

Japan generic drug business



Expanding production capacity, ensuring quality, and building a strategic product portfolio to meet all expectations

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We reformed our corporate culture and strengthened governance to establish a trustworthy corporate foundation

Top management is leading corporate culture reform centered on town hall meetings with employees

The most important initiative in the year under review was the Corporate Culture Reform Project, launched under the President's direct control in response to the improper testing of Teprenone Capsules discovered in April 2023. The project centers on town hall meetings, which I personally lead, that provide a forum for direct dialogue between management and employees, with a focus on younger employees who represent the company's future leadership. To date, we have held over 40 meetings at business sites nationwide and continue meeting about twice a month. I listen to their concerns, provide advice based on my experience, and discuss more complex issues with department heads and then follow up with the person who raised the matter, completing a PDCA cycle.

Town hall meetings began as a way to prevent the recurrence of fraudulent incidents, but they have evolved into opportunities to address and resolve issues on the minds of younger employees. Persisting issues could lead to necessary tasks being left undone. These dialogues create an environment where employees can work with peace of mind, and I believe such open discussions help prevent misconduct.

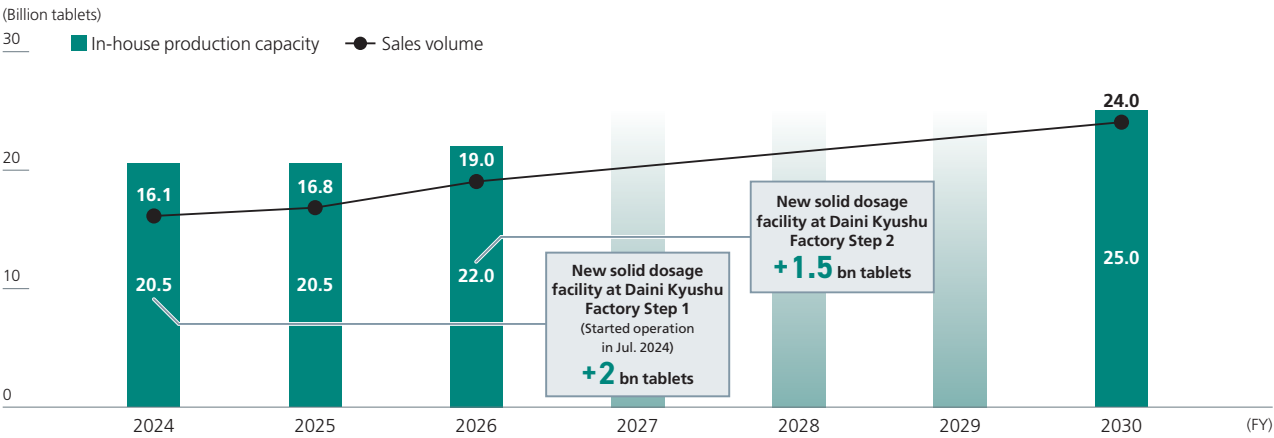
Fortifying governance and increasing resources for stronger on-site capabilities

In the current fiscal year, we fortified our governance system to build a trusted corporate foundation. Following the administrative sanctions, we prohibited concurrent roles for Vice President of the Reliability Assurance Division and marketing director of pharmaceuticals. The marketing director, which is positioned above the quality assurance manager and safety control manager, is one of three roles required of drug manufacturers and distributors under the Pharmaceuticals and Medical Devices Act. By separating these roles, the Vice President of the Reliability Assurance Division and the marketing director of Pharmaceuticals can consult with and monitor each other. In addition, the Group

SWOT analysis

Strengths	Weaknesses	Opportunities	Threats
- Brand strength as top manufacturer - Stable financial base - Strengthened production capacity following quick investments - Development of capabilities that enabling us to launch products first and exclusively - Growing share of high value-added products	- Securing and developing talent that can handle growing production capacity - Constraints on productivity due to high-mix, low-volume production	- Chance to reorganize the generic drug industry - Growing demand due to advance of aging society - Growing healthcare and medical needs - Generic drugs as social infrastructure - Company scoring system that promotes sales at reasonable prices	- Increase in launch of AGs - Lower reliability due to generic drug supply instability - Growing raw material and utility costs - Lower NHI drug prices due to annual drug price revisions - Changes in various systems

Expanding in-house production capacity towards FY2030



Chief Quality Officer now submits monthly reports to the President and the Sawai Pharmaceutical Board of Directors, which in turn reports to the Sawai Group Holdings Board of Directors. This structure strengthens checks and balances, enhances advisory functions, and ensures objective and transparent governance.

In addition, the Corporate Culture Reform Project designated December 22, the date the sanctions were imposed, as our annual Compliance Day, on which will reinforce our dedication to preventing improper conduct. On Compliance Day in 2024, all employees viewed video messages from wholesalers, pharmacies, doctors, and other business partners.

After the incident, it took about six months to complete the mandated comparison review of authorization documents and manufacturing status. Among the many new products we develop and market each year, this review identified areas where manufacturing conditions for certain products could be improved. In response, we established a new office in the R&D Division to implement these improvements. We regard maintaining a stable and efficient production system as a core responsibility in ensuring and

continuously enhancing quality.

We are also strengthening on-site competencies by providing education and promoting multi-skilling, quantifying and visualizing proficiency levels, and deepening understanding and application of Good Manufacturing Practice (GMP) and Good Quality Practice (GQP). As another layer of reliability, we are introducing the Laboratory Information Management System (LIMS) with the goal of full adoption across all factories by fiscal 2026. We are continuing to incorporate the Manufacturing Execution System (MES) to further improve manufacturing process management and in July 2024 installed a new solid dosage facility at the Daini Kyushu Factory.

As company representative, it is my responsibility to clearly communicate our initiatives both internally and externally, and I make it a point to provide thorough progress updates during meetings with executives from wholesale companies and other business partners. One of their greatest needs is a stable product supply, and we remain deeply aware of the importance of meeting that expectation.

We are fortifying our earnings base by optimizing our product portfolio and increasing production capacity

Revised targets achieved, but rising raw material costs and growth investments increased expenses

Fiscal 2024, the first year of “Beyond 2027,” our medium-term business plan, began with slow sales in the first half, ultimately forcing us to lower our earnings targets. While we achieved the revised sales target, profit fell short due to factors including impairment losses from restructuring our business portfolio through selection and concentration, and expenses related to provisions for product litigation losses. We recognize the need for greater precision in budget planning. Starting this year, we are preparing a Group budget based on detailed individual budgets for our top 200 products, which account for over 70% of total sales. I am determined to ensure we meet our budgets and continue driving sales growth.

The Elective Care Scheme introduced in October 2024 requires patients who choose an original drug to pay 25% of the price difference compared with an available generic.

The new scheme contributed to our fiscal 2024 performance by boosting sales of existing products, particularly those previously subject to shipment restrictions. As a major presence in Japan’s generic drug industry, we believe the growing need for a stable medicine supply will drive demand for our products. We fully expect our ongoing efforts to expand the Group’s production capacity, along with the forthcoming lifting of shipment restrictions on roughly 80 products, to further boost our business performance.

At the same time, we are contending with rapidly rising labor and material costs, and we expect foreign exchange rates to keep costs for active pharmaceutical ingredients high for the foreseeable future. Upfront investments for future growth started in 2021 are also raising fixed costs. These include the acquisition of Trust Pharmatech, construction of a new building at the Daini Kyushu Factory, and expanded recruiting aimed at hiring 200 new employees in both fiscal 2025 and 2026, which will also inevitably add to labor costs in the future. Like our ongoing investment in new businesses, our investment in human resources is a strategic move to enhance our production capabilities and propel future growth.

Sawai Pharmaceutical and Trust Pharmatech production personnel structure

	Personnel at the end of FY2024		End of FY2025 Plan
	Initial plan	Results*	
Sawai Pharmaceutical	2,477 persons	2,425 persons (increase of 91)	2,629 persons (increase of 204)
Trust Pharmatech	325 persons	366 persons (increase of 59)	433 persons (increase of 67)
Total	2,802 persons	2,791 persons (increase of 150)	3,062 persons (increase of 271)

* Figures in parentheses indicate a comparison with the end of the previous year

Review of production volume

		FY2024		FY2025 Plan	FY2026 Plan
		Initial plan	Results		
Production volume (tablets)	Trust Pharmatech	0.9 billion	0.88 billion	1.8 billion	2.4 billion
	New solid dosage facility of Daini Kyushu Factory	0.3 billion	0.07 billion	0.9 billion	1.6 billion
	Other existing factories (excluding contract manufacturing)	14.7 billion	13.7 billion	13.5 billion	—
	Total (including contract manufacturing)	17.7 billion	16.6 billion	18.3 billion	—
Number of products	Trust Pharmatech	9	15	22	26
	New solid dosage facility of Daini Kyushu Factory	10	3	19	28

Building a well-balanced product portfolio strategy to improve budget accuracy

Our product portfolio strategy will be the single most important factor in setting next year’s budget. After failing to meet the initial fiscal 2024 budget, we launched the Portfolio Strategy Meeting in fiscal 2025 to closely manage revenue for each product. This monthly meeting serves as a forum for comprehensive, lively discussion on topics including new product development plans, evaluations of existing product value, decisions to expand, scale back, withdraw from production, and future market prospects. The Product Strategy Department acts as secretariat, and the meeting includes myself, all division heads, and their deputies. Projects requiring deeper examination are assigned to subcommittees. We believe this process is an effective way to optimize our portfolio for both profitability and societal needs.

These discussions will enable our Group to pursue a well-balanced product portfolio strategy that focuses not only on developing new products but also on nurturing profitable existing ones, while gradually reducing products with low market demand. This will shift our profit structure from one heavily dependent on new products to a more balanced mix that includes existing products capable of generating a sustainable profit flow into the long term.

Steadily expanding production capacity and investing in human capital for further growth

The medium-term business plan identifies increasing production capacity a top priority. We are steadily progressing toward our quantitative target of increasing in-house capacity from 20.5 billion tablets to 22 billion tablets annually by fiscal 2026. We are also discussing investing in further expansion through three approaches: increasing capacity at our own factories, outsourcing to subcontractors, and acquiring external factories resources. Under the Sawai Group Vision 2030, we aim to be producing 25 billion tablets annually by fiscal 2030. While this is an ambitious goal, but we recognize it still may not be enough to meet demand if the generic drug substitution rate rises as expected, and we are prepared to consider additional measures to respond to the demand trend.

Another priority is investing in human capital. This investment includes salaries, measures to improve supervisor-subordinate relationships, and designing comfortable work structures. We encourage employees to use our programs, such as the half-day work-from-home program and childcare leave for men. Our personnel system now features an internal transfer program in which departments post openings and any employee can apply. The flexibility we have added to accommodate diverse work styles stems from feedback at the town hall meetings. We are also implementing measures to improve the employee retention rate, boost motivation, and support career development. I believe our success in attracting talented



individuals, even amid intensifying competition for human resources, reflects the impact of our sustained external public relations and IR activities in strengthening our brand power.

I am proud that Sawai Pharmaceutical is a leader in the generic drug industry. And as a leading company, we have a responsibility to address current supply issues quickly and to fulfill our mission of ensuring stable supply and quality.

The Group still has ample room for growth. We will accurately read changes in the market and society, turn them into opportunities, and steadily advance toward our medium-term business plan targets and long-term vision, thereby meeting the expectations of all stakeholders.

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