DRAFT DOCUMENT

Title: Safety Alert Dissemination System: Safety Alert Dissemination Criteria, Procedures and Form

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Date: 20 April 2007

1. Objectives

This document provides guidance to regulatory authorities (RA) on the following:

- The criteria for determining whether to disseminate a safety alert to other SADS participants;
- The procedures to follow when disseminating a safety alert; and
- How to fill in a SADS Form for disseminating the safety alert.

2. Definitions

2.1 Field Safety Corrective Action (FSCA)

A field safety corrective action is any remedial action, including preventive and corrective, taken by a manufacturer for reducing the risk of death or serious deterioration in the state of health associated with the use of the medical device. The action includes product recalls, device modifications and upgrades and changes in labelling, operations, methods and procedures.

2.2 Confidential Information:

Information that due to its nature may be prejudicial to one or more persons, or that may be deemed as such by regional confidentiality acts and regulations, and that, for this reason, has been marked by the information provider as being confidential or not for general release.

2.3 Public Information

Public information is regarded to be non-confidential. This information may not necessarily be widely or easily available. For example, information contained in recall notifications, safety alerts, hazard alerts, product notifications and other product advisories is considered to be public information

2.4 Serious Public Health Threat or Concern

Any event type, which results in imminent risk of death, serious injury, or serious illness to the public that may require prompt remedial action.

2.5 Safeguard Action

This describes the action taken by any AHWP member economies to withdraw, prohibit or otherwise restrict a device from the market or from being put into service.

3. Dissemination Criteria

3.1 In order to avoid flooding of safety information and safety alerts, SADS participants should only disseminate safety alerts related to serious cases or cases causing serious public health threat or concern.

3.2 Cases complying with all following criteria are considered serious and should be disseminated:

- ✡ Dangerous or defective products that predictably could cause serious health problems or deaths;
- ✡ Field safety corrective actions are warranted; and
- ✡ The affected products have or may have been placed in the market of other AHWP member economies.

3.3 A single-event case should not be disseminated unless its cause is unknown and that may occur elsewhere with serious consequences.

3.4 Cases causing serious public health threat or concern should always be disseminated through the SADS no matter whether the criteria under 3.1 are satisfied or not in order to alert the other regulatory authorities to step up their surveillance and get prepared.

3.5 All cases satisfying the criteria for dissemination (see sections 3.2, 3.3 and 3.4) would require immediate actions to be taken for protecting the public health while both the confidential and public information might be involved. The regulatory authorities should restrict the circulation of the confidential information to only those that really need to know (e.g. related authorities, affected hospitals and healthcare professionals and the manufacturer's representatives) and should involve the manufacturers or their representatives in the investigation of adverse incidents and resolution of issues and actions. The manufacturers should also be consulted before any safety alerts are disseminated.

4. Dissemination Procedures

4.1 Complete the SADS Form in accordance with the instructions given in Paragraph 5 below.

4.2 Prepare an email to all the representatives and alternative representatives of SADS participants with the title "AHWP SADS alert XXX – YYY" where XXX represents the 3-letter code (see Appendix 3) of the originating AHWP member economy and YYY represents the serial number in ascending order

starting from “001”. The serial number shall be the same and unique for each case.

4.3 Add comments or requests to other participants in the body of the email. For example, the originator may request other participants to provide contact information about the manufacturer of the affected product.

4.4 If the information is considered of particular important e.g. the case has caused a public health threat, the originator could request the recipients to reply to his/her email by adding the statement “Please reply to confirm the receipt of this email.” in the email.

4.5 Attach the completed SADS Form to the email.

4.6 Check the “URGENT” box of the email.

4.7 Send the email out.

4.8 Remember the following:

- ✡ Always use the latest list of SADS participants which could be downloaded from the AHWP website. In case of doubt, the Chair of WG2 can be contacted;
- ✡ Keep quoting the same “AHWP SADS alert XXX – YYY” for each case while additional information could be added in the title if appropriate; and
- ✡ The originator of the safety alert should act as the co-ordinator of the case (unless specified otherwise) and other participants may contact the originator for more information or provide information to the originator if appropriate.

5. Instructions for Filling in the SADS Form

5.1 The form should be completed in English.

5.2 The SADS participant filling in and disseminating the Form would be responsible for the quality of the content as well as the appropriateness of dissemination. Guidance on determining which case should be selected for dissemination is given in Section 3 above.

5.3 This form should be completed by SADS participants only for exchanging safety information related to the prevention of adverse incidents concerning medical devices. This form is designed for exchanging information between regulatory authorities and it should not be passed directly on to patients, users, third persons or the general public. If there is a need to communicate the safety information to them, another form of notice should be used.

5.4 If the case concerns a specific manufacturer's device, the manufacturer or its representative should be consulted about the contents and distribution prior to dissemination – preferably by providing a copy for the manufacturer or its representative to comment on. This will help to ensure the accuracy of the Form and an appropriate time frame for receiving manufacturers comments should be set. However, this process should not cause any unnecessary delay to the dissemination. If a case concerns a range of devices from different manufacturers, the regulatory authority should make an effort to contact and obtain comments from all relevant manufacturers or their representatives known.

6. Explanatory Notes for the SADS Form

Please read carefully the following notes before filling in the SADS Form appended in Appendix 1 and the item numbers below refer to the corresponding field numbers in the Form. Originators should fill in as much information known as possible.

1a - Please be sure to check Yes or No for confidentiality. This tells the recipient RA if the information provided can be released publicly or not.

1b - Please check Yes or No to indicate any public health threat/concern to indicate the seriousness and sensitivity of the case.

2 - Each RA shall use the 3-letter code selected in the application to join SADS to number the Forms originated. For example: HKG-2007-10-15/2 is the second SADS alert originated by Hong Kong and disseminated on 15 October 2007.

3 - Insert any local reference number used by your RA relevant to this alert here.

4 - If there have been previous SADS alert exchanged relating to this one, regardless of source, insert their RA exchange numbers here.

5 - Insert the manufacturer's reference/recall number here, if applicable.

6 - Identify the person and organization sending the SADS alert.

7 - Identify contact person for any information / technical discussion of the topic.

8~10- Telephone, Fax and e-mail of person in (7) above.

11 - Kind of device or generic descriptor.

12~13 Identify the GMDN Term and Code.

14 - Trade name / Brand name AND Model number

15~16 Identify the serial number / lot or batch number of the affected product.

17 Identify the software version.

18 - Manufacturer of device - full address, including member economy, fax, phone numbers and e-mail.

19 - Identify the manufacturer's representative in originating member economy (who is legally responsible for placing the subject device on the market where the incidents occurred), full address, including member economy, fax, phone numbers and e-mail.

20 - Indicate the name of Conformity Assessment Body involved.

21a- Identify the approval status of the device in the member economy where the alert originates. For example: approval number or licence number.

21b- Device risk class according to the jurisdiction of the originating RA.

22 - Identify any regulatory, legal or company-initiated action taken in advance of sending out the alert. This could for instance refer to a Recall or the use of Safeguard action.

23a - Provide a description of what has happened, including consequences to patients or users. Describe the reason for the alert and why you want to inform other RAs about these events. Such information will lead to a better understanding by the recipient on what is considered to be appropriate follow-up.

23b - Indicate if the investigation of the report is complete or not.

24a - Describe the outcome or conclusion of the investigation, to date. If useful, include a copy of the manufacturer or RA advisory notice(s) associated with the alert and make reference to them within the SADS Form.

24b- Indicate whether the manufacturer's actions have been made public.

24 c Indicate whether the originating RA is willing to take the lead to co-ordinate the investigation.

25a - Recommendations to recipients of this alert

25b - List member economies known to have the device placed on market. Put considerable care and effort into obtaining accurate information from the manufacturer for this field.

25c - List the trade name(s) in other member economies, if different.

26a - Indicate to whom the report has been sent. Confidential alerts should only be sent to SADS participants and regulatory authorities.

26b - Indicate the last SADS Alert no. issued by your economy so that the other participants could check for any missing alerts.

7. References

7.1 AHWP/WG2/SADS/001: Framework for AHWP Safety Alert Dissemination System (SADS)

7.2 GHTF SG2-N79R8:2006 – Medical Devices: Post Market Surveillance: Regulatory authority Report Exchange Criteria and Report Form

Safety Alert Dissemination System Form

This form should be used for the exchange of safety information between SADS participants and regulatory authorities only.

Completed forms should not be released to the public.

1a. Is this report confidential? Yes [ ] No [ ] *1b. Has public health threat/concern? Yes [ ] No [ ]*

Originator and References

2. SADS Alert no.:	3. Local RA reference no.:	4. Related SADS Alert nos.: (if any)
5. Manufacturer Ref/Recall no.:	6. Sent by: (Name and Organization)	7. Contact person: (if different from 6)
8. Tel:	9. Fax:	10. E-mail:

Device Data

11. Generic name/ kind of device**:**		20. Conformity Assessment Body:
12. GMDN Term:	13. GMDN Code:	
14. Trade Name and Model:		21a. Device approval status:
15. Software version:		
16. Serial no.:	17. Lot/batch no.:	21b. Risk Class:
18. Manufacturer: Member economy: Full Address: Contact: Tel: Fax: E-mail:	19. Representative: Member economy: Full Address: Contact: Tel: Fax: E-mail:	22. Action taken: [ ] None [ ] Safeguard Action [ ] Field Safety Corrective Action [ ] Other (specify)

Event Data

23a. Background information and reason for this report: 23b. Is the investigation complete? [ ]Yes [ ] No

24a. Conclusions: 24b. Have the manufacturer's actions been made public? Yes [ ] No [ ] 24c. The originator of this SADS will take the lead and co-ordinate the investigation [ ]Yes [ ] No

25a. Recommendation to receivers of this report: 25b. Device known to be in the market in (include copy of manufacturer's letter):

25c. Device also marketed as (trade name):

Report Distribution

26a. Besides AHWP SADS participants, this form is being distributed to:

[ ] The GHTF NCAR Secretariat for further distribution to FULL NCAR PARTICIPANTS

[ ] The GHTF NCAR Secretariat for further distribution to ALL NCAR PARTICIPANTS

[ ] The following targeted RAs:

[ ] The manufacturer / representative:

[ ] Others::

26b. The last AHWP SADS Form distributed by this RA was (_____)