Health Sciences Authority

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16 April 2018

Dear Sponsors,

SIMPLIFIED PROCESS FOR THE IMPORTATION OF TELECOMMUNICATION DEVICES FOR USE IN CLINICAL TRIALS

As communicated during the CRCS-CRP Forum on 1 Dec 2017, importers of telecommunication devices (e.g. tablets or mobile phones) into Singapore for use in a clinical trial, need to apply for a Technical Trial Permit from the Infocomm Media Development Authority (IMDA). IMDA has recently reviewed the regulatory requirements for such importation, and a simplified process will be implemented to facilitate the import of devices for use in clinical trial.

- 2. With immediate effect, importers of wireless telecommunication devices (limited to tablets and mobile phones) into Singapore for use in a clinical trial, will no longer be required to apply for a Technical Trial Permit from IMDA.
- 3. Instead of applying for a permit, importers will need to provide the following information prior to the importation:
 - (i) If the telecommunication device is *imported* into Singapore,
 - The importer should declare the import via the <u>TradeNet's online declaration</u> form:
 - Indicate the purpose of importing the device in the "Remarks" column within the form
 - Indicate whether the local or overseas SIM cards are used, and if so, indicate the name(s) of the local or overseas telecommunication service provider(s) in the "Remarks" column
 - (ii) If the telecommunication device is hand-carried into Singapore,
 - The importer should inform IMDA about the import <u>via email</u> (email: tlsinfo@imda.gov.sg)
 - Provide relevant information, e.g. contact details, details of import, purpose of import, duration and location of trial
 - Indicate whether the local or overseas SIM cards are used, and if so, indicate the name(s) of the local or overseas telecommunication service provider(s)
- 4. It would be recommended that the telecommunication services provided by authorised public network service providers (e.g. Singtel Mobile, M1, StarHub Mobile, etc.) be used during the clinical trial.

- 5. The telecommunication device should be exported and returned to the overseas supplier after trial completion. Dealer's Licence and device registration would apply, if the device is to be used in Singapore after the trial.
- 6. Please refer to the attached slides for more information, on the simplified process for importation of telecommunication devices for use in clinical trials. A copy of the slides had been uploaded on the HSA website (Clinical Trials > Industry Communications).
- 7. Please contact HSA CT@hsa.gov.sg, if you have any questions. Thank you.

Yours sincerely,

Dr Lisa Tan Acting Director

Innovation Office & Clinical Trials Branch
Medicinal Products Pre-Market Cluster
Health Products Regulation Group