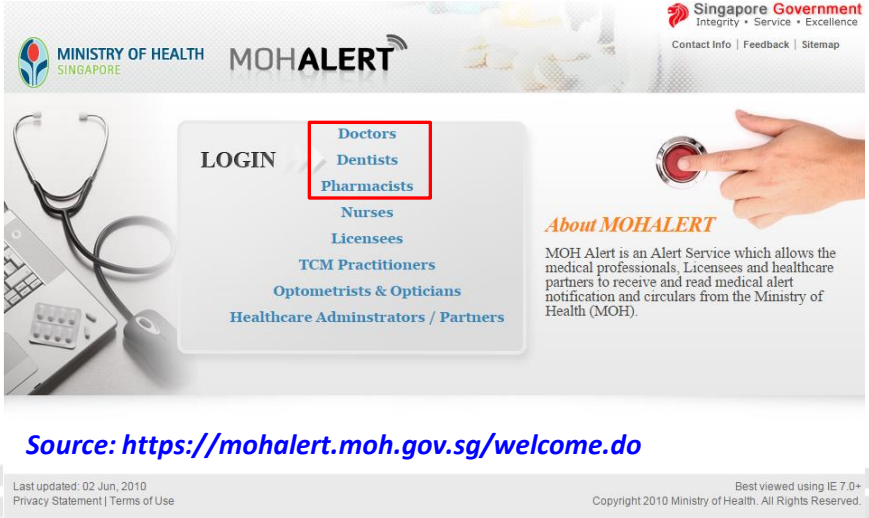
Publication of Field Safety Notices (FSN) on HSA website

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

Publication of FSN on HSA website (for information)

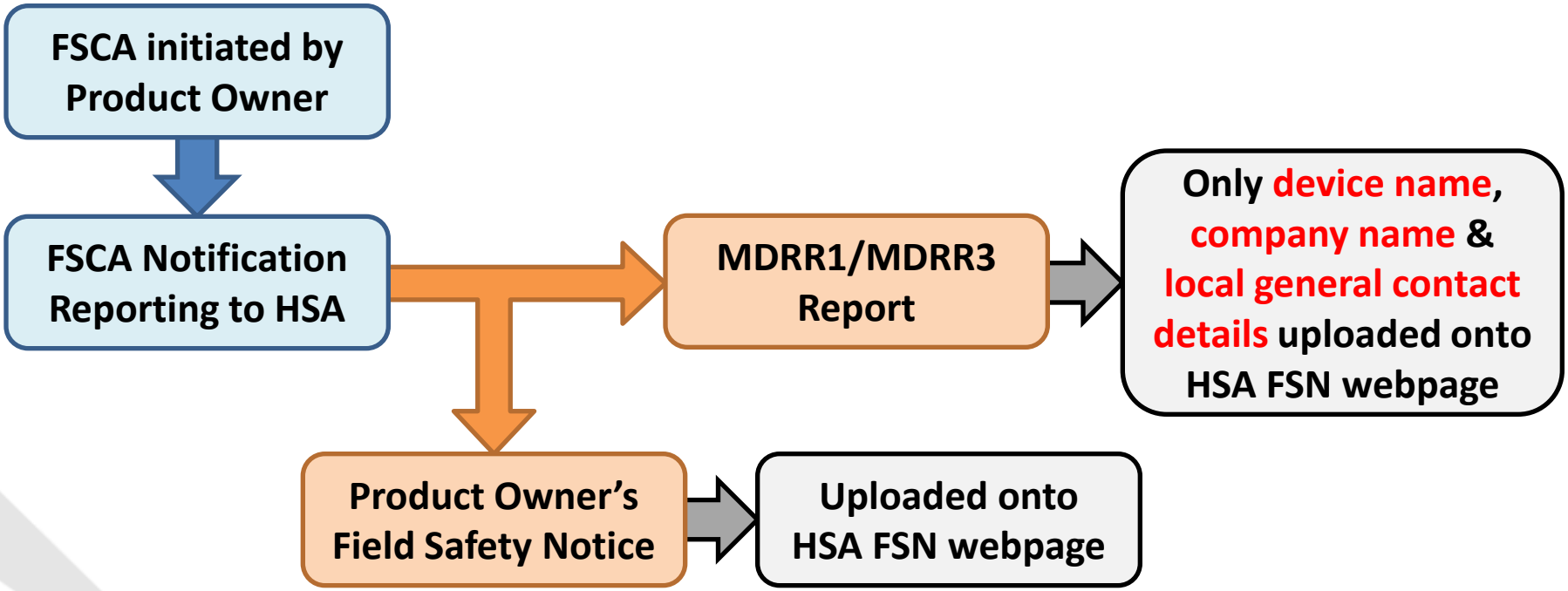
Feedbacks were received from various departments in the healthcare facilities to have the safety information more readily accessible to them.

FSNs for FSCAs notified[1] 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].

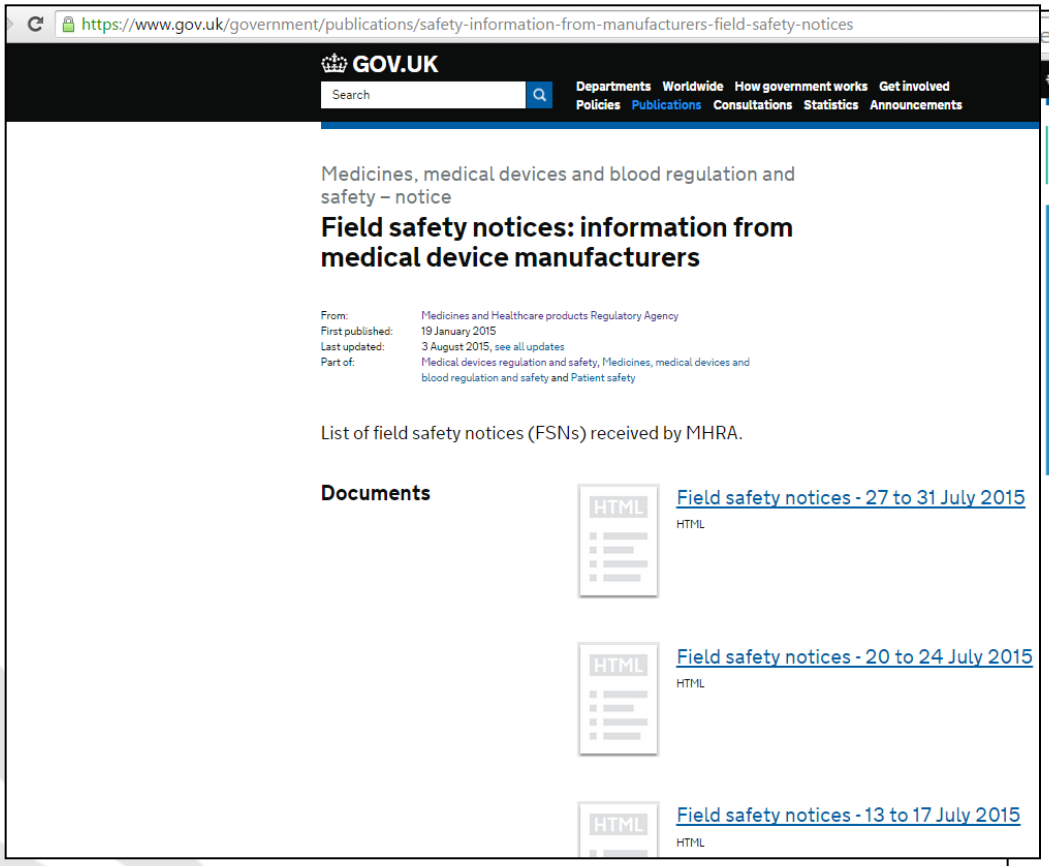
1 Notified either through MDRR1 and MDRR3 Reports
2 UK MHRA – Medicines and Healthcare Products Regulatory Agency
3 Germany BfArM – Bundesinstitut für Arzneimittel und Medizinprodukte

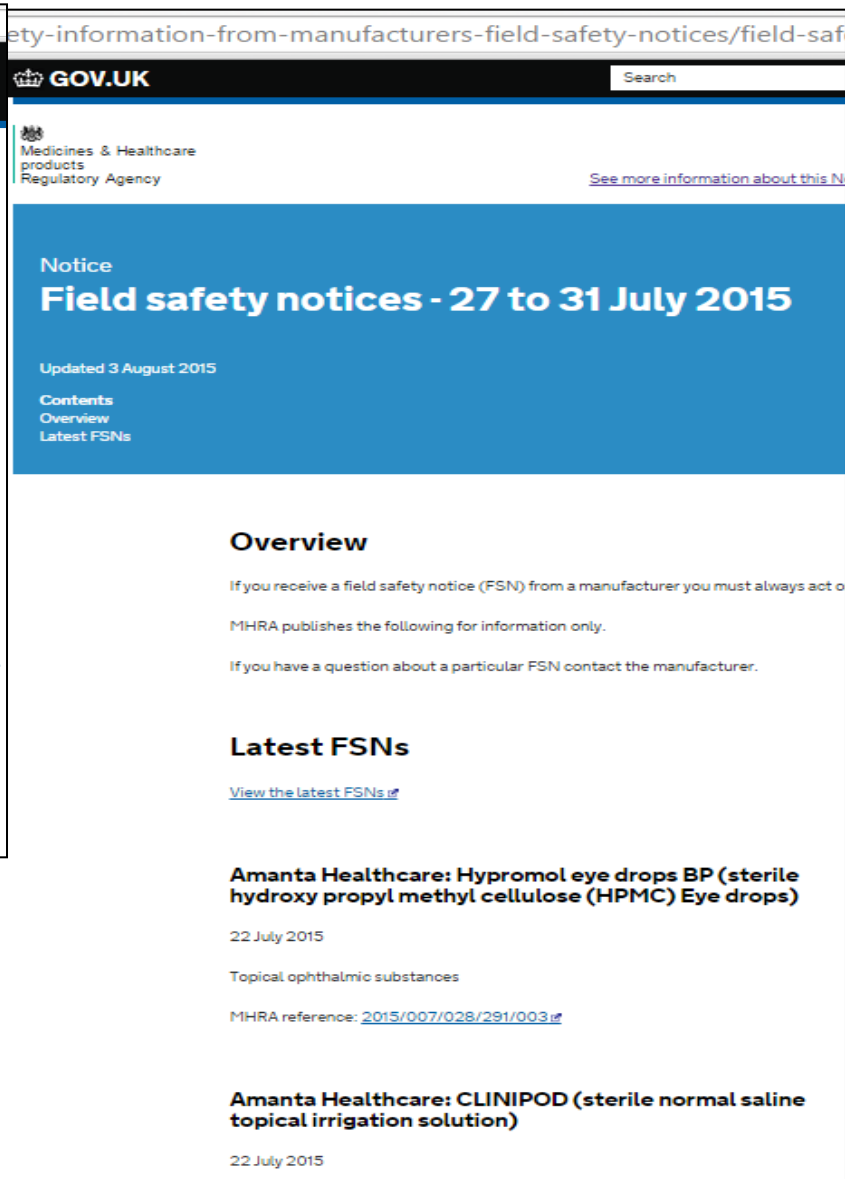
Publication of FSN on HSA website (for information)



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

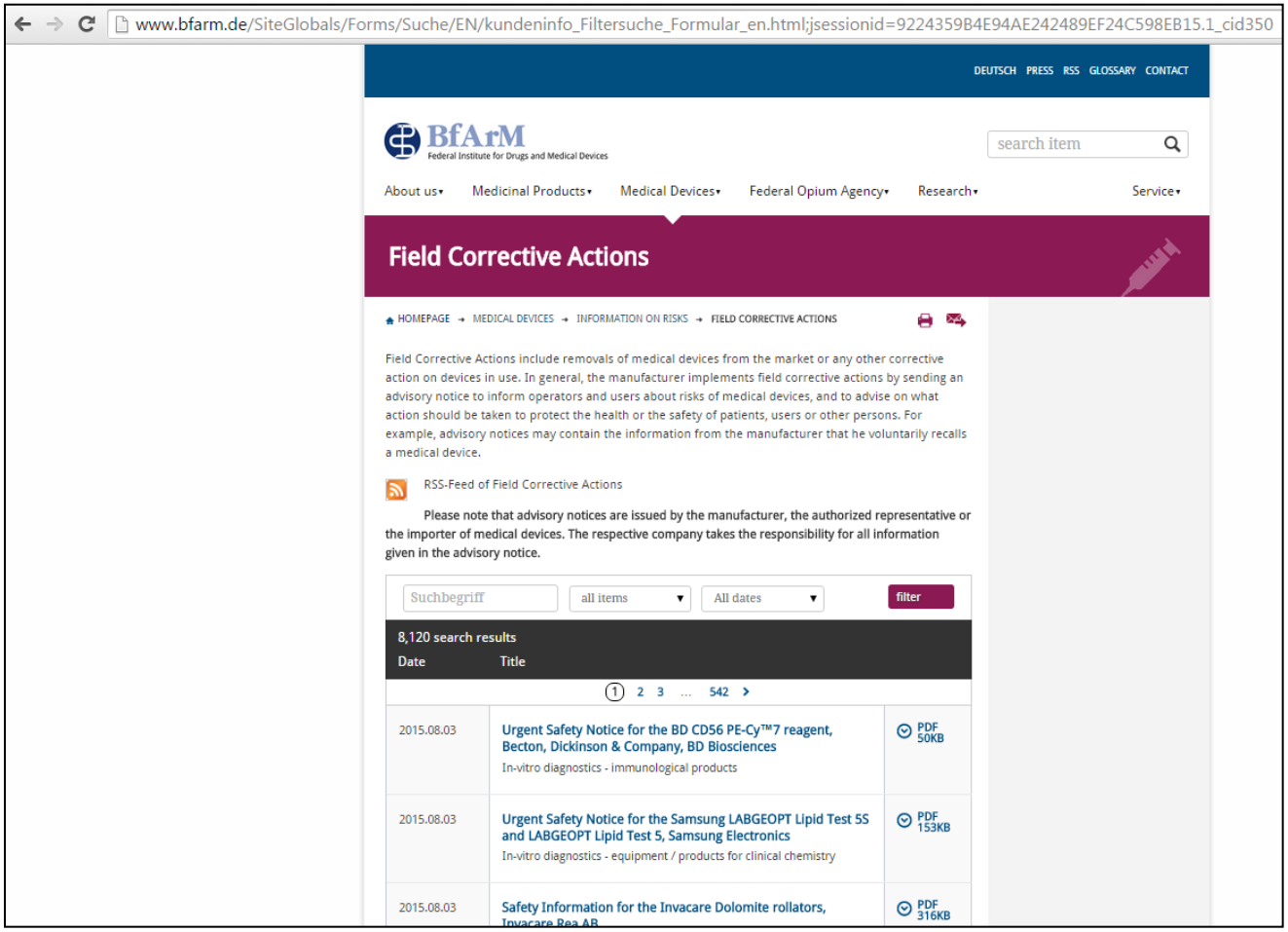
Publication of FSN on MHRA website





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

Publication of FSN on BfArM website



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

HSA FSN Webpage

HSA homepage

HSA FSN Webpage

HSA homepage

HPRG webpage

HSA FSN Webpage

HSA homepage

HPRG webpage

Medical Devices

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

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  - Transition List
  - TradeNet® Controls
  - Regulatory Guidances
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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

HSA FSN Webpage

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Medical Devices

Safety Reporting

FSCA

www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Medical_Devices/Safety_reporting/Field_Safety_Corrective_Action.html

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    - Post-market Information Reporting
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- Complementary Health Products

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:

HSA FSN Webpage

HSA homepage

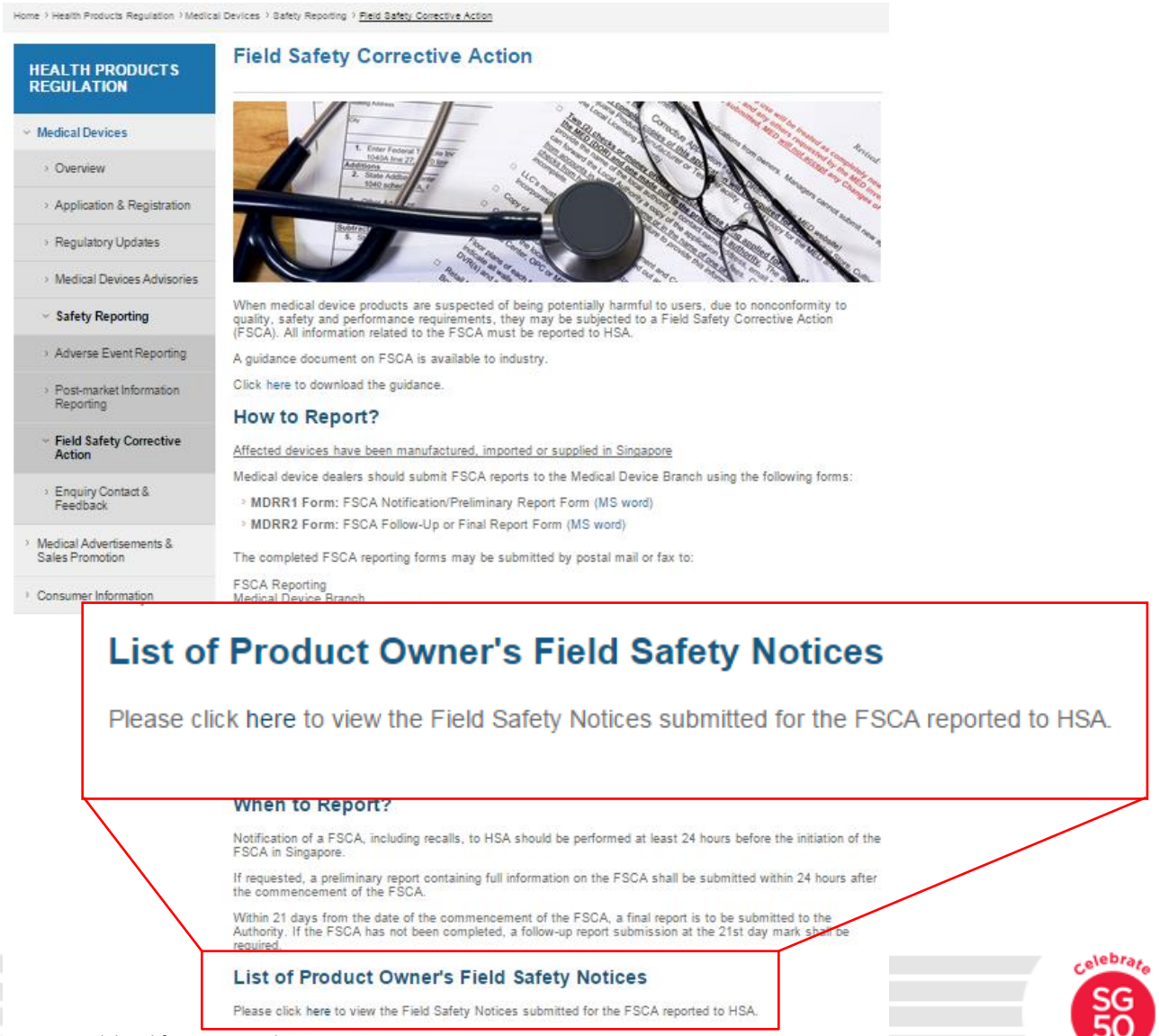
HPRG webpage

Medical Devices

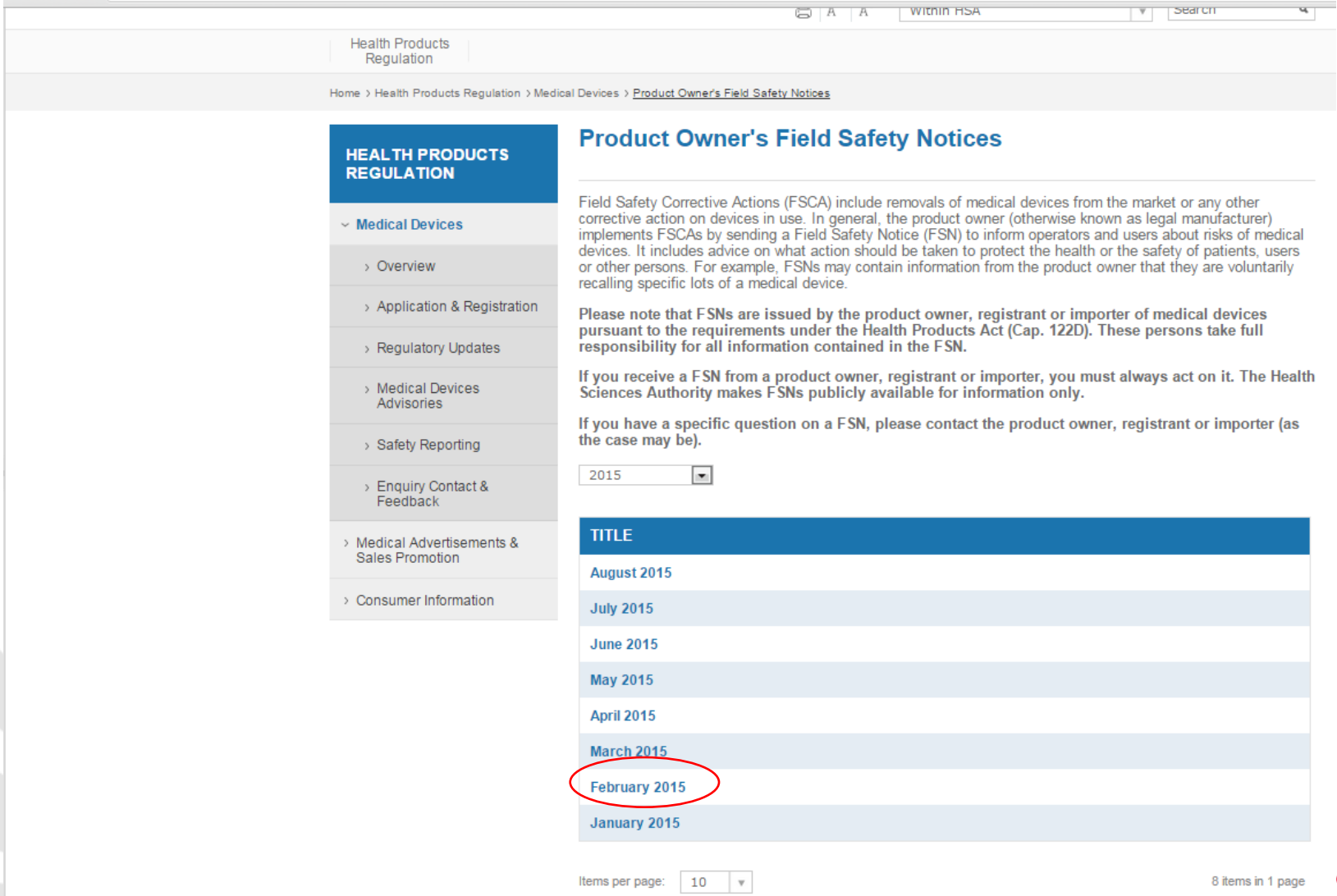
Safety Reporting

FSCA

FSN webpage



HSA FSN Webpage



Health Products Regulation

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- Consumer Information

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).

2015

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

Items per page: 10

8 items in 1 page

HSA FSN Webpage

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February 2015

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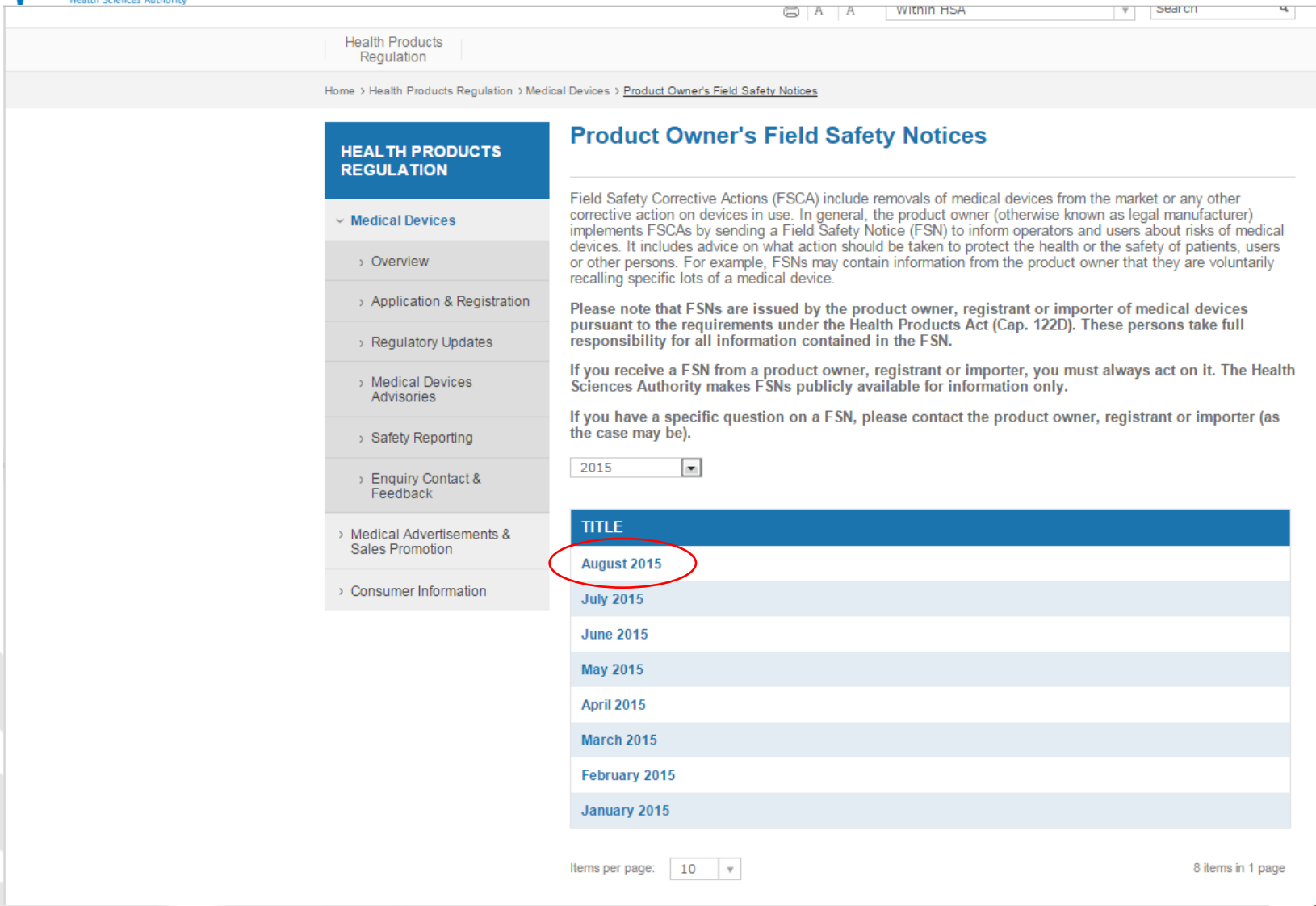
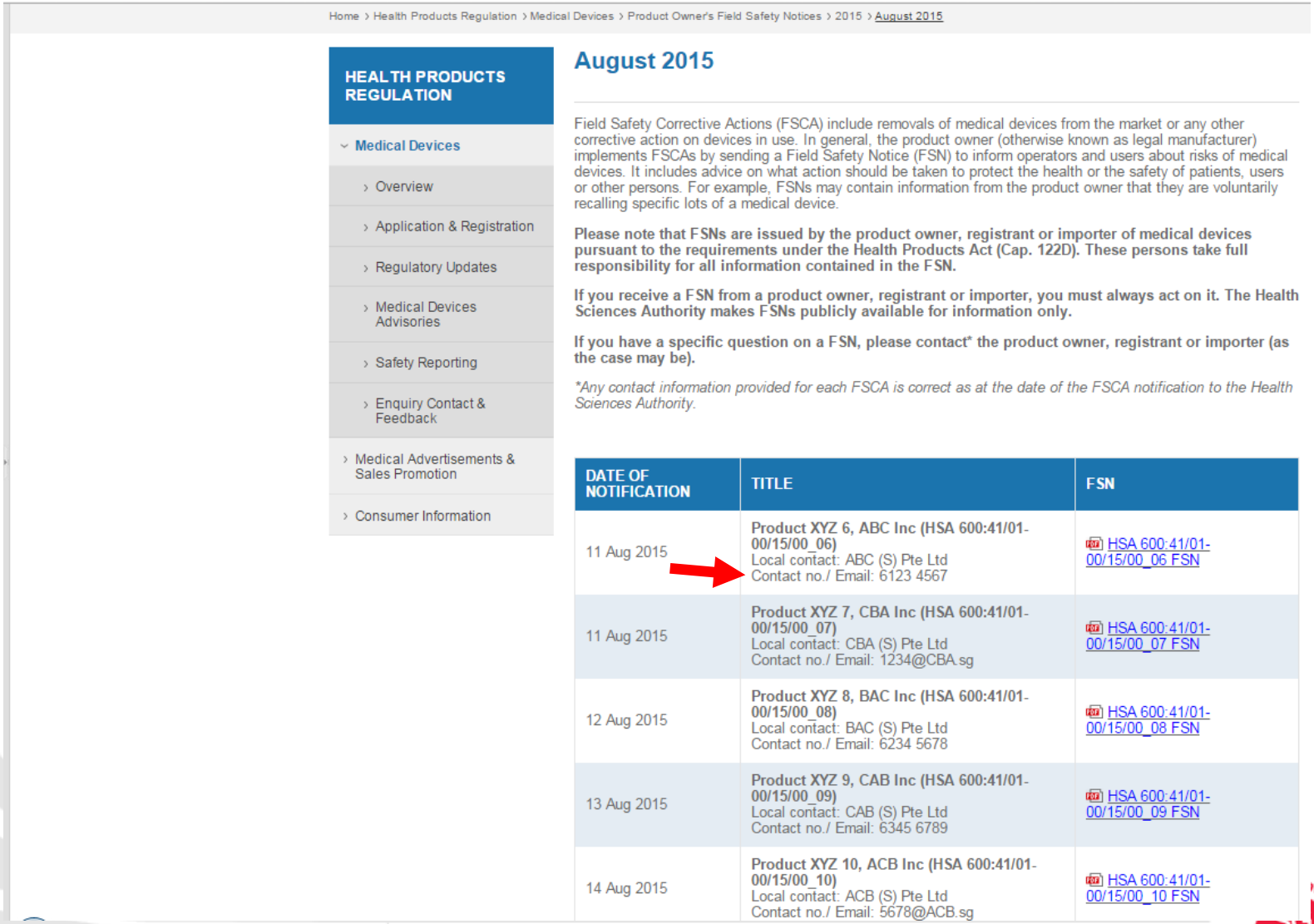
DATE OF NOTIFICATION	TITLE	FSN
01 Feb 2015	**Product XYZ 1, ABC Inc (HSA 600:41/01-00/15/00_01)** Local contact: ABC (S) Pte Ltd	HSA 600:41/01-00/15/00_01 FSN
01 Feb 2015	**Product XYZ 2, CBA Inc (HSA 600:41/01-00/15/00_02)** Local contact: CBA (S) Pte Ltd	HSA 600:41/01-00/15/00_02 FSN
01 Feb 2015	**Product 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

HSA FSN Webpage



HSA FSN Webpage



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August 2015

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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).

**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.