ArisGlobal

WHITE PAPER

LifeSphere Safety: Extending a Worldwide Pharmacovigilance Program into the Japanese Market

Table of Contents

Extending a Worldwide Pharmacovigilance Program into the Japanese Market

In nearly all industries and markets, companies are subject to increasing regulation concerning transactions, transparency and privacy. In the life sciences industry, the cost of compliance is further compounded by the risk of the safety and efficacy related to the use of their products. Regardless of geographic location or organization size, all manufacturers of devices or pharmaceuticals have the regulatory requirement of collecting, investigating and monitoring suspected adverse reactions and all associated product use and complaint information.

Companies doing business in the United States, Europe and Japan must ensure the processes and systems supporting product safety tasks comply with all the regulations from the health authorities including, but not limited to, the US Food and Drug Administration (FDA), European Medicines Agency (EMA), and Japanese Ministry of Health, Labor and Welfare (MHLW).

Most global companies have in the last few years come to grips with the regulatory requirements of the major regulatory authorities, which have mandated the electronic submission of safety data for clinical safety reports (SUSARs) and spontaneous reports (ICSRs). However, the challenge most companies are facing today is meeting the unique requirements from the Japanese regulators, MHLW. The MHLW has defined a unique set of requirements for the collection, assessment and reporting of adverse event data in Japan. These reporting obligations differ significantly from those published by the FDA, EMA and other national competent authorities. Often these regulations change as the MHLW continues to refine its safety reporting procedures, and keeping current with these changing requirements is a constant challenge faced by all sponsors and marketing authorization holders.

Global safety and pharmacovigilance systems must fulfill the regulations regarding validated availability and reliability and enforce proper security controls with confidentiality, integrity and audit trails. This is where ArisGlobal's LifeSphere Safety™ suite comes into the picture—enabling global life science organizations, regardless of size, to implement effective domestic and global pharmacovigilance, clinical safety and risk management programs.

This paper summarizes ArisGlobal's LifeSphere Safety global solution for companies that are either headquartered in Japan or have Japanese affiliates and focuses on the key benefits of deploying a single safety and pharmacovigilance system. An unified safety and pharmacovigilance system with worldwide business processes helps companies realize significant productivity benefits.

Domestic Case Reporting to MHLW

Global organizations often have two different and disconnected safety drug systems – making domestic cases reporting to MHLW a challenge. The headquarters will have their own system for data input. This data gets captured, stored and managed in the central system used by the global headquarters. The Japanese affiliate sends adverse events (AE) information by fax or PDF – requiring staff at headquarters to retype the data. Some companies opt to have the Japanese affiliate also enter the data in the local Japanese system, resulting in double entry and duplicate information.

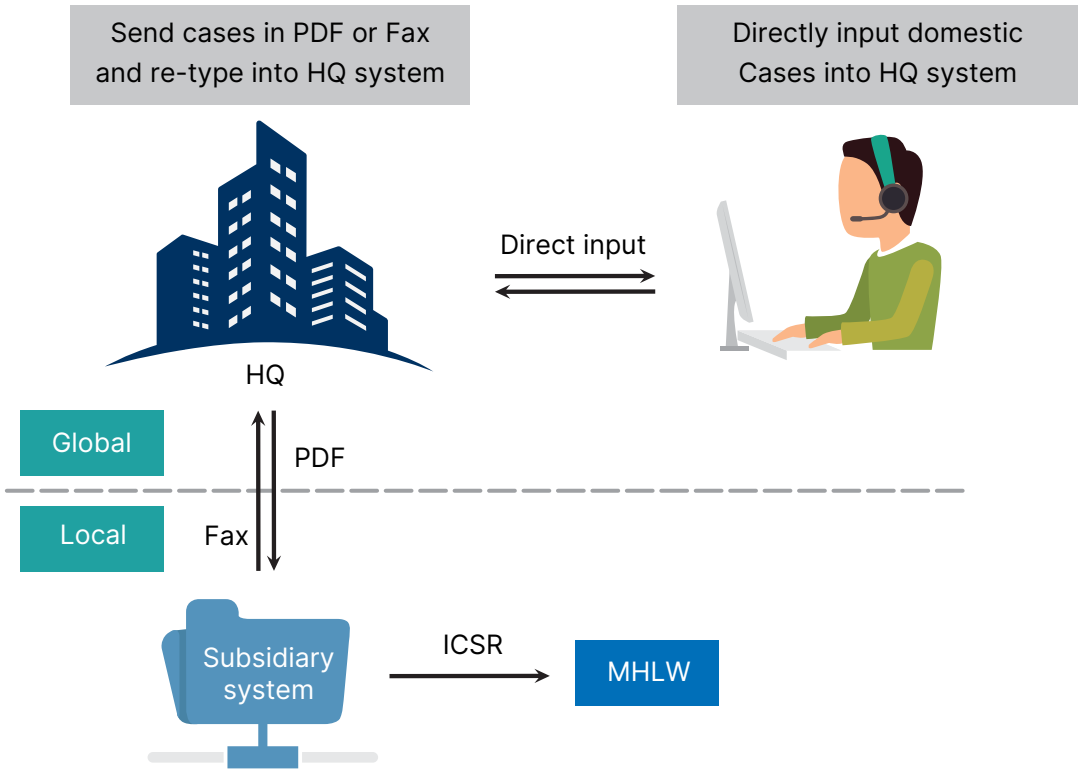

Figure 1. Overview of domestic case reporting to MHLW

Foreign Cases Reporting to MHLW

Sending and submitting foreign cases to the MHLW presents another significant challenge for an organization. While data is exchanged electronically, the use of disparate databases can create discrepancies, and there is still a need for manual checking. This raises the risk of duplications of Individual Case Safety Report (ICSR), which must be checked during review. Some companies may even send the submission data back to headquarters so the central system can be updated.

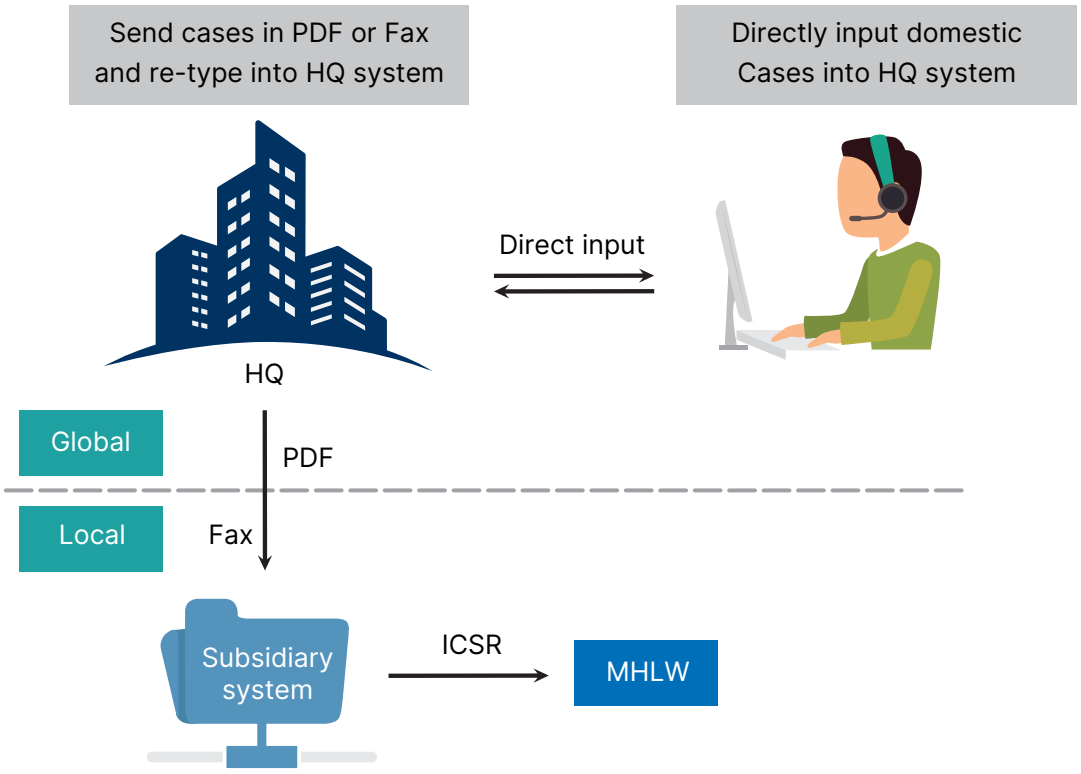

Figure 2. Overview of foreign case reporting to MHLW

Number of Cases Increasing

The PMDA (Pharmaceuticals and Medical Devices Agency) is Japan's regulatory agency, and it works together with MHLW. Their obligation is to protect the public health by assuring safety, efficacy and quality of pharmaceutical and medical devices. They conduct scientific reviews of the marketing authorized application of pharmaceuticals and medical devices and monitor post-marketing safety. There are an ever-increasing number of adverse reactions/events that are reported to PMDA and the number will only increase as shown in the table below (reported cases to PMDA in 2015). This puts huge pressure on PMDA and MHLW staff to address a large volume of safety tasks.

The number of the reported cases to PMDA in 2015 for pharmaceutical drugs

Domestic cases	51,065
Foreign cases	345,193
Healthcare	6,129

The number of the reported cases to PMDA in 2015 for medical device

Domestic cases	17,603
Foreign cases	26,395
Healthcare	406

Figure 3: Reported PDMA cases

With an increased focus by regulators on early detection and overall risk/benefit, organizations need to be able to respond rapidly to global regulatory challenges and minimize the uncertainty surrounding the performance of their products.

Companies are also struggling to implement global and effective data-mining exercises involving spontaneous reports submitted to the authorities. Adding to the complexity is the fact that the current processes for signal detection are laborious and data/computationally intensive – especially for organizations running multiple databases, tools and data models.

LifeSphere MultiVigilance 10 (LSMV10): The Complete Solution

The ideal solution is a single, comprehensive application to support Japanese domestic adverse event reporting – eliminating redundant data entry and automating the many case-processing functions involving data exchange facilitation of ICSRs between headquarters and local affiliates. It should provide one underlying application with multi-language support, which is compliant with international regulations – United States, Japan and Europe while providing improved efficiencies regarding data entry and validation.

LSMV10 is the industry-leading adverse event processing platform for the life sciences market. Available in March 2020, it is the industry's first end-to-end safety system with production-ready automation, built in close partnership with top life sciences organizations. A fully Japanese language-enabled system is designed to support the data capture and reporting requirements as defined by the MHLW.

Developed on an entirely new, state of the art platform, LSMV10 incorporates the latest in cognitive automation technology to deliver groundbreaking case processing efficiency gains to global PV teams. It incorporates the latest in robotic process automation and cognitive computing technologies, including natural language processing (NLP) and machine learning to address key pharmacovigilance (PV) activities. LSMV10 is also the first and only unified platform able to integrate seamlessly with quality and MI systems.

LSMV10 provides extensive capabilities to support the collection, assessment and distribution of both clinical and post-marketing adverse event data.

Figure 4: LSMV10 Data Collection and Analysis

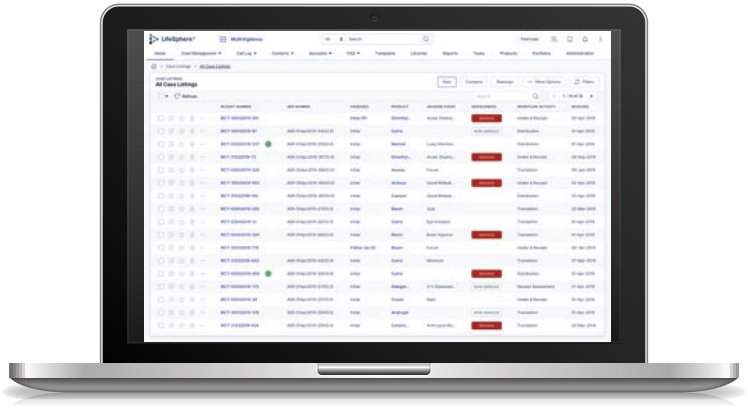

Figure 5: LSMV10 Adverse Event Listing

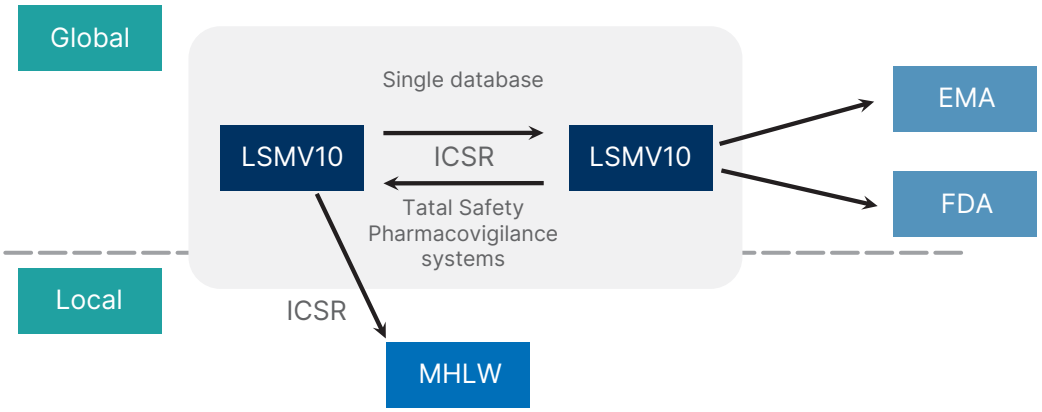

Figure 6: LSMV10 unified environment

LifeSphere MultiVigilance 10 key features include:

- Automation of repetitive and routine manual tasks in case processing leveraging advanced technology, such as artificial intelligence and machine learning
- A fully configurable case processing system supporting data entry compatible with E2B and E2B(R3) submissions as well as tracking and export
- Built on industry standard practices (ISP) to bring harmonization to deployments and streamline upgrades
- A MedDRA browser provides the ability to automatically code terms or search for appropriate terms based on a variety of search criteria
- Ability to track all communications and follow-up activity, workflow monitoring, KPIs and metrics
- Collaboration and sharing of case information between all major ICH regions, including Japan
- Single, E2B (R3) compliant global safety database
- Built with the industry, for the industry
- Production-ready automation
- Brand new architecture and design
- Best-in-class implementation

LifeSphere MultiVigilance 10 (LSMV10) Delivers Unique Functionality

LSMV10's Japanese-language capabilities provide the perfect solution for organizations working or partnering with Japanese companies and affiliates. Supporting all domestic reporting requirements, LSMV10 enables organizations to establish a worldwide platform for pharmacovigilance and clinical safety. We strive to support all the current and future MHLW legislation, including all domestic reporting obligations for electronic submission.

LSMV10's Japanese specific capabilities include:

- Support AE reporting for drugs, devices, vaccine, quasi-drugs, cosmetics and combination products

- Multilingual support - Data entry with full Japanese-language support for all case types including clinical, spontaneous and literature reports. The multilingual capability allows users to enter and assess cases in Japanese and enter an English (or other) translation required for international reporting. Similarly, if cases are received from international partners, the text can be translated into Japanese with all standard lookup values (code-lists) automatically. All local data items such as the J-items are also available and can be entered prior to reporting to the MHLW.
- Support for MHLW E2B Report (E2B(R2)/E2B(R3)), JDSUR, JPSR, Research Report and Measures Taken Report, MHLW Medical Device Incident Report etc.
- Support for Japanese specific dictionaries like - Japanese MedDRA and Japanese Drug Dictionary, Japanese hospital code
- Support for querying and messaging in Kanji
- Support for the common Japanese date format and automatic conversion from Imperial era to the Western era. Furthermore, support for name of the era after 1900 (Meiji, Taisho, Showa, Heisei) can be added or edited

Literature data management and case linking features:

Literature information is maintained independent of case data. LSMV 10 provides full support for Japanese dictionary management, including MedDRAj and Japanese product/hospital codes with look-up functions.

LSMV10: A Single, Global View of Safety Issueszed

With a centralized solution, organizations have a single global view of safety issues enabling a worldwide pharmacovigilance program. A centralized solution ensures companies are in compliance with Japanese, U.S. and European regulations. Complete support for all MHLW requirements ensure LSMV10 is constantly updated and the system complies with the latest regulations. Also with LSMV10, there is no longer a need to first combine data and deal with different formats, data structures, and back-office systems to further analyze and report on the data.

Harmonizes Drug Safety Data

When companies deploy a single safety solution, they are ensuring data is being entered consistently.

Unified Enterprise Architecture

The LSMV10 solution is an open system based on industry standard architecture. It can be easily integrated with regulatory, clinical and medical information systems to improve collaboration and information consistency.

Enhanced Case processing and Business Workflows

The advanced workflow module supports the automatic routing of cases based on company defined procedures, facilitating compliance with reporting timelines. An integrated solution enables companies to deploy international workflows from a single global database for consistent case processing and reporting procedures.

Improves End-User Productivity

Japanese companies no longer need to perform double data entry and international headquarters no longer need to re-enter the cases they receive from the Japanese affiliate. The multilingual capabilities in LifeSphere MultiVigilance 10 also allow for online translations to be done from Japanese to English.

Enables Risk Management and Data Mining

ArisGlobal's advanced data mining and signal detection enables in-depth clinical safety data analysis, incorporating all relevant data sources, to help companies better understand the risk/benefit ratio of a product and discover product-adverse event relationships. The platform uses an optimized pharmacoepidemiological database with a robust front-end reporting tool to ensure fast and easy clinical safety data management.

Lowers Implementation Time and Ongoing Maintenance Costs

The system is highly configurable, allowing companies to easily configure the Web user interface, extend the database, create user-defined workflows and add custom libraries. With an integrated solution and single database, the system is installed, configured and validated only once. Companies can recognize tremendous cost savings when licensing a single database and performing subsequent upgrades.

Unified Database

With a single database solution, there is no need to transfer data between different databases, systems or database instances. Data redundancy and disaster recovery processes will be more efficient since only one database is being backed up.

Allows for Faster and Easier Global Electronic Submissions

LifeSphere MultiVigilance 10 is seamlessly integrated with LifeSphere Submissions Tracking™ for electronic submissions. A single electronic submission and receipt system is used for meeting the worldwide requirements for E2B and E2B(R3) reporting, including reporting to MHLW. Periodic, spontaneous, and clinical expedited reports can simply and easily be transmitted to the PMDA.

A truly global pharmacovigilance program requires collaboration and sharing of case information between all major ICH regions, including Japan.

LSMV10 has been specifically designed to support the data capture and reporting requirements as defined by the MHLW. When LSMV10 is deployed on a single central database, companies gain significant benefits from an integrated solution, allowing all configurations – including workflow and data entry templates – to be set up once and easily shared by all global affiliates.

LSMV10 is the only proven solution for companies that need to establish a global pharmacovigilance and clinical safety program. The system has been successfully deployed at many of the leading Japanese pharmaceutical companies, enabling them to effectively meet both their domestic MHLW and international reporting obligations.

About ArisGlobal

ArisGlobal is transforming the way today's most successful Life Sciences companies develop break-throughs and bring new products to market. Our end-to-end drug development technology platform, LifeSphere®, integrates our proprietary Nava® cognitive computing engine to automate all core functions of the drug development lifecycle. Designed with deep expertise and a long-term perspective that spans more than 30 years, LifeSphere® is a unified platform that boosts efficiency, ensures compliance, delivers actionable insights, and lowers total cost of ownership through multi-tenant SaaS architecture.

Headquartered in the United States, ArisGlobal has regional offices in Europe, India, Japan and China. For more updates, follow ArisGlobal on LinkedIn and Twitter.