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HSA introduces new Self-guided Algorithm and Revised MIV Enquiry Form

The Health Sciences Authority ("**HSA**") has introduced a new self-guided algorithm for post-approval variation applications ("**MIV**"), as part of ongoing efforts to enhance clarity and transparency in the healthcare regulatory process.

The new self-guided algorithm, which enables applicants to determine the application type, variation category and the documentary requirements for MIVs, has been implemented into the revised MIV Filing and Submission Enquiry Form (the "**Enquiry Form**"). There are no technical changes made to the application types, variation categories or documentary requirements.

Accordingly, Appendix 12 of HSA's Guidance on Therapeutic Product Registration in Singapore, which concerns the Enquiry Form, has been updated and will take effect from 1 July 2018.

The current version of the Enquiry Form may be used until 31 August 2018. From 1 September onwards, HSA will only accept enquiries that are accompanied by the new Enquiry Form.

The revised Enquiry Form may be found here.

HSA releases Regulatory Guidelines for Telehealth Products and Devices for Modification of Appearance or Anatomy

We previously discussed HSA's amendments to the medical device regulatory regime, which provide greater clarity to existing policies and requirements for:

- telehealth devices; and
- high risk devices for the modification of appearance or anatomy.

Our earlier newsletter on this topic may be found here.

These amendments have been made to the *Health Products (Medical Devices) Regulations*, and have been implemented with effect from 1 June 2018.

To provide greater clarity on these amendments and to reflect HSA's current policy stance and practice on the relevant products, HSA has released a Regulatory Guideline for Telehealth Products ("**Telehealth Products Guideline**"), and a Regulatory Guideline for Devices for Modification of Appearance or Anatomy ("**Modification Devices Guideline**"), respectively.

In particular, the Telehealth Products Guideline provides flowcharts to aid in the categorisation and risk classification of telehealth products. The HSA has also clarified that these guidelines do not cover the practice of telehealth services, as

this falls outside of the HSA's purview. Both the Telehealth Products Guideline and the Modification Devices Guideline may be found here.

The provision of telehealth / telemedicine services would instead be regulated by the Ministry of Health ("**MOH**"), and to this end, the MOH has created a regulatory sandbox for telemedicine providers, which will be in place until such services are officially regulated by the upcoming Healthcare Services Act.

MOH releases Research Study on Singapore Residents' Perceptions and Behaviours in Relation to Tobacco Packaging

We previously discussed the *Public Consultation Paper on Proposed Tobacco-Control Measures in Singapore* (the "**Public Consultation Paper**"), released by the Ministry of Health ("**MOH**") on 5 February 2018. Our earlier newsletter on this topic may be found here.

As part of Phase 4 of the Public Consultation, MOH commissioned Blackbox Research, a market research consultancy, to conduct a *Research Study on Singapore Residents' Perceptions and Behaviours in Relation to Tobacco Packaging* (the "**Research Study**"). The Research Study was published by MOH on 11 June 2018.

The Research Study aimed to address two main objectives, namely:

- perceptions of current non-cigarette tobacco products; and
- reactions towards standardised packaging when compared against current branded packaging for non-cigarette products.

This was done via qualitative research gathered from a total of 15 focus group discussions.

In particular, findings from the Research Study found that standardised packaging of tobacco products would:

- reduce their overall appeal and attractiveness;
- increase the perceived harm that they pose to health; and
- increase the noticeability of graphic health warnings.

In light of these findings, the Research Study was generally supportive of the public health objectives of standardised packaging stated by MOH in the Public Consultation Paper.

The Research Study may be found here.

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