Standard Measures

NOTE: Reporting Person refers to the manufacturer, importer, supplier or registrant who submitted the FSCA Notification Report to HSA.

Pursuant to the HPA, Reporting Person shall ensure all the following measures are undertaken in relation to this FSCA:

a. Cease the supply (other than by way of export) of correction-in-progress medical devices unless prior written approval from HSA is obtained. Subject to HSA's concurrence, medical devices that are affected by the FSCA shall be determined from the product owner's Field Safety Notice (FSN);
b. Supply of medical devices not affected by this FSCA or supply of corrected medical devices may proceed subject to any other applicable regulatory requirements in Singapore being complied with;
c. Requests for the supply of correction-in-progress medical devices on grounds of medical necessity may be made in such form and manner as HSA may require. Upon HSA's approval, a temporary and restricted lifting of the cessation of supply will be granted via a Letter of No Objection issued by HSA. This Letter of No Objection would be limited to the requested supply of medical devices affected by this FSCA, subject to the conditions set out in the Letter. In such an instance, supply shall only proceed upon receipt of the Letter of No Objection from HSA;
d. Reporting Person may supply by export affected devices out of Singapore, subject to marketing authorisation. Reporting Person should notify the appropriate regulatory authority of the country of import regarding the exportation of devices affected by the FSCA;
e. Notify all consignees with existing supply of affected medical devices immediately of this FSCA. For the purposes of this Notice, 'existing supply' refers to any affected MDs supplied to consignees in Singapore prior to Date of Notification of FSCA to HSA. Medical devices imported but not supplied prior to Date of Notification of FSCA to HSA shall not be considered to be part of existing supply. Any supply, other than existing supply, of affected medical devices will hereinafter be referred to as 'new supply';
f. Written acknowledgements of receipt of the product owner's FSN shall be obtained from consignees supplied with affected medical devices. Records of acknowledgement receipts shall be provided to HSA when requested;
g. Where on-site device modification or recall/replacement of existing supply of affected medical devices is required, written acknowledgement (e.g. service report) confirming effective completion of the field corrections required as per product owner's FSN shall be obtained from consignees supplied with affected medical devices. Written records of acknowledgements shall be provided to HSA when requested;
h. For implantable medical devices, written acknowledgement of receipt of the product owner's FSN shall be obtained from qualified practitioners who have been supplied with and/or implanted the affected medical devices. Records of acknowledgement receipts shall be provided to HSA when requested;
i. Where Dear Healthcare Professional Letter (DHCPL) is required, written acknowledgement of receipt of the product owner's DHCPL shall be obtained from qualified practitioners who have been supplied with and/or performed treatment using the affected medical devices. Records of acknowledgement receipts shall be provided to HSA when requested;
j. Where notified by HSA that the DHCPL or FSN requires amendment, Reporting Person shall ensure that the necessary amendments are made, and proceed to disseminate the amended DHCPL or FSN only upon receipt of HSA's written permission to do so;

k. Ensure that documents requested in relation to this FSCA are submitted within the requested timelines in HSA's Notices. If necessary, measures (other than those in the product owner's FSN) may be imposed on corrected devices. A failure to provide supporting documents for CAPA effectiveness, inter alia, may lead to imposition of additional measures on corrected devices;

l. (*Applicable to registered devices only*) Prior to new supply of corrected medical devices, verify whether a Change Notification (CN) submission is required. Refer to GN-21: Guidance on Change Notification for further information. If a CN submission and approval is necessary, new supply shall not proceed unless prior approval from HSA has been received. Any new supply shall be subject to the conditions or restrictions that may be imposed as part of HSA's approval. Measures to ensure strict compliance to these conditions or restrictions shall be undertaken by Reporting Person. More information on CN is available on our website at https://www.hsa.gov.sg/.

NOTE: For avoidance of doubt, correction-in-progress device is a medical device which is affected by the FSCA and has not completed the CAPA intended by the product owner to wholly correct for the FSCA. For example, a medical device affected by a FSCA and only having interim risk mitigation measures implemented will be considered as a correction-in-progress device.

NOTE: Subject to HSA's concurrence, medical devices that have completed the full correction required by the product owner's FSN shall be deemed corrected devices. Supply of corrected devices may proceed subject to any other applicable regulatory requirements (e.g. change notification) in Singapore that must be complied with. HSA reserves its rights to impose subsequent measures on corrected devices if deemed necessary.

NOTE: Marketing authorisations would include (i) registration on Singapore Medical Device Register (SMDR), (ii) devices listed on Class A database, or (iii) Special Authorisation Route (SAR) for local supply (GN26, GN-27, GN-29 or GN30(CR))..

Please be informed that the penalties that apply for failure to perform the measures required under this Notice are a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months, or to both.