

Launch of the new Field Safety Notices webpage

Publication of medical devices field safety notices to facilitate your access to safety information

HSA's new medical devices (MD) Field Safety Notices (FSN) webpage, an initiative launched in September 2015, was developed with the objective to make MD safety information more readily available to stakeholders in healthcare.

Previously, FSN were uploaded onto the Ministry of Health Alert website which could only be accessed by doctors, dentists and pharmacists using their professional accounts. The initiative allows other stakeholders such as biomedical engineers of healthcare institutions (HCI) to access the information, thereby facilitating timely identification of the affected MD and the resolution of the corrective actions in their facilities. Such checks by HCI would complement

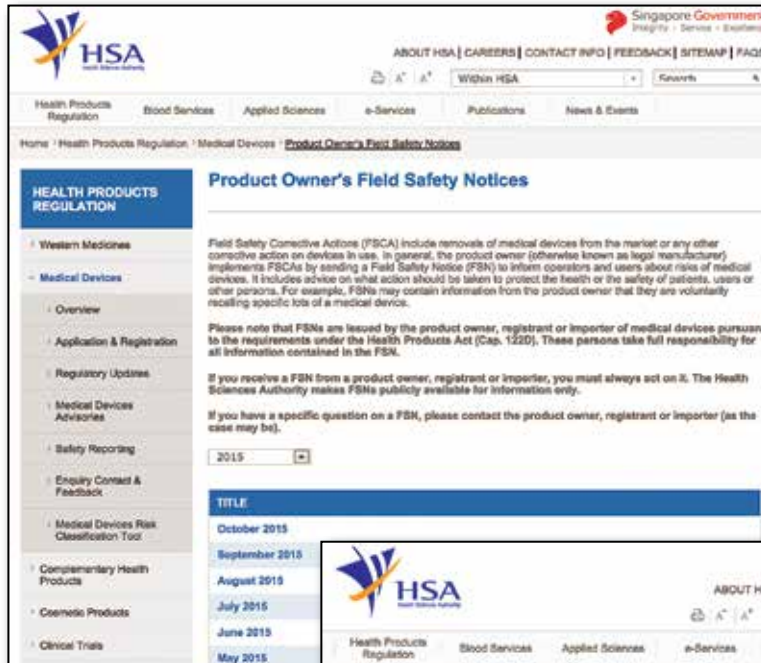
HSA's post-market activities which include the monitoring of the effective conduct of MD field safety corrective actions by the companies.

The new FSN webpage is updated on a monthly basis, and HSA has included the company contact points (i.e., the product owner or the local representative) for each listed FSN. This will facilitate end-users and HCIs in their follow up actions should they need further information or clarification on the matter.

The following pictorials highlight the key features of the FSN webpage. Should you have any comments or feedback on the webpage, please feel free to send them via e-mail to HSA_MD_Info@hsa.gov.sg.

1) New FSN page ▶

The page consolidates a list of FSN sorted according to the date. (http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Medical_Devices/Product_Owners_FSN.html)



▼ 2) Monthly update of the page

Each month, FSN submitted to HSA will be published on the webpage. Users may click on the hyperlinks provided to view a copy of the FSN.



A FSN is a communication to customers and/or users sent out by a medical device product owner or its representative in relation to a safety issue. It is a risk communication tool used by the product owner for risk management.

To access the MD FSN webpage from HSA homepage (www.hsa.gov.sg), please follow the directions:

- A) (1) Go to "Health Products Regulation" webpage
- (2) Select "Medical Devices"
- (3) Locate the "Safety Reporting" tab in the sidebar
- (4) Click on "Field Safety Corrective Action"
- (5) Access the FSN webpage via the hyperlink at the bottom of the webpage
- B) Alternatively, you may search for "Field Safety Notice" to access the FSN webpage directly.

Editor-in-Chief:
A/Prof Chan Cheng Leng

Editorial team:
Chin Ching Siang, Adena Lim,
Peck Li Fung, Wong Woei Jiuang

Please send your enquiries, comments and suggestions to:

Vigilance and Compliance Branch,
Health Products Regulation Group,
Health Sciences Authority
11 Biopolis Way, #11-01, Helios, Singapore 138667
Tel: (65) 6866 3538 Fax: (65) 6478 9069
Website: <http://www.hsa.gov.sg>
Email: HSA_productsafety@hsa.gov.sg

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