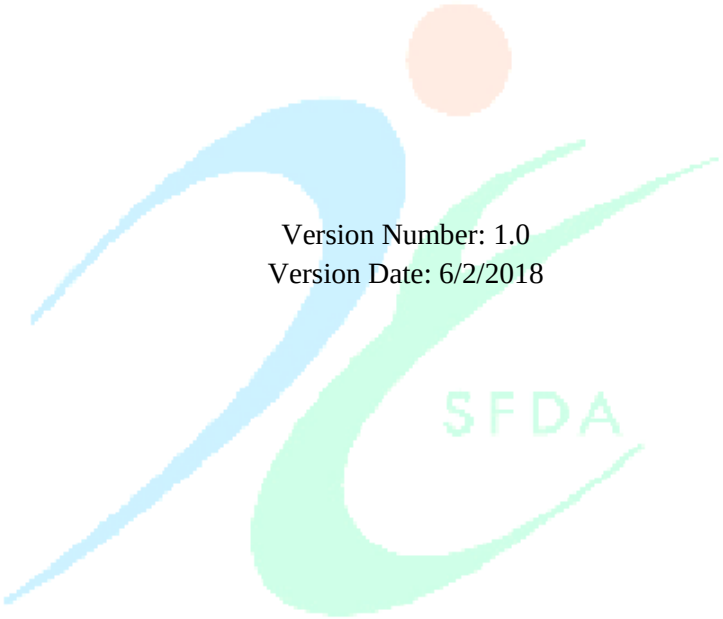
MDS-G22

Guidance on Requirements for Following Up and Closing Medical Devices Field Safety Notices (FSNs)



Version Number: 1.0
Version Date: 6/2/2018

This guidance document has been published after being distributed for public comments dated on 26/11/2017 for 30 days.

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Introduction

Purpose

The purpose of this guidance is to clarify the requirements for following up and closing medical devices field safety notices (FSNs)

Scope

This guidance applies to local manufacturers and authorized representatives (ARs) related to medical devices FSNs.

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, SFDA/MDS reviews adverse events reported to its NCMDR and takes appropriate action to safeguard public health; and issues medical devices FSNs to warn from risks involved in continuing to use the device; and informs about the manufacturer's corrective action plan. SFDA takes the appropriate measures to ensure that the manufacturer or its authorized representative performs and closes the corrective action plan associated with such notices according to the requirements specified in this guidance document.

Requirements

General	1	Local manufacturers (or their ARs) and ARs of overseas manufacturers shall: A. close the FSN by following the procedure specified in section (2) of "Requirements" below, when the FSN is received from SFDA/MDS. B. inform SFDA/MDS within two working days by completing the "Add New Device Recall" form through the NCMDR on the SFDA's website (for information about sources of FSNs, see Annex 4), and close the FSN by following the procedure specified in section (2.B) of "Requirements" below, when the FSN (related to medical devices placed on KSA market and/or put into service) is received from the manufacturers or any another source.
FSNs Closing Procedure	2	A. When KSA market is not affected by the FSN (FSN-related medical devices are NOT placed on KSA market and/or put into service), the documents specified in section (A) of "Required Documents" below shall be submitted to (NCMDR.MD@sfda.gov.sa). B. When KSA market is affected by the FSN (FSN-related medical devices are placed on KSA market and/or put into service), the documents specified in section (B) of "Required Documents" below shall be submitted to (NCMDR.MD@sfda.gov.sa), in addition to: - section (C.7), if the manufacturer's recommended action requires on-site correction for the affected medical devices, - section (C.8), if the manufacturer's recommended action requires local destruction for the affected medical devices, - section (C.9), if the manufacturer's recommended action requires withdrawal for the affected medical devices, or - section (C.10), if the manufacturer's recommended action requires replacing the affected medical devices.
	3	Document specified in section (A.1) or (B.2) of "Required Documents" shall be provided as follows: - (2) working days if the FSN is classified as very high risk. - (5) working days if the FSN is classified as high risk.

		- (10) working days if the FSN is classified as moderate risk. For information about SFDA's classification for FSNs risks, see Annex (3).
	4	The FSN is NOT considered closed until an email is received from SFDA/MDS stating that FSN has been closed.

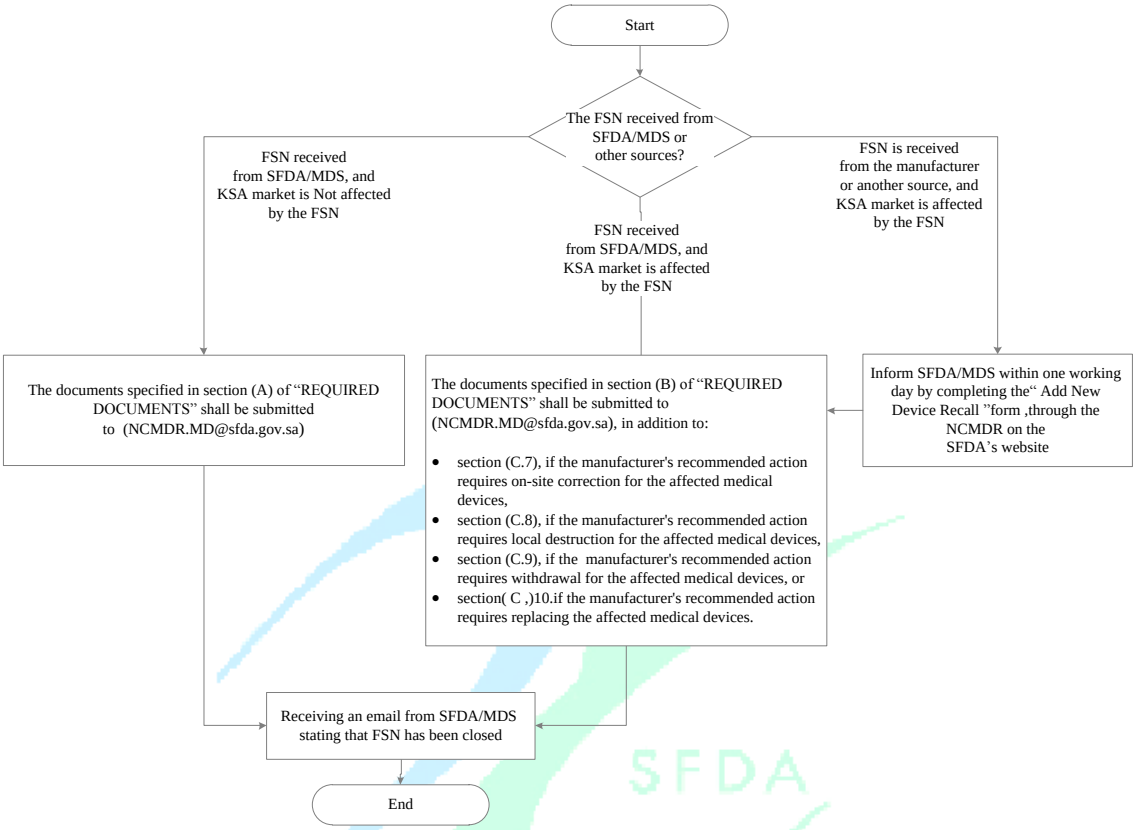
Required Documents

	Required Documents	Sample	Notes
A. Required Documents if KSA Market is Not Affected by the FSN			
1	Statement Confirming Saudi Arabia is Not Affected by FSN	Annex (1)	-
B. Required Documents if KSA Market is Affected by the FSN			
2	Corrective Action Plan (including time frame)	-	• It shall include an expected date of procedure completion. SFDA/MDS may require justifications if the period is considered overstated.
3	Periodic Progress Report about the Corrective Action Plan	-	• This document shall be submitted only upon SFDA/MDS request.
4	Depth of the FSN	-	• It shall include: - list of affected healthcare providers/users - the category affected by FSNs (e.g. the whole society , healthcare providers that have affected medical devcies or a special group of users) - number of medical devices affected by the FSN that are with healthcare providers/users in KSA
5	Proof of Notifying Healthcare Providers/Users Affected by the FSN	-	• It shall include: - manufacturer reference number of the FSN and its issuance date - model/part numbers and lot/serial numbers of the medical devices affected by the FSN - names of healthcare providers who have been notified, with the date of informing and authorized persons' signatures, positions, and contact details

			Note: This document shall be submitted only upon SFDA/MDS request
6	Confirmation Statement for Completing the Corrective Actions Required in the FSN	Annex (2)	-
C. Required Documents for Special Procedures (Note: The following documents shall be submitted only upon SFDA/MDS request).			
7	Service Reports for the Affected Medical Devices that have been Corrected	-	• It is required only if the FSN requires on-site correction for the affected medical devices • It shall include: - manufacturer reference number of the FSN and its issuance date - model/part numbers and lot/serial numbers of the affected medical devices that have been corrected - detailed description of the action taken as required by FSN - names of healthcare providers whose medical devices have been corrected, with authorized persons' signatures, date, positions, and contact details
8	Proof of Local Destruction for the Affected Medical Devices	-	• It is required only if the FSN requires local destruction for the affected medical devices • It shall be issued by the party that conducted the destruction and shall be offical and approved by SFDA • It shall include: - number of the affected medical devices that have been destructed, with model/part numbers and lot/serial numbers - signature of the authorized person of the party that conducted the destruction and its stamp

9	Proof from the Manufacturer of the Receipt of the Affected Medical Devices	-	• It is required only if the FSN requires local withdrawal of the affected medical devices and delivery to the manufacturer • It shall include: - confirmation statement of receipt of affected medical devices - number of the affected medical devices that have been received, with model/part numbers and lot/serial numbers - signature of the person authorized by the manufacturer • If the proof is not available, a confirmation statement from the company that transports/re-exports the affected medical devices shall be provided (including number of affected medical devices that have been transported/re-exported, with model/part numbers and lot/serial numbers)
10	Proof from the Healthcare Provider of Replacing the Affected Medical Devices	-	• It is required only if the FSN requires replacing the affected medical devices • It shall include: - number of the affected medical devices that have been replaced, with model/part numbers and lot/serial numbers - names of healthcare providers whose medical devices have been replaced, with authorized persons' signatures, date, positions, and contact details

Flowchart


Start
The FSN received from SFDA/MDS or other sources?
FSN received from SFDA/MDS, and KSA market is Not affected by the FSN
FSN received from SFDA/MDS, and KSA market is affected by the FSN
FSN is received from the manufacturer or another source, and KSA market is affected by the FSN
The documents specified in section (A) of "REQUIRED DOCUMENTS" shall be submitted to (NCMDR.MD@sfda.gov.sa)
The documents specified in section (B) of "REQUIRED DOCUMENTS" shall be submitted to (NCMDR.MD@sfda.gov.sa), in addition to:
section (C.7), if the manufacturer's recommended action requires on-site correction for the affected medical devices,
section (C.8), if the manufacturer's recommended action requires local destruction for the affected medical devices,
section (C.9), if the manufacturer's recommended action requires withdrawal for the affected medical devices, or
section(C ,)10.if the manufacturer's recommended action requires replacing the affected medical devices.
Inform SFDA/MDS within one working day by completing the" Add New Device Recall "form ,through the NCMDR on the SFDA's website
Receiving an email from SFDA/MDS stating that FSN has been closed
End

Annexes

Annex (1): Statement Confirming Saudi Arabia is Not Affected by FSN

[To be printed on Manufacturer/Authorized Representative Letterhead]

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 إشعار إنذار السلامة أدناه إلى المملكة العربية السعودية أو طرحها في أسواقها أو استخدامها فيها، لذا نود إفادتكم بأن المملكة لم تتأثر بالإشعار المذكور.

رمز التأكيد/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:
Stamp		الختم

Annex (2): Confirmation Statement for Completing the Corrective Actions Required in the FSN

[To be printed on Manufacturer/Authorized Representative Letterhead]

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

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 Requirements for Following Up and Closing Medical Devices Field Safety Notices (FSNs) (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 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 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 لمتطلبات متابعة وإغلاق إشعارات إنذار 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 إغلاق الإشعار.

رمز التأكيد/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:
Stamp		الختم

Annex (3): SFDA Classification for FSNs Risks

SFDA Classification for FSNs Risks	Examples of FSN risk class equivalent to other international authorities/organizations	Response Time
Very High Risk	- FSNs issued by U.S. FDA or TGA which classified as class 1 (high risk). - FSNs issued by ECRI which classified as critical priority. - FSNs issued by BfArM, Swissmedic or NCMDR which assessed by SFDA as very high risk based on the following criteria: o the severity of the potential injury o the detectability of occurrence, the likelihood of occurrence, and o the impact on the KSA market.	Maximum (2) working days
High Risk	- FSNs issued by U.S. FDA or TGA which are classified as class 2 (medium risk) and are included to remove or stop the use of the affected medical devices. - FSNs issued by ECRI which are classified as high priority and are included to remove or stop the use of the affected medical devices. - FSNs issued by NCMDR, BfArM or Swissmedic and which assessed by SFDA as high risk based on the following criteria: o the severity of the potential injury, o the detectability of occurrence, the likelihood of occurrence, and o the impact on the KSA market. - FSNs for home use medical devices or implantable medical devices that included removal action and not classified as very high risk in other authority.	Maximum (5) working days
Moderate Risk	- FSNs issued by U.S. FDA or TGA which are classified as class 2 (medium risk) and are included a corrective action for the affected medical devices. - FSNs issued by ECRI which are classified as high priority and are included a corrective action for the affected medical devices.	Maximum (10) working days

	- FSNs issued by NCMDR, BfArM or Swissmedic included a corrective action for the affected medical devices and not mentioned in the above.	

Annex (4): FSNs Sources and their Classifications

	FSNs Sources		Sources Classification of FSNs
1	U.S. FDA	Food and Drug Administration (FDA)	Class 1 (high risk) Class 2 (moderate risk) Class 3 (low risk)
2	US ECRI	Emergency Care Research Institute	Critical Priority High Priority Low Priority
3	MHRA	Medicines and Healthcare products Regulatory Agency (United Kingdom)	-
4	BfArM	Federal Institute for Drugs and Medical Devices (Germany)	-
5	TGA	Therapeutic Goods Administration (Australia)	Class 1 (high risk) Class 2 (moderate risk) Class 3 (low risk)
6	Swissmedic	Swiss Agency for Therapeutic Products	-
7	MDCO	Medical Device Control Office (Hong Kong)	-
8	Health Canada	Healthy Canadians	-
9	HPRA (Formerly IMB)	Health Products Regulatory Authority	-
10	NCMDR	SFDA National Center for Medical Devices Reporting	Very High Risk High Risk Medium Risk

Annex (5): 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.
Field Safety Corrective Action	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 (FSNs)/Recall	a notification from the SFDA to relevant medical device users in relation to a Field Safety Corrective Action.
National Center for Medical Device Reporting (NCMDR)	an organization managing a database of information on safety and/or performance related aspects of medical devices and employing staff capable of taking appropriate action on any confirmed problems.