

# MDS - G6

## GUIDANCE ON POST-MARKETING SURVEILLANCE

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## PART I

# Post-Marketing Surveillance

### A. General Principles

1. After 31<sup>st</sup> December 2011 only medical devices that meet specific safety and performance provisions of the Medical Devices Interim Regulation are authorized to be placed on the KSA market. However, not withstanding such measures, post-marketing problems may emerge. For example:
  - a device is involved in an adverse event<sup>1</sup> within the KSA;
  - an adverse event occurs outside the KSA but has implications for a medical device within the KSA;
  - an adverse event occurs within the KSA that involves a medical device that predates the application of the Interim Regulation but has implications for an authorized medical device, e.g. it occurs with an earlier variant of the authorized device;
  - a device is put into service but subsequently found to not comply with the Interim Regulation..
2. The purpose of the post-marketing surveillance, referred to in the Interim Regulation, is to identify and manage these different situations.

*Exerts from CHAPTER EIGHT of the **MEDICAL DEVICES INTERIM REGULATION***

#### **Article Thirty One**

If during its market surveillance activities, the SFDA comes across a non-compliance that has implications for public health, it shall alert patients, users or other persons, as appropriate.

<sup>1</sup> **An adverse event** is any malfunction or deterioration in the characteristics and/or performances of a medical device, including any inadequacy in its labelling or the instructions for use which may lead to compromise the health or safety of patients, users or third parties.

Exerts from Implementing Rule MDS-IR 7 on *Post-Marketing Surveillance*

**Article Four: General Principles**

- A. Chapter Eight of the Medical Device Interim Regulation requires the SFDA to take all appropriate measures to ensure that medical devices authorized by the SFDA to be placed on the market in the KSA are subject to **post-marketing surveillance** and comply with the requirements of the Interim Regulation.
- B. Post-marketing surveillance comprises two activities, namely medical device **adverse event management**, of which a medical device vigilance system is an integral part, and **market control**. Together these help to ensure and maintain a high level of patient health and safety with respect to medical devices.
- C. **Medical device vigilance** is a process whereby an **adverse event**, involving a medical device that is authorized to be placed on the KSA market and put into service, of which the manufacturer has been informed, is investigated by the manufacturer and reported to the SFDA, where appropriate. The SFDA may monitor the investigation process. Where justified, the manufacturer and/or the SFDA shall take all appropriate measures to reduce or remove the likelihood of the incident occurring again.
- D. **Market control** is a procedure to ensure that in the absence of a medical device **adverse event** report, any medical device that has been authorized to be placed on the KSA market and is found, before it is put into service, to compromise the health or safety of patients, users or third parties, or does not comply with the relevant provisions of the Medical Devices Interim Regulation and its Implementing Rules, is either withdrawn from the market, or subject to appropriate corrective action to eradicate the non-compliance.
- E. The SFDA is responsible for ensuring both **market control** and medical device **adverse event management** are operated effectively.

## COMMENTS

1. The SFDA monitors the safe use of medical devices within the KSA by:
  - a. encouraging medical device users and patients to notify any **adverse events** of which they become aware. Further information on this procedure is provided in **Part II** of this document;
  - b. implementing a **market control** programme to verify the conformity to the Medical Devices Interim Regulations of a sample of authorized devices that have been supplied to the KSA market. This procedure has particular value where the device has been classified by the GHTF Founding Member as being of low risk and therefore exempt from independent conformity assessment by the Regulatory Authority or a Conformity Assessment Body. Further information on this procedure is provided in **Part IV** of this document.
2. The medical device regulation of the GHTF Founding Member jurisdictions upon which SFDA marketing authorization is based, may require a manufacturer to perform a **post-marketing study** of a particular device that has been supplied to the KSA market. Further information on this procedure is provided in **Part III** of this document.
3. All parties involved in post-marketing procedures must comply with the **confidentiality requirements** of the Interim Regulation. Further information is provided in **Part V** of this document.

## PART II

### Adverse Events

#### B. General Principles

*Exerts from CHAPTER EIGHT of the **MEDICAL DEVICES INTERIM REGULATION***

##### Article Thirty Two

The SFDA shall institute and maintain a web-based National Centre for Medical Device Reporting (NCMDR) to fulfil the following purposes:

- A. Improve protection of the health and safety of patients, users and other parties.
- B. Disseminate relevant device related information which may reduce the likelihood of, or prevent repetition of adverse events, or alleviate consequences of such repetition.
- C. Execute a key aspect of the SFDA's post-market activities.
- D. Encourage collaboration between manufacturers and health care facilities to identify and investigate **adverse events** associated with medical devices and take appropriate action.
- E. Encourage the reporting of **adverse events** by medical device institutions and users, manufacturers, authorised representatives and organizations involved in supplying medical devices to the KSA.
- F. Provide a database of information on the safety and performance of medical devices that is suitable for the exchange of **adverse events** information with other Regulatory Authorities.

##### Article Thirty Three

The SFDA shall review **adverse events** reported to its NCMDR and take appropriate action to safeguard public health.

### Article Thirty Four

The SFDA shall establish a mechanism to issue Field Safety Notices to medical device users and, where relevant, patients. Before issuing such a Notice, its text shall be discussed with the organizations responsible for manufacturing the device and supplying it to the KSA.

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### *Exert from Implementing Rule MDS-IR 7 on Post-Marketing Surveillance*

#### Article Five : General

- A. The SFDA shall ensure the appropriate and efficient operation of the necessary medical device **vigilance procedures**. It shall, in particular, advise users and persons involved in the provision of healthcare in the KSA to inform without delay the manufacturer concerned of any **adverse event** and the SFDA of any **reportable adverse event** they become aware of involving a specific medical device.
- B. All parties concerned shall be made aware of the existence and responsibilities of the SFDA being the medical device vigilance authority. Furthermore, the SFDA shall indicate how it may be contacted to notify medical device **reportable adverse events**.

### COMMENTS

1. When an adverse event involving medical device occurs in the KSA, the user or the healthcare provider is requested by the SFDA to notify the manufacturer concerned of the event. When the adverse event meets the criteria of a **reportable adverse event**<sup>2</sup> the manufacturer and the SFDA shall both be notified of the event. In this case the manufacturer has responsibilities to both the GHTF Founding Member jurisdiction upon which the

<sup>2</sup> **Reportable adverse event:** means any adverse event or any technical or medical reason leading to a Field Safety Corrective Action, which, directly or indirectly, might lead to or may have led (a) to the death of a patient, a user or another person or (b) to a serious deterioration in their state of health.

SFDA marketing authorization was based, as well as to the SFDA under the provisions of the Interim Regulation.

2. The SFDA will publicise the availability of, and the access to, its National Centre for Medical Devices Reporting (NCMDR) and emphasise its importance in improving public health within the KSA.
3. The SFDA shall evaluate all reportable adverse events notified to it, monitor the outcome of the manufacturer's investigation of the cause, and may intervene or initiate an independent investigation, if appropriate.
4. If the outcome of the investigation warrants it, the SFDA shall issue a Field Safety Notice to healthcare facilities.
5. The SFDA shall monitor and analyse the NCMDR database and use the information it collects to support its market control activities.

### **C. Management of 'reportable' or 'non-reportable' adverse events.**

1. Adverse event management comprises the evaluation of adverse events by a manufacturer to establish the cause of the event and, if it is established that the medical device caused, or was a contributing factor to the event, taking the appropriate measures to avoid re-occurrence.
2. The manufacturer should have a documented adverse event management procedure that includes, in particular:
  - The initial recording and evaluation of the event;
  - Establishing the cause of the event in co-operation with the person who notified the adverse event and whether or not it was due, in part or whole, to a technical deficiency of the device or its labelling;
  - Establishing whether the event is '**reportable**' and if so notifying the GHTF founding member regulatory authority



that has regulatory oversight of the manufacturer;

- Redesigning the device or labelling to prevent re-occurrence, where such is necessary;
- Establishing a corrective action plan and, when appropriate, agreeing a **field safety corrective action programme** with the regulatory authority of the GHTF founding member jurisdiction that provides regulatory oversight to the device; and
- Co-operating with the GHTF founding member regulatory authority if it is necessary for the RA to issue a **field safety notice**.

The procedure is subject to control through the manufacturer's quality management system, where it has one.

3. Where the adverse event occurs in the KSA and falls into the **non-reportable category**, it is the manufacturer's responsibility to apply the adverse event management procedure outlined in § 2 above, or any equivalent procedure which is specified in the GHTF Founding Member jurisdiction upon which the SFDA marketing authorization was based and, in addition, take account of any relevant provisions of the Interim Regulation.
4. Where the adverse event occurs in the KSA and falls into the **reportable category**, it is the manufacturer's responsibility to apply the adverse event management procedure outlined in § 2 above, and, in addition, notify the SFDA/NCMDR thereof, using the internet link "<http://ncmdr.sfda.gov.sa>" (see Section D, below). The manufacturer shall in particular:
  - identify the medical devices that have been placed on the KSA market, together with the organisations involved in their supply;
  - report to the SFDA, at appropriate intervals, on the progress it is making with investigating the adverse event;

- when the cause of the adverse event has been established, obtain the agreement of the SFDA to its proposed **field safety corrective action plan** for the KSA;
  - seek the agreement of the SFDA to the text of an appropriate draft **Field Safety Notice**, if such is required, for communication by the SFDA to all persons concerned through written notifications and on its website; and
  - report to the SFDA, at appropriate intervals, on its progress towards completing the agreed **field safety corrective action plan** within the KSA. Where the manufacture is unable to complete the agreed corrective action plan, despite using its best endeavours, the SFDA may require the authorised representative to publish the contents of the Filed Safety Notice in one or more KSA newspapers.
5. The SFDA shall make users and healthcare providers aware that their co-operation with the manufacturer is essential to enhance the efficiency of the procedure. They shall, in particular, allow the manufacturer or the authorised representative to examine, where appropriate under SFDA supervision, the device suspected of having contributed to the adverse event.

## D. Reportable Adverse Events occurring within the KSA

*Exert from CHAPTER SIX of the MEDICAL DEVICES INTERIM REGULATION*

### Article Eighteen

A) The manufacturer or its authorised representative shall for the medical devices it wishes to place on the market of the KSA:

8. Undertake to report to the SFDA's National Centre for Medical Device Reporting (NCMDR), any **relevant adverse event** of which it becomes aware, that involves the medical device.

*Exerts from Implementing Rule MDS-IR7 on **post-marketing surveillance***

**Article Six: Medical device reportable adverse events occurring within the KSA**

- A. The SFDA will encourage users and persons involved in the provision of healthcare within the KSA to inform the manufacturer, where appropriate, through its authorised representative and the SFDA, through its National Centre for Medical Device Reporting (NCMDR), of any **adverse event** that meets the following criteria:
- Any malfunction or deterioration in the characteristics and/or performance of a medical device, as well as any inadequacy in the labelling or the instructions for use, which has led, or might have led, to the death of a patient, user or third person, or to a serious deterioration in the state of health of a patient, user or third person.
- B. When the SFDA receives the information it shall ensure that the manufacturer of the device, or his authorised representative, is immediately and fully informed of the **adverse event**.
- C. The manufacturer shall investigate the **adverse event**, working in collaboration with the health practitioner or user concerned and with the SFDA. If the manufacturer confirms the event falls into the reportable category referred to in paragraph A, above, it shall submit an **adverse event report** to the SFDA and agree a **corrective action plan**. Where justified, the SFDA shall issue a **field safety notice** to medical device users and/or hospital authorities, informing them of the manufacturer's corrective action plan and of the risks involved in continuing to use the device. The SFDA shall use its best endeavours to agree with the manufacturer the text of the field safety notice.
- D. Once a corrective action plan has been agreed with the SFDA, the manufacturer shall submit a report to the authorizing GHTF CA.

This report is a written statement of the outcome of the relevant investigations performed and of the corrective action plan agreed with the SFDA.

- E. If the manufacturer considers the event **not** to be a **reportable adverse event**, it shall provide the SFDA with a justification of its conclusion and with details of what use will be made of the information received.

## COMMENTS

1. The SFDA encourages medical device users and those involved in the provision of healthcare within the KSA to notify all **reportable adverse events** to both the SFDA and to the manufacturer of the device concerned. Where the manufacturer is established outside the KSA, the notification shall be provided to the manufacturer through his authorised representative.
2. The SFDA and the manufacturer will accept a reportable adverse event notification from a patient or other lay person, also.
3. These notifications are made to the National Centre for Medical Devices Reporting (NCMDR), accessed through the SFDA's website and to the manufacturer through its authorised representative.
4. The SFDA will confirm the manufacturer has received a notification of the adverse event from the user or healthcare facility and, if not, provide it with the necessary information.
5. The SFDA requires the manufacturer to investigate the cause of the adverse event, report all circumstances to the SFDA and subsequently, the outcome of its investigation into the incident (see Section D § 4, above). The NCMDR will monitor the investigation and may intervene or initiate an independent investigation, if appropriate. The manufacturer shall implement **field safety corrective action**<sup>3</sup> to prevent reoccurrence of the

<sup>3</sup> 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.

event as well as modify future versions of the medical device.

6. Where justified and after consultation with the manufacturer, the SFDA shall issue a **Field Safety Notice**<sup>4</sup> to device users and to healthcare facilities. The Notice shall provide sufficient information to identify the affected medical devices, an explanation of the reasons for the issuing the Notice, and advice on actions to be taken by customers, users or other persons concerned.

## E. Reportable Adverse Events occurring outside the KSA

*Exerts from Implementing Rule MDS-IR7 on post-marketing surveillance*

### Article Seven: Medical device reportable adverse events occurring outside the KSA

- A. When an **adverse event** falling within the category described in Article Six paragraph A (reportable adverse event) occurs outside the KSA and has potential consequences for a medical device that is placed on the KSA market, the manufacturer, through its authorised representative, shall immediately inform the SFDA of the circumstances and provide all available details on the medical device concerned and the measures taken in cooperation with the authorizing GHTF CA.
- B. Where the SFDA considers **the adverse event is reportable** and could have consequences for a medical device that is placed on the KSA market, it shall ensure the event is recorded at its National Centre for Medical Devices Reporting and properly managed.
- C. When the manufacturer, having investigated the **adverse event**, decides to instigate a field safety corrective action within the KSA, the manufacturer through its authorised representative shall inform the SFDA of this decision. Where justified, the

<sup>4</sup> A notification from the SFDA to relevant medical device users in relation to a field safety corrective action.

SFDA shall issue a field safety notice to medical device users and/or hospital authorities, informing them of the manufacturer's corrective action plan and of the risks involved in continuing to use the device. The SFDA shall use its best endeavours to agree with the manufacturer the text of the field safety notice.

## COMMENTS

1. Where a reportable adverse event (or equivalent incident) occurring outside the KSA has possible or actual consequences for a medical device within the KSA, the manufacturer, through its authorised representative if relevant, shall inform the NCMDR of the event and subsequently report the outcome of its investigation. Furthermore, the report shall describe the field safety corrective action implemented by the manufacturer, and, where appropriate, include the text of any Field Safety Notice issued by the RA of the overseas jurisdiction where the adverse event occurred.
2. The relevant information shall be recorded in the NCMDR and the SFDA shall issue, where justified and in co-operation with the manufacturer, a Field Safety Notice to device users and healthcare providers.

SFDA

## Part III

### Post-Marketing Studies

*Exert from Implementing Rule MDS-IR 7 on post-marketing surveillance*

#### **Article Eight: Medical device reportable adverse events occurring during post-marketing follow-up**

When a **reportable adverse event**, which was identified during the manufacturer's post-marketing follow-up activities performed in the framework of its GHTF authorization, leads to a field safety corrective action for a medical device that is authorized to be placed on the KSA market, the manufacturer shall inform the SFDA of the **adverse event**, through its authorised representative, where appropriate, of the measures it intends to take and provide the SFDA with a copy of any relevant Field Safety Notice issued by the authorizing GHTF RA concerned.

#### **COMMENTS**

1. The medical device regulation of the GHTF Founding Member jurisdictions upon which SFDA marketing authorization is based may require a manufacturer to undertake a post-marketing study of a particular device. For example, the long term safety and benefits of an orthopaedic implant require monitoring across a range of patients over many years.
2. The GHTF Founding Member will monitor the study, its outcome and, in particular, findings that lead the manufacturer to withdraw, initiate a field safety corrective action, or to make a significant design change to the device.
3. Any consequence for the safety or performance of medical devices in service within the KSA will be reported to the SFDA by the manufacturer's authorised representative, as described in Part II Section E above.
4. The SFDA shall assess the need to issue, in co-operation with the manufacturer, a Field Safety Notice to all KSA users and healthcare providers.

## PART IV

### Market Control

#### F. General Principles

*Exert from Implementing Rule MDS-IR 7 on **post-marketing surveillance***

##### Article Nine: General

- A. The SFDA shall be the market controlling authority. It shall implement the appropriate market control policy and associated procedures, intended to monitor medical devices placed on the KSA market and to ensure, in cases of non-compliance, that appropriate actions to enforce conformity are taken. The procedures specify also the responsibilities of the organizations involved in importation and/or distribution activities regarding their market control activities and responsibilities.
- B. The SFDA shall review the functioning of its **market control** activities periodically and take appropriate measures to increase their effectiveness, where necessary.

#### COMMENTS

1. For the purpose of this Medical Device Interim Regulation, market control is a procedure to ensure that in the absence of a medical device **adverse event** report, any medical device that has been authorized to be placed on the KSA market and is found, before it is put into service, to either:
  - compromise the health or safety of patients, users or third parties,or
  - does not comply with the relevant provisions of the Medical Devices Interim Regulation and its Implementing Rules,



is either withdrawn from the market, or subject to appropriate corrective action to eliminate the non-compliance.

2. Market control activities are carried out by the SFDA itself, or by importers and/or distributors in cooperation with the SFDA.
3. Users, healthcare facilities and lay persons are encouraged to report to the NCMDR if they suspect a medical device they have purchased is unsafe or does not comply with the Interim Regulation. Also, they should inform the distributor who supplied the device to them.
4. The SFDA, local manufacturers, authorised representatives of overseas manufacturers, importers and distributors shall each maintain records of the reported problems and of the actions taken.

## G. Market Control by the SFDA

*Exert from Implementing Rule MDS-IR 7 on **post-marketing surveillance***

### **Article Ten: Market control activities by the SFDA**

- A. Where the SFDA has reason to suspect a medical device, authorized to be placed on the KSA market, does not, under normal conditions of use, meet the manufacturer's specification for safety and performance, it shall undertake appropriate checks by means of documentary verifications and, where justified, by physical inspection and/or testing of medical devices, placed on the market but not yet to be put into service, to assess the non-compliance and analyse the factor/s causing it. When non-compliance is proven, an examination is performed, where necessary, on an adequate sample of the medical devices to verify the systematic character of the non-conformity. Where relevant test reports or certificates, attesting conformity, issued by a NCA or, on a voluntary basis, a recognized Conformity Assessment Body, are made available to the SFDA, it shall take due account

of such reports or certificates.

- B. The SFDA shall first require the manufacturers, through its authorised representative where appropriate, the importers or the distributors to take the appropriate corrective action and ensure proper implementation. Where those actions are not applied or are not sufficient the SFDA shall take safeguard measures, as specified in Implementing Rule MDS- IR 8, to ensure that non-conforming devices are withdrawn from the market or their availability is prohibited or restricted. Furthermore, the SFDA shall take appropriate measures to ensure that potential users of the devices are informed accordingly.
- C. Importers and distributors shall cooperate with the SFDA and assist it in performing an efficient **market control**. Importers shall submit, when required by the SFDA, the documentation it needs concerning the contact details of the local manufacturer or of the authorised representatives of the overseas manufacturers from whom they import devices. Distributors shall inform the SFDA of the address of the establishment that has supplied them with the devices and the address of the establishment or final user to whom they have supplied the devices.

## COMMENTS

1. The SFDA shall, in cooperation with all parties concerned, set up and implement a market control programme. This shall include monitoring the activities of importers and distributors as described in Sections K (see comment 3) and L (see comment 4) of MDS-G1 *Guidance for Medical Device Importers and Distributors*, in respect of their post-marketing obligations.
2. When the SFDA has been made aware of potential non-conforming medical devices, it shall investigate the circumstances to verify if the alleged non-compliance is an isolated case or has a systematic character. It may, where justified, enter establishments and perform physical inspections and/or testing of any suspected non-complying medical devices.

3. The SFDA may require the authorised representative and/or the importer and/or the distributor to provide it with information and other assistance during this investigation and/or inspections. Furthermore, SFDA may, where duly justified, enter premises and remove or quarantine the medical devices concerned.
4. In case of a systematic non-compliance the SFDA shall apply one or more of the measures specified in Article Ten B of the Implementing Rule MDS-IR 7 (see exert above). Where the SFDA deems it necessary, it may destroy or render inoperable devices presenting a serious risk. The SFDA shall ensure that any restrictive measure taken is proportionate and states the exact grounds on which it is based.
5. The SFDA shall take appropriate measures to alert users and, where necessary, customs authorities within an adequate timeframe of the hazards identified so as to reduce the risk of injury.

## H. Market Control by Importers and Distributors

*Exert from Implementing Rule MDS-IR 7 on **post-marketing surveillance***

### **Article Eleven: Market control by importers and distributors**

- A. Where an organization involved in the importation of medical devices into the KSA or one involved in furthering the availability of medical devices to end users has reason to believe that a medical device, it intends to place on the KSA market, does not comply with the relevant provisions of the Medical Device Interim Regulation and its Implementing Rules, it shall take all appropriate actions within its competence to safeguard the health and/or safety of patients or to end the infringement. Furthermore, it shall inform immediately the SFDA and, when appropriate, the manufacturer concerned, where appropriate through its authorised representative, of its concerns and of the actions taken.
- B. The SFDA shall review any reports submitted to it by importers or

distributors, on issues relating to established health or safety non-conformities of medical devices and the corresponding actions taken. The SFDA shall, in close cooperation with the reporting person, decide on any further safeguard measure, as specified in MDS - IR 8, that it may consider necessary to supplement the actions mentioned above to end the infringement or to withdraw devices from the market to prevent the risks caused or expected to be caused by the medical devices concerned. They shall, where appropriate, inform all parties concerned within the KSA of the non-conformities they have identified and the measures taken.

## COMMENTS

1. Importers and Distributors shall, before supplying SFDA authorized medical devices on the KSA market, perform appropriate controls to verify that the devices concerned are in compliance with the relevant regulatory requirements. These controls shall be limited to activities within their competences such as ensuring, by sampling, that the devices are accompanied with the necessary documents in the appropriate language, the contact details of the manufacturer and the relevant indications allowing their identification.
2. Where an importer or a distributor has reasons to believe (e.g. through receiving complaints from a user) that a medical device it supplied to the market legitimately does not, in fact, comply with the Interim Regulation, it shall inform the SFDA and the manufacturer, through its authorised representative, where relevant.

## PART V

### Confidentiality of Information

*Exert from Implementing Rule MDS-IR 7 on **post-marketing surveillance***

#### Article Twelve

- A. Chapter Ten of the Medical Devices Interim Regulation places obligations upon the SFDA and other parties to observe confidentiality with regard to the information received while carrying out their duties, with the exception of the information described in paragraph 2 of this Article. The SFDA shall ensure that all parties involved in the application of the market control and device vigilance activities are aware of these responsibilities.
- B. The following information shall not be treated as confidential:
1. Information on the registration of persons responsible for supplying medical devices on the KSA market.
  2. Information to users sent out by the manufacturer or his authorised representative in relation to any field safety corrective action for the devices.
  3. Information contained in certificates issued, modified, supplemented suspended or withdrawn.
  4. Information to be given to overseas market surveillance authorities in order to ensure the effectiveness of **market surveillance** activities.

#### COMMENTS

1. All parties involved in **market surveillance** are required to preserve the confidentiality of both commercially sensitive information and of personal data in respect of providing

information to parties other than those directly involved in a particular post-marketing surveillance activity.

2. The obligation described in the previous paragraph does not apply to:
  - reporting information to the NCMDR;
  - information provided to support the manufacturer's field safety corrective action activities;
  - the publication of Field Safety Notices;
  - the publication of notices to support the SFDA's safeguard responsibilities;
  - informing the relevant GHTF Founding Member RA where the device concerned has been authorized to be marketed in the KSA through the provisions of the Interim Regulation;
  - providing information on relevant adverse events, to other National Regulatory Authorities, using a National Competent Authority Report<sup>5</sup> (NCAR).

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<sup>5</sup> A report to and from GHTF National Competent Authority members concerning a medical device related adverse event and recalls. SFDA is a NCAR member.