

Sawai Group Safety Policy

Sawai Group shall establish and maintain a robust safety vigilance system such as Pharmacovigilance System and so on, based on the Sawai Corporate Philosophy and the Sawai Code of Conduct to ensure the effective and proper performance of product safety-related activities appropriate for the nature of our products*. All Sawai Group officers and employees shall maintain close and timely communication with stakeholders on matters related to product safety, and shall contribute to preserve patient safety by involvement in product safety-related activities under our safety vigilance system.

We, Sawai Group, make the following commitments according to the nature of our products:

1. To ensure proper and safe use of our products by conducting safety surveillance and investigations, and effectively managing risks throughout the product life cycle
2. To comply with relevant safety-related regulations of the regions where our products are developed and marketed, and to provide regulatory authorities with complete and accurate information in a timely manner
3. To enhance the awareness of products safety through continued training of all officers, employees, and relevant vendors
4. To monitor benefit / risk balance for our products by thoughtful and objective evaluation of safety information
5. To provide information on proper use of our products based on the latest medical / scientific evidence and product labeling

Sawai Group officers shall demonstrate commitment to support the safety vigilance system including Pharmacovigilance System.

*Products means all products provided by Sawai Group, regardless of whether or not compensation, such as pharmaceuticals, medical devices, combination products, health food products, and application software for health management and so on.

Supplementary Provisions

The subdivision in control of this Policy shall be the Group Chief Quality & Safety Officer of Sawai. The amendment and repeal of this Policy shall require the resolution of the Board of Directors of Sawai Group Holdings.

Enacted and enforced on September 26, 2017

Revised and enforced on December 24, 2021