Work Group 2 (WG2)

Post-market Surveillance and Vigilance

AHWP/WG2/SADS/001

Draft Document:

Framework for AHWP

Safety Alert Dissemination System (SADS)

Objectives

- To define a structure for disseminating medical device safety alerts among AHWP members;
- To define the roles and responsibilities of regulatory authorities in receiving and disseminating safety alerts; and
- To define the roles and responsibilities of manufacturers or their representatives in reporting safety alerts.

Definitions

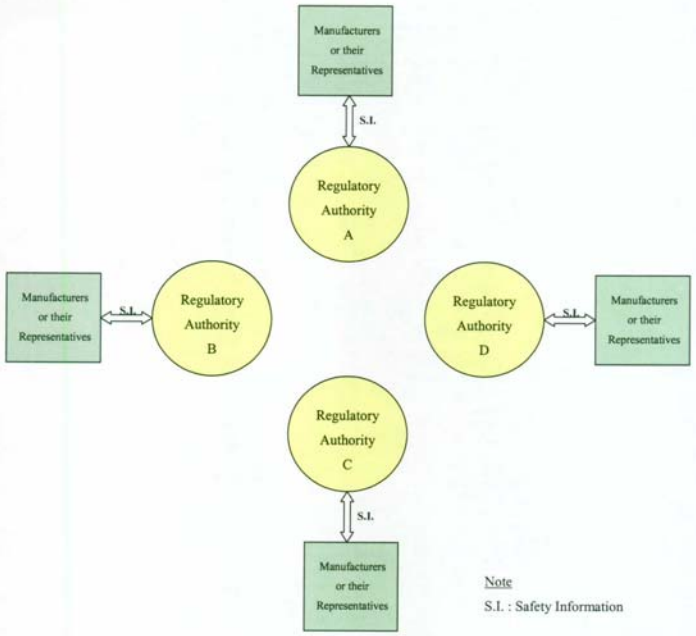
- **Safety information** is any information related to the safety and performance of a medical device including but not limited to recalls, field safety corrective actions, advices, guidance, warnings and messages issued by the manufacturer or any regulatory authorities.
- A **safety alert** is any safety information concerning individuals or types of medical devices issued by the regulatory authority to healthcare institutions, professionals, patients, users, general public or other regulatory authorities for protecting the public health. A safety alert could be initiated by the manufacturer and issued by the regulatory authority.

Structure of SADS

Appendix 1

Fig 1: Communication between Regulatory Authorities and Manufacturers

Regulatory Authorities communicates with the medical device manufacturers or their representatives on safety information related to medical devices as part of the post-market surveillance activities.



Note
S.I. : Safety Information

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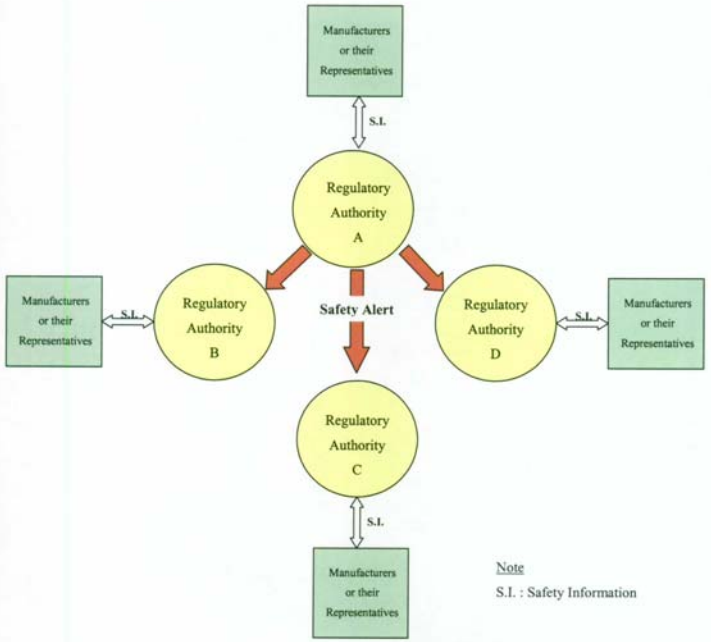
Appendix 2

Fig 2: Dissemination of Safety Alerts under SADS

"Regulatory Authority A" originates and disseminates a safety alert to other regulatory authorities when the safety alert falls within the scope of SADS.



Note
S.I. : Safety Information

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Roles & Responsibilities of Originating Regulators

- Communicate with the manufacturer on latest safety information;
- Identify the safety information falls within the scope of SADS;
- Inform the manufacturer of the intended actions and seek their comments on the information to be disseminated;
- Prepare the safety alert in the specific format and then disseminate it to all SADS participants;
- Co-ordinate the investigations of the case; and
- Provide further information to other SADS participants.

Roles & Responsibilities of Recipient Regulators

- Limit the circulation of the information to only those who really need to know;
- Understand from the manufacturer about the distribution of the affected product in the local market and any field safety corrective actions;
- Consult the manufacturer on intended; and
- Inform the manufacturer prior to taking any actions in particular disseminating the safety alert to the public.

Roles & Responsibilities of Manufacturer / Representative

- Cooperate with the RA in conducting investigations on adverse incidents, performing remedial actions and disseminating safety information;
- Develop a procedure for communicating with the RA on adverse incidents and safety information;
- Upkeep the distribution records of their products in all the AHWP member economies so that remedial actions could be effectively taken; and
- Develop an efficient communication channel among all the offices in different AHWP member economies so as to effect concerted remedial actions together.

Requirements for Joining SADS

- AHWP member;
- Nominate a representative and an alternate representative and their emails; and
- At least one of the representatives has attended training organized by AHWP.

Application Form

Appendix 3

Note: The completed application form shall be sent to the Chair, AHWP WG2 by fax (+852 31571286) or email (see_mda@dh.gov.hk).

Application to Join the AHWP Safety Alert Dissemination System

As a member of Asian Harmonization Working Party and the regulatory authority of medical devices, we would like to nominate the following officers to be our contact points of the AHWP Safety Alert Dissemination System:

	Name	Email Address
Representative:		
Alternate Representative:		

We confirm that we have attended the related AHWP training on _____ and hereby agree to observe and comply with all the requirements of the AHWP Safety Alert Dissemination System. We propose to use _____ (a 3-letter code) for numbering the safety alerts to be originated by us.

Signature: _____
Name: _____
Post: _____
Organization: _____
Country / Economy: _____
Email Address: _____

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Draft Document:

Safety Alert Dissemination System:

Safety Alert Dissemination Criteria, Procedures and Form

Dissemination Criteria

- Cases complying with all following criteria :
  - 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.
- A single-event case should not be disseminated unless its cause is unknown and that may occur elsewhere with serious consequences.
- Cases causing serious public health threat or concern should always be disseminated.

Dissemination Procedures

- Complete the SADS Form.
- Prepare an email to all the representatives and alternative representatives .
- Add comments or requests to other participants in the body of the email.
- If the information is considered of particular important, add the statement “Please reply to confirm the receipt of this email”.
- Attach the completed SADS Form.
- Check the “URGENT” box.
- Send the email out.

SADS Form

APPENDIX 1

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):

APPENDIX 1

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 (_____)

SADS Form (20 April 2007)

Comments?