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Committee of Inquiry into SingHealth Cyberattack Invites Public Submissions

Following the cyberattack on SingHealth's patient database that occurred between 27 June to 4 July 2018, a Committee of Inquiry ("**COI**") has been convened to look into the incident and examine the contributing factors. The cyberattack affected 1.5 million SingHealth patients, who had their personal particulars such as their names, NRIC numbers and addresses illegally accessed. Amongst them, the outpatient prescriptions of 160,000 patients were also illegally accessed.

The first hearing by the four-member COI, which was held in private, took place on 28 August 2018. This was followed by a two-week long series of hearings held at the Supreme Court starting from 21 September 2018, of which some hearings may be open to the public while the others will remain private. Prior to these hearings, the COI has invited the public to submit written representations detailing their views, comments and recommendations regarding the cyberattack.

In particular, written submissions are sought regarding the following matters:

1. Measures to enhance the incident response plans for similar incidents;
2. Measures to better protect SingHealth's patient database system against similar cybersecurity attacks; and
3. Measures to reduce the risk of such cybersecurity attacks on public sector IT systems which contain large databases of personal data, including in the other public healthcare clusters.

These written representations should be accompanied by the author's particulars, such as their occupation and contact details. If the representation is made on behalf of any organisation, disclosure of such an affiliation is required. The author will also need to disclose any financial interest that he or she may have with regards to their recommendations.

The COI will then take the written submissions into consideration. It may call on certain authors of the written representations to give evidence at the hearing or to provide clarification on their written representations. The COI may also wish to publish certain submissions received.

All written submissions are to be emailed to coi_secretariat@mci.gov.sg by **31 October 2018, at 5 pm**.

The press release by the Ministry of Communications and Information can be found here, and more information about the hearings can be found here.

We also previously discussed the SingHealth cyberattack in our recent edition of the Healthcare newsletter (see the August edition here).

Removal of Screening Process for MIV-1 Applications for Registered Therapeutic Products

Effective from 17 September 2018, the Health Sciences Authority ("**HSA**") has removed the screening process for certain minor variation ("**MIV**") applications to streamline the process of varying an existing registration for a therapeutic product.

MIV applications are applications that companies make if there is a variation to the therapeutic product after it has been successfully registered. In particular, should there be a variation to the quality aspects of the product (i.e. chemistry, manufacturing controls and/or product labelling), an MIV-1 application should be made. If there is a minor variation or administrative change, an MIV-2 application should be made.

The removal of the screening step only applies to MIV-1 applications.

The HSA has noted that the introduction of self-help tools and the provision of application checklists have helped applicants to familiarise themselves with the process. As the quality of submissions have improved, in the sense that applicants are increasingly able to select the appropriate MIV, this has served as a catalyst for the removal of the screening step.

The HSA expects that such an initiative will render overall processing timelines more predictable and shorten timelines by at least 25 working days, since applications can now proceed straight to the evaluation stage after submission.

Other than the removal of the screening process for MIV-1 applications, the MIV application process remains otherwise unchanged.

More information regarding the updated MIV application process can be found here.

Information Sharing Within Australia-Canada-Singapore-Switzerland Consortium to Streamline Application Processing

The Australia-Canada-Singapore-Switzerland Consortium ("**ACSS Consortium**") comprises four health regulatory authorities, namely the Therapeutic Goods Administration ("**TGA**") of Australia, Health Canada, Swissmedic of Switzerland, and the Health Sciences Authority ("**HSA**") of Singapore. In recognition of the similar challenges faced by the four authorities, the ACSS Consortium was formed to facilitate and promote interaction between these authorities in efforts to improve public health and safety in the respective countries.

The ACSS Consortium aims to address gaps in technical knowledge and expertise, and to leverage resources to help expedite risk assessment processes, while preserving and improving quality and safety standards. Amongst its activities, the consortium focuses largely on work-sharing initiatives, especially in the areas of generic medicines registration and assessment reports for new prescription medicines. The synergies created by the consortium's work-sharing initiatives have the potential to reduce unnecessary duplication and differences between countries, thereby promoting greater regulatory collaboration and alignment of regulatory requirements, and enhancing the effectiveness and efficiency of each domestic regulatory system.

For instance, in a work-sharing trial held in July 2018, a pilot drug for the treatment of prostate cancer was jointly reviewed by Health Canada and Australia's TGA, and was completed with greater efficiency due to the division of the evaluation tasks between the two regulators. Health Canada notes that work-sharing has the potential to reduce regulatory burdens (if applicants can simply file a common dossier), and enable regulators to give similar market authorisation dates between countries and consolidated questions to applicants.

To advance such work-sharing initiatives, which necessarily involve the exchange of information between the four regulatory authorities, the HSA has included a new section to the application checklists (for the registration of therapeutic products) which seeks to obtain the applicant's consent for disclosure of information within the ACSS Consortium. If disclosure of information to the ACSS Consortium is eventually made, the HSA will also notify the applicant in writing.

Applicants submitting applications to the HSA from 17 September 2018 are to use the updated version of the Application Checklist.

More information about the new Application Checklist can be found here. Further details on the ACSS Consortium and its work-sharing initiatives can be found here and here.

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