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Guidance

Effective field safety notices (FSNs): guidance for manufacturers of medical devices

Advice on writing clear notices and maximising replies to your FSNs.

From:
Medicines and Healthcare products Regulatory Agency (/government/organisations/medicines-and-healthcare-products-regulatory-agency)

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The medical devices regulations state that manufacturers must tell users about corrective actions involving their device as soon as possible using a Field Safety

Notice (FSN).

There are existing guidelines for writing and distributing FSNs in the MEDDEV 2.12/1 rev.8 section 5.4.4.2 (https://ec.europa.eu/docsroom/documents/32305/attachments/1/translations).

In this guidance for manufacturers, we provide supplementary information to the MEDDEV and give advice on how to produce and distribute effective FSNs.

Good traceability

You should keep records to help trace your distributed product. This should include:

- records of medical devices by manufacturing date and batch or serial number
- unique device identifiers (UDI)
- keeping traceability of medical devices directly supplied to users and distributors

Contracts with distributors should include keeping onward traceability records to end users as far as is practicable. If distributors are not willing to share customer lists with you, your contract should require them to do so directly with the MHRA on request.

When supplying to NHS organisations, recording the name of the NHS trust is important. This will help you to get maximum replies to your FSNs.

FSN content

Write the FSN in a clear style and at an appropriate level for the intended audience. Remember that in some cases patients will read the notice so it's best to avoid jargon or unnecessary technical language.

The risk to the user is the key element of the notice. Make it clear what the problem is and what the recipient must do.

Don't delay sending an FSN because you're waiting to include information on the cause of the problem. In such circumstances, there is the option to send a follow-up FSN.

We consider it best practice to include unique device identifiers (UDIs) in your field safety corrective action (FSCA) communications.

We have worked with GS1 (https://www.gs1uk.org/) and HIBCC (https://www.hibcc.org/) to produce the following templates for the incorporation of detailed device information in field safety notices (FSNs) and we encourage you to use these.

If you use GS1 UDIs this is the spreadsheet (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/885597/GS1_UDI_Device_and_Header_Spreadsheet_.xlsm) you need. This document (https://www.gs1uk.org/sites/default/files/061119_Field_Safety_Corrective_Actions_document.pdf) provides background information and details on how to fill in the spreadsheet.

If you use HIBCC UDIs, this is the spreadsheet (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/885598/HIBCC_UDI_Device_and_Header_Spreadsheet.xlsx) you need.

Section 5.4.4.2 of the MEDDEV describes the content of the FSN and there is also a template (https://ec.europa.eu/docsroom/documents/32521) that you can use to write your FSNs.

First read the FSN template Q&A (https://ec.europa.eu/docsroom/documents/31933)

There are also FSN customer reply (https://ec.europa.eu/docsroom/documents/32516) and FSN distributor/importer reply (https://ec.europa.eu/docsroom/documents/32517) templates.

Manufacturers have the option of sending their draft FSN to us for comment (except for urgent FSNs).

These are some of the common problems we've found in draft and in published FSNs:

- missing lot numbers
- too much jargon
- badly explained or missing instructions on what to do next
- missing detailed description of the problem
- missing explanation of how the problem affects the patient
- incorrect or missing contact details for the UK
- missing acknowledgment form
- final FSN hasn't been signed or dated
- poor translations – we suggest asking your UK Responsible Person/Northern Ireland Authorised Representative or importer/distributor in the UK to check the English

What we're looking for in your final version FSN:

- the correct contact details for the UK
- only generic information about the recipients - do not use a sample with an individual's name or address on it
- include covering letters in the FSN

- send it to us as a single PDF file with all the relevant information rather than separate files with versions of FSNs (such as one aimed at distributors and another at customers)
- the PDF must not be a scanned version of a paper document because it can't be searched for serial numbers etc.
- the UDIs of the affected devices, preferably on the UDI Device and Header Excel spreadsheet
- if possible, include NHS Supply Chain codes to help your customers decide if they have your product in stock
- if the FSCA covers all lots, state this as well as listing all the numbers.

We publish weekly lists of FSNs that affect the UK on our web pages (https://www.gov.uk/drug-device-alerts). Although these are for information only, they are extremely popular – there are over 10,000 subscribers to these pages.

Effective targeting of FSNs and maximising response rates

Issue the FSN, with the crucial acknowledgement instructions, as soon as possible after the final version has been agreed.

The MHRA doesn't stipulate the method of distributing FSNs. The key element in maximising response rates is to make sure the right people know that the FSN is urgent and needs a response.

A 'read receipt' of an email is not acceptable proof of acknowledgement of an FSN because it doesn't prove that the FSN has been read and acted on. Some companies are now using an e-signature portal as confirmation that FSNs have been received, and acted on, by the organisation and we would encourage this route of distributing FSNs.

Registered post only proves that the FSN arrived at its destination, not that it has been read and acted on by the intended recipient.

One tactic to help you get replies to FSNs is to use the network of Medical Device Safety Officers (MDSO) in healthcare establishments throughout England. The way to access the list of contacts is through an account with our manufacturer's online reporting environment (MORE) (https://aic.mhra.gov.uk/). With a MORE account, you can submit and manage your reports online, or just use the MDSO email lists to send FSNs. The list is updated monthly and includes the contact details for Scottish equipment co-ordinators.

MDSOs have to be registered with the MHRA and part of their role is to act as an additional senior point of contact for manufacturers and support local actions on FSNs. Although not all healthcare organisations have an MDSO, over 95% of NHS trusts do, so it is a great advantage to include MDSOs when sending FSNs to your customers.

The MHRA has a flyer (https://www.gov.uk/government/publications/field-safety-notice-fsn-what-it-is-and-why-its-important) that explains FSNs and why they are important, which manufacturers can send to their customers to help achieve target reconciliation on responses.

The manufacturer's FSCA strategy

The FSCA strategy will need to specify whether a general, public warning (advertisement, a helpline number for 24-hour access to further information or media release) is needed and whether more specialised news media are to be used. The latter can allow targeting of specific segments of the population to prevent unnecessary public anxiety and advise that consultation between patients and their healthcare professional is essential.

Whichever method is used, manufacturers should inform the MHRA first and send us a draft copy for comment. There is advice on advertising and using the media in the PROSAFE Corrective Action Guide (http://prosafe.org/index.php/library/knowledgebase/item/corrective-action-guide).

Confidentiality of FSNs

MHRA keeps information from manufacturers on proposed field safety corrective actions (FSCAs), including draft copies of FSN, confidential as required by the Medical Devices Regulations (SI 2002 No 618, as amended) (UK MDR 2002). Once a manufacturer has issued an FSN to customers, it is no longer treated as confidential because it is considered to be in the public domain.

MHRA has agreements in place with other international regulatory authorities, where we circulate notifications about FSCAs (in confidence) to promote co-ordinated actions between international regulatory authorities.

What the MHRA does when there is an FSCA

Where there is doubt, the MHRA will provide its interpretation of whether the action proposed by the manufacturer falls within the definition of an FSCA and will give advice on FSNs and associated FSCA strategies.

As soon as possible after we receive sufficient information from the manufacturer, the details of every FSCA are reviewed. The MHRA expects manufacturers to reply quickly to queries about FSCAs. Delayed replies increase the likelihood of the MHRA publishing separate advice to the health service in the interests of protecting public health. It may also lead to the MHRA initiating legal compliance action.

Circumstances where the MHRA might have to issue separate advice include the need to:

- supplement information provided by the manufacturer e.g. when the message of the FSN is not clear or where additional advice is needed
- bring the FSCA to the attention of a wider user base than that contacted directly by the manufacturer, e.g. to target different or additional professionals
- notify chief executives of NHS trusts or other management personnel, for reasons of clinical governance, of information being issued directly to healthcare professionals
- issue an MHRA statement where a safety issue has sufficiently high profile that the health service would expect it
- help ensure the message gets to everyone affected when a very large number of customers and centres are affected, and/or where there is a possibility that devices may have been moved between healthcare providers/centres without the knowledge of the manufacturer or distributor
- give different advice to that provided by the manufacturer, although through negotiation we try to avoid this wherever possible

The manufacturer, or their authorised representative, will almost always get the opportunity to comment on the draft of any safety-related notice that the MHRA produces.

For FSCAs with public, media or a particular health interest, the MHRA will liaise with colleagues in the Department of Health and Social Care and with the manufacturer to prepare information for general release. Media statements should be worded to minimise any public alarm. Where necessary, UK health ministers will be kept informed.

The MHRA will agree appropriate milestones with the manufacturer or authorised representative for receiving FSCA status reports, including a final report.
We examine all the reports from the manufacturer and keep an ongoing assessment of the effectiveness of the FSCA action. This may include further referral to the weekly management meeting.

Where an FSCA is initiated following a report of an incident submitted to the MHRA, we will communicate the outcome of the investigation to the person who sent us the report. In the interests of worldwide patient and user safety, we may also provide copies of MHRA safety warnings issued to the health service in the UK to other regulatory authorities.

MHRA’s FSN review and monitoring process

1. FSCA/FSN input and assigned to specialist
2. Specialist conducts initial review of safety message and required actions
3. Specialist may ask for more information from manufacturer or seek clinical opinion
4. Management group meeting selectively reviews FSN

5. Specialist may ask for more information from manufacturer or seek clinical opinion
6. Information on reconciliation and long-term Corrective Action Preventive Action (CAPA) received from manufacturer
7. Specialist completes risk assessment including recommendations for MHRA actions relating to the FSCA
8. Assessment is reviewed by the senior management
9. Specialist fulfils the actions agreed e.g. continue to monitor, publish safety communications etc.

About field corrective actions

Although they are outside the scope of the notification requirements of the UK MDR 2002, the MHRA encourages manufacturers to deal with field corrective actions in a similar way to FSCAs.

A field corrective action may arise from a more minor device-related safety issue that does not pose a risk of death or serious injury.

Examples of field actions considered to be FSCAs

Example 1: Class IIa medical device (Heaf test)

Following reports that a device seemed to give an abnormally high level of ‘false negative results’, the manufacturer identified that, although it was performing to specification and requirements, the firing mechanism could be interrupted if it was not handled in a specific way. The instructions for use supplied with the device did not clearly identify this handling requirement. The manufacturer changed the instructions so that the handling of the unit was clearly highlighted in both text and diagram form. The manufacturer felt this was necessary due to the potential problem of misfired units giving rise to false negatives, which in turn could result in inappropriate tuberculosis immunisation. Therefore, the manufacturer not only amended the instructions for units still under manufacture, but also identified all units with users to ensure their instructions were similarly updated.

Example 2: Syringe pump alarm failure

A manufacturer of a syringe pump identified a small risk that pumps within a range of serial numbers may not alarm if the syringe plunger clamp was left open, putting patients at risk from over- or under-infusion. The manufacturer issued instructions on detecting and correcting the problem. Instructions on checking the ‘Clamp Open’ detection mechanism during routine maintenance were also added to the service manual.

Example 3: Active implantable medical device

A manufacturer identified that due to a battery defect the rate of battery depletion towards the end of service life of one of their pacemaker models was more rapid than originally anticipated through accelerated testing. There were no un-implanted units remaining with distributors or in hospital supplies available for return to the manufacturer. The manufacturer issued written advice to clinicians following patients implanted with these pacemakers, emphasising the need to schedule clinic visits more frequently than indicated within the physicians' manual supplied with the product to check the pacemaker battery status. Failure to detect early signs of battery depletion would risk the patient losing pacing therapy.

Example 4: An in vitro diagnostic medical device

A test for detecting bacterial antigen in cerebrospinal fluid is found to cross-react with another bacterium which causes meningitis. This could result in the wrong antibiotics being administered. A full FSCA is initiated.

Example 5: A device used in the community

Following reports of users falling from powered wheelchairs due to failures of castor assemblies it was found that the instructions for use did not include adequate user checks and regular maintenance requirements to ensure that the castors could continue to operate correctly. The manufacturer revised the instructions for use and incorporated new requirements for user functional checks and regular maintenance.

Examples of field actions NOT considered to be FSCAs

Example 1: General medical device

A manufacturer places an incorrect expiry date of 18 months on the labelling of a batch of product. The supported shelf life is 2 years. The manufacturer chooses to send new labels with the correct expiry date to customers.

Example 2: Out-of-box failure

A product is shipped with a reagent missing. Users cannot run the test without it. The manufacturer exchanges distributed product for complete test kits.

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