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Committee of Inquiry concludes hearings into SingHealth cyberattack

On 30 November 2018, the Committee of Inquiry ("**COI**") convened to investigate the SingHealth cyberattack, wrapped up its last day of public hearings.

The COI was first convened on 24 July 2018, and held its first in-camera session on 28 August 2018. This was followed by two tranches of hearings from 21 September 2018 to 5 October 2018, and from 31 October 2018 to 14 November 2018. The last day of hearing was on 30 November 2018.

A total of 37 witnesses had given evidence to the COI over the course of 21 days. The COI has also received 26 written submissions from individuals, organisations and industry associations.

In his closing statement, the Solicitor-General gave 16 recommendations spanning both strategic and operational matters, applicable to critical information infrastructure systems such as those held by healthcare clusters. These included staff training to raise awareness on cybersecurity, and also government and private sector collaborations to promote security efforts, amongst others.

The COI is due to submit its final report by the end of the year.

Previous editions of our newsletter discussing the SingHealth cyberattack can be found here (August) and here (September).

Ministry of Health to introduce standardised packaging for tobacco products in Singapore

Following a series of public consultations from 2015 to mid-2018, the Singapore Ministry of Health ("**MOH**") has issued a final assessment on the proposal to use standardised packaging on all tobacco products sold in Singapore, along with enlarged mandatory graphic health warnings ("**GHWs**"). This follows other jurisdictions such as Australia, the United Kingdom, and France, which have also implemented standardised packaging and the use of mandatory GHWs.

The key features of the standardised packaging proposal include, amongst others:

- Brand owners would no longer be allowed to use marks or trade marks (other than the brand and variant name) on the packaging;
- Such names must follow a standardised format / layout;
- GHWs must take up 75% (formerly 50%) of the total surface area of the retail package;
- Surfaces are to be in a standardised colour, must not be embellished, and must be opaque with a matt finish;



- No information as to product emission yields can be displayed;
- Promotional information on the packaging of tobacco products should be limited to only the brand and variant name; and
- Retail package size, shape and materials are to be standardised.

The new measures may be expected to take effect from 2020, with legislative amendments to the *Tobacco (Control of Advertisements and Sale) Act*, the *Trade Marks Act*, and the *Registered Designs Act* proposed in early 2019. To minimise the burden on the industry, the new measures will also provide for a transition period to allow for old stock to be cleared.

More information can be found in MOH's press release here, and the documents published by the MOH in respect of the public consultation and decision here.

Health Sciences Authority announces plans to implement electronic Common Technical Document (eCTD) to facilitate data transfer

In efforts to facilitate the movement of regulatory information between pharmaceutical companies and the Health Sciences Authority ("**HSA**"), the HSA has announced its plans to implement the electronic Common Technical Document ("**eCTD**").

The eCTD will serve as an interface in which such information can be transferred in a structured format. It aims to speed up data transfer, and offer pharmaceutical companies better oversight of their products' life cycle. Furthermore, it would also enable companies to make use of eCTD dossiers, that have already been prepared for another agency or purpose, for HSA regulatory submissions.

Commencement of the development phase will begin in 2019, with a view to begin accepting eCTD submissions in Singapore by 2020. The HSA will start with a phased-in approach in order to give the industry time to familiarise itself with the new processes.

Firstly, the use of eCTD submissions will commence with new original marketing applications (New Drug Applications ("NDAs") and Generic Drug Applications ("GDAs")). Thereafter, products which have been originally registered via eCTD submissions will be expected to continue in eCTD format for the remainder of its life-cycle. While the eCTD submissions will be voluntary during the initial implementation period, the HSA will review and make a decision as to whether eCTD submissions should be made mandatory at a later date.

The HSA has noted that the eCTD version it will be implementing is version 3.2.2, and that applicants should note that eCTD submissions will be applicable for the ICH CTD format only. The HSA will also be reviewing requirements for baseline submissions (quality dossiers) for currently registered products at a later date.

In order to facilitate a smooth transition into the new interface, the HSA will be inviting the industry to provide input during the development phase, through



consultations concerning the validation requirements and draft guidelines, as well as opportunities to be involved in User Acceptance Testing.

More information can be found in the HSA's press release found here.

Public consultation on possible measures to reduce sugar intake from pre-packaged sugarsweetened beverages

The high prevalence of diabetes amongst Singapore residents has caused the Ministry of Health ("MOH") to declare a "War on Diabetes". In efforts to tackle this serious health concern, the MOH and the Health Promotion Board ("HPB") are proposing possible measures that can be taken to reduce the sugar intake of Singaporeans, particularly from pre-packaged sugar-sweetened beverages ("SSBs"). As such, a public consultation will be held to seek feedback and views from both the public and key stakeholders.

At present, the average sugar levels for SSBs with medium to high sugar levels remain high at 5 teaspoons, and such SSBs constitute more than half the total amount of sales of SSBs in Singapore. The measures have thus been proposed with efforts to encourage industry reformulation to reduce sugar levels in SSBs, and enable Singaporeans to make more informed and healthier choices.

The proposed measures to SSBs are as follows:

1. Mandatory front-of-pack nutrition label

The first possible measure is the mandatory introduction of a nutrition label to the front of the SSB, so as to enable consumers to easily identify which SSBs are less healthy, such as those that are high in sugar.

2. Advertising regulations

The second possible measure is the regulation of advertisements of less healthy SSBs online and in the mass media, so as to reduce their influence on consumer preferences. The possible regulations include:

- Making the current restrictions (for which compliance is voluntary)
 on the advertising of less healthy food and drinks to children
 mandatory and expanding such restrictions to cover more TV
 time-belts and media channels that children are exposed to; or
- b. Banning advertisements of less healthy food and drinks across all time-belts and mass media channels.



3. Excise duty on manufacturers and importers

The third possible measure is the introduction of an excise duty on manufacturers and importers of SSBs to influence the behaviour of manufacturers and consumers. The implementation of such duties on SSBs might encourage manufacturers to reformulate their products, as well as encourage consumers to choose healthier drinks with lower sugar content or to simply drink plain water.

4. Ban on higher-sugar pre-packaged SSBs

The fourth possible measure is to introduce a nationwide ban on the sale of higher-sugar SSBs to further discourage consumption of such SSBs. At present, SSBs with more than three teaspoons of sugar per 250ml cannot be sold in schools and on government premises. However, this only restricts access to higher-sugar SSBs in those locations, and students and the general public are still able to obtain such SSBs from other sources.

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Interested parties may submit their views regarding the proposed measures from 4 December 2018 until 25 January 2019 via the REACH website, located at https://www.reach.gov.sg/sugarydrinks. The MOH and HPB will also be organising dialogues with the public and industry in the near future as part of the public consultation exercise.

More information about the public consultation can be found <u>here</u>, and the consultation paper in full can be found <u>here</u>.

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