Healthcare
Singapore

BAKER & MCKENZIE.WONG & LEOW

Newsletter
November 2015

In This Issue:

Public Consultation on Singapore Standard for Good Distribution Practice for Medical Devices

ASEAN Community to be Established by End 2015

Indian Food Laws in Flux

Public Consultation on Singapore Standard for Good Distribution Practice for Medical Devices

SPRING Singapore, an agency under Singapore's Ministry of Trade and Industry, has launched a public consultation on 6 November 2015 for the Singapore Standard for Good Distribution Practice for Medical Devices ("**GDPMDS**").

The Health Sciences Authority of Singapore ("**HSA**") has previously issued guidance documents setting out the requirements of GDPMDS and how companies may apply GDPMDS to their processes. It is mandatory for importers and wholesalers of medical devices to be GDPMDS-certified, in order to obtain import and wholesale licences from the HSA.

Briefly, GDPMDS ensures that companies dealing with medical devices have a quality distribution system in place, and it safeguards the quality and integrity of medical devices throughout the storage and distribution process.

As a medical device may have to pass through several companies in the distribution chain before reaching the consumers, the Singapore Standard for GDPMDS seeks to provide a benchmark for the various stakeholders in the supply chain, which will set out the requirements for a quality management system for the handling, storage, delivery, installation, servicing and secondary assembly of medical devices.

The Singapore Standard for GDPMDS is expected to be used extensively by importers, distributors, logistics providers and freight forwarders in the medical device industry in Singapore.

Other than the Singapore Standard for GDPMDS, SPRING Singapore is also inviting public comments on standards for a non-exhaustive list of nomenclature for traditional Chinese medicine and prescription labelling for traditional Chinese medicine.

All interested parties may submit their feedback to SPRING Singapore via email before the public consultation ends on **7 January 2016**. More details of the public consultation are available at SPRING Singapore's website, which can be accessed here.

ASEAN Economic Community to be Established by End 2015

The establishment of the Association of South East Asian Nations ("ASEAN") Community was officially declared on 22 November 2015 by leaders of the 10 ASEAN member states. The leaders of the ASEAN member states signed the Kuala Lumpur Declaration on the establishment of the ASEAN Community and endorsed a 10-year roadmap to bring the member states closer. The declaration, which brings with it the promise of greater regional integration for the member states, will come into effect on 31 December 2015.

The establishment of the ASEAN Community reaffirms the member states' commitment to the ASEAN Vision 2020. ASEAN aims to build a community involving vibrant and competitive economies which are highly integrated with a common identity.

One of the pillars of the ASEAN Community in the making is the ASEAN Economic Community ("**AEC**"). To date, ASEAN member states have removed most tariff barriers and are co-operating to increase the competitiveness of ASEAN globally, to gradually transit into a single market and production base. Businesses can benefit by learning more about the opportunities that the AEC may offer and how they can best make use of these opportunities to gain access to more markets.

For our articles on the harmonisation of medical device regulations and health supplements and traditional medicine regulations in ASEAN, please refer to our previous newsletters (*"ASEAN Medical Device Directive will standardize medical device registrations* (link)" and *"ASEAN to harmonise health supplements and traditional medicines regulations by 2015* (link)").

The 2015 edition of our ASEAN Healthcare Harmonization Guide has also been published. This Guide addresses five key AEC harmonization issues and aims to provide information on how to navigate your business through the ASEAN pharmaceutical harmonization process. Please contact us if you would like to have a copy of this Guide.

Indian Food Laws in Flux

(This article was contributed by Pawan Chopra and Mohan Rajasekharan of Dua Associates, India)

The year 2011 witnessed a paradigm shift in the focus of Indian food laws. The erstwhile Prevention of Food Adulteration Act, 1954 along with several other legislations were repealed and consolidated into a single legislation, namely the Food Safety and Standards Act, 2006 ("**FSS Act**"). While the principal objective of the Prevention of Food Adulteration Act, 1954 was to prevent the manufacture and sale of adulterated food, the FSS Act seeks to ensure the 'availability of safe and wholesome food for human consumption'.

Though the FSS Act was enacted in 2006, the regulations that brought into force various provisions of the FSS Act including the standards of food, licensing norms, etc., came into effect only on August 5, 2011.

Food Standards

The food standards are broadly divided into Vertical Standards and Horizontal Standards. The horizontal standards refer to the standards such as hygiene and cleanliness that are applicable across the entire food sector or categories thereof. Vertical standards, on the other hand, define the standard for a given product such as chocolates, ice cream, biscuits, carbonated and non-carbonated beverages, etc.

The Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 ("**Food Additive Regulations**") lay down the vertical standards for food products. However, the Food Additive Regulations only provide the vertical standards for about 370 food products and the same does not include all the internationally recognised standards laid down by CODEX ALIMENTARIUS. Food products in respect of which no standards were provided under the Food Additive Regulations were regarded as proprietary food.

Proprietary Food

Section 22 of the FSS Act provides as follows:

> "*Save as otherwise provided under this Act and regulations made thereunder, no person shall manufacture, distribute, sell or import any novel food, genetically modified articles of food, irradiated food, organic foods, foods for special dietary uses, functional foods, neutraceuticals, health supplements, proprietary foods and such other articles of food which the Central Government may notify in this behalf*".

The Explanation to Section 22 defines proprietary and novel food to mean a food item:

(a) for which no standards have been provided;

(b) is not unsafe; and

(c) does not contain any of the foods and ingredients prohibited under the FSS Act and the regulations made thereunder.

Section 22 of FSS Act places a blanket restriction on the manufacture, distribution, sale and import of proprietary and novel foods, health supplements, etc., for which no standards were provided under the regulations.

As a result, several food items, which have a history of safe consumption in other jurisdictions but for which standards were not prescribed under Indian law, fell within the category of proprietary food and were restricted from being sold in India. Similarly, existing products in the Indian market, to the extent they did not meet the standards laid, were also regarded as proprietary food with the restrictions being made applicable to them as well.

In view of this precarious situation, a need was felt to have in place a premarket approval mechanism whereby proprietary food and other food items that use ingredients whose safety is known or established under CODEX or other recognised international bodies such as US FDA or EFSA, etc., were considered. This was referred to as Product Approval.

Product Approval

The Product Approval as introduced by the FSSAI was a product-specific premarket approval to be obtained from the FSSAI in respect of all proprietary food, including novel foods, nutraceuticals, health supplements for which no standards were laid down under Indian laws. Accordingly, an importer or a manufacturer (in India) of a proprietary or novel food was required to submit an application in the prescribed format to the Product Approval Division of FSSAI.

The guidelines for product approval were introduced by way of advisories which were published on the FSSAI's website.

Case Study: Vital Nutraceuticals Case

The Product Approval advisories were challenged before the Bombay High Court in the case of *Vital Nutraceuticals Private Limited v. Union of India*. Though the circumstances which prompted Vital Neutraceuticals to file the case was to challenge a penalty sought to be imposed by the FSSAI on

For further information please contact

Andy Leck
+65 6434 2525
Andy.leck@bakermckenzie.com

Lim Ren Jun
+65 6434 2721
Ren.jun.lim@bakermckenzie.com

Baker & McKenzie.Wong & Leow
8 Marina Boulevard
#05-01 Marina Bay
Financial Centre Tower 1
Singapore 018981

www.bakermckenzie.com

existing food business operators, the petitioners also challenged the Product Approval advisories on the ground that the same were *ultra vires* the FSS Act and it did not have the force of law.

The Bombay High Court held that standards for various articles of food, prescribing food labelling standards such as health claims, amongst others, could not be regulated by issuing administrative instructions or advisories. It is obligatory on the part of FSSAI to frame regulations following the procedure prescribed under the FSS Act. Since the product approval advisories laid down the procedure and guidelines for issue of a product approval "No Objection Certificate" in respect of those products for which standards were not prescribed under the FSS Act and the rules and regulations made thereunder, it was in respect of matters covered under Section 16 (2)(a) to (i) and Section 92(2)(a) to (v) of the FSS Act and therefore, the same ought to have been issued by framing regulations and not through advisories.

Based on the aforesaid grounds, in June 2014, the Bombay High Court held that the Product Approval advisories do not have the force of law and the same are not covered within the ambit and scope of the powers conferred on the FSSAI under the FSS Act.

Though the FSSAI had appealed against this decision, on August 19, 2015, the Supreme Court of India dismissed the appeals, holding that it found no grounds for interference with the order of the Bombay High Court.

Therefore, all the advisories on Product Approval have been struck down and so has the process.

Current Situation

Though the Product Approval advisories were struck down by the court, no interim arrangement was provided for regulating the manufacture, import and sale of proprietary food.

There is an uncertainty on the status of foods such as proprietary and novel foods, health supplements, nutraceuticals, etc., as in the absence of any such procedure or guidelines (in accordance with Section 22 of the FSS Act), it is unclear if such products can be introduced in the market. Several companies have taken the aggressive view that since the license to manufacture / distribute / import issued by the State or Central division of FSSAI also mentions the category of the food product, this indirectly confers the authority to sell the proprietary food in the market.

Further to the Supreme Court order, the FSSAI announced on August 26, 2015 that it would be introducing regulations governing Section 22 products though the same is still awaited. Draft regulations in respect of nutraceuticals, health supplements and novel foods have been circulated for public comments and the same is yet to be finalised. Further, several draft regulations for amending the Food Additive Regulations to provide for additional standards for food products have also been circulated.

The FSSAI is an autonomous body under the Department of Health and Family Welfare entrusted with the responsibility of ensuring the availability of safe and wholesome food for human consumption. Any change in the standards of food items would need to be implemented by the FSSAI. In view of the uncertainties, industry participants are keenly looking forward to the new measures to be put in place.