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Cybersecurity's Role in Medical Devices Regulation

The Government Technology Agency of Singapore ("**GovTech**") recently cited an industry report stating that healthcare ranked among the top five industry sectors that experienced the highest incidences of cyberattacks. Such attacks are only likely to intensify as medical devices become increasingly connected to each other, to public hospital networks, and to the Internet.

The susceptibility of medical devices to cyberattacks not only poses a threat to individuals, but to communities and organisations. While it is clear that certain compromised medical devices (e.g. life support systems) pose a direct risk to patients, it is perhaps less evident that such devices could also be easy targets for highly-sensitive and confidential information as well. Without the necessary security arrangements in place, real-time health data can easily be appropriated to reverse-engineer information—like the location and layout of secret military bases, as was the case with the Strava fitness app.

Many countries in Asia Pacific have recognized the increasing danger that such devices pose, and have acted swiftly to regulate them. For example, the Ministry of Food and Drug Safety of South Korea recently issued draft medical device cybersecurity guidelines which impose heightened technical standards for medical devices with wired and/or wireless communication functions. Under these draft guidelines, companies must comply with cybersecurity-related requirements before the regulator will process the application.

However, GovTech acknowledges that in Singapore, while "*medical device manufacturers and hospitals are seeking to improve their own cybersecurity measures, there is currently no industry standard for them to abide by*." The *Health Products (Medical Devices) Regulations*, issued pursuant to the *Health Products Act*, only classifies medical devices according to non-cybersecurity-related factors, such as their degree of invasiveness and their duration of contact with the body. Further, HSA's *Regulatory Guideline for Telehealth Products* only requires dealers of telehealth medical devices to perform post-market surveillance duties, such as the reporting of adverse events, without specific guidelines on the technical standards required.

It remains to be seen how Singapore will address cybersecurity issues relating to medical devices, whether by imposing obligations on medical device manufacturers or otherwise.

Public Consultation on Proposed Tobacco-Control Measures in Singapore

On 5 February 2018, the Ministry of Health ("**MOH**") released the *Public Consultation Paper on Proposed Tobacco-Control Measures in Singapore* (the "**Consultation Paper**").

In summary, MOH is considering introducing standardised packaging and enlarged graphic health warnings for tobacco products sold in Singapore (the "**SP Proposal**"). This is in line with Singapore's long-standing public health objective to promote and move towards a tobacco-free society.

Specifically, the SP Proposal contemplates the removal of all logos, colours, brand images, and promotional information on packaging, other than brand names and product names displayed in a standard colour and font style, and an increase in the minimum size of the mandatory graphic health warnings from the existing 50% to cover 75% of all specified tobacco product packaging surfaces.

The application of standardised packaging to all categories of tobacco products and packaging is recommended by the World Health Organization's *Framework Convention on Tobacco Control* ("**FCTC**"), to which Singapore is a party. The FCTC obliges Parties, in accordance with their capabilities, to implement comprehensive tobacco control strategies in order to "*reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke*".

If you wish to provide comments or feedback, the closing date to do so is **16 March 2018**. MOH's Consultation Paper may be found here.

Amendments to ASEAN Cosmetic Directive

On 14 to 17 November 2017, the 27th ASEAN Cosmetic Committee endorsed recommendations proposed by the 27th ASEAN Cosmetic Scientific Body to amend Annexes II, III, IV and VI of the ASEAN Cosmetic Directive ("**ACD**").

The recommendations include three additional substances which must not form part of the composition of cosmetic products, as stated below:

- 3- and 4-(4-Hydroxy-4-methylpentyl) cyclohex-3-ene-1-carbalde-hyde ("**HICC**");
- 2,6-Dihydroxy-4-methyl-benzaldehyde ("**Atranol**"); and
- 3-Chloro-2,6-Dihydroxy-4-methyl-benzaldehyde ("**Chloroatranol**")

HICC, Atranol, and Chloroatranol are chemical compounds which may be found in fragrances, and are known to cause skin or respiratory allergies.

In Singapore, the ACD is implemented by way of the *Health Products (Cosmetic Products - ASEAN Cosmetic Directive) Regulations* ("**ACD Regulations**"), issued pursuant to the *Health Products Act*. We note that the ACD Regulations have not been updated as of the publication of this Newsletter.

A summary of the updates made to the ACD may be found here.

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