HSA COMPLIANCE BRANCH

FIELD SAFETY CORRECTIVE ACTION NOTIFICATION / PRELIMINARY REPORT

MDRR1 Form
Last revised 02 Sep 2013

Instructions

1. This form may take you 30 minutes to fill in. You will need to prepare some information to fill in the form.
2. This form is to be submitted to the Compliance Branch either (i) as a scanned signed copy in pdf version via email to hsa_medical_device@hsa.gov.sg. For submissions via email, ensure email size (inclusive of all attachments) is under 2MB, (ii) through fax at (65) 6478 9038 or (iii) through postal mail to Compliance Branch, Health Products Regulation Group, Health Sciences Authority, 11 Biopolis Way, #11-01 Helios, Singapore 138667
3. If the space provided in the form is insufficient, please provide the information as an attachment.
4. The notification report should be submitted at least 24 hours before the commencement of the field safety corrective action.
5. In the preliminary report, please provide required information that was not available at the notification stage and also any updated information.

Type of Field Safety Corrective Action (FSCA)	☐ Product recall ☐ Other corrective actions		
Type of Report	☐ Notification ☐ Preliminary Report (Compliance Branch FSCA Ref.No. _____)		
Company Particulars			
Name of company			
Company address			
Contact person name			
Job title			
Tel No.		Fax No.	
Email Address			
Device Details			
Device Name			
Device intended use			
Device Regulatory Status (e.g. SMDR Listing No. if device is registered)			
Model No.			
Catalogue No.			
Serial No.			
Lot/Batch No.			
Accessories/Associated Devices affected *(if any)*			
Product owner Name			
Product owner Address			
Manufacturer(s) and contact details			
Importer(s) and contact details			
Wholesaler(s) and contact details			

Registrant and contact details *(if device is registered)*	
FSCA Information	
Did the FSCA arise due to an adverse event? *(Please select only one)*	☐ Yes ☐ No
If yes, what is the category of adverse event? *(Please select all applicable)*	☐ Serious Public Health Threat ☐ Death ☐ Serious Injury ☐ Non-serious Injury
Did this adverse event occur in Singapore?	☐ Yes ☐ No
Has the adverse event been reported to HSA? (Please select only one)	☐ Yes (Adverse event ref. no.: _____) ☐ No
Evaluation of the risk associated with affected device (Health Hazard Evaluation Report)	
Reason for the FSCA	
A copy of the FSCA communication	
Has the FSCA communication been sent to all consignees?	☐ Yes (Date sent: _____(dd/mm/yyyy)) ☐ No (Expected date to be sent: _____(dd/mm/yyyy))
FSCA strategy	
Number of affected units supplied to each consignee	
No. of affected units and the period that affected units are manufactured/imported/supplied in Singapore	Manufactured in Singapore: _____ Period: _____(mm/yyyy) to _____ (mm/yyyy)
	Imported into Singapore: _____ Period: _____ (mm/yyyy) to _____ (mm/yyyy)
	Supplied in Singapore: _____ Period: _____(mm/yyyy) to _____ (mm/yyyy)
	Expected shipments to Singapore: _____ Expected date of arrival: _____(mm/yyyy)
Countries to which this FSCA has been reported *(if any)*	
Date of commencement of FSCA by product owner (dd/mm/yyyy)	
Date of commencement of FSCA in Singapore (if applicable) (dd/mm/yyyy)	
Proposed date of completion of FSCA in Singapore (if applicable) (dd/mm/yyyy)	

Other Information

I attest that the information submitted is true and correct.

Signature : _____

Name of Reporting Person : _____

Date of this notification : _____ (dd/mm/yyyy)

Company stamp : _____

This page should not be included in the submission

Guidance on how to fill this form

Please answer every question with an appropriate answer, N/A (not applicable) or N/K (not known at this time). If some of the applicable information required in this form is not available by the time the deadline for the particular category of report has expired, a report should be submitted containing all the available information.

A statement as to why any required information is not available and a date when it will be submitted must be included.

The form may be filled longhand or electronically using Word® - simply <tab> to the appropriate field and type the required information.

The following provides some guidance on what information is required in some parts of the form. It is envisaged that the fields not mentioned in this explanatory note are self-explanatory.

For guidance on handling of medical device recall, please refer to the "Guidance on Medical Device Recall" and "Guidance on Field Safety Corrective Action" which is available on the HSA website.

Definition of Field Safety Corrective Action:
A field safety corrective action (FSCA) is an action taken by a product owner to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device.

This may include:
- the return of a medical device to the product owner or its representative;
- device modification;
- device exchange;
- device destruction;
- advice given by product owner regarding the use of the device.

Device modifications may include (non-exhaustive):
- retrofit in accordance with the product owner's modification or design change;
- permanent or temporary changes to the labelling or instructions for use;
- software upgrades including those carried out by remote access;
- modification to the clinical management of patients to address a risk of serious injury or death related specifically to the characteristics of the device.

Device Details

Device Regulatory Status: Indicate the regulatory approval numbers that apply to all devices affected by the FSCA, i.e.. SMDR Listing No., Transition List No., Special Authorisation Route Licence No. If device has been exempted from product registration, indicate the basis for exemption, e.g. class A non-sterile MD.

SMDR Listing No.: The number assigned to the device in the Singapore Medical Device Register (SMDR).

Wholesaler(s) and contact details: A wholesaler is a person who supplies the medical device by wholesale in Singapore. Please refer to the Health Products Act for the full definition of wholesale. Wholesalers will include distributors.

FSCA Information

If yes, has the adverse event been reported to HSA?: Adverse event ref no refers to the reference number assigned to the adverse event report submitted by the company to HSA. This reference number can be found in HSA's letter of acknowledgement of receipt of adverse event report.

Evaluation of the risk associated with affected device (Health hazard evaluation report): This refers to a report containing an assessment of the hazard posed by the affected medical device and an estimation of the probability of the defect or malfunction occurring, the severity of injury to individuals exposed to the product and the probability of the injury occurring during exposure to the medical device.

Reason for the FSCA: Please include in this section a description of device defect or possible defect, consequences of using the affected device, date on and circumstances under which the defect or possible defect was discovered.

A copy of the FSCA communication: This refers to any communication issued by the company to notify its consignees about the FSCA. Consignee means anyone who has received, purchased or used the product being recalled or corrected.

FSCA strategy: Please include in this section information on depth of FSCA, FSCA communications, effectiveness checks and stock control.