Pharmaceutical Manufacturing and Sales Business

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

Nihon Generic was established in 2005 to provide high-quality generic drugs. Ever since, we have been providing generic drugs to medical institutions and pharmacies across the country.
Taking advantage of our synergies within the Nihon Chouzai Group, we plan new drugs that reflect feedback from patients and pharmacies. In our manufacturing, trained staff use state-of-the-art equipment to ensure rigorous quality control in line with strict Good Manufacturing Practice (GMP) rules, so that patients can use our drugs without worry.

Net sales

Operating profit

Message from the Business Manager

Masahiro Inoue
President and CEO
Nihon Generic Co., Ltd.

Q Looking Back on FY2023

The Pharmaceutical Manufacturing and Sales Business faced two major challenges in FY2021: a fire at the West Japan Logistics Center used by Nihon Generic, and administrative disciplinary action taken against Choseido Pharmaceutical based on the Pharmaceuticals and Medical Devices Act. Even in this context, we continued to steadily gain new business, mainly in relation to drugs manufactured in-house and new drugs. Our operating profit was able to recover to 250 million yen as a result. Along the way, we also sought to steer the business away from manufacturing a wide range of generic drugs in small volumes, narrowing down the lineup of the drugs we sell from 681 items (FY2019) to 516 items (FY2023). We will continue to move forward on this trajectory, while striving for more efficient manufacturing, distribution, and management.

We regret to report that improvement efforts at some Choseido Pharmaceutical plants have fallen short of the business improvement plan that was in place. Choseido Pharmaceutical has now revised its improvement plan with the help of outside experts. Going forward, Nihon Generic and Choseido Pharmaceutical will join forces to become key manufacturers in the generic drug industry.

Q Initiatives for FY2024, Mid-Term Issues and Initiatives with a View to the Long-Term Vision

Nihon Generic is steadily honing its R&D capabilities and improving its manufacturing technologies. New products are truly the driving force behind our growth—in FY2023 we exclusively launched two new active ingredients, and continue to ensure a stable supply of these products. In particular, EzeAto Tablets JG have been well received in the market. In August 2024, we also obtained manufacturing and sales approval for EzeRosu Tablets JG, which has the same efficacy, and began sales in December of the same year. The drugs Nihon Generic develops and manufactures have also received high praise from pharmacies, medical institutions, and other customers. We plan to take a leading role in the industry by proactively increasing production efficiency and ensuring the quality of the drugs we develop and manufacture in-house. One step is the roll-out of a manufacturing management system tailored to generic drug manufacturers. We will also explore a continuous production system, a new manufacturing technology, to further increase market penetration of the JG brand.

Three strengths

Value-added product development capabilities

Having pharmacies within the Group allows us to develop drugs that incorporate the perspectives of patients and healthcare professionals. For example, we are trying to differentiate our generic drugs from those of other companies by offering added value, such as changing the size or flavor of a drug to make it easier for patients to take.

Additionally, by printing the name and volume of active ingredients on tablets, we are making drugs easier to identify and developing formulations that are easier to use in clinical settings.

Reduced procurement costs

Building on the foundation of our drug sales to Nihon Chouzai, we have a stable network of sales channels, including to customers outside the Group, which enables us to secure a certain volume of sales.

Being able to produce large quantities of drugs for medical institutions both within and outside the Group makes it possible to lower procurement costs for drug substances and materials. Through our website, we also disclose the country of origin of drug substances and the companies that manufacture and sell them, as part of our commitment to responsible procurement.

Capacity control

Our leading-edge plants and equipment enable low environmental impact and support high productivity. Equipped with the requisite manufacturing facilities and testing equipment, we are working to optimize the allocation of drugs between plants and automate production. We are committed to producing high-quality drugs under a manufacturing management and quality control framework that complies with revised GMP regulations.

Growth strategy

Strengthening In-House Manufacturing Capabilities P.48
Ensuring Stable Supply P.49
Initiatives to Improve Quality P.50

Strengthening In-House Manufacturing Capabilities

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 the 3,843 pharmacists staffing 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.

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

Under an increasingly stringent 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 launch of new drugs is essential for growth. We carry out R&D activities in a planned way both to avoid missing out on the 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 FY2022

Dasatinib Tablets JG, Febuxostat Tablets JG, Escitalopram Tablets JG, Ramelteon Tablets 8mg JG

Launched in FY2023

Azilsartan Tablets JG, Sildenafil Tablets RE JG, EzeAto Tablets JG, Ambrisentan Tablets JG

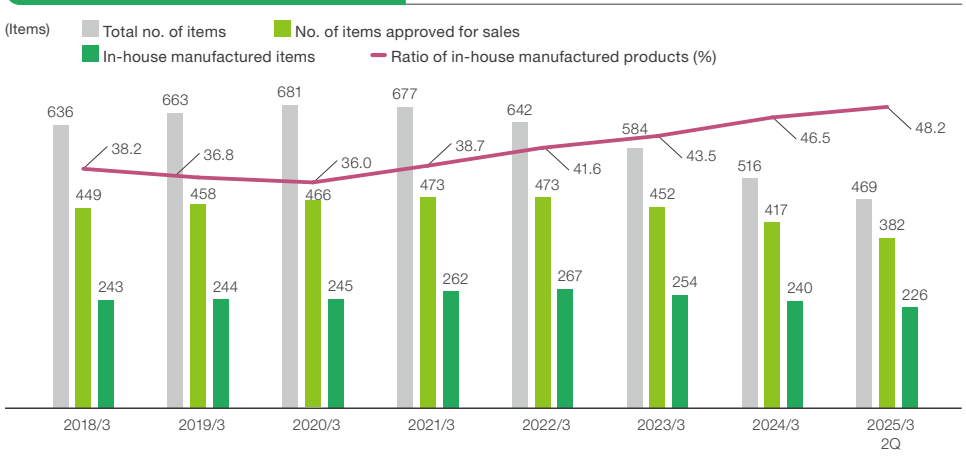
Increasing the Proportion of Drugs Manufactured In-House

We are shifting our strategy from expanding the drug lineup with an emphasis on sales to optimizing the drug lineup with an emphasis on stable supply. Given the relative ease of controlling costs for drugs manufactured in-house, we can expect to boost profitability by means of process improvements and increasing the scale of manufacturing. We see sales growth temporarily slowing down due to the discontinuation of in-licensed drugs and other drugs manufactured by outside companies. Going forward, however, we will continue to work toward significantly expanding the proportion of drugs manufactured in-house, which has now risen to 48.2%.

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.

Proportion of drugs manufactured in-house



Ensuring Stable Supply

Initiatives to ensure stable supply

To address recent instability in the supply of generic drugs, we are reviewing production plans over the medium term and adjusting to market 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.

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 have 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. 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 226 products the Group manufactures, we also expect to bring down manufacturing costs.

The production framework of Nihon Generic centers on two locations: the Tsukuba Plant, which handles the production of a wide range of drugs in small quantities, and the Tsukuba Plant No. 2, which handles large-scale production. By adopting a production framework that capitalizes on the characteristics of each plant, we are working to ensure stable production volumes and enhance productivity.

Tsukuba Plant No. 2

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. In addition to hiring new graduates, we also continue to hire mid-career employees who already possess the skills needed to work. We are also focusing on education, centered around on-the-job training, so that the people we hire can play an active role as soon as possible.

Establishing a Supply Framework

To improve our logistics services, we have located logistics centers in eastern and western Japan and in Sapporo, in Hokkaido. These three bases enable us to smoothly make wide-area deliveries. Furthermore, we have secured ample space for inventory management to support stable supply, anticipating the need to handle large-scale shipments. We have thus put in place a robust framework to ensure the smooth delivery of high-quality generic drugs to customers and patients across the country.


East Japan Logistics Center

Initiatives to Improve Quality

Rigorous Quality Control

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 FY2024, 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.

Response to Manufacturing Management Deficiencies at Choseido Pharmaceutical

Choseido Pharmaceutical has formulated a business improvement plan with the help of outside 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 framework, including a review of its management structure.

Please see the following discussion for details. https://www.choseido.com/

FY2024 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.