Pharmaceutical Manufacturing and Sales Business

Nihon Generic Co., Ltd., Choseido Pharmaceutical Co., Ltd.

Instability in the drug supply stemming from quality issues continues to pose challenges to delivering drugs to the patients who need them. Group company Choseido Pharmaceutical Co., Ltd. was also subjected to administrative disciplinary action due to quality issues. Recognizing the seriousness of this issue, the Group is pursuing rigorous efforts to rebuild trust. In the Pharmaceutical Manufacturing and Sales Business, we will work together to ensure a stable supply of high-quality drugs at reasonable prices, earning the trust of patients and medical professionals.

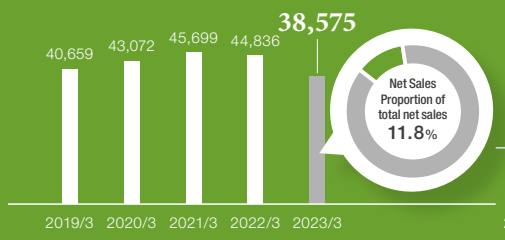
Quality Control Initiatives

To deliver a stable supply of generic drugs to patients, we are working to produce high-quality drugs under a manufacturing control and quality control framework that complies thoroughly with GxP* government regulations. We have introduced a system to ensure proper manufacturing and quality control. In addition, we are practicing quality risk management, setting quality targets based on our Quality Policy, and carrying out regular education and training for all employees at manufacturing sites, including in the manufacturing and quality departments. We pursued even more thorough-going quality control measures in FY2022, while also actively taking part in initiatives of the Japan Generic Medicines Association and working to help raise the level of quality across the generic drug industry as a whole.

*Abbreviation of Good x Practice. A general term for standards established by government agencies for the purpose of ensuring safety and quality. Includes GMP, GVP, etc.

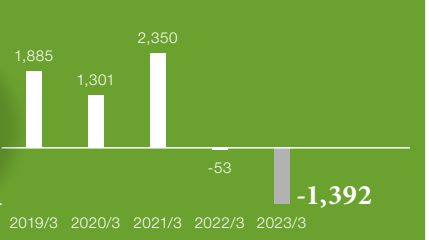
Net sales

Segment sales (millions of yen)



Operating profit*

Operating profit (millions of yen)



*The Pharmaceutical Manufacturing and Sales Business posted an operating loss due to one-time factors and was excluded from the calculation of the operating profit composition.

FY2023 Quality Targets

1. **Fostering a quality culture**
   Emphasizing quality, raising compliance awareness, enhancing education and training, ongoing communication from management, etc.

2. **Maintaining, managing approval documentation that matches actual manufacturing conditions**
   Confirming consistency in GMP audits and request forms, eliminating inconsistencies through proper regulatory procedures, properly evaluating change management, etc.

3. **Practicing quality risk management**
   Appropriately managing suppliers of drug substances, raw materials, drugs, etc., complying with elemental impurity guidelines, evaluating and managing mutagenic impurities, etc.

4. **Strengthening the framework for delivering quality information to medical institutions and patients**
   Strengthening the ability to respond to inquiries related to manufacturing and quality, etc.

5. **Ongoing improvements to a robust quality control system**
   Making GQP arrangements that reflect revised GMP regulations, revising drug quality manuals, exploring introduction of a document management system, etc.

Value Chain and Competitive Advantages of the Pharmaceutical Manufacturing and Sales Business

Development	Sourcing	Manufacturing	Sales
Developing generic drugs to achieve profitability and meet demands from society ■ Newly developing existing products (shift to in-house production) ■ Investing in ongoing research	**Stable sourcing of raw materials** ■ Disclosing country of origin of pharmaceutical ingredients ■ Responsible sourcing	**Lessening environmental impact and boosting productivity with leading-edge plants and equipment** ■ Environmentally aware production ■ Plant optimization ■ Automation (systematization)	**Expanding internal sales spurs external sales** ■ Tie-ups with pharmaceutical wholesalers nationwide ■ External pharmacies, and other medical institutions nationwide
■ Developing new products (in-house, jointly)	■ Lowering sourcing costs	■ Capacity control	■ Internal sales: to Nihon Chouzai Group pharmacies
Strengths	Strengths	Strengths	Strengths
Development that can draw on feedback from Nihon Chouzai pharmacists Efficient R&D centered on items used in large quantities at Nihon Chouzai pharmacies	Ability to produce large quantities of drugs for medical institutions inside and outside the Group enables lower sourcing costs	State-of-the-art facilities enable stable supply capacity	Expanding internal sales to Group pharmacies can feed into growth in external sales

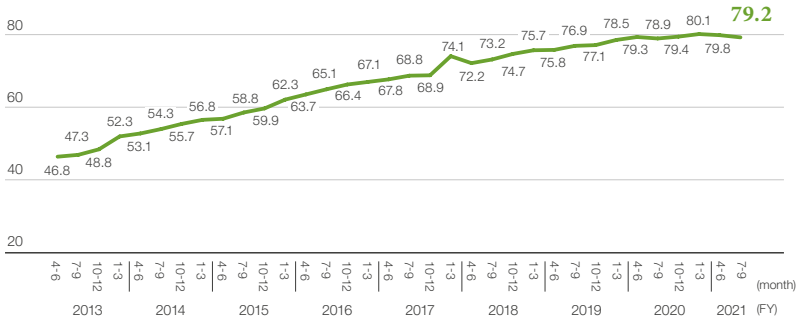
Business Environment

Against the backdrop of measures by the Ministry of Health, Labour and Welfare to promote the use of generic drugs, the scope of Group businesses has also expanded. In June 2021, the ministry set a new target, aiming for 80% or more generic drug use in all prefectures by the end of FY2023, while ensuring the reliable quality and stable supply of such drugs. To help reach this goal, the Nihon Chouzai Group will carry out strategic sales activities targeting the more widespread use of our drugs.

The business environment for generic drugs grows more challenging year by year, with drug prices in Japan being revised for the sixth year in a row in April 2023. By thoroughly managing profit for each product category and revising the product portfolio, the Group is working to enhance profitability in this business.

Moreover, starting in around 2020, some companies in Japan stopped manufacturing generic drug products where quality issues were identified, causing shortfalls in the domestic drug supply. Although the various companies have boosted production of alternative drugs, so far they have not been able to ensure an adequate supply of drugs nationwide, and supplies remain unstable. Group company Choseido Pharmaceutical was subjected to administrative disciplinary action due to quality issues. To fulfill its obligation to provide a stable supply of drugs, that company is moving forward with initiatives according to a business improvement plan. To address the issue of unstable supply, the Nihon Chouzai Group took immediate steps to boost production, and is working to resolve supply issues across all drug categories as soon as possible.

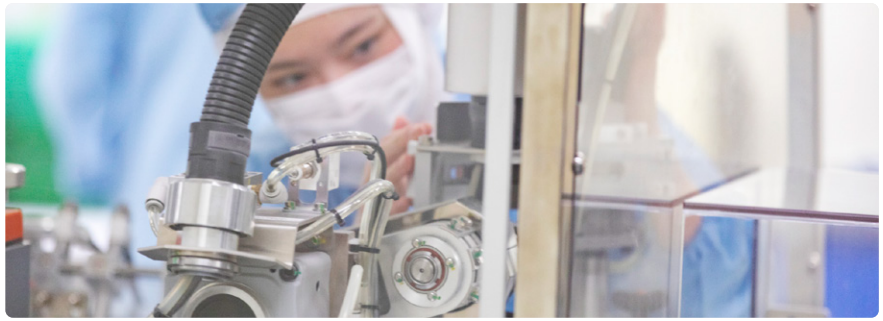
Generic Drug Volume Share (%)



Initiatives for Sustainable Supply

Initiatives to ensure stable supply

To address recent instability in the generic drug supply, we are reviewing production plans over the medium term and promptly adjusting to changing demand. Although COVID-19 and recent international developments have lengthened lead times for the supply of drug substances and materials, we are working to secure inventories, taking various risks into consideration. Group drug inventories suffered a loss following the November 2021 fire at a contractor logistics center, forcing limitations on shipments of numerous drugs and impeding a stable product supply. With inventory levels now recovering, we are in the process of lifting limitations on shipments for drugs that have a stable supply framework in place.



Shifting Outsourced Production to In-house

We are also exploring the in-house production at Group plants of drugs currently outsourced to other manufacturers, for which Nihon Chouzai already has manufacturing and sales approval. Producing these drugs in-house will enable us to shorten production lead times, respond more agilely to market demand, and boost profit margins.

Plant Investment

The product portfolio of each plant is changing year by year with the launch of new drugs, transfers of drugs between manufacturing sites, and our efforts to shift outsourced production to in-house. Amid these changes, we continue to invest in the optimal equipment configuration for each context. We are also adding production lines as needed to enable us to manufacture more formulations. Plant equipment is basically made-to-order by equipment manufacturers, and manufacturing sometimes takes years. We created forward-looking investment plans by working backwards from the production plans of our plants down the road so that we can roll out new equipment at the appropriate time. In addition, when making plant investments, we carefully consider the likelihood of recovering investments and strive to realize investments that are efficient.

Production Efficiency Capitalizing on the Characteristics of Each Plant

The Group has five plants. To ensure a stable drug supply, we are reviewing the manufacturing site for each product to create an optimal production framework for the Group as a whole. We will ramp up production for drugs that gain market share post-launch, commensurate with their sales volume. Increasing the amount of a drug that can be manufactured at one time will feed into greater production efficiency. In addition to enabling more efficient production planning for the more than 250 products the Group manufactures, we also expect to bring down manufacturing costs.

Securing and Cultivating Human Resources

We are hiring and cultivating human resources with the aim of boosting production volume and improving operating rates at our plants. A larger workforce will make it possible to build a stable shift-based production framework. About 60 new graduates joined the company in April 2023. We also continue to hire mid-career employees who already possess the skills needed to work. Moreover, we are focusing on education, centered around on-the-job training, so that the people we hire can play an active role as soon as possible.

Efforts to ensure a sustainable production framework

In the Pharmaceutical Manufacturing and Sales Business, we are designing environmentally-friendly plants from the construction stage. Also, by introducing solar power generation and carbon neutral city gas, we are pursuing sustainable production activities, seeking to preserve the natural environment through the lower and more efficient use of electricity, gas, water, and other resources.

Click here for details of initiatives:
https://www.nicho.co.jp/en/sustainability/esg/environment/

Growth Strategy

Ongoing New Product Development Showcases Nihon Chouzai Group Synergies

With both a Dispensing Pharmacy Business and a Pharmaceutical Manufacturing and Sales Business, the Nihon Chouzai Group is motivated to develop generic drugs in-house that reflect realities on the ground in the healthcare field, to address the needs of pharmacists on the front line in our pharmacies. To meet the needs of these pharmacies, which are the largest users of our drugs, we aim to develop a wide range of drugs without specifying certain disease areas, which allows us to accumulate the latest technology and expertise. We actively file patent applications for technologies obtained through our R&D activities while publicizing the results of new developments.

In FY2021, we integrated the R&D functions of Nihon Generic and Choseido Pharmaceutical into the Tsukuba Research Institute of Nihon Generic, centralizing the research and development knowledge of both companies. Moreover, because we can anticipate sales volumes to the Group's Dispensing Pharmacy Business in advance, we can forecast returns on investment from our drug development and realize efficient development planning. We will pursue effective R&D activities as we navigate annual NHI drug price revisions and an increasingly challenging earnings environment.

Continuous in-house development of new products

In the past, the launch of a single new generic drug would sometimes draw two dozen or more drug manufacturers into market. Now, however, the challenges of R&D are mounting, reflecting the fact that the government has lowered selling price levels of generic drugs at first listing and also revises drug prices annually, as well as the growing number of complex formulations. The number of manufacturers entering the generic drug market at first listing has declined as a result. Under this strict drug pricing system, achieving dramatic growth with existing drugs alone is difficult. Nihon Chouzai thus conducts R&D based on the notion that the ongoing introduction of new drugs is essential for growth. We carry out R&D activities in a planned way both to avoid missing out on the twice-a-year timing of NHI drug price listings and to stay abreast of other companies launching generic drugs with the same active ingredients. Our focus going forward will be on carrying out in-house development to ensure that we can steadily bring new drugs to market that can become growth drivers.

Drugs Recently Developed In-House

Launched in 2021	Launched in 2022	Launched in 2023
Zilmlo Tablets HD/LD JG, Solifenacin Succinate OD Tablets JG, Tadalafil Tablets 20mg AD JG, Methotrexate Tablets 2mg JG, Lamotrigine Tablets for Children JG, Duloxetine Capsules JG, Levetiracetam Tablets JG, Levetiracetam Dry Syrup 50% JG	Dasatinib Tablets JG, Febuxostat Tablets JG, Escitalopram Tablets JG, Ramelteon Tablets 8mg JG	Azilsartan Tablets JG, Sildenafil Tablets RE JG, Ezeato Tablets JG

Quality Initiatives at Choseido Pharmaceutical

Response to quality issues since occurrence

In light of the administrative action taken against Choseido Pharmaceutical Co., Ltd. in October 2021, the Group has formulated a “Business Improvement Plan” with members including lawyers and GMP specialists familiar with the “Act on Quality, Efficacy and Safety Assurance of Drugs and Medical Devices” (Pharmaceutical Affairs Law), and is working to establish and maintain a quality-conscious system, including a review of its management structure.

Please see the following discussion for details.

Submission of business improvement plan (Japanese only):
https://www.choseido.com/news/pdf/211025.pdf

Progress of business improvement plan Choseido Pharmaceutical website (Japanese only)
https://www.choseido.com/improvement/

Administrative disciplinary action based on the Pharmaceuticals and Medical Devices Act and the report of the special fact-finding team (Japanese only):
https://www.choseido.com/news/pdf/211011.pdf

Deliberating on Results of Tokushima Prefectural Pharmaceutical Affairs Council

In October 2021, the Tokushima Prefectural Pharmaceutical Affairs Council discussed and approved the “Business Improvement Plan” formulated by Choseido Pharmaceutical. The progress of the business improvement plan is discussed at the Tokushima Prefectural Pharmaceutical Affairs Council (about twice a year). So far, the progress of each of these plans has been confirmed to be satisfactory.

Click here for information on the Second Pharmaceutical Affairs Council in FY2022
https://www.pref.tokushima.lg.jp/kenseijoho/kenseisogo/shingikai/chijibukyoku/5049080/

Efforts to Rebuild Trust

In FY2021, having completed reforms to the management framework and other preparations to lay the foundation needed to rebuild trust, we shifted into a practical action phase in FY2022.

1 Fostering a New Corporate Culture

We continue to work on fostering a new corporate culture from the following three perspectives.

Fostering a new corporate culture

Valuing quality and norms

Message from top management
Explaining the importance of renewed awareness and the significance of future efforts

Ongoing education and training
Compliance with approvals, importance of records, compliance, etc.

Quality management reviewEstablishing a procedure manual
Realizing quality policies, action guidelines through regular reviews

Encouraging diligence

Online GMP education, confirming effectiveness

Group-wide training
- Importance of complying with approval documents
- Significance of record-keeping
- Importance of drugs from a patient perspective

Seminars by outside lecturers
- Compliance training
- Regulatory compliance lectures
  -About roles, education, and training of responsible officers
  -Data integrity
  To ensure reliability

Culture of openness

Tri-Plant Joint Council
- Discussion among three plants about businesses deviating from standards
- Formulating shared action targets for all three plants

Posting of cases of improvement
Sharing examples of improvements made by each department

Pick up

Encouraging diligence Fostering a new corporate culture

Online GMP education, confirming effectiveness

One of Nihon Chouzai’s quality targets for FY2022 was to plan and promote effective education and training. Each department formulated an action plan to pursue this goal.

All departments completed the online GMP education offered by Jiho, Inc. by the end of March 2023. We evaluated the effectiveness of education and training at the end of each fiscal year.

Moreover, we implemented on-the-job training based on an annual plan, evaluating the skills of each section employee at fiscal year-end and compiling a skill map.

Introductory course (during new employee orientation)
Completed by all eligible staff

Basic course (general employees)
Completed by all eligible staff

Practical course (managers, staff in charge)
Completed by all eligible staff

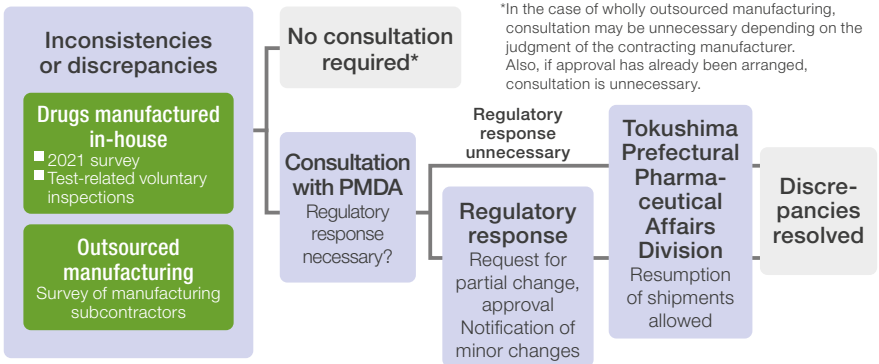
Evaluating effectiveness of education and training

We will evaluate the following categories and consider needed improvements for the following year.
- Were quality targets achieved? Did any deviations or quality issues arise in the past year that might be considered the result of inadequate education, etc.?
- Was the level of education and training materials commensurate with newly issued and updated regulations?

2 Status of resolution of inconsistencies with approval documents and procedures

We implement the necessary procedures after prior consultation with PMDA for all items for which discrepancies with the approval documents and procedures are found.

Roughly 55% of discrepancies were resolved as of July, 2023 (up 35% from October 2022).



3 Accessible Employee Internal Reporting System

Seeking More Widespread Use of the System

We hold sessions on an ongoing basis to familiarize employees with the purpose of the internal reporting system, our basic stance of protecting employees who report, and contact points for reporting.

Evaluating Effectiveness of the Reporting System

In the last two surveys of randomly selected employees (conducted five times each involving about 50 employees) found that recognition of the reporting hotline was high, at 100%. This confirmed the effectiveness of our actions to disseminate information on the system through explanatory sessions, the distribution of cards, and digital signage.

On the other hand, almost 70% of employees reported feeling that they would be dealt with appropriately if they reported, citing concerns about the confidentiality of information and the response after consultation.

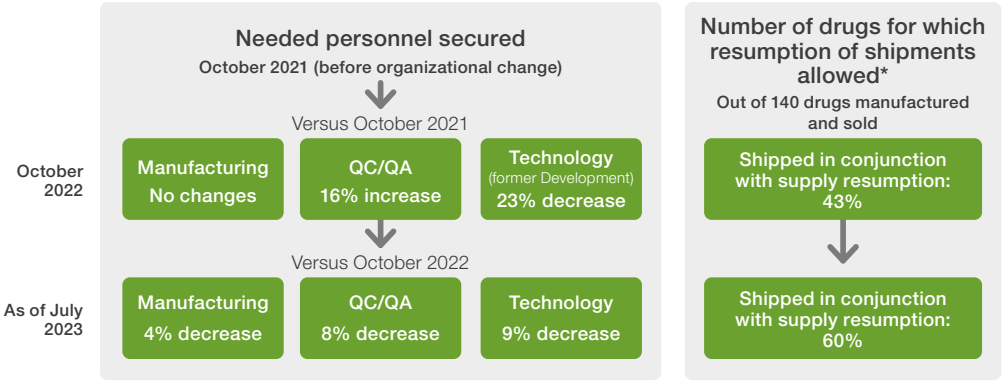
In light of these findings, the explanatory sessions used specific case studies to explain the ways in which we ensure privacy and underscore that employees who report are not disadvantaged.

Recurrence prevention measures by manufacturers

1 Optimization of Production Plans

Staff secured as of July 2023 (compared to October 2022 and October 2021 prior to the framework change) and the number of drugs that can be shipped are as follows. We continue to secure new staff while actively working to cultivate existing staff.

As of July 31, 2023
*Applies to drugs manufactured in our own plants



2 Enhanced Monitoring at Manufacturers

We have launched a support initiative called Tekuteku Support in which officers in charge visit worksites and support workers. To prevent deviations and work-related accidents, the officers make various proposals and confirm worksite operations. Moreover, implementation status is highlighted using digital signage.