NIS Considerations - Japan
An overview of the considerations when conducting Non-interventional Studies in Japan

Stuart McCully • Compliance Healthcheck Consulting UK Ltd • NIS-C-JP-2012
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Disclaimer

Although this Compilation contains information of a legal nature, it has been developed for informational purposes only and does not constitute legal advice or opinions as to the current operative laws, regulations, or guidelines of any jurisdiction. In addition, because new standards are issued on a continuing basis, this Compilation is not an exhaustive source of all current applicable laws, regulations, and guidelines relating to non-interventional studies. While reasonable efforts have been made to assure the accuracy and completeness of the information provided, researchers and other individuals should check with local authorities and/or research ethics committees before starting research activities.
## Regulatory Requirements

### COUNTRY-SPECIFIC REGULATORY REQUIREMENTS

### REGULATORY BODIES

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* The MHLW is in charge of pharmaceutical regulatory affairs in Japan (veterinary drugs are under the jurisdiction of the Ministry of Agriculture, Forestry and Fisheries)

^ The Pharmaceuticals and Medical Devices Agency (PMDA) focuses on three key areas: relief services for adverse health effects, product reviews, and post-marketing safety measures. These three encompass the entire life cycle of drugs and medical devices from development through to the post-marketing period. This so-called “safety triangle” system, which contributes to public health, is unique to Japan. Under this system, PMDA is committed to fulfilling its responsibilities in line with its philosophy, which was developed by all its employees (as per the PDMA Profile of Service: 2012 - 2013)
Services of PMDA

- Relief for Adverse Drug Reactions
- Relief for Infections Acquired through Biological Products
- Health Allowances for SMON Patients
- Health Allowances for HIV-Positive and AIDS Patients
- Relief for Individuals Affected by Hepatitis C through Specified Products

- Consultations
- Drug Reviews
- Medical Device Reviews
- GLP/GCP/GPSP Inspections
- GMP/QMS Inspections
- Standards Development

- Information Collection/Organization
- Research and Analyses
- Consultations
- Information Services
- Risk Management Plan (RMP)

- Post-marketing Safety Measures

- Its Key Services:

In addition to reinforcing the review system by increasing the number of expert reviewers and inspectors, PMDA is striving to enable patients and healthcare professionals to have faster access to drugs and medical devices by using a team review system. In the review system, the same review team is responsible for each step of the review process, from clinical trial consultations to product reviews to ensure that precise advice are provided and appropriate reviews and inspections are conducted.

In order to respond to "medical innovation," which has been the subject of greater attention placed in recent years, and to handle the scientific and regulatory aspects of state-of-the-art technology products more appropriately, in May 2012, PMDA established the Science Board consisting of leading experts.

PMDA’s Reviews and Related Services Provided at Each Stage of Drug/Medical Device Development

- Research and development
- Non-clinical tests
- Clinical trials
- Filing of application
- Approval
- Marketing
- Consultation
- Pharmaceutical Affairs Consultation on R&D Strategy
- Clinical Trial Consultation

- Regulatory Review
- Pre-market Review
- Re-examination/Re-evaluation

- Conformity Audit
- GLP Inspection
- GCP Inspection
- GPSP Inspection

- GMP/QMS Inspection
- GMP/QMS Inspection

- Standards Development

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DEFINITIONS

Good Post-marketing Study Practice (GPSP)

The GPMSP ordinance was enacted to specify the system and scope of activities of pharmaceutical companies to assure proper implementation of post-marketing surveillance of drugs and reliability of the data obtained after marketing (Ordinance No. 10 of the MHLW dated March 10, 1997). Thereafter, the GPMSP was divided into Good Vigilance Practice (GVP) and Good Post-marketing Study Practice (GPSP. The GPSP ordinance was enforced from April 1, 2005 (as per the [JPMA Pharmaceutical Administration and Regulations in Japan - 2012](#)).

Post-Marketing Surveys

(i) Post-marketing surveys, etc. refers to drug use-results surveys or post-marketing clinical studies that the marketing authorization holder of drugs conducts in order to collect, screen, confirm or verify information relating to the quality, efficacy and safety of drugs.

(ii) Among post-marketing surveys, drug use-results survey refers to a survey by the marketing authorization holder to screen or confirm information related to the incidence of each disease due to adverse drug reactions, together with the quality, efficacy and safety of drugs, without specifying the condition of the patients that use the drugs.

(iii) Among drug use result surveys, specified drug-use survey refers to a survey by the marketing authorization holder to screen or confirm information relating to the incidence of each disease due to adverse drug reactions, together with the quality, efficacy and safety of drugs, in specified populations of patients, such as pediatric patients, elderly patients, pregnant women, patients with renal and/or hepatic disorders, and patients using the drug for long periods.

(iv) Among post-marketing surveys, post-marketing clinical study refers to a clinical study performed to verify assumptions arrived at as a result of studies undertaken with regard to results of clinical studies or drug-use surveys, or studies conducted in accordance with approved dosage and administration, and indications to collect information on quality, efficacy and safety unobtainable in routine medical practice.
Post-Marketing Study Investigator
The term “post-marketing study investigator” as used in this Ministerial Ordinance means a physician or dentist who supervises activities related to a post-marketing study conducted at the medical institution (as per Article 2.4 of the Ministerial Ordinance on Good Clinical Practice for Drugs (as amended)).

Post-Marketing Study Sub-Investigator
The term “post-marketing study sub-investigator” as used in this Ministerial Ordinance means a physician or a dentist who takes charge of part of the activities related to a post-marketing study under the supervision of the post-marketing study investigator at a medical institution (as per Article 2.12 of the Ministerial Ordinance on Good Clinical Practice for Drugs (as amended)).

Post-Marketing Study Drug
The term “post-marketing study drug” as used in this Ministerial Ordinance means a test drug and a comparator (limited to the drug products that are used for the post-marketing study) (as per Article 2.8 of the Ministerial Ordinance on Good Clinical Practice for Drugs (as amended)).

Post-Marketing Study Collaborators
The term “post-marketing study collaborators” as used in this Ministerial Ordinance means pharmacists, nurses, or other healthcare professionals who collaborate in activities related to a post-marketing study under the supervision of either the post-marketing study investigator or the post-marketing sub-investigator at a medical institution (as per Article 2.15 of the Ministerial Ordinance on Good Clinical Practice for Drugs (as amended)).
**Monitoring**

The term “monitoring” as used in this Ministerial Ordinance means the act of overseeing the progress of a clinical trial or post-marketing study, and of determining whether the clinical trial or post-marketing study is being conducted in compliance with this Ministerial Ordinance and the protocol of the clinical trial (hereinafter referred to as “protocol”) or the protocol of the post-marketing study (hereinafter referred to as “post-marketing protocol”), in order to ensure that the clinical trial or post-marketing study is properly conducted. Such act is performed at the medical institutions by a person sponsoring a clinical trial (hereinafter referred to as “sponsor”) or a person sponsoring a post-marketing study (hereinafter referred to as “post-marketing study sponsor”), or by an individual appointed by a sponsor-investigator (as per Article 2.16 of the Ministerial Ordinance on Good Clinical Practice for Drugs (as amended)).

**Audit**

The term “audit” as used in this Ministerial Ordinance means an examination of trial-related activities to determine whether the clinical trial or post-marketing study has been conducted in compliance with this Ministerial Ordinance and the protocol or the post-marketing protocol, in order to assure the reliability of data collected in the clinical trial or post-marketing study. Such examination is performed by a sponsor or a post-marketing study sponsor, or by an individual appointed by a sponsor-investigator (as per Article 2.17 of the Ministerial Ordinance on Good Clinical Practice for Drugs (as amended)).

**Adverse Event**

The term “adverse event” as used in this Ministerial Ordinance means any disease or its clinical signs occurring in a subject who has been treated with an investigational product or post-marketing study drug (as per Article 2.18 of the Ministerial Ordinance on Good Clinical Practice for Drugs (as amended)).
POST-MARKETING SURVEILLANCE (PMS) OF DRUGS

Post-marketing surveillance (PMS) to assure the efficacy and safety of drugs after they go on the market and to establish proper methods of use of drugs consists of three systems: the ADR collecting and reporting system, the reexamination system, and the reevaluation system (See diagram below - Pharmaceutical Post-marketing Surveillance System) (as per Chapter 4 of the JPMA Pharmaceutical Administration and Regulations in Japan - 2012).
The re-examination system for new drugs was introduced in the 1979 amendment of the Pharmaceutical Affairs Law, and Good Post-marketing Surveillance Practice (GPMSP) came into effect from April 1993 to assure proper implementation of PMS and also to assure the reliability of such PMS data. Thereafter, major revisions were made in the Pharmaceutical Affairs Law and its Enforcement Regulations in 1996 to 1997 to further strengthen post-marketing safety measures, and the GPMSP, which had formerly been considered as an administrative notification, became law and came into effect on April 1, 1997 (MHW Ordinance No. 10 date March 10, 1997) (as per Chapter 4 of the [JPMA Pharmaceutical Administration and Regulations in Japan - 2012](#)).

The Drug GPMSP was partially revised by Ordinance No. 151 of MHW dated December 27, 2000, and “Early Post-marketing Surveillance” for new drugs was newly established to reinforce safety measures in an early phase of marketing (to be enforced from October 1,
2001) (as per Chapter 4 of the *JPMA Pharmaceutical Administration and Regulations in Japan - 2012*).

The GPMSP is applied as standards requiring compliance by manufacturers or importers when performing post-marketing surveillance or studies, and also as compliance criteria for preparation of data (as per Chapter 4 of the *JPMA Pharmaceutical Administration and Regulations in Japan - 2012*).

Periodic reporting of safety information on new drugs, etc. was agreed at the ICH in January 1996, and the periodic safety update report (PSUR) system was introduced by Notification No. 32 of the Safety Division, Pharmaceutical and Medical Safety Bureau dated March 27, 1997 and the Guidelines on Methods for Surveillance of Results of Use of Prescription Drugs (Notification No. 34 of the Safety Division, Pharmaceutical and Medical Safety Bureau dated March 27, 1997) were specified. However, because of an increase in post-marketing ADRs not observed in the clinical trial stage of drug development and implementation of safety measures, regulations on safety measured for drugs (Notification No. 25 of the Safety Division, Pharmaceutical and Medical Safety Bureau) and entries in case report forms for ADRs and infections were specified in March 11, 1998. Furthermore, a new guideline, Implementation of Early Post-marketing Surveillance for Prescription Drugs (Notification No. 0324001, the Safety Division, PFSB dated March 24, 2006) to further strengthen the safety monitoring of medical products (See flowchart below - Post-marketing Collection and Reporting of Pharmaceutical Safety Information) (as per Chapter 4 of the *JPMA Pharmaceutical Administration and Regulations in Japan - 2012*).
Data Privacy Considerations

DATA PRIVACY AND DATA PROTECTION CONSIDERATIONS WHEN CONDUCTING NIS IN JAPAN

NATIONAL AGENCY AND LEGISLATION

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DEFINITIONS

Personal Information

"Personal information" means information about a living individual which can identify the specific individual by name, date of birth or other description contained in such information (including such information as will allow easy reference to other information and will thereby enable the identification of the specific individual) (as per Article 2.1 of the Act on the Protection of Personal Information).

Personal Information Database

"A personal information database, etc." means a set of information including personal information as set forth below:

1. a set of information systematically arranged in such a way that specific personal information can be retrieved by an electronic computer; or

2. other than those described in the preceding paragraph, a set of information designated by a Cabinet order as being systematically arranged in such a way that specific personal information can be easily retrieved.
Personal Data

"Personal data" means personal information constituting a personal information database, etc. (as per Article 2.4 of the Act on the Protection of Personal Information).

Retained Personal Data

"Retained personal data" means such personal data over which an entity handling personal information has the authority to disclose, to correct, add or delete the content, to suspend its use, to erase, and to suspend its provision to third parties, excluding the data which is specified by a Cabinet order as harming public or other interests if its presence or absence is known and the data which will be erased within a period of no longer than one year that is specified by a Cabinet order (as per Article 2.5 of the Act on the Protection of Personal Information).

Person

"Person" as to personal information means a specific individual identified by personal information (as per Article 2.6 of the Act on the Protection of Personal Information).

Entity Handling Personal Information

"an entity handling personal information" means an entity using a personal information database, etc. for its business; however, the following entities shall be excluded:

1. The State institutions
2. Local public bodies
3. Independent administrative agencies, etc. (which means independent administrative agencies as prescribed in Paragraph 1 of Article 2 of the Act on the Protection of
Best Practice Considerations

BEST PRACTICE CONSIDERATIONS WHEN CONDUCTING NIS IN JAPAN

POST-MARKETING SURVEILLANCE

Post-Marketing Safety Control Operations and Post-Marketing Surveillance

Member Companies are required to properly understand the purpose of establishing proper usage of the drug after marketing and shall carry out post-marketing safety control operations and post-marketing surveillance based on scientific fairness in compliance with related laws and regulations and self-regulations, and should not use these activities as a sales promotion tool (as per Section 5 of the JPMA Promotion Code for Prescription Drugs - 2012).

Commentary

Appropriate implementation of post-marketing safety control management is an important requirement to obtain permissions as a marketing approval holder. Post-marketing safety management operations include safety assurance activities and early post-marketing phase vigilance (EPPV), etc. Safety assurance activities are defined in the GVP Ordinance as follows; “collection and review of safety management information, and necessary measures based on the review results.” (as per Section 5 of the JPMA Promotion Code for Prescription Drugs - 2012).

Post-marketing surveillance is defined in the GPSP Ordinance as follows; “PMS indicates drug use results surveys (including specific use results surveys) or post-marketing clinical studies which are conducted by a company to collect, obtain, verify or validate information on the quality, efficacy and safety of medicines.” (as per Section 5 of the JPMA Promotion Code for Prescription Drugs - 2012).

As mentioned above, post-marketing safety management operations and post-marketing surveillance, etc. bear importance related to the nature of drugs, and therefore,
pharmaceutical companies have the social responsibility to constantly seek for a more effective and safer usage based on the post-marketing condition of the use of drugs (e.g. conditions of patient compliance, interaction with other drugs, treatment period, etc.) and the change of conditions (e.g. advancement of medical technology, change of assessment criteria, new pathologies and pathological images, change in pathogenic microorganisms, etc.) (as per Section 5 of the JPMA Promotion Code for Prescription Drugs - 2012).

Needless to say, implementation of post-marketing safety management operations and post-marketing surveillance, etc. must be evidence based. If the data are ever to be used as a disguise for sales promotion, this action would inflict damage on the inherent nature of drugs and would invite considerable loss of trust in drugs and pharmaceutical companies (as per Section 5 of the JPMA Promotion Code for Prescription Drugs - 2012).

Compliance with related laws and regulations such as the GVP Ordinance and the GPSP Ordinance, etc. and the Fair Competition Code is absolutely necessary, so that post-marketing safety control management and post-marketing surveillance, etc. are not doubted or mistaken as a disguise for sales promotion (as per Section 5 of the JPMA Promotion Code for Prescription Drugs - 2012).

TRANSPARENCY

Corporate Ethics of Pharmaceutical Companies in the IFPMA Code

The JPMA Promotion Code is the embodiment of principles and action standards for promotional activities of pharmaceutical companies. The JPMA Promotion Code is based on the desirable way of promotional activities that society expects from pharmaceutical companies, or the promotional activities pharmaceutical companies must carry out to meet society’s expectations. In other words, it is based on the corporate ethics of pharmaceutical companies towards promotional activities (as per the JPMA Promotion Code for Prescription Drugs - 2012).

Regarding such desirable promotional activities and the promotional activities that must be carried out, the IFPMA Code has set the “IFPMA Guiding Principles on Ethical Conduct and Promotion” as the basic principles and has provided eight basic standards.

1. The healthcare and well-being of patients are the first priority for pharmaceutical companies.
Pharmaceutical companies will conform to high standards of quality, safety and efficacy as determined by regulatory authorities.

Pharmaceutical companies’ interactions with stakeholders must at all times be ethical, appropriate and professional. Nothing should be offered or provided by a company in a manner or on conditions that would have an inappropriate influence.

Pharmaceutical companies are responsible for providing accurate, balanced, and scientifically valid data on products.

Promotion must be ethical, accurate, balanced and must not be misleading. Information in promotional materials must support proper assessment of the risks and benefits of the product and its appropriate use.

Pharmaceutical companies will respect the privacy and personal information of patients.

All clinical trials and scientific research sponsored or supported by companies will be conducted with the intent to develop knowledge that will benefit patients and advance science and medicine. Pharmaceutical companies are committed to the transparency of industry sponsored clinical trials in patients.

Pharmaceutical companies should adhere to both the spirit and the letter of applicable industry codes. To achieve this, pharmaceutical companies will ensure that all relevant personnel are appropriately trained.

The IFPMA Code also mentions the following about “ethical promotion” and “interactions between pharmaceutical companies and health professionals” (as per the JPMA Promotion Code for Prescription Drugs - 2012).

**Ethical Promotion**

“The ethical promotion of prescription medicines is vital to the pharmaceutical industry’s mission of helping patients by discovering, developing, and marketing new medicines. Ethical promotion helps to ensure that healthcare professionals have access to information they need, that patients have access to the medicines they need and that medicines are prescribed and used in a manner that provides the maximum healthcare benefit to patients.” (as per the JPMA Promotion Code for Prescription Drugs - 2012).