Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

PROPOSED FINAL DOCUMENT

Title: AHWP Safety Alert Dissemination System (SADS)

Authoring Group: Work Group 4, Post-Market

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Ms. Jennifer MAK

Chair, Work Group 4

Content

1. Objectives

1.1 This document provides guidance to Regulatory Authorities (RAs) on the following:

(a) The structure of the Safety Alert Dissemination System (SADS);

(b) The roles and responsibilities of SADS members, manufacturers or their authorized representatives in SADS;

(c) The reporting criteria of the SADS report; and

(d) How to fill in a SADS reporting form.

1.2 This document was prepared by Work Group 4 of AHWP as an update to the following SADS guidance:

(a) Framework for AHWP Safety Alert Dissemination System (SADS) (AHWP/WG2/SADS/001); and

(b) Safety Alert Dissemination System: Safety Alert Dissemination Criteria, Procedures and Form (AHWP/WG2/SADS/002).

2. Definitions

2.1 **Confidential information** means any information that subject to an investigation, has never been publicized in the public domain, and is protected from public disclosure by law.

NOTE: Confidential information shall **NOT** be disseminated to other parties or publicized in any other public domain without the permission of the originating sender of the SADS report.

2.2 **Investigatory information** means any information communicated for the purpose of further investigation by RAs. It is normally either unproven or inconclusive and shall not be publicized until it is proven or becomes conclusive. Its circulation shall be limited to only those who need to know.

2.3 **Public information** means any information that has been publicized in the public domain though the information may not necessarily be widely or easily available.

NOTE: Information contained in recall notifications, safety alerts, hazard alerts, product notifications and other product advisories are considered to be public information.

2.4 **Safety information** means any information related to the safety, effectiveness, performance and quality of a medical device including but not limited to recalls, field safety corrective actions, advices, guidance, warnings and messages issued by either the manufacturer or the RA.

2.5 **Serious public health threat** means any event type, which results in imminent risk of death, serious injury, or serious illness that may require prompt remedial action.

3. Safety Alert Dissemination System (SADS)

3.1 Scope of SADS

3.1.1 SADS is a safety information sharing system among RAs of AHWP member economies. SADS members shall share the safety information through the **SADS On-line**[1].

3.1.2 To avoid flooding of safety information, SADS members should only disseminate information related to **serious cases** or **cases causing serious public health threat**. The details of the reporting criteria will be listed out in **Section 3.5** of this document.

3.2 Members of the SADS

3.2.1 ***RAs of AHWP member economies*** could voluntarily join the SADS as members.

3.2.2 Any RA of an AHWP member economy who intends to be a SADS member should complete the Application Form (Appendix 1) and submit it to the AHWP Secretariat.

3.2.3 Each RA of AHWP member economies who intend to be a SADS member must ***at least*** nominate **ONE** representative as the contact point of SADS in the Application Form.

3.2.4 The AHWP Secretariat will pass the application to the WG4. The WG4 Chair will seek views from the WG4 Members on the application. The application will be accepted if not more than 10% of the WG4 members object the application.

[1] ***SADS On-line*** was introduced and launched since May 2014, providing a secured location at AHWP website for RA's sharing.

3.2.5 Successful applicant will receive SADS member account(s) to log-in the SADS On-line for accessing the safety information shared.

3.3 Dissemination Mechanism of SADS

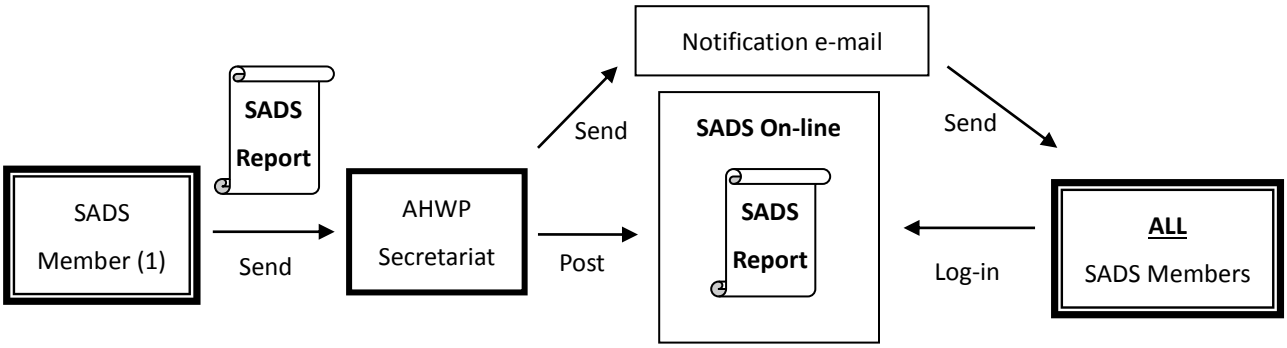
3.3.1 Once received safety information related to a medical device from a manufacturer or its authorized representative, the SADS member should consider whether to disseminate the safety information to other SADS members via the SADS On-line, according to the reporting criteria listed out in **Section 3.5** of this document.

3.3.2 SADS members should complete the SADS Reporting Form (Appendix 2) and send it to the AHWP Secretariat.

3.3.3 The AHWP Secretariat will post the received SADS report on the SADS On-line for sharing. The AHWP Secretariat will send out a notification e-mail to all SADS members about the new post on the SADS On-line at the same time.

3.3.4 SADS members could log-in the SADS On-line to gain access to the SADS report. Figure 1 shows the dissemination mechanism of SADS.

Figure 1 The dissemination mechanism of SADS



3.4 Roles and Responsibilities of SADS members, manufacturers or their authorized representatives in SADS

3.4.1 SADS members (RAs of the AHWP member economies)

3.4.1.1 SADS member ***originating*** a SADS report should:

(a) Communicate with the manufacturer or its authorized representative, who sends out the safety information, on the

latest safety information;

(b) Confirm that the safety information falls within the scope of SADS and meets all the reporting criteria;

(c) Discuss with the manufacturer or its authorized representative about the intended actions and seek their comments on the information to be disseminated where necessary;

(d) Prepare the SADS Report;

(e) Conduct investigations of the case or co-ordinate the investigations of the case in conjunction with the manufacturer or its authorized representative if appropriate; and

(f) Provide further information to other SADS members regarding the case where applicable, e.g. the latest status of the investigation or the completion or closure of the case.

3.4.1.2 SADS members ***receiving*** a SADS report should:

(a) Seek permission from the SADS member originating the SADS report before the confidential information is disseminated to other parties or publicized in any other public domain;

(b) Limit the circulation of the safety information, in particular the investigatory ones, to only those who really need to know (for example, related authorities, affected hospitals and healthcare professionals and the manufacturer's representatives);

(c) Understand from the manufacturer or its authorized representative about the distribution of the affected product in the local market, any actions already taken and any intended actions to be taken; and

(d) Provide further information to other SADS members regarding the case where applicable.

3.4.2 Manufacturers or their authorized representatives

3.4.2.1 Manufacturers or their authorized representatives should:

(a) Establish an efficient communication channel with the RAs of AHWP member economies for exchange of safety information;

(b) Co-operate with the RAs in conducting investigations on the case, implementing remedial plans, performing remedialactions and disseminating safety information;

(c) Maintain the supply chain records including distribution records of their products in all the AHWP member economies, so that

remedial plans / actions can be effectively taken when needed;

(d) Develop an efficient communication protocol among their subsidiaries/ authorized representatives in all AHWP member economies for ensuring concerted remedial plan / actions taken together, if applicable.

3.5 Reporting Criteria of SADS Report

3.5.1 SADS members should only disseminate safety information related to **serious** cases or **cases causing serious public health threat**.

3.5.2 Cases that considered **serious** should comply with **ALL of** the following criteria:

(a) Dangerous or defective products that predictably could cause serious injuries or deaths; and

(b) Field safety corrective actions are warranted;.

3.5.3 Safety information related to cases **causing serious public health threat** should **ALWAYS** be disseminated no matter whether the criteria under section 3.5.2 are satisfied or not, in order to alert other SADS members to step up their surveillance.

3.5.4 A single-event case should not be disseminated **UNLESS** its cause is unknown **AND** that may occur elsewhere with serious consequences.

3.6 SADS Reporting Form (Appendix 2)

3.6.1 The SADS Reporting Form should be completed in English.

3.6.2 The SADS member originating the SADS Report should fill in the form and be responsible for the quality of the content, as well as the appropriateness of dissemination.

3.6.3 The SADS Reporting Form is designed for exchanging information among SADS members and **should NOT be passed directly to patients, users, third parties or the general public**. If there is a need to communicate the safety information to other parties or the general public, another form of notice should be used.

3.6.4 To ensure the accuracy of the SADS Report, it is recommended to consult

the manufacturer(s) or its authorized representative(s) about the contents of the case and the distribution of the affected product before dissemination. An appropriate time frame for receiving manufacturer's comments should be set; however, this process should not cause any unnecessary delay to the dissemination of the SADS Report.

3.6.5 The explanatory notes in the SADS Reporting Form should be read carefully before filling in. Originators should enter as much information known as possible.

4. References

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

4.2 Safety Alert Dissemination System: Safety Alert Dissemination Criteria, Procedures and Form (AHWP/WG2/SADS/002)

Appendix 1

Note: The completed application form shall be sent to the AHWP Secretariat via email (secretariat@ahwp.info) or Fax (+852 2788 5002)

Application to Join the AHWP Safety Alert Dissemination System (SADS)

Being a member of AHWP and the regulatory authority of medical devices, we would like to nominate the following officers to be our contact points of the AHWP SADS:

Member Economies#			
Representative (1) #	**Title**	**Dr / Ir / Mr / Mrs / Ms***	
	Name	*(Last Name)*	*(First Name)*
	Post		
	e-mail		
Representative (2) #	**Title**	**Dr / Ir / Mr / Mrs / Ms***	
	Name	*(Last Name)*	*(First Name)*
	Post		
	e-mail		

We hereby agree to observe and comply with all the requirements of the AHWP Safety Alert Dissemination System (SADS) with details specified in the AHWP guidance document **AHWP/WG4/XXX:2016**.

Regulatory Authority# *(Primary/Secondary Representative*)*	**Date#** *(dd/mmm/yyyy)*
(Signature)	
(Name)	

(#) Indicates Mandatory Field; (*) Delete as appropriate

Appendix 2

AHWP Safety Alert Dissemination System (SADS) Reporting Form

T***his form should be used for the exchange of safety information among SADS members ONLY.***

Completed form should NOT be released to the public.

(Please read the explanatory notes before completing this form)

1a. This report is [□] *Confidential (No dissemination of this SADS Report to other parties or general public is allowed)*

[□] *Investigatory (Circulation of this SADS Report should be restricted)*

[□] *Public information*

1b. Causing serious public health threat? [□] *Yes* [□]*No*

Originator and References

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

Medical Device Data

11. Generic name / kind of device:				20. Conformity Assessment Body (if Known):
12. Nomenclature Term:		13. Nomenclature 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 name		19. Authorized Representative name :		22. Action taken: [□] None [□] Field Safety Corrective Action [□] Withdrawal/ Recall/removal [□] Other (specify)
Member economy		Member economy		
Full Address		Full Address		
Contact		Contact		
Tel:		Tel:		
Fax		Fax		
E-mail		E-mail		

Event Data
23a. Background information and reason for this report
23b. Is the investigation complete? [☐] Yes [☐] No
24a. Conclusions: (include copy of manufacturer's / RA advisory notice(s), if any)
24b. Have the manufacturer's action been made public? [☐] Yes [☐] No
24c. The originator of this SADS Report will take the lead and co-ordinate the investigation? [☐] Yes [☐] No (please specify the coordinator: _____)
25a. Recommendation to receivers of this report:
25b. Medical device known to be available in the market of:
25c. Device also marketed as (trade name): (if the trade name marketed in other member economies is different from 14)
Report Distribution
26. This SADS Report is being distributed to: [☐] SADS Members [☐] The manufacturer /authorized representatives [☐] Others:

Explanatory Notes for the AHWP SADS Reporting Form	
1a	Please identify the type of SADS Report – "confidential", "investigatory" or "public information". This tells the recipient about the sensitivity of the information provided.
1b	Please check Yes for cases causing serious public health threat to indicate the seriousness.
Originator and References	
2	Each SADS member shall use the 2-letter code selected in the application to member the SADS Report Form originated (XX-YYYY-MM-DD-NNN). For example: HK-2016-06-30-001 is the first SADS Report originated by Hong Kong and disseminated on 30 June 2016.
3	Insert any local reference number used by your RA relevant to this safety information here.
4	If there have been previous SADS Report exchanged related to this safety information, insert their numbers here.
5	Insert the manufacturer's reference/FSN /recall number here, if any.
6	Identify the person and organization sending this SADS Report.
7	Identify contact person for any information/technical discussion of the topic, if such person is different from (6).
8-10	Contact information (Telephone, Fax and e-mail) of the person mentioned in (7).
Medical Device Data	
11	Kind of medical device or generic descriptor
12-13	Identify the medical device nomenclature system used and corresponding Term and Code (e.g. GMDN Term and Code), if appropriate.
14	Trade name/Brand name AND Model number
15	Identify the software version
16-17	Identify the serial number/lot or batch number of the affected product
18	Manufacturer of the medical device – full address, including member economy, contact person, fax, phone numbers and e-mails
19	Identify the manufacturer's authorized representative in *originating member economy* – full address, including member economy, contact person, fax, phone numbers and e-mails
20	Indicate the name of Conformity Assessment Body involved, if any.
21a	Identify the approval status of the medical device in the member economy where the SADS Report originates, e.g. approval number or licence number of the device.
21b	Indicate the medical 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 this SADS Report
23a	Provide a description of what has happened, including consequences to patients or users. Describe the

Explanatory Notes for the AHWP SADS Reporting Form	
	reason for the SADS Report and why you want to inform other SADS member about this event. 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. It would be useful to include a copy of the manufacturer or RA advisory notice(s) associated with this safety information and make reference to them within the SADS Report.
24b	Indicate whether the manufacturer's action have been made public
24c	Indicate whether the originator of this SADS Report is willing to take the lead to co-ordinate the investigation.
25a	Recommendations to recipients of this SADS Report
25b	List member economies known to have the device placed on the market. Put considerable care and effort into obtaining accurate information from the manufacturer.
25c	List the trade name(s) of the affected product in other member economies, if different from (14)
Report Distribution	
26	Indicate to whom this SADS Report should be sent.