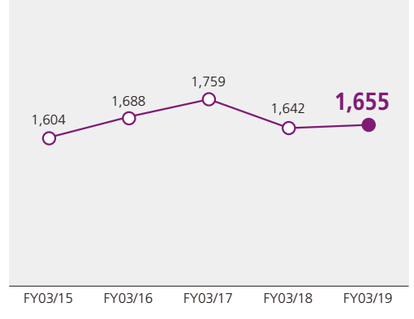
Total wastewater (thousand m³)



Total specified chemical substance emissions and transfers (kg)



Waste, etc. generated (t)



* Refer to pg. 10 for energy use and CO_2 emissions

Financial Summary

(Millions of yen)

	JGAAP								IFRS	
	2010/11	2011/11	2012/3	2013/3	2014/3	2015/3	2016/3	2017/3	2018/3	**2019/3**
Financial Highlights										
Performance (actual results on a consolidated basis)										
Revenue	64,352	77,740	26,998	93,926	103,622	127,021	143,513	163,372	164,717	**166,592**
(Of which, Nichi-Iko Group*1)								151,224	128,659	**131,076**
(Of which, Sagent Group)								12,148	36,058	**35,515**
Operating profit	7,097	7,492	2,139	8,229	7,383	9,619	12,910	8,554	10,301	**8,223**
(Of which, Nichi-Iko Group*1)								8,181	12,035	**11,370**
(Of which, Sagent Group)								372	(1,733)	**(3,147)**
Core operating profit									14,368	**13,320**
(Of which, Nichi-Iko Group*1)									12,074	**11,745**
(Of which, Sagent Group)									2,294	**1,575**
Profit attributable to owners of parent	3,865	3,908	1,330	5,129	4,588	6,592	11,031	4,788	8,070	**6,864**
Financial Position										
Total assets	65,575	82,786	88,455	102,921	129,130	139,834	161,128	270,890	278,364	**306,838**
Net assets	26,099	44,593	45,528	48,810	66,195	74,487	82,597	87,580	87,542	**116,323**
Cash flow										
Cash flow from operating activities	2,747	1,371	3,627	9,770	5,546	21,179	7,097	3,951	18,925	**23,811**
Cash flow from investing activities	(5,409)	(9,504)	(1,594)	(7,192)	(9,826)	(14,647)	(3,485)	(81,754)	(15,896)	**(24,983)**
Cash flow from financing activities	2,826	10,645	(126)	(3,294)	20,676	(14,146)	10,626	64,620	3,206	**24,803**
Financial and management indices										
Amount of capital investment	4,079	5,318	1,666	10,709	4,586	5,949	9,880	11,076	12,705	**5,053**
Amount of R&D investment	2,006	2,065	783	3,250	4,441	4,984	4,874	7,263	9,045	**10,841**
Depreciation expenses	2,857	4,201	1,458	4,592	5,797	4,784	4,913	6,591	8,659	**9,401**
Net D/E ratio (multiple)	0.66	0.27	0.29	0.30	0.12	0.05	0.03	1.13	1.21	**0.76**
Ratio of total equity attributable to owners of parent	39.8%	53.9%	51.5%	47.4%	51.2%	53.2%	50.4%	32.2%	31.4%	**37.9%**
Return on equity attributable to owners of parent	17.2%	11.1%	3.0%	10.9%	8.0%	9.4%	14.1%	5.6%	9.5%	**6.7%**
Dividend payout ratio	26.1%	31.5%	32.5%	25.0%	27.0%	24.1%	16.3%	35.7%	21.0%	**26.0%**
Total shareholder return	123.6%	75.1%	79.5%	94.1%	72.5%	122.3%	116.4%	81.9%	80.9%	**73.5%**
Stock price at end of period (yen)	2,930	1,724	1,819	2,139	1,590	2,768	2,596	1,731	1,675	**1,468**
Per share information										
Basic earnings per share (yen)	122.50	101.54	32.92	128.14	104.75	110.26	184.45	84.09	143.19	**115.46**
Per share equity attributable to owners of parent (BPS/yen)	805.62	1,123.82	1,144.65	1,236.93	1,112.19	1,246.36	1,377.53	1,552.67	1,550.65	**1,825.00**
Dividend per share (yen)	32.00	32.00	10.70	32.00	28.30	26.60	30.00	30.00	30.00	**30.00**

* JGAAP applied through the fiscal year ended March 31, 2017; IFRS applied thereafter.
*1 Nichi-Iko Group excluding Sagent Group (consolidated companies of Sagent) from its consolidated basis.

Consolidated Financial Statements

Consolidated Statement of Financial Position

(Millions of yen)

Assets	2018 (March 31, 2018)	2019 (March 31, 2019)
Current Assets		
Cash and cash equivalents	18,529	42,093
Trade and other receivables	32,087	30,035
Inventories	74,321	66,783
Income taxes receivable	—	72
Other financial assets	974	447
Other current assets	2,365	3,290
Total current assets	128,278	142,722
Non-current Assets		
Property, plant and equipment	54,045	55,710
Goodwill	38,536	42,892
Intangible assets	45,735	46,721
Investments accounted for using equity method	6,380	12,993
Other financial assets	3,962	5,724
Deferred tax assets	1,326	9
Other non-current assets	99	64
Total non-current assets	150,086	164,115
Total Assets	278,364	306,838

(Millions of yen)

Liabilities and Equity	2018 (March 31, 2018)	2019 (March 31, 2019)
Liabilities		
Current liabilities		
Trade and other payables	50,686	44,172
Borrowings	35,499	37,435
Other financial liabilities	994	956
Income taxes payable	1,676	74
Provisions	2,928	—
Refund liabilities	—	2,196
Contract liabilities	—	116
Other current liabilities	5,608	6,884
Total current liabilities	97,394	91,837
Non-current liabilities		
Borrowings	85,625	90,739
Other financial liabilities	2,232	1,589
Retirement benefit liability	465	173
Provisions	56	57
Refund liabilities	—	75
Contract liabilities	—	865
Deferred tax liabilities	2,823	3,329
Other non-current liabilities	2,224	1,847
Total non-current liabilities	93,427	98,677
Total liabilities	190,821	190,514
Equity		
Share capital	19,976	23,360
Capital surplus	18,827	21,896
Other equity financial instruments	—	9,918
Treasury shares	(9,046)	(2,893)
Retained earnings	51,912	55,016
Other components of equity	5,872	9,025
Total equity attributable to owners of parent	87,542	116,323
Non-controlling interests	0	0
Total equity	87,542	116,323
Total Liabilities and Equity	278,364	306,838

Consolidated Statement of Income

(Millions of yen)

	2018 (April 1, 2017 to March 31, 2018)	2019 (April 1, 2018 to March 31, 2019)
Revenue	164,717	**166,592**
Cost of sales	123,914	**133,434**
Gross profit	40,803	**33,157**
Selling, general and administrative expenses	23,136	**22,504**
R&D expenses	4,467	**3,503**
Other operating profit	948	**1,528**
Other operating expenses	3,845	**455**
Operating profit	10,301	**8,223**
Core operating profit	14,368	**13,320**
Finance income	76	**192**
Finance expenses	1,259	**890**
Profit (loss) on investments accounted for using equity method	(51)	**1,377**
Profit before tax	9,067	**8,903**
Income tax expense	997	**2,039**
Profit	8,069	**6,864**
Profit attributable to:		
Owners of parent	8,070	**6,864**
Non-controlling interests	(0)	**(0)**
Profit	8,069	**6,864**
Earnings per share		
Basic earnings per share (yen)	143.19	**115.46**
Diluted earnings per share (yen)	142.92	**114.04**

Consolidated Statement of Comprehensive Income

(Millions of yen)

	2018 (April 1, 2017 to March 31, 2018)	2019 (April 1, 2018 to March 31, 2019)
Profit	8,069	**6,864**
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	800	**537**
Re-measurement of defined benefit plans	478	**162**
Share of other comprehensive income of investments accounted for using equity method	167	**(350)**
Total of items that will not be reclassified to profit or loss	1,446	**349**
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	(3,810)	**2,990**
Share of other comprehensive income of investments accounted for using equity method	(8)	**(71)**
Total of items that may be reclassified to profit or loss	(3,818)	**2,919**
Other comprehensive income (net of tax)	(2,372)	**3,268**
Comprehensive income	5,697	**10,132**
Comprehensive income attributable to:		
Owners of parent	5,698	**10,132**
Non-controlling interests	(0)	**(0)**
Comprehensive income	5,697	**10,132**

Consolidated Statement of Cash Flows

(Millions of yen)

	2018 (April 1, 2017 to March 31, 2018)	2019 (April 1, 2018 to March 31, 2019)
Cash flow from operating activities		
Profit before tax	9,067	**8,903**
Depreciation and amortization	8,659	**9,401**
Impairment loss	4,067	**4,730**
Interest and dividend income	(73)	**(56)**
Interest expenses	627	**650**
Share of loss (profit) of investments accounted for using equity method	51	**(1,377)**
Loss (gain) on retirement of property, plant and equipment	187	**108**
Decrease (increase) in trade and other receivables	383	**1,599**
Decrease (increase) in inventories	(7,061)	**8,085**
Increase (decrease) in trade and other payables	2,179	**(3,837)**
Increase (decrease) in provisions	603	**(1,042)**
Increase (decrease) in contract liabilities	—	**290**
Other	1,225	**(653)**
Subtotal	19,916	**26,800**
Dividends received	80	**86**
Interest received	18	**23**
Interest paid	(608)	**(663)**
Income taxes paid	(1,358)	**(2,443)**
Income tax refund	877	**7**
Cash flow from operating activities	18,925	**23,811**
Cash flow from investing activities		
Purchase of property, plant and equipment	(8,360)	**(7,440)**
Purchase of intangible assets	(5,940)	**(7,338)**
Purchase of investments	(7)	**(998)**
Purchase of investments accounted for using equity method	(1,665)	**(5,678)**
Collection of loans receivable	49	**598**
Proceeds from reversal of international interests	—	**999**
Business transfer expenditure	—	**(4,957)**
Other	27	**(168)**
Cash flow from investing activities	(15,896)	**(24,983)**
Cash flow from financing activities		
Net increase (decrease) in short-term borrowings	(123)	**(2,123)**
Proceeds from long-term borrowings	15,200	**16,700**
Repayments of long-term borrowings	(9,408)	**(7,920)**
Proceeds from issuance of new shares	—	**6,724**
Proceeds from disposal of treasury shares	235	**4,143**
Repayments of finance lease obligations	(1,010)	**(943)**
Proceeds from issuance of other equity financial instruments	—	**9,918**
Dividends paid	(1,686)	**(1,734)**
Other	(0)	**39**
Cash flow from financing activities	3,206	**24,803**
Effect of exchange rate changes on cash and cash equivalents	(163)	**(66)**
Net increase (decrease) in cash and cash equivalents	6,071	**23,564**
Cash and cash equivalents at beginning of period	12,457	**18,529**
Cash and cash equivalents at end of period	18,529	**42,093**

Company Information/Share Information

As of March 31, 2019

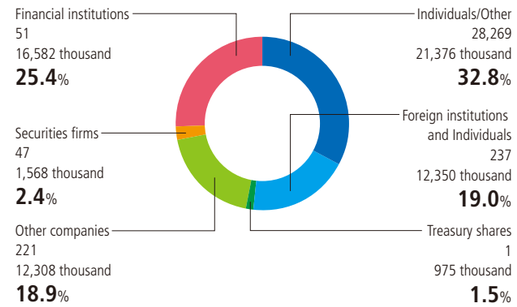
Company Information

Company Name	Nichi-Iko Pharmaceutical Co., Ltd.
Headquarters	1-6-21 Sogawa, Toyama-shi, 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
Employees	1,573 (consolidated)
R&D Sites	Global Development and Quality Control Center (Namerikawa-shi, Toyama Prefecture)
Production Sites	Hokkaido Plant (Kitahiroshima-shi, Hokkaido); Yamagata Plant (Tendo-shi, Yamagata Prefecture); Saitama Plant (Saitama-shi, Saitama Prefecture); Shizuoka Plant (Fuji-shi, Shizuoka Prefecture); Aichi Plant (Kasugai-shi, Aichi Prefecture); Toyama Plant 1/Toyama Plant 2 (Namerikawa-shi, Toyama Prefecture) Omega/Montreal Plant (Canada); Sagent/Raleigh Plant (U.S.); SterRx/Plattsburgh Plant (U.S.)
Distribution Centers	Hokkaido Distribution Center (Kitahiroshima-shi, Hokkaido); Nichi-Iko Distribution Center (Namerikawa-shi, Toyama Prefecture); East Japan Distribution Center (Kuki-shi, Saitama Prefecture); West Japan Distribution Center (Kobe-shi, 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
Domestic Group Companies	• Elmed Co., Ltd. (Toyama-shi, Toyama Prefecture) • Yakuhan Pharmaceutical Co., Ltd. (Kitahiroshima-shi, Hokkaido) • EMI Inc. (Osaka-shi, Osaka Prefecture) • Nichi-Iko Osaka Co., Ltd. (Higashiosaka-shi, Osaka Prefecture)
Overseas Group Companies	• Sagent Pharmaceuticals, Inc. (Chicago, U.S.) • Omega Laboratories, Ltd. (Montreal, Canada) • SterRx (New York, U.S.) • NIXS Corporation (Kansas City, U.S.) • Nichi-Iko (Thailand) Co., Ltd. (Bangkok, Thailand)

Share Information

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	28,826

Distribution of stock ownership by shareholder



Major Shareholders

As of March 31, 2019

Name	Address	Number of shares held (thousands)	Number of shares held as a percentage of the total number of shares issued (excluding treasury stock)
TAMURA Co., Ltd.	1-5-24 Sogawa, Toyama-shi, Toyama Prefecture	4,543	7.08
The Hokuriku Bank, Ltd.	1-2-26 Tsutsumicho-dori, Toyama-shi, Toyama Prefecture	2,831	4.41
The Master Trust Bank of Japan, Ltd. (Trust Account)	2-11-3 Hamamatsucho, Minato-ku, Tokyo	2,599	4.05
Taku Co., Ltd.	1-5-24 Sogawa, Toyama-shi, Toyama Prefecture	2,122	3.31
Japan Trustee Services Bank, Ltd. (Trust Account No. 9)	1-8-11 Harumi, Chuo-ku, Tokyo	2,023	3.15
Japan Trustee Services Bank, Ltd. (Trust Account)	1-8-11 Harumi, Chuo-ku, Tokyo	2,014	3.14
Yuichi Tamura	Toyama-shi, Toyama Prefecture	1,790	2.79
Nipro Corporation	3-9-3 Honjo-Nishi, Kita-ku, Osaka-shi, 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.	1,109	1.73
Japan Trustee Services Bank, Ltd. (Trust Account No. 5)	1-8-11 Harumi, Chuo-ku, Tokyo	967	1.51
Total	—	21,322	33.22

(Notes) 1. Of the above number of shares held, the number involving trust operations is as follows:

The Master Trust Bank of Japan, Ltd. (Trust Account)	2,599 thousand
Japan Trustee Services Bank, Ltd. (Trust Account No. 9)	2,023 thousand
Japan Trustee Services Bank, Ltd. (Trust Account)	2,014 thousand
Japan Trustee Services Bank, Ltd. (Trust Account No. 5)	967 thousand

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