NAGASHIMA OHNO & TSUNEMATSU
長島·大野·常松 法律事務所

NO&T Japan Legal Update

December, 2017 No.12

This issue covers the following topics:

■ Dispute Resolution/Product Safety

Product Safety Obligations for Manufacturers and Importers under the Japanese Consumer Product Safety Act

I. Introduction

One of the main pieces of legislation regarding product safety in Japan is the Consumer Product Safety Act (Act No. 31 of 1973) (the 'CPSA'). The primary purpose of the CPSA is to ensure that products supplied to general consumers for everyday use do not pose any danger to the lives or health of general consumers. This article provides a brief overview of the CPSA with respect to the product safety labelling system, reporting of consumer product accidents and the specific obligations regarding certain long-term use products.

The CPSA defines "consumer products" broadly as "any product to be supplied mainly for use by general consumers for their routine everyday activities" and covers a wide spectrum. The CPSA does, however, exempt a number of products that are already covered by other legislation, including, food, additives and detergents under the Food Sanitation Act (Act No. 233 of 1947); road trucking vehicles under the Road Trucking Vehicle Act (Act No. 185 of 1951); and medicines, quasi-medicines, cosmetics and medical equipment under the Pharmaceutical Affairs Act (Act No. 145 of 1960). The provisions of the CPSA do not apply for these products.

Conversely, some products covered by the CPSA are additionally subject to overlapping legislation that is specific to certain industries or sectors, such as the Electrical Appliances and Materials Safety Act (Act No. 234 of 1961), the Gas Business Act (Act No. 51 of 1954), and the Act on the Securing of Safety and the Optimization of Transaction of Liquefied Petroleum Gas (Act No. 149 of 1967).

II. Overview of the CPSA

The regulatory framework that applies to a person engaging in manufacturing and importation under the CPSA is mainly composed of three parts, (i) the Product Safety of Consumer Products ('PSC') Mark System, (ii) Reporting and Publication of Information regarding Product Accidents, and (iii) Inspection and Labelling to Prevent Accidents due to Deterioration Caused by Long-term Use. Each of these is described in more detail below.

(i) 'PSC Mark' Labelling System

The PSC mark system is a pre-marketing method used to ensure product safety

Authors in this Issue

■ Dispute Resolution / Product Safety

Takayuki Fujii
Partner
+81-3-6889-7346
takayuki_fujii@noandt.com

■ Pharmaceutical/Health Care

Yoshinobu Koyama
Partner
+81-3-6889-7203
yoshinobu_koyama@noandt.com

by regulating the sale and display of consumer products that are deemed to be highly likely to cause danger to the lives or health of general consumers. These products are decreed by Cabinet Order and are determined by reference to their structure, material and usage. No person engaging in the manufacturing, importation or sale of specified products is permitted to sell, or display for the purpose of selling, such specified products without affixing the PSC mark.

A person engaging in the manufacturing or importation of the specified products may only place the PSC mark on the specified products if they:

(i) have notified the competent minister of certain specific items required for each classification of product; and

(ii) have inspected the products and prepared and kept an inspection record to confirm that the products meet the technical requirements necessary to prevent the occurrence of danger to the lives or health of general consumers.

For certain specified products where, among the manufacturers or importers thereof, there are manufacturers or importers that are deemed to have failed to obtain the level of quality necessary to prevent the occurrence of danger to the lives or health of general consumers, as provided for by Cabinet Order, the person engaging in the manufacturing or importation shall additionally have certain items inspected by a person registered with the competent minister. Those manufacturers or importers must obtain and keep this additional certification in order to affix the PSC mark.

(ii) Reporting and Publication of Information regarding Product Accidents

The CPSA requires a person engaging in the manufacturing or importation of consumer products to report information regarding serious product accidents, in order to be publicized by the Secretary General of the Consumer Affairs Agency (the 'CAA'). Under the CPSA, product accidents are defined as accidents (other than those not caused by a defect in the product) resulting from the use of consumer products:

(i) where danger to the lives or health of general consumers has occurred; or

(ii) where consumer products are lost or damaged and are deemed likely to cause danger to lives or health of general consumers.

Additionally, serious product accidents are those falling under certain requirements provided for by Cabinet Order with respect to the level of danger or the manner of accident.

Any person engaging in the manufacturing or importation of consumer products who becomes aware that a serious product accident has been caused by the consumer products that he/she manufactured or imported, must, within ten days from the date on which he/she becomes aware, report certain related information to the Secretary General of the CAA. In cases where the Secretary General of the CAA has received such a report or otherwise comes to know of the occurrence of a serious product accident, if deemed necessary, the Secretary General may publicly announce the name and type of the consumer products pertaining to the serious product accident, the details of the accident and any other matters that contribute to avoiding the dangers associated with the use of the offending consumer products.

With respect to a product accident that does not amount to a serious product accident, manufacturers and importers of the relevant consumer product are encouraged to report the accident to the National Institute of Technology and Evaluation (the 'NITE'), an independent administrative agency. In such cases, retailers and other parties involved with such products are also encouraged to

Recent Publications

- ***Getting the Deal Through - Real Estate 2018 Japan***
  (Law Business Research Ltd, December 2017)
  by Hiroto Inoue, Junji Yamanaka, Makoto Saito (co-author)
- ***Getting the Deal Through - Cartel Regulation 2018 Japan***
  (Law Business Research Ltd, December 2017)
  by Eriko Watanabe
- ***Civil Code reform***
  (International Financial Law Review, December 2017/January 2018 International Briefings: Japan)
  by Yoshiaki Satake
- ***The International Comparative Legal Guide to: Gambling 2018 - Chapter 23 Japan***
  (Global Legal Group Limited, December 2017)
  by Masayuki Fukuda
- ***The International Comparative Legal Guide to: Merger Control 2018 - Chapter 22 Japan***
  (Global Legal Group Limited, December 2017)
  by Eriko Watanabe
- ***Getting the Deal Through - Environment & Climate Regulation 2018 Japan***
  (Law Business Research Ltd, November 2017)
  by Kiyoshi Honda and Takumi Naito (co-author)
- ***The International Comparative Legal Guide to: Corporate Tax 2018 - Chapter 22 Japan***
  (Global Legal Group Limited, November 2017)
  by Shigeki Minami
- ***Getting the Deal Through - Private M&A 2018 Japan***
  (Law Business Research Ltd, November 2017)
  by Kayo Takigawa and Yushi Hegawa (co-author)

notify the NITE; however, this is not an obligation under the CPSA. The NITE then publishes information regarding non-serious product accidents on its website.

(iii) Inspection and Labelling to Prevent Accidents due to Deterioration Caused by Long-term Use

The CSPA imposes certain additional obligations on consumer products that are deemed highly likely to cause serious danger to the lives or health of general consumers particularly because of their lack of reliable safety due to deterioration caused by long-term use, such as hot water heaters and bathroom hand dryers.

A person engaging in the manufacturing or importation of these products shall determine and notify the competent minister of certain specific items within 30 days prior to their sale to general consumers. Additionally, the manufacturer or importer shall determine:

(i) a standard period of use where, if used under standard conditions, no safety issues should arise (the 'Design Standard Use Period'); and

(ii) a period of inspection that is necessary to prevent the occurrence of injury due to age-related deterioration once the Design Standard Use Period has expired (the 'Inspection Period').

The manufacturer or importer shall place labelling which shows, among others, the Design Standard Use Period and time of commencement and expiration of the Inspection Period on the relevant products.

The manufacturer or importer is also required to prepare a list containing the information of individuals who have purchased these products and who have provided such information. Prior to the commencement of the Inspection Period, the competent ministry may designate a time period for certain products where the manufacturer or importer must, except in cases where there are justifiable grounds, issue a notice in writing to the owners of the products that the relevant product is due for inspection. The manufacturer or importer is obligated to comply with any request during the inspection period, including any other period of time provided for by the competent ministry to inspect the relevant products that he/she manufactured or imported, except in cases where there are justifiable grounds.

Additionally, the competent ministry will establish certain standards regarding inspection and maintenance of such products, and applicable manufacturers and importers are required to develop a system to properly inspect and carry out maintenance of the products accordingly in compliance with the ministry standards.

Similarly, consumer products which do not have a high likelihood of causing a serious accident, but do have a high volume of reports of accidents due to deterioration over time, such as electric fans and air conditioners, are required to bear labels that detail the manufacturing year, the Design Standard Use Period and other related information.

III. Comment

Product safety regulations in Japan are somewhat complicated and are not necessarily easy to understand with multiple obligations being imposed under the CPSA and other parallel legislation. Nonetheless, a person engaging in the manufacturing, importation or sale of consumer products is required to carefully check such regulations and take the necessary steps to comply.

■ **Pharmaceutical/Health Care**

The "*SAKIGAKE*" Designation System: Accelerating the Approval Process of Pharmaceuticals in Japan

I. Introduction

The Ministry of Health, Labour and Welfare of Japan (the 'MHLW') introduced the "*SAKIGAKE*" designation system in 2015 (in Japanese, '*sakigake shinsa shitei seido*') (the 'SAKIGAKE Designation System'), aiming to accelerate the time to market for innovative pharmaceuticals by providing a series of benefits in both the pre-application and review stages of the approval process. On December 15, 2017, the MHLW approved the first pharmaceutical selected under the SAKIGAKE Designation System.

II. Designation Criteria

In order to qualify for the SAKIGAKE Designation System, the pharmaceutical in question must satisfy four separate criteria. Namely, it must (i) be innovative, (ii) target serious diseases, (iii) be effective and (iv) plan to obtain its early development and regulatory approvals in Japan first. Each of these criteria is outlined in more detail below.

(i) Innovation

In principle, the nominated pharmaceutical should have a new action mechanism, which differs from existing drugs on the market. However, this requirement will also be satisfied in cases where the nominated pharmaceutical has the same action mechanism as an existing drug, but has an innovative method of targeting a disease or uses a new drug delivery system which results in significantly improving efficacy.

(ii) Targeting Serious Diseases

The nominated pharmaceutical must target either (a) serious diseases which inflict grave consequences on a patient's life or (b) diseases which have no permanent cure with continuous symptoms that hinder a patient's participation in wider society.

(iii) Prominent Effectiveness

There must not be a comparable drug currently available on the market or the nominated pharmaceutical must anticipate significant improvements in effectiveness (including safety) compared to existing curative drugs or treatment methods.

(iv) Early Development and Regulatory Approvals in Japan First

The nominated pharmaceutical must intend to apply for regulatory approval firstly in Japan ahead of the rest of the world (or simultaneously with another country). Ideally, First in Human clinical trials and/or Proof Of Concept studies of the nominated pharmaceutical should be conducted in Japan in order to confirm the intention of the nominated pharmaceutical to be developed and steadily promoted domestically.

III. Benefits of the Designation System

As mentioned above, the primary aim of the SAKIGAKE Designation System is to accelerate the time to market for newly developed pharmaceuticals. To that end, a number of procedural approval steps are expedited for selected pharmaceuticals. This section outlines the main ways in which the SAKIGAKE Designation System achieves its goals.

(i) Priority Consultation

In the review process by the Pharmaceuticals and Medical Devices Agency (the 'PMDA'), nominated pharmaceuticals selected under the SAKIGAKE Designation System will be prioritized and, thus, the waiting time for a clinical trial consultation, following the submission of materials, will be shortened from two months to one month.

(ii) Pre-Application Consultation

If the nominated pharmaceutical is selected under the SAKIGAKE Designation System, the PMDA will hold a pre-application consultation (a de facto review prior to an application being submitted) where the PMDA accepts materials in the English language and provides feedback on the proposed application. The purpose of this pre-application consultation is to ensure that all the necessary documentation is in right order prior to

submission and to limit to the greatest extent the need for the PDMA to request additional information after submission, allowing the PDMA to expedite the review process.

(iii) Priority Review

The PMDA will prioritize the review of nominated pharmaceuticals selected under the SAKIGAKE Designation System as such nominated pharmaceuticals are recognized as "particularly imperative for medical treatment" as set forth in Article 14, Paragraph 7 of The Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (the 'Pharmaceutical Affairs Act'). In effect, the length of the review process will be shortened from 12 months to six months.

(iv) Assigning a Review Partner

The PMDA will assign a review partner to coordinate the overall management of the entire process regarding the approval of the nominated pharmaceutical selected under the SAKIGAKE Designation System. This review partner will oversee all areas of the approval process, including conformity assurance, quality management, safety measures and application reviews.

(v) Post-Marketing Safety Measures

For pharmaceuticals that obtain approval through the SAKIGAKE Designation System, post-marketing safety measures will be strengthened by extending the re-examination period after approval has been granted to up to ten years, in addition to facilitating partnerships with scientific societies and disseminating information about the particular pharmaceutical globally.

IV. Comment

To market pharmaceuticals in Japan, approval from the Minister of Health, Labour and Welfare must be obtained for each item under the Pharmaceutical Affairs Act. Since the approval process in Japan generally takes longer than that of Europe and the United States, and European and American pharmaceutical markets are larger, in recent years, Japanese pharmaceutical companies have been inclined to first obtain product approval in Europe and the United States rather than domestically.

Earlier this month, a selected pharmaceutical was granted approval under the SAKIGAKE Designation System for the first time. It is important to note that if the second and third cases are soon approved, swift approval processes using the SAKIGAKE Designation System have the potential to become common practice in Japan. If that is the case, Japan could well be considered as the first destination for companies to obtain pharmaceutical approval, which would, in turn, have a positive effect on the Japanese pharmaceutical market and, ultimately, on the health of people in Japan.

NAGASHIMA OHNO & TSUNEMATSU www.noandt.com

JP Tower, 2-7-2 Marunouchi, Chiyoda-ku, Tokyo 100-7036, Japan
Tel: +81-3-6889-7000 (general) Fax: +81-3-6889-8000 (general) Email: info@noandt.com

Nagashima Ohno & Tsunematsu, having offices in Tokyo, New York, Singapore, Bangkok, Ho Chi Minh City, Hanoi and Shanghai, is widely known as a leading law firm and one of the foremost providers of international and commercial legal services in Japan. The firm represents domestic and foreign companies and organizations involved in every major industry sector and in every legal service area in Japan. The firm has structured and negotiated many of Japan's largest and most significant corporate and finance transactions, and has extensive litigation strength spanning key commercial areas, including intellectual property, labor and taxation. The firm comprises around 400 lawyers capable of providing its clients with practical solutions to meet their business needs.