الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

MDS-G22

Guidance on Medical Device Field Safety Corrective Actions

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Introduction

Purpose

The purpose of this guidance is to explain the requirements and procedures of handling medical device field safety corrective actions (FSCA).

Scope

This guidance applies to manufacturers, authorized representatives (ARs) and Importers (for medical devices registered through low risk registration system).

Background

In accordance with the "Medical Devices Interim Regulation" issued by the Board of Directors of the Food and Drug Authority (1-8-1429) dated 29/12/1429 H and amended by the SFDA executive board decision (4-16-1439 H) dated 9/4/1439 H SFDA/MDS evaluates and follow up the Field Safety Notices submitted in NCMDR or published globally and takes the appropriate actions to safeguard public health; and ensure the field safety corrective actions has been conducted according to the requirements specified in this guidance document.

Stages of Field Safety Corrective Actions (FSCA)

Stage One: Reporting FSCA to SFDA or Receiving an Inquiry from the SFDA

This stage means to report the FSCA when the KSA is affected (imported and/or placed on the market and/or put into service in KSA)

1. **How to report or respond:**

   A. Manufacturer through its Authorized Representative (AR) or importer shall report to the SFDA any FSCA when the KSA is affected by filling the) Add New Device FSN) form via NCMDR website.

   B. In case of receiving inquiries from the SFDA about a medical device FSCA, respond to the SFDA inquires through ncmdr.md@sfda.gov.sa and fill the (Add New Device FSN) form via NCMDR website when the KSA is affected by this FSN.

   C. Authorized Representative and Importer shall have a tracking system to record the data and information of all imported and distributed medical devices within KSA.

2. **Required information** for reporting:

   All mandatory information on the website shall be filled, in addition to attaching the FSN letter issued by the manufacturer, see Annex (B) for the FSN content.

3. **Reporting and response period**:

   A. Reporting: SFDA shall be informed within (2) working days from FSCA issuance date by manufacturer.

   B. Response: corrective action plan shall be provided according to the permitted period mentioned in stage three: Corrective Action plan (Point 1).

Note: In case the KSA market is not affected by the FSCA (none of the affected medical devices were imported and/or placed on the market and/or put into service in KSA) please move to Stage Five: Closure (point 2)

Stage Two: Notifying the Affected Users

This stage means to notify the affected users of FSN letter according to permitted period as a first step to do of the FSCA. By notifying the affected customer, that means they will be aware of the reason for the problem, its impact, instructions required to be taken, and any other required procedure to solve this problem.

1. Procedure of notifying affected users:
   The affected users shall be notified by the FSN letter and to take proof of the notification. Notifying the affected users can be made by multiple channels including:
   A. Send an E-mail
   B. Send a fax
   C. Visit the affected users
   D. A phone call in case of shortness of time, but still, the AR shall deliver the FSN letter and explain its content
   E. Send registered mail
   F. Any other appropriate method

2. Permitted Period: Affected users shall be notified directly from the issuance date of the FSCA but no more than (5) working days. While the "acknowledgments letters" could be provided later

3. Notification data:

   FSN letter issued by the manufacturer

4. How to prove the notification:

   User signature on the acknowledgment letter found in the FSN confirms the receiving; in addition to that, the contact information should be provided. If the acknowledgment letter wasn't included in the FSN letter, then, FSN letter only can be signed.

   - For acknowledgment letter content, see Annex (C).

Note: Uncooperative users shall be contacted at least (3) times and in two different methods. And if no response, SFDA shall be informed.

5. Communication Records:
   AR, manufacturer and importer shall keep records of communication made with their users. This will prove that all possible means to deliver the FSN has been made.
   These records may contain the following: (date of communication, person's name, mean of communication, contact information if the communication has been done, has the action been taken and understood by the user, a signed copy of the acknowledgment or FSN letter, any documents or other relevant details).

Stage Three: Corrective Action Plan

This stage means the plan that AR will follow along with the time frame to close FSCA.

1. Permitted period for providing the corrective action plan is (5) working days and it starts from the date of informing SFDA or the date of receiving an email from SFDA.

2. The corrective action plan shall include the following:
    A. The expected date for completing the procedure with providing justification for the long requested period. SFDA could request justifications for prolonged deadlines, and in case the procedure is in stages, the time frame for each stage shall be mentioned.
    B. List of related healthcare providers/concerned customers.
    C. The category affected by the FSCA (e.g. public, healthcare providers)
    D. Details of the numbers of medical devices affected by the FSCA in the KSA.
    E. A description of the procedures to be performed, in addition to notifying the users (e.g. withdrawal, destruction, replacement, software update, updating instructions for use)
    F. FSCA risk assessment form - Annex (D)

Note: In case the period of implementing the corrective action mentioned in the plan is long, a periodic report may be requested to follow up on the implementation.

Stage Four: Implementing Corrective Actions

The manufacturer or AR and importer shall implement or follow-up FSCA according to the approved plan.

A proof of any action has been taken shall be recorded and documented, whether it is withdrawing, replacing, destruction, re-exporting or other, see "Required Data in the proof of implementing the FSCA"- Annex (A).

- In case not being able to complete the procedure within the approved date, a request to extend the expected date shall be provided with the reason for the delay and the remaining actions before the end of the specified period.
- If there was an agreement to provide a periodic progress report within a certain period of time, SFDA shall be notified before the agreed date if the report cannot be provided.
- The periodic report shall include the percentage of implementation of the corrective actions that have been completed and the remaining procedures (e.g. number of users who have been notified, number of withdrawn or corrected devices, etc. ...).

Stage Five: Closure

This stage means to provide the necessary statement to close FSCA, which includes the following:

1. In case the KSA market is affected by FSCA, and after confirming implementing the corrective actions for all affected medical devices in the KSA and collecting all implementation proofs, then provide "Confirmation Statement for Completing the Field Safety Corrective Actions (FSCA)"- Annex (F).
2. In case the KSA market is not affected by FSCA (none of the affected medical devices included in the Field Safety Notice (FSN) were imported and/or placed on the market and/or put into service in KSA), then provide "Statement Confirming KSA is Not Affected by FSCA" - Annex (E) during the permitted period which is (5) working days from the date of receiving an email from the SFDA related to medical devices FSCA.

Note:

- The closure is not considered complete until receiving an email from SFDA stating that the FSCA has been closed.
- SFDA has the right to request any document supporting the closure.

Annexes

Annex (A): Required Data in the proof of implementing the FSCA

- Reference number of FSN.
- Model/lot numbers/serial numbers of the affected medical devices.
- Names of healthcare providers whose medical devices have been corrected, with authorized persons' signatures, date, positions, and contact details.
- Detailed description of the action taken as required by FSCA.

Annex (B): Contents of FSN Letter

- The subject in bold (URGENT FIELD SAFETY NOTICE) indicating the name of the affected device
- Reference number of FSN
- Attention to User: (user / healthcare provider information)

- Purpose of FSN:
  1. Purpose of FSCA
  2. If any serious injuries and/or deaths have occurred or could occur as a result of the failure of the device, it shall be mentioned and the probability of its occurrence.

- Affected devices:
  1. Indicating all affected devices
  2. How to identify the affected devices

- Reason of FSCA:
  1. Background on the medical device and how it works.
  2. Description of the problem
  3. Predicted risk to patient/users
  4. Frequency of failures and complaints
  5. Background about Issue

- Risk on Health:
  1. How the device failure or problem will affect patients, health care providers, or other persons who are exposed to the device. If the device failure can cause injuries, delays in surgical procedures, or other delays in treatment or therapy, provide an explanation of why that is so
  2. A method to help the user how to identify devices that failed or may fail with the explanations

- Action to be taken by user
  1. Identify the affected devices
  2. Description of the action required by the user (e.g. isolating the affected devices, returning, following instructions, etc.)
  3. In case there are actions to be taken by the user, the period shall be indicated.
  4. In case the recommendation is to inform the patient of a FSN or advise to review the patients' previous results, this shall be indicated
  5. In case the manufacturer requested the user to be acknowledged by (Acknowledgment letter), the reply period shall be indicated

- The action to be taken by the manufacturer
  1. Description of the action the manufacturer will take (e.g. withdrawing, modifying, providing instructions for use, updating software, etc.)
  2. Determine the required period to implement the action.
  3. In case the patient needs to be notified by FSN, this shall be indicated

- Contact information of AR
  - Name, email, phone, address

Note: For FSN, it is prohibited to alleviating the problem, risks that may occur, or marketing for the device.

Annex (C): Contents of Acknowledgment Letter

- FSCA information:
  1. Reference number
  2. Date of issue
  3. Medical device name
  4. Medical device identifier

- User information:
  1. Name of User/healthcare provider
  2. Address
  3. Name, position, phone, email

- User actions:
  It may include the following:
  1. I have received the FSN and read/understand its content.
  2. I performed all actions mentioned in the FSN.
  3. I performed (disposal/isolation/return/ ....) the mentioned devices (number, date, identifier), or that the devices are not available (out of service or missing) mentioning (number, date, identifier)
  4. Authorized person information: name, date, contact information: phone or mail, signature.

- Information needed to reply the (proof of user acknowledgment) to the company
  1. Email, phone, address, fax.
  2. Required period to respond.

Note: Required fields are marked with (*).

Annex (D): FSCA risk assessment Form

FSCA Risk Assessment Form

FSN Ref:	
Medical Device Name:	

Severity		
Check Applicable	Level	Example
	4 - Critical	Directly results in Death
	3 - Serious	Series injury: permanent impairment
	2 - Moderate	Moderate injury: temporary impairment
	1 - Minor	Minor or no injury

Probability		
Check Applicable	Level	Example
	5 - Always	Occurs Every time
	4 - Frequent	Good chance to occur
	3 - occasional	Expected to occur from time to time
	2 - Remote	Not expected to occur
	1 - Impossible	Inconceivable, Not Possible

Detectability		
Check Applicable	Level	Example
	4 - Impossible	It is impossible to see or detect the fault at all
	3 - Unlikely	It is impossible to see or detect the fault before use
	2 - Likely	Fault is very obvious before use, but the device can be used
	1 - Always	Fault is very obvious before use, and the device cannot be used

Depth of distribution in Saudi Arabia		
Check Applicable	Level	Example
	3 - Public/ Implants	Home-use, Retails, point of sales
	2 - Hospitals/ polyclinics	Healthcare providers (Not sold to the public)
	1 - Warehouse	Distributors, importers (Not distributed yet)

Quantity in Saudi Arabia		
Check Applicable	Level	Example
	3 - Huge	More than 10,000 products
	2 - Many	from 100 to 10,000 products
	1 - Limited	Less than 100 products

Authorized Person Name:	
Signature:	
Date:	

Annex (E): Statement Confirming Saudi Arabia is Not Affected by FSCA

[To be printed on Manufacturer/Authorized Representative Letterhead]
Click here for printable and editable version

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Dear Surveillance and Biometrics Executive Department at Medical Devices Sector/Saudi Food and Drug Authority,

We ..Name of Manufacturer or Authorized Representative... confirm that none of the affected medical devices included in the Field Safety Notice (FSN) below were imported and/or placed on the market and/or put into service in Saudi Arabia, therefore, Saudi Arabia is not affected by this FSN.

السادة/ الإدارة التنفيذية للرقابة والقياسات الحيوية بقطاع الأجهزة والمنتجات الطبية في الهيئة العامة للغذاء والدواء المحترمين
السلام عليكم ورحمة الله وبركاته،،،

نحن ..... اسم المصنّع أو الممثل القانوني..... نؤكد بأنه لم يتم استيراد أي من الأجهزة والمنتجات الطبية المتأثرة والواردة في إنذار السلامة أدناه إلى المملكة العربية السعودية أو طرحها في أسواقها أو استخدامها فيها، لذا نود إفادتكم بأن المملكة لم تتأثر بالإشعار المذكور.

رمز التاكيد/الرقم المرجعي بالمركز الوطني لبلاغات الأجهزة والمنتجات الطبية Confirmation Code/NCMDR Reference Number	اسم الجهاز/المنتج الطبي Medical Device Name

Authorized Person Name:		اسم الشخص المفوض:
Signature:		التوقيع:
Date:		التاريخ:

Annex (F): Confirmation Statement for Completing the Field Safety Corrective Actions (FSCA)

[To be printed on Manufacturer/Authorized Representative Letterhead]
Click here for printable and editable version

Dear Surveillance and Biometrics Executive Department at Medical Devices Sector/ Saudi Food and Drug Authority,

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We ..Name of Manufacturer or Authorized Representative… emphasize to conduct recommended corrective actions in the below Field Safety Notice (FSN) for the affected medical devices. We confirm the fulfillment of all requirements specified in SFDA's guidance document entitled “Guidance on Medical Devices Field Safety Corrective Action (FSCA) (MDS-G22)", and we are committed to provide them immediately upon SFDA request. The SFDA reserves the right to take the appropriate actions when any of the previous is violated. Therefore, we kindly request to close the below FSCA.

السادة/ الإدارة التنفيذية للرقابة والقياسات الحيوية بقطاع الأجهزة والمنتجات الطبية في الهيئة العامة للغذاء والدواء المحترمين
السلام عليكم ورحمة الله وبركاته،

نحن ..... اسم المصنّع أو الممثل القانوني..... نؤكد قيامنا بتنفيذ جميع الإجراءات الموصى بها في إشعار إنذار السلامة للأجهزة والمنتجات الطبية المتأثرة المشار إليه أدناه، كما نؤكد استيفائنا جميع المتطلبات المشار إليها في " الدليل الإرشادي للإجراءات التصحيحية لإنذارات السلامة للأجهزة والمنتجات الطبية (MDS-G22)"، ونلتزم بتقديمها فور طلبكم لها، وللهيئة اتخاذ الإجراءات المناسبة عند مخالفة أي مما سبق.
واستناداً على ما سبق نأمل منكم الإجراء التصحيحي لإنذار السلامة أدناه.

رمز التاكيد/الرقم المرجعي بالمركز الوطني لبلاغات الأجهزة والمنتجات الطبية Confirmation Code/NCMDR Reference Number	اسم الجهاز/المنتج الطبي Medical Device Name

Authorized Person Name:		اسم الشخص المفوض:
Signature:		التوقيع:
Date:		التاريخ:

Annex (G): Definitions & Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
MDS	Medical Devices Sector
Manufacturer	Means any natural or legal person with responsibility for design and manufacture of a medical device with the intention of making it available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person.
Authorized Representative (AR)	Means any natural or legal person established within the KSA who has received a written mandate from the manufacturer to act on his behalf for specified tasks including the obligation to represent the manufacturer in its dealings with the SFDA.
Importer	Means any natural or legal person in the supply chain who is the first to make a medical device, manufactured in another jurisdiction, available in the KSA.
Field Safety Corrective Action (FSCA)	Means an action taken by a manufacturer to reduce or remove a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market.
Field Safety Notice (FSN)	A notification from the SFDA to relevant medical device users in relation to a Field Safety Corrective Action.
Acknowledgment letter	A document proving that the user has viewed the information and the corrective actions mentioned in FSN.
National Center for Medical Device Reporting (NCMDR)	A database management system for all information related to safety and/or performance of medical devices that support SFDA taken the appropriate actions on incidents or FSCA.
User	The person who use the medical device either professional or patient or layperson.