

Publication of Field Safety Notices (FSN) on HSA website

Publication of FSN on HSA website (for information)

Since 2013, the Health Sciences Authority (HSA) has been publishing safety communications on medical device field safety corrective actions (FSCA) to enhance public safety in terms of post-market communication.

Such safety information is currently shared electronically as field safety notices (FSN) through the **MOH Alert Website**.



Source: <https://mohalert.moh.gov.sg/welcome.do>

Last updated: 02 Jun, 2010
Privacy Statement | Terms of Use

Best viewed using IE 7.0+
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Publication of FSN on HSA website (for information)

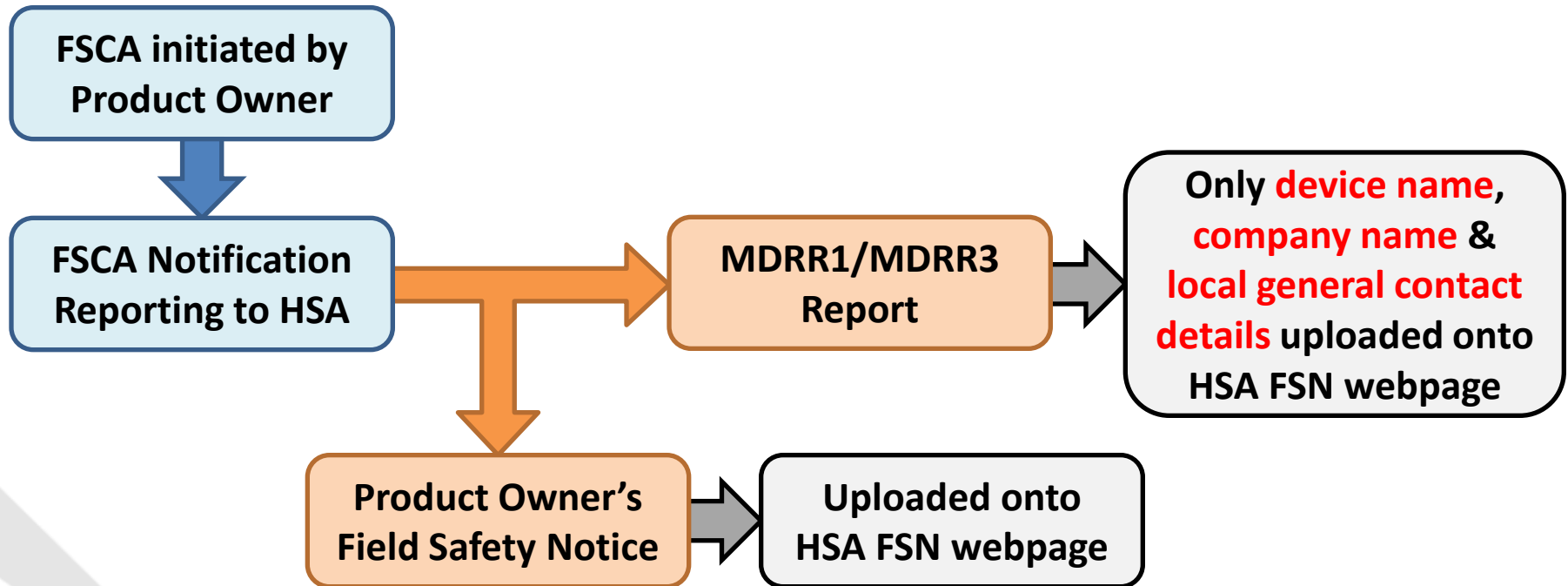
Feedbacks were received from various departments in the healthcare facilities to have the safety information more readily accessible to them.

FSNs for FSCAs notified¹ to HSA would be publicly accessible from HSA's Medical Devices webpage.

The publication of FSNs on HSA's webpage is in alignment with that of major regulatory agencies, including the **UK MHRA**² and **Germany BfArM**³.

- 1 *Notified either through MDRR1 and MDRR3 Reports*
- 2 *UK MHRA – Medicines and Healthcare Products Regulatory Agency*
- 3 *Germany BfArM – Bundesinstitut für Arzneimittel und Medizinprodukte*

Publication of FSN on HSA website (for information)



Note: Please use the latest revision of MDRR1/ MDRR3 Forms when submitting FSCA reports.

Publication of FSN on MHRA website

https://www.gov.uk/government/publications/safety-information-from-manufacturers-field-safety-notice

GOV.UK

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Medicines, medical devices and blood regulation and safety – notice

Field safety notices: information from medical device manufacturers

From: Medicines and Healthcare products Regulatory Agency
First published: 19 January 2015
Last updated: 3 August 2015, see all updates
Part of: Medical devices regulation and safety, Medicines, medical devices and blood regulation and safety and Patient safety

List of field safety notices (FSNs) received by MHRA.

Documents

-  [Field safety notices - 27 to 31 July 2015](#)
HTML
-  [Field safety notices - 20 to 24 July 2015](#)
HTML
-  [Field safety notices - 13 to 17 July 2015](#)
HTML

GOV.UK

Search

Medicines & Healthcare products Regulatory Agency

[See more information about this notice](#)

Notice

Field safety notices - 27 to 31 July 2015

Updated 3 August 2015

Contents
Overview
Latest FSNs

Overview

If you receive a field safety notice (FSN) from a manufacturer you must always act on it.

MHRA publishes the following for information only.

If you have a question about a particular FSN contact the manufacturer.

Latest FSNs

[View the latest FSNs](#)

Amanta Healthcare: Hypromol eye drops BP (sterile hydroxy propyl methyl cellulose (HPMC) Eye drops)

22 July 2015

Topical ophthalmic substances

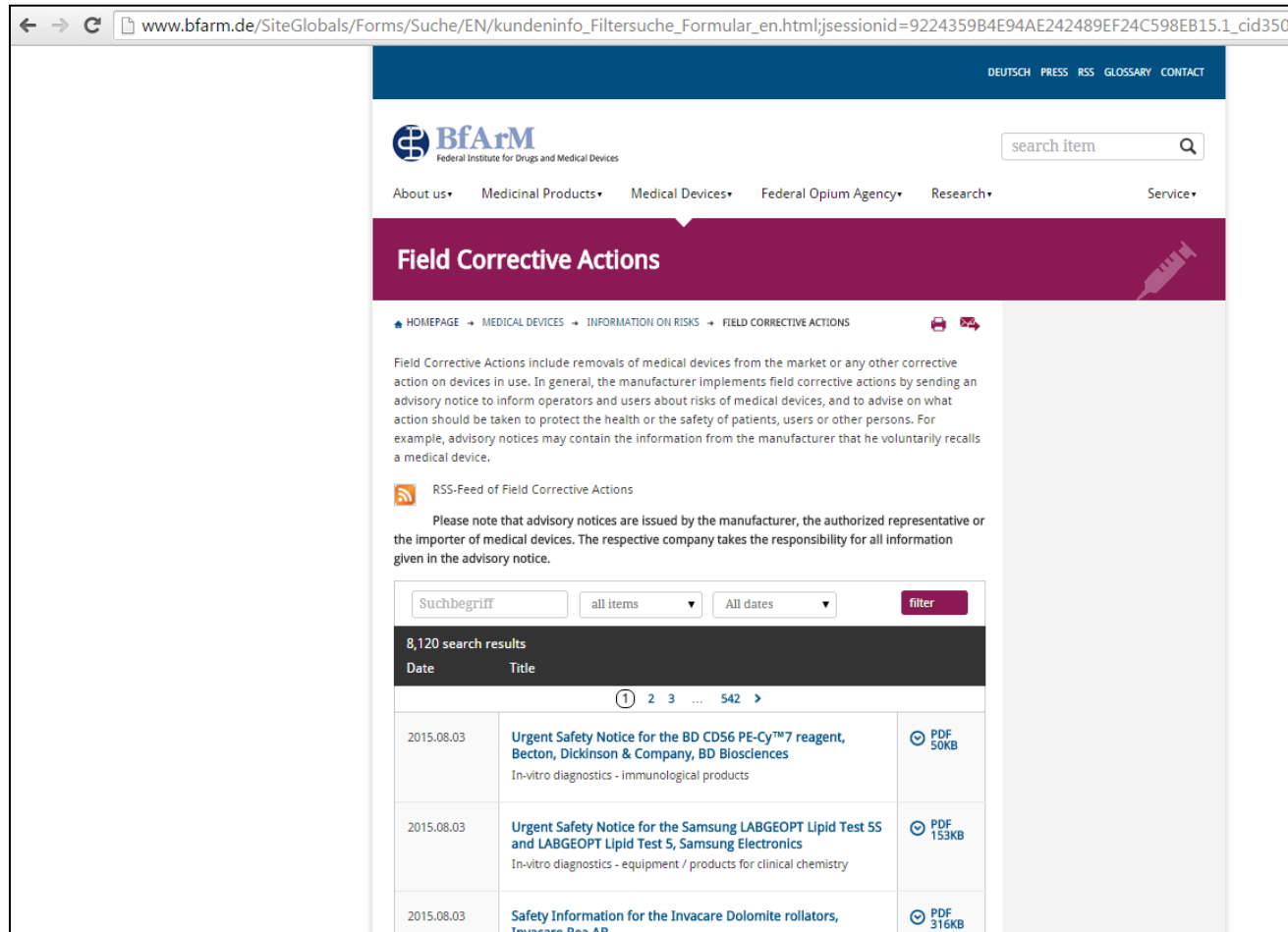
MHRA reference: [2015/007/028/291/003](#)

Amanta Healthcare: CLINIPOD (sterile normal saline topical irrigation solution)

22 July 2015

Source: <https://www.gov.uk/government/publications/safety-information-from-manufacturers-field-safety-notice>

Publication of FSN on BfArM website



DEUTSCH PRESS RSS GLOSSARY CONTACT

BfArM
Federal Institute for Drugs and Medical Devices

search item

About us • Medicinal Products • Medical Devices • Federal Opium Agency • Research • Service •

Field Corrective Actions

HOME PAGE → MEDICAL DEVICES → INFORMATION ON RISKS → FIELD CORRECTIVE ACTIONS

Field Corrective Actions include removals of medical devices from the market or any other corrective action on devices in use. In general, the manufacturer implements field corrective actions by sending an advisory notice to inform operators and users about risks of medical devices, and to advise on what action should be taken to protect the health or the safety of patients, users or other persons. For example, advisory notices may contain the information from the manufacturer that he voluntarily recalls a medical device.

RSS-Feed of Field Corrective Actions

Please note that advisory notices are issued by the manufacturer, the authorized representative or the importer of medical devices. The respective company takes the responsibility for all information given in the advisory notice.

Suchbegriff all items All dates

8,120 search results

Date	Title	
2015.08.03	Urgent Safety Notice for the BD CD56 PE-Cy™7 reagent, Becton, Dickinson & Company, BD Biosciences In-vitro diagnostics - immunological products	PDF 50KB
2015.08.03	Urgent Safety Notice for the Samsung LABGEOPT Lipid Test 5S and LABGEOPT Lipid Test 5, Samsung Electronics In-vitro diagnostics - equipment / products for clinical chemistry	PDF 153KB
2015.08.03	Safety Information for the Invacare Dolomite rollators, Invacare Rea AB	PDF 316KB

Source:
http://www.bfarm.de/SiteGlobals/Forms/Suche/EN/kundeninfo_Filtersuche_Formular_en.html;jsessionid=9224359B4E94AE242489EF24C598EB15.1_cid350



HSA FSN Webpage

HSA homepage



← → ↻ www.hsa.gov.sg/content/hsa/en.html

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ABOUT HSA | CAREERS | CONTACT INFO | FEEDBACK | SITEMAP | FAQs

Print A- A+ Within HSA Search

Health Products Regulation | Blood Services | Applied Sciences | Academy | e-Services | Publications | News & Events

To be the leading innovative authority protecting and advancing national health and safety

[Announcement] Important! Dear blood donors, our blood banks will be closed on 7 and 9 August (open on 8 August) over the Jubilee Weekend. All blood banks will resume operations on 10 August (Mon), except for the Bloodbank@HSA, which will resume operations on 11 August (Tues).

Health Products Regulation

Ensures health products are safe, of good quality and efficacious

- > PRISM
- > MEDICS
- > Bringing personal medication into Singapore

Medicines | Medical Devices
Complementary Health Products
Tobacco Control | Clinical Trials

VIEW MORE

Blood Services

Provides forensic and analytical testing to support law enforcement and the courts

Provides a safe and sustainable national blood supply

Bloodbank@Westgate Tower is Now Open!

HSA Highlights

- HSA Opens Third Satellite Blood Bank in Jurong East
23 Jun 2015
- HSA Seizes More Than 11,000 Units of Illegal Health Products During Week ...
18 Jun 2015
- HSA Alerts Public to Two Cosmetic Products Sold Online That Were Found
9 Jun 2015

Dangers of Illegal Medicines [LEARN MORE](#)

Newsletter for our Health Products [LEARN MORE](#)

Report Adverse Events [LEARN MORE](#)

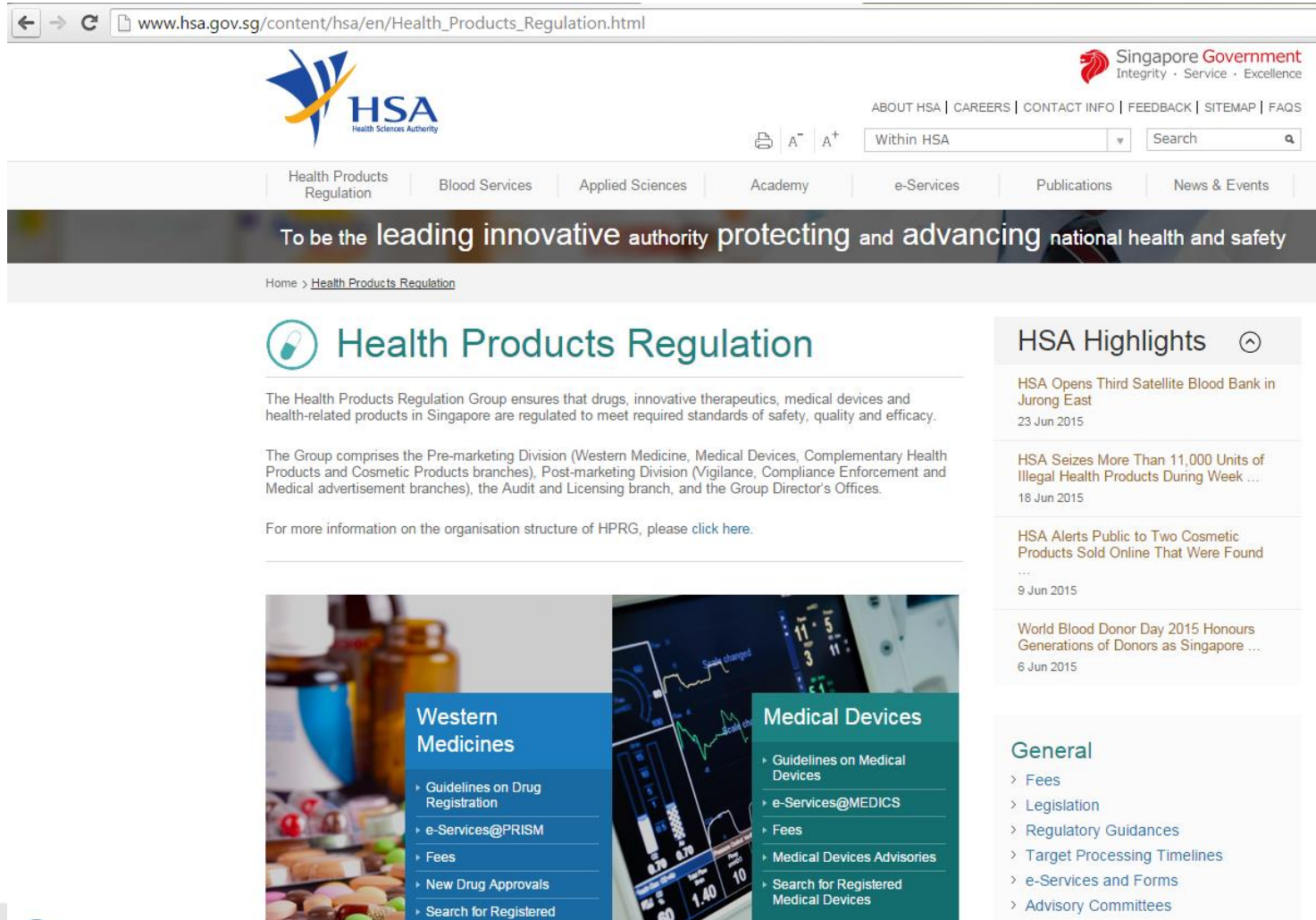


HSA FSN Webpage

HSA homepage



HPRG webpage



www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation.html

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ABOUT HSA | CAREERS | CONTACT INFO | FEEDBACK | SITEMAP | FAQs

Within HSA Search

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To be the leading innovative authority protecting and advancing national health and safety

Home > [Health Products Regulation](#)

Health Products Regulation

The Health Products Regulation Group ensures that drugs, innovative therapeutics, medical devices and health-related products in Singapore are regulated to meet required standards of safety, quality and efficacy.

The Group comprises the Pre-marketing Division (Western Medicine, Medical Devices, Complementary Health Products and Cosmetic Products branches), Post-marketing Division (Vigilance, Compliance Enforcement and Medical advertisement branches), the Audit and Licensing branch, and the Group Director's Offices.

For more information on the organisation structure of HPRG, please click [here](#).

Western Medicines

- Guidelines on Drug Registration
- e-Services@PRISM
- Fees
- New Drug Approvals
- Search for Registered

Medical Devices

- Guidelines on Medical Devices
- e-Services@MEDICS
- Fees
- Medical Devices Advisories
- Search for Registered Medical Devices

HSA Highlights

- HSA Opens Third Satellite Blood Bank in Jurong East
23 Jun 2015
- HSA Seizes More Than 11,000 Units of Illegal Health Products During Week ...
18 Jun 2015
- HSA Alerts Public to Two Cosmetic Products Sold Online That Were Found ...
9 Jun 2015
- World Blood Donor Day 2015 Honours Generations of Donors as Singapore ...
6 Jun 2015

General

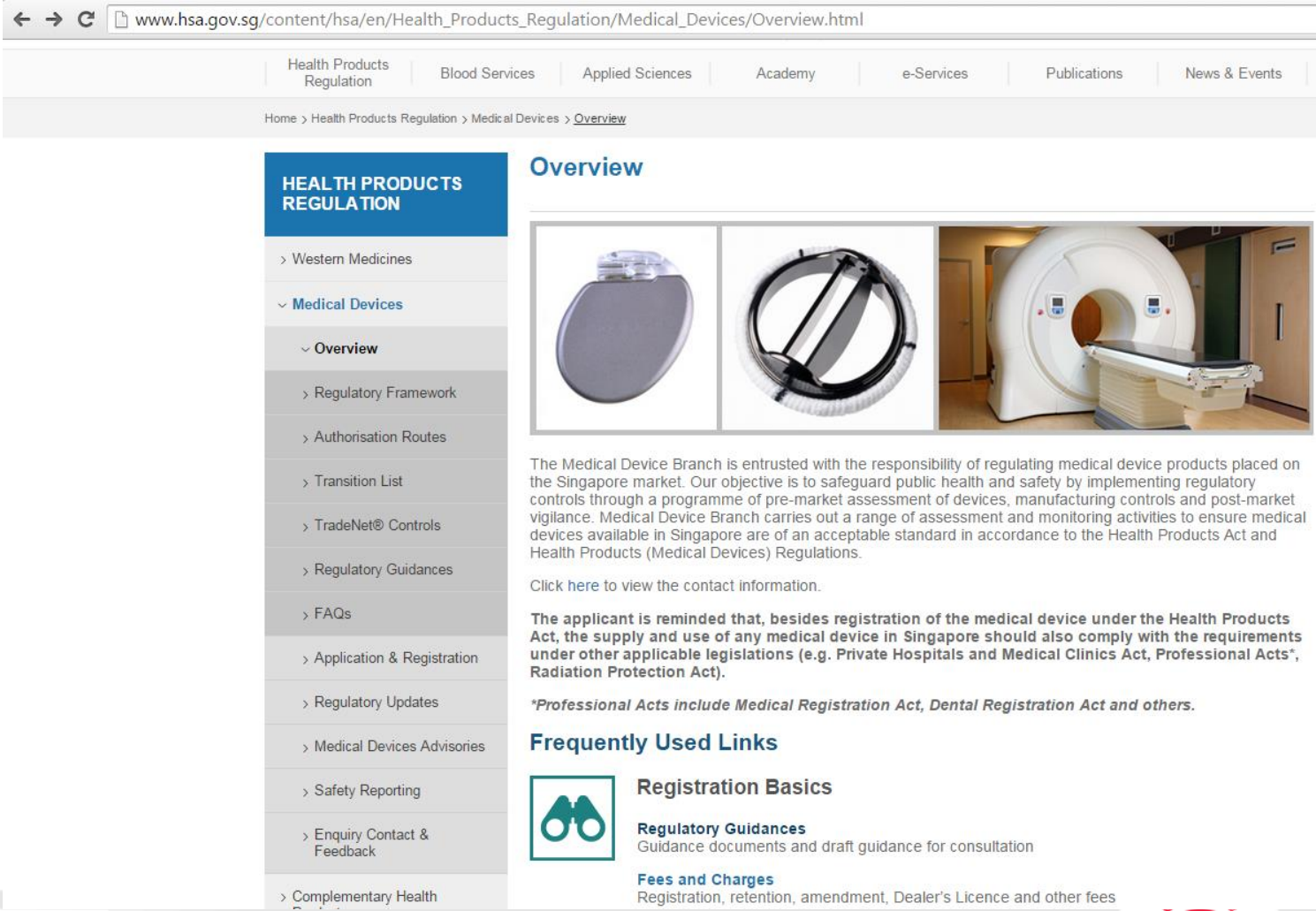
- Fees
- Legislation
- Regulatory Guidances
- Target Processing Timelines
- e-Services and Forms
- Advisory Committees

HSA FSN Webpage

HSA homepage

HPRG webpage

Medical Devices



www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Medical_Devices/Overview.html


Health Products Regulation | Blood Services | Applied Sciences | Academy | e-Services | Publications | News & Events

Home > Health Products Regulation > Medical Devices > Overview

HEALTH PRODUCTS REGULATION

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 - > Enquiry Contact & Feedback
 - > Complementary Health

Overview




The Medical Device Branch is entrusted with the responsibility of regulating medical device products placed on the Singapore market. Our objective is to safeguard public health and safety by implementing regulatory controls through a programme of pre-market assessment of devices, manufacturing controls and post-market vigilance. Medical Device Branch carries out a range of assessment and monitoring activities to ensure medical devices available in Singapore are of an acceptable standard in accordance to the Health Products Act and Health Products (Medical Devices) Regulations.

[Click here to view the contact information.](#)

The applicant is reminded that, besides registration of the medical device under the Health Products Act, the supply and use of any medical device in Singapore should also comply with the requirements under other applicable legislations (e.g. Private Hospitals and Medical Clinics Act, Professional Acts*, Radiation Protection Act).

**Professional Acts include Medical Registration Act, Dental Registration Act and others.*

Frequently Used Links

-  **Registration Basics**
- Regulatory Guidances**
Guidance documents and draft guidance for consultation
- Fees and Charges**
Registration, retention, amendment, Dealer's Licence and other fees

HSA FSN Webpage

HSA homepage

HPRG webpage

Medical Devices

Safety Reporting



The screenshot shows a web browser window with the URL www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Medical_Devices/Safety_reporting/Adverse_Event_Reporting.html. The page header includes the HSA logo and the Singapore Government logo. The navigation menu includes links for Health Products Regulation, Blood Services, Applied Sciences, Academy, e-Services, Publications, and News & Events. The breadcrumb trail is: Home > Health Products Regulation > Medical Devices > Safety Reporting > Adverse Event Reporting.

The main content area is titled "Adverse Event Reporting" and includes the following text:

Health Sciences Authority uses a number of post-marketing risk assessment approaches to ensure the continued safe use of medical devices. These measures include reporting from healthcare professionals, mandatory reporting from medical device manufacturers and dealers, and exchange of regulatory information with other medical device regulatory agencies.

The mandatory reporting of adverse events by manufacturers and dealers is an important part of the post-market surveillance system.

A guidance document on adverse event reporting is available to industry.

Click [here](#) to download the guidance.

How to Report?

1. Mandatory reporting by medical device dealers

[Clinical trial \(CT\) adverse event reporting](#)

For CT adverse event reporting, please refer to the [Guidelines on Adverse Event Reporting in Medical Device Clinical Trial](#).

[Adverse event reporting not related to clinical trials](#)

For adverse event reporting, dealers should submit reports using the following form:

- > **MDAR1 Form: Adverse Event Report Form (MS word) (Interactive PDF)**

Either the PDF or MS word version is to be submitted, not both. The interactive PDF or the MS word version forms may be submitted via email to hsa_medical_device@hsa.gov.sg. In addition, the MS word version form may be submitted using the following methods:

- > Fax: (65) 6478 9028

HSA FSN Webpage

HSA homepage

HPRG webpage

Medical Devices

Safety Reporting

FSCA



The screenshot shows the HSA website interface. The top navigation bar includes the HSA logo, the Singapore Government logo, and links for ABOUT HSA, CAREERS, CONTACT INFO, FEEDBACK, SITEMAP, and FAQs. A search bar is also present. The main navigation menu lists Health Products Regulation, Blood Services, Applied Sciences, Academy, e-Services, Publications, and News & Events. The breadcrumb trail indicates the current location: Home > Health Products Regulation > Medical Devices > Safety Reporting > Field Safety Corrective Action.

The left sidebar menu is titled "HEALTH PRODUCTS REGULATION" and includes the following items: Western Medicines, Medical Devices (expanded), Overview, Application & Registration, Regulatory Updates, Medical Devices Advisories, Safety Reporting (expanded), Adverse Event Reporting, Post-market Information Reporting, Field Safety Corrective Action (expanded), Enquiry Contact & Feedback, and Complementary Health Products.

The main content area is titled "Field Safety Corrective Action" and features an image of a stethoscope over a document. The text below the image states: "When medical device products are suspected of being potentially harmful to users, due to nonconformity to quality, safety and performance requirements, they may be subjected to a Field Safety Corrective Action (FSCA). All information related to the FSCA must be reported to HSA. A guidance document on FSCA is available to industry. Click [here](#) to download the guidance. How to Report? Affected devices have been manufactured, imported or supplied in Singapore. Medical device dealers should submit FSCA reports to the Medical Device Branch using the following forms: > **MDRR1 Form:** FSCA Notification/Preliminary Report Form (MS word) > **MDRR2 Form:** FSCA Follow-Up or Final Report Form (MS word). The completed FSCA reporting forms may be submitted by postal mail or fax to:


HSA FSN Webpage

Home > Health Products Regulation > Medical Devices > Safety Reporting > Field Safety Corrective Action

HEALTH PRODUCTS REGULATION

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 - Application & Registration
 - Regulatory Updates
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 - Safety Reporting**
 - Adverse Event Reporting
 - Post-market Information Reporting
 - Field Safety Corrective Action**
 - Enquiry Contact & Feedback
 - Medical Advertisements & Sales Promotion
 - Consumer Information

Field Safety Corrective Action



When medical device products are suspected of being potentially harmful to users, due to nonconformity to quality, safety and performance requirements, they may be subjected to a Field Safety Corrective Action (FSCA). All information related to the FSCA must be reported to HSA.

A guidance document on FSCA is available to industry.
[Click here to download the guidance.](#)

How to Report?

[Affected devices have been manufactured, imported or supplied in Singapore](#)

Medical device dealers should submit FSCA reports to the Medical Device Branch using the following forms:

- ↳ MDRR1 Form: FSCA Notification/Preliminary Report Form (MS word)
- ↳ MDRR2 Form: FSCA Follow-Up or Final Report Form (MS word)

The completed FSCA reporting forms may be submitted by postal mail or fax to:

FSCA Reporting
 Medical Device Branch



List of Product Owner's Field Safety Notices

Please click [here](#) to view the Field Safety Notices submitted for the FSCA reported to HSA.

When to Report?

Notification of a FSCA, including recalls, to HSA should be performed at least 24 hours before the initiation of the FSCA in Singapore.

If requested, a preliminary report containing full information on the FSCA shall be submitted within 24 hours after the commencement of the FSCA.

Within 21 days from the date of the commencement of the FSCA, a final report is to be submitted to the Authority. If the FSCA has not been completed, a follow-up report submission at the 21st day mark shall be required.

List of Product Owner's Field Safety Notices

Please click [here](#) to view the Field Safety Notices submitted for the FSCA reported to HSA.



HSA FSN Webpage

WITHTIN HSA

Health Products Regulation

Home > Health Products Regulation > Medical Devices > Product Owner's Field Safety Notices

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Product Owner's Field Safety Notices

Field Safety Corrective Actions (FSCA) include removals of medical devices from the market or any other corrective action on devices in use. In general, the product owner (otherwise known as legal manufacturer) implements FSCAs by sending a Field Safety Notice (FSN) to inform operators and users about risks of medical devices. It includes advice on what action should be taken to protect the health or the safety of patients, users or other persons. For example, FSNs may contain information from the product owner that they are voluntarily recalling specific lots of a medical device.

Please note that FSNs are issued by the product owner, registrant or importer of medical devices pursuant to the requirements under the Health Products Act (Cap. 122D). These persons take full responsibility for all information contained in the FSN.

If you receive a FSN from a product owner, registrant or importer, you must always act on it. The Health Sciences Authority makes FSNs publicly available for information only.

If you have a specific question on a FSN, please contact the product owner, registrant or importer (as the case may be).

TITLE
August 2015
July 2015
June 2015
May 2015
April 2015
March 2015
February 2015
January 2015

Items per page:
8 items in 1 page



HSA FSN Webpage

Home > Health Products Regulation > Medical Devices > Product Owner's Field Safety Notices > 2015 > [February 2015](#)

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February 2015

Field Safety Corrective Actions (FSCA) include removals of medical devices from the market or any other corrective action on devices in use. In general, the product owner (otherwise known as legal manufacturer) implements FSCAs by sending a Field Safety Notice (FSN) to inform operators and users about risks of medical devices. It includes advice on what action should be taken to protect the health or the safety of patients, users or other persons. For example, FSNs may contain information from the product owner that they are voluntarily recalling specific lots of a medical device.

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If you have a specific question on a FSN, please contact the product owner, registrant or importer (as the case may be).

DATE OF NOTIFICATION	TITLE	FSN
01 Feb 2015	Product XYZ 1, ABC Inc (HSA 600:41/01-00/15/00_01) Local contact: ABC (S) Pte Ltd	 HSA 600:41/01-00/15/00_01 FSN
01 Feb 2015	Product XYZ 2, CBA Inc (HSA 600:41/01-00/15/00_02) Local contact: CBA (S) Pte Ltd	 HSA 600:41/01-00/15/00_02 FSN
01 Feb 2015	Product XYZ 3, BAC Inc (HSA 600:41/01-00/15/00_03) Local contact: BAC (S) Pte Ltd	 HSA 600:41/01-00/15/00_03 FSN
03 Feb 2015	Product XYZ 4, CAB Inc (HSA 600:41/01-00/15/00_04) Local contact: CAB (S) Pte Ltd	 HSA 600:41/01-00/15/00_04 FSN
04 Feb 2015	Product XYZ 5, ACB Inc (HSA 600:41/01-00/15/00_05) Local contact: ACB (S) Pte Ltd	 HSA 600:41/01-00/15/00_05 FSN

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Please note that FSNs are issued by the product owner, registrant or importer of medical devices pursuant to the requirements under the Health Products Act (Cap. 122D). These persons take full responsibility for all information contained in the FSN.

If you receive a FSN from a product owner, registrant or importer, you must always act on it. The Health Sciences Authority makes FSNs publicly available for information only.

If you have a specific question on a FSN, please contact the product owner, registrant or importer (as the case may be).

2015

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HSA FSN Webpage

Home > Health Products Regulation > Medical Devices > Product Owner's Field Safety Notices > 2015 > [August 2015](#)

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August 2015






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If you receive a FSN from a product owner, registrant or importer, you must always act on it. The Health Sciences Authority makes FSNs publicly available for information only.

If you have a specific question on a FSN, please contact* the product owner, registrant or importer (as the case may be).

*Any contact information provided for each FSCA is correct as at the date of the FSCA notification to the Health Sciences Authority.

DATE OF NOTIFICATION	TITLE	FSN
11 Aug 2015	Product XYZ 6, ABC Inc (HSA 600:41/01-00/15/00_06) Local contact: ABC (S) Pte Ltd Contact no./ Email: 6123 4567	 HSA 600:41/01-00/15/00_06 FSN
11 Aug 2015	Product XYZ 7, CBA Inc (HSA 600:41/01-00/15/00_07) Local contact: CBA (S) Pte Ltd Contact no./ Email: 1234@CBA.sg	 HSA 600:41/01-00/15/00_07 FSN
12 Aug 2015	Product XYZ 8, BAC Inc (HSA 600:41/01-00/15/00_08) Local contact: BAC (S) Pte Ltd Contact no./ Email: 6234 5678	 HSA 600:41/01-00/15/00_08 FSN
13 Aug 2015	Product XYZ 9, CAB Inc (HSA 600:41/01-00/15/00_09) Local contact: CAB (S) Pte Ltd Contact no./ Email: 6345 6789	 HSA 600:41/01-00/15/00_09 FSN
14 Aug 2015	Product XYZ 10, ACB Inc (HSA 600:41/01-00/15/00_10) Local contact: ACB (S) Pte Ltd Contact no./ Email: 5678@ACB.sg	 HSA 600:41/01-00/15/00_10 FSN



For any enquiries, please contact:

Email: HSA_MD_Info@hsa.gov.sg

Tel: 6866 3560

Thank you.