Baker McKenzie Wong & Leow.

Healthcare
Singapore

Product Recall

In Singapore, specific product recall regimes apply to:

- medicines and therapeutic products;
- complementary medicines (including Chinese proprietary medicine, homoeopathic medicine, quasi-medicinal products, traditional medicine and health supplements);
- cosmetic products;
- medical devices; and
- food products and appliances.

Two types of product recalls are provided for in these regimes:

- voluntary recalls directed by the product owner / license holder, manufacturer or importer; and
- compulsory recalls directed by the relevant governmental agencies.

Agencies Involved

The following government agencies are involved in product recalls:

- medicines, therapeutic products, complementary medicines and cosmetic products - the Enforcement Branch of the Health Sciences Authority;
- medical devices - the Medical Device Branch of the HSA; and

Awards

Ranked Band 1 for Life Sciences
Chambers Global rankings 2014 - 2020

Ranked Band 1 for Intellectual Property
Chambers Global 2009 - 2020

Medical and Healthcare Law Firm of the Year
Asian Legal Business Southeast Asia Law Awards 2019

Tier 1 Intellectual Property Firm in Asia
ALB IP Rankings 2018 - 2019

Asia Pacific IP Firm of the Year
Managing IP Asia Pacific Awards 2018 - 2019

Ranked Band 1 for Intellectual Property Firm in Singapore
Chambers Asia Pacific 2010 - 2020

Ranked Tier 1 for Intellectual Property Firm in Singapore
Legal 500 Asia Pacific 2010 - 2019

- food products and appliances - the Food Control Division of the Singapore Food Agency ("SFA"; previously the Agri-Food & Veterinary Authority of Singapore).

Reporting Requirements & Recall Procedures

The reporting requirements and recall procedures differ according to the different regimes.

Regime for Medicines, Therapeutic Products, Complementary Medicines & Cosmetic Products

Voluntary recalls may be initiated by the product owner/license holder, manufacturer or importer as a result of defective reports from various sources such as manufacturers, wholesalers, retailers, medical practitioners, hospital and retail pharmacists, end-users and members of the public.

Compulsory recalls may be initiated by the HSA as a result of adverse drug reaction monitoring, product quality surveillance or defective reports from reputable sources.

Generally, a recall may be classified as a Class 1 recall or a Class 2 recall, depending on the potential hazard of the defective product. Class 1 recalls are initiated when the product defect poses a life-threatening situation to users. Class 2 recalls are initiated when the defect is unlikely to cause serious harm to users (e.g. minor labeling errors).

The product owner / license holder, manufacturer or importer must inform the HSA's Enforcement Branch upon receipt of any product defect information, regardless of whether the information leads to a subsequent recall of the product. Upon receipt of such information, the company must undertake to inform the HSA's Enforcement Branch recall officer within 24 hours. The classification, level and strategy of the recall will then be finalized after discussion with the HSA.

In the event that a product recall is necessary, the product owner/ license holder, manufacturer or importer must cease sales of and quarantine all defective products immediately, and inform all affected wholesalers, distributors and retailers to do likewise.

Arrangement must then be made for the collection of defective stocks from affected wholesalers, distributors and retailers for collation and quarantine in a warehouse. Mandatory timelines are also imposed for submitting recall reports and corrective action proposals to the HSA.

When there is a risk of significant hazard to consumers and the distribution has been extensive, the product owner / license holder, manufacturer or importer responsible is required to employ all possible mass communication media available to disseminate the recall information to the consumers.

Regime for Medical Devices

Every manufacturer, importer or wholesaler of a medical device shall, upon becoming aware of any event or other occurrence that reveals any

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defect in the medical device or that concerns any adverse effect arising from the use thereof, report that event to the HSA within the stipulated time periods depending on the seriousness of the occurrence.

Depending on the medical device's degree of hazard and extent of distribution, the recall strategy will specify the level in the distribution chain to which the recall is to extend.

Registrants and dealers should promptly notify each of their consignees about the recall, stating the product description, product hazards and actions to be taken.

A final report (or if not possible, interim reports) must be eventually submitted to the HSA.

Medical devices returned to registrants and dealers should be properly identified and isolated until a decision has been made with approval from the HSA on its eventual fate.

Upon completion of a recall, the product owner should provide details to the HSA of the proposed corrective action to prevent recurrence of the problem that gave rise to the recall.

Regime for Food Products and Appliances

Food product recalls can be initiated by producers and by the SFA upon testing for disease, poisoning, spoilage organisms and harmful chemicals.

Non-compliance with food labeling and advertisement requirements may also lead to recalls.

There are no specific legislation or guidelines concerning reporting requirements and recall procedures.

Where the recall is voluntary, the parties involved may wish to notify the public through notices in mainstream newspapers, so as to minimize adverse publicity and potential damage to corporate reputation. Also, the SFA should be consulted to demonstrate that the parties are responsible corporations that have the interests of consumers in mind.

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