Toru Terashima

Director, Senior Executive Officer, and
Group Chief Quality & Safety Officer

Message from the Group CQO

We do everything we can to ensure a quality assurance system for the stable supply of drugs that we would recommend to our own families

Over the past few years, there have been a number of misconduct cases involving several generic drug manufacturers, shaking confidence in the generic drug industry as a whole. The biggest issue is ensuring quality. For our Group, which has Sawai Pharmaceutical at its core, this issue is the foundation of our business and the very reason for our existence. Our mission is to provide a stable supply of top-quality, affordable drugs. So what must Sawai Pharmaceutical do in order to achieve this mission? The drugs supplied by Sawai Pharmaceutical are not 100% manufactured by us alone. All of our active pharmaceutical ingredients (APIs) are procured externally, and we purchase some 300 ingredients from 200 manufacturing sites in Japan and 300 sites outside Japan. Naturally, we confirm there are no issues with the APIs we purchase through acceptance testing and rigorous management, but our efforts do not end there. Our inspectors conduct regular onsite audits of the manufacturing environment, processes, and quality control for APIs. Audits are conducted at five sites a month and 60 sites a year on a five-yearly cycle, both in Japan and overseas.

On the other hand, in-house manufacturing accounts for almost all of our formulation processing. In compliance with the GMP standards stipulated in the Pharmaceuticals and Medical Devices Act and PIC/S-GMP, which is the global standard, we record the actual work performed and conduct process control tests to verify at each step that the required quality is achieved through the correct procedures for all products, lots, and processes. Lastly, by evaluating shipping test records and all manufacturing records for the final products, we have built a quality assurance system that ensures we supply only products of sufficient quality to medical facilities. In addition, as we do for APIs, we conduct regular onsite audits once every three years at our own six factories as well as approximately 50 factories to which we outsource formulation.

We have also taken a variety of other initiatives to ensure quality. The basis of these initiatives is the confirmation of any discrepancies between approval forms and actual manufacturing conditions. In addition to the annual quality verification required for each product under GMP, we are conducting simultaneous voluntary inspections in fiscal 2021. In addition, to prevent mistakes due to human error, we regularly provide workers with education and training in knowledge and practical skills. Under our two-worker system, the results of work performed by the primary person responsible for the work are verified objectively by a separate person to confirm that the work was performed and recorded correctly. Furthermore, if there are any issues, we immediately dispatch staff from the Quality Assurance Division, which is independent from the Manufacturing Division, to investigate the cause and take countermeasures in cooperation with the manufacturing site.

Pharmaceuticals only have the anticipated effect when products of sufficient quality are used correctly and safely. Therefore, in addition to quality assurance and regulatory affairs management, a variety of departments, including the Medical Information Center, work together, striving to achieve the peace of mind and confidence of patients and medical institutions by communicating correct information in a timely and appropriate manner, including information on side effects, precautionary information (formerly package inserts), and labelling.

Ultimately, it is people who make pharmaceuticals. The confidence that we make high quality products and can recommend them to our own families is the foundation of the entire Group. Staying true to this foundation, and with an awareness that we are members of the pharmaceutical industry which protects life, the Group's management and employees will work steadily to maintain and develop a quality assurance system that puts health first and provides peace of mind and confidence.

WEB **Sawai Pharmaceutical**
- A video that introduces our quality initiatives

Group CQO Toru Terashima also delivers a message directly to stakeholders. (Only available in Japanese)
https://www.sawai.co.jp/sawaigenerics/initiatives/quality_movies/

Yoshiki Sakurai

Executive Officer,
Group Chief Financial Officer,
General Manager of Group
Financial Department

Message from the Group CFO

Working toward our long-term Sawai Group Vision 2030 and striving to build a financial foundation conducive to dynamic investment

Fiscal 2020 Performance

In fiscal 2020, while weathering the impacts of on-going reform of the drug pricing system in Japan, in addition to reticence toward medical visits due to the COVID-19 pandemic, we were able to book sales revenue in line with expectations thanks to the results of efforts to sell newly listed generics, including Pregabalin OD Tablets, Capsules. Additionally, amidst a spate of quality issues in the generic drug industry, we have made product quality our highest priority by carrying out rigorous manufacturing and quality control, while also striving for more efficient production by using multiple raw ingredient suppliers, closing the Osaka Factory, and moving its operations to the Sanda Nishi Factory. Through these efforts, we worked to further strengthen our cost competitiveness and improve production capacity with an eye toward growing our market share.

In the U.S., the business environment continued to increase in severity due to a variety of factors, including increasing purchasing power for buyers from consolidation among wholesalers, drug stores, and other parties, price declines for generic drugs, entry of competitors selling products competing with our mainstay branded products, and intangible asset impairment losses from poor sales of Tosymra™ due to the COVID-19 pandemic. Within this context, we strove to enhance and expand both our generic and branded products on the market by forming an alliance with Upsher-Smith.

As a result, although operating profit was down slightly compared to the previous year, we were able to increase revenue.

Outlook for Fiscal 2021

In fiscal 2021, despite falling unit selling prices due to on-going reform of the drug pricing system in Japan, we forecast continued, steady growth of sales volume for generic drugs as we launch new products accompanying patent expiration for originator drugs. At the same time, there is the possibility of a continuously challenging competitive environment in the U.S. due to negative impacts from the COVID-19 pandemic.

Despite this operating environment, we will follow START 2024, our new Medium-Term Business Plan that kicks off this fiscal year, and we will gather the strengths of the R&D, Manufacturing, Reliability Assurance, Marketing, and other divisions as we strive for steadfast growth in both Japan and the U.S.

Policy on Investments and Shareholder Returns

Sawai expects accelerated restructuring in the industry driven by a worsening operating environment accompanying annual drug price revisions. Additionally, as noted in our Medium-Term Business Plan, we are committed to aggressive investment in new businesses and R&D, and we plan to carry out this investment flexibly and dynamically. We will also strive to maintain and secure a solid financial foundation while keeping aware of the global environment, including at Upsher-Smith. In response to the COVID-19 pandemic, we made efforts to improve free cash flow and ensure a certain level of inventory to maintain a stable pharmaceutical supply structure, which is essential for preserving human health and life.

We strive for balance with our growth-oriented investments, while conducting comprehensive assessments that take into account factors such as the consolidated financial results in each period, the dividend payout ratio, and other shareholder return measures. Our goal is to achieve a stable and ongoing dividend payment with a payout ratio of approximately 30%. In fiscal 2020, Sawai Pharmaceutical paid an annual dividend of ¥130 per share (a total return to shareholders of ¥5.7 billion).