Corporate Regulatory Compliance & Quality Assurance / Medical Science

Establishment of a global quality assurance system for delivering “A-N-SHI-N”*1

The Sumitomo Dainippon Pharma Group is developing new drugs in Japan, the U.S., China, and other countries, and, after receiving approval from each country’s regulatory authority, delivering products. In order to provide products that patients and healthcare professionals around the world can use with “A-N-SHI-N,” the Group has established global policies*2 for quality and safety management. Under a Global Regulatory Compliance System, we are striving to provide high quality products.

Furthermore, we supervise all manufacturing and packaging contractors for our pharmaceutical products in their various countries to assure the quality of pharmaceuticals across the entire supply chain. This approach to quality assurance activities, from development to post-marketing services, is implemented under a framework unifying our Group.

Efficient inquiry-response system with our quality information system

In Japan, Sumitomo Dainippon Pharma’s Quality Information System is designed to ensure efficient responses to inquiries about product quality from healthcare professionals. We use this system in conformity to Good Quality Practices (GQP)*3. When an inquiry is raised in this system, the plant at which the product was manufactured begins investigation immediately, checking retained samples from the same lot, and verifying manufacturing records to confirm the quality of the product in question. The root cause of the quality issue is also investigated, and when necessary, the plant plans and implements actions to prevent recurrence.

Departments such as Safety Management, Sales & Marketing, Manufacturing, and Quality Assurance can access the system so that they can promptly evaluate safety and respond to complaints. Our Quality Information System also has a search function which enables us to analyze inquiry and quality issue trends per each product type and time period to prevent similar problems in the future. In addition, our MRs carry tablet terminals that have answers to many expected inquiries.

Centralized management of safety information from development to post-marketing

Adverse reactions that were unexpected during the development stage can occur once pharmaceuticals have started to be used by a large number of patients under various conditions after manufacturing and marketing approval. Because of this, we collect a wide range of post-marketing information from medical institutions, partner companies, and regulatory authorities etc. in each country, in addition to safety information generated at the early development stages.

A centralized global database manages and evaluates safety information collected in Japan and overseas, leading to the planning of the necessary measures to ensure the safety and proper use of pharmaceuticals and the implementation of safety measures in a timely manner. We implement safety management activities of this nature as part of product pharmacovigilance in compliance with the Pharmaceuticals, Medical devices and Other Therapeutic Products Act and Good Vigilance Practice (GVP).*4

While pharmaceutical products are effective when used properly, their improper use can not only negate their

*1 A-N-SHI-N: Trustworthiness, reliability, peace of mind, making people feel reassured and safe.
*3 Good Quality Practice: A standard for managing the quality of pharmaceuticals, quasi-pharmaceuticals, cosmetics and medical devices (manufacturing and marketing quality assurance standard).
*4 Good Vigilance Practice: A standard for managing the post-marketing safety of pharmaceuticals, quasi-pharmaceuticals, cosmetics and medical devices (post-marketing safety management standard).
Medical Science

Medical needs are learned on site
Offering true value with our pharmaceutical products

Sumitomo Dainippon Pharma’s Medical Information Department and Medical Affairs Department work in close coordination as the Company’s Medical Science framework, with the same Executive Officer responsible for both departments. Their objective is to strengthen our capability to accurately grasp the needs of healthcare professionals and to execute medical communication and provision of medical information to address those needs in a scientifically objective, unbiased, reliable, and evidence-based manner.

By communicating the efficacy and safety of products from a scientific perspective, our Medical Science framework meets the needs of patients and healthcare professionals, while presenting the true value of our products. Furthermore, our Medical Science Liaisons (MSLs) work to grasp unmet medical needs through scientific communication with healthcare professionals, which will lead to new evidence generation, additional dosage formulation, and additional indications. MSL also serves as a contact person for clinical research and provides medical information with informed scientific knowledge in response to requests from healthcare professionals.

Promoting the provision of accurate product information based on scientific evidence

In providing accurate information to healthcare professionals, we create appropriate information on our products, support MRs’ provision of information, review information and materials directed to external parties, and check slides for lecture meetings.

We also provide documents such as “Kusuri-no-shiori”, drug information sheet, and “Instructional Leaflets” which are used by healthcare professionals in explaining to patients. In order to be able to offer 24-hour support for regional healthcare, we will utilize our website and other methods, and continue to deliver and communicate easy-to-understand information to patients and families, while addressing the on-site needs of healthcare institutions.

Further utilizing customer input as an information hub

Sumitomo Dainippon Pharma established the Product Information Center within our Medical Information Department as a customer support contact center for inquiries about our products from patients and their families, in addition to healthcare professionals. Going forward, we will continue to contribute to the health of patients by swiftly and politely providing accurate information on the proper use of pharmaceuticals, while pursuing appropriate internal feedback on content learned from external requests, and using this to strengthen improvements of our products and materials.

Inquiries during FY2018: Approximately 38,900

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<thead>
<tr>
<th>Category</th>
<th>Inquiries</th>
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<tr>
<td>Drug formulation</td>
<td>30.5%</td>
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<tr>
<td>Requests for materials</td>
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<td>Safety</td>
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<tr>
<td>Clinical-related</td>
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<tr>
<td>Law / Prescriptions</td>
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<tr>
<td>Pharmacokinetics-related</td>
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<tr>
<td>Complaints-related</td>
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<tr>
<td>Other</td>
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