BROUGHT TO YOU BY
HEALTH PRODUCTS REGULATION GROUP

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## ENGAGING INTERNATIONAL PARTNERS

**HSA is now a Regulatory Member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)**
*November 2017*

HSA joins the ranks of reputable regulators, including the US Food and Drug Administration, the European Commission and Japan's Pharmaceutical & Medical Devices Agency as a Regulatory Member of the ICH. This reinforces HSA's international standing as a competent regulator for pharmaceuticals.

HSA's membership will also facilitate the entry of local pharmaceutical industries into other markets.

Click HERE for more information.

## FACILITATING ACCESS

**Priority Review Scheme and Pre-market Consultation Scheme for Medical Devices**
*August - October 2017*

The Priority Review Scheme and Pre-market Consultation Scheme were launched in August and October 2017, respectively.

The Priority Review scheme provides medical device companies the option of faster registration and market entry, while the Pre-market Consultation Scheme enables stakeholders to consult HSA early on the regulatory requirements from the device development phase to the pre-registration phase, hence supporting innovation and device development.

Click HERE for more Information.

## ENHANCING PROCESSES

**Enhancement of the Therapeutic Products Registration Process**

***Implementation of Verification Route for Minor Variation Type 1 (MIV-1) Application***
*December 2017*

This new route was implemented on 1 December 2017 to provide a shorter processing timeline of 90 working days as compared to the abridged route with a timeline of 120 working days. This enhancement further improves process efficiency through leveraging the assessments done by HSA's reference agencies, thereby minimising the duplication of efforts.

***Upcoming Implementation of New Overall Screening Turn-Around Time (TAT)***
*April 2018*

To improve predictability of screening time for applications, an overall screening TAT of 50 working days will be introduced for the following application types:

- New drug applications (NDA)
- Generic drug applications (GDA)
- Major variation applications (MAV)

This new TAT starts from the date of receipt of the application dossier and ends on the date of acceptance or non-acceptance/ withdrawal of the application, excluding stop-clock.

Click HERE for more Information

**Streamlining Contact Numbers for Health Products Regulation Group (HPRG)**
*August 2017*

We have implemented a new phone line at 6866 1111 to facilitate your business needs by centralising all the calls and matching them with the appropriate officer.

There will be no change to the contact numbers for our Enforcement Branch (Tel: 6866 3485 for illegal dealing of health products) and Tobacco Regulation Branch (Tel: 6684 2031 for licensing enquiry and Tel: 6684 2036 for tobacco-related offences).

**Use of CorpPass for HSA E-Services**
*May 2017*

HSA has adopted the use of CorpPass for business users to login to HSA E-Services since 2 May 2017. It is a nation-wide initiative for companies to enjoy the benefits of the single digital identity for business transactions with the Government for better control, enhanced security and convenience.

CorpPass will progressively replace SingPass as the only login method for online corporate transactions with the Government. Please register for CorpPass now at www.CorpPass.gov.sg.

**Simplification of Cosmetic Products Notification Form**
*April 2017*

With effect from 25 April 2017, the online notification form for cosmetics products has been simplified. Information needed for product traceability will still be required for the notification, while other information relating to product supply, safety and technical aspects are to be submitted only upon request by HSA.