Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Safety Alert Dissemination System (SADS)

AHWP TC WG02

Post-market Surveillance and Vigilance

13th AHWP Meeting

NEW DELHI, INDIA, 5-6 November 2008

Objective

- Regulatory authorities work together with manufacturers to provide a better protection to the public in the use of medical devices by sharing important safety information.

Targets

- To provide a platform for the sharing of non-confidential medical device safety information among regulatory authorities for the better protection of the public
- To merge with GHTF National Competent Authority Report (NCAR) Exchange Program for the global sharing of medical device safety information

Part I: Latest Development in GHTF IVD related documents

SADS vs NCAR

	SADS	NCAR (Associate)	NCAR (Full)
Participants	Regulatory Authorities	Regulatory Authorities + Related Parties	Regulatory Authorities
Safety Information	Investigatory + Non-confidential	Non-confidential	Confidential + Non-confidential
Secretary	Originating Party	TGA	TGA
Requirement	AHWP Member + Training	Training	Training + Reporting System
Contact Point	2 (+ Alternate)	1	1
Admin Charge	No	Possible	Possible

History of SADS

- Project initiated in the 11th AHWP Meeting (Sep 2006)
- WG2 formed (early 2007)
- Draft documents discussed in 6th AHWP TC Meeting (Apr 2007)
- Final documents approved in 7th AHWP TC Meeting (Mar 2008)
- SADS launched (June 2008)

Progress

- 7 participants
  - Hong Kong
  - Indonesia
  - Malaysia
  - Philippines
  - Singapore
  - Saudi Arabia
  - Thailand
- 2 cases disseminated

Final Documents

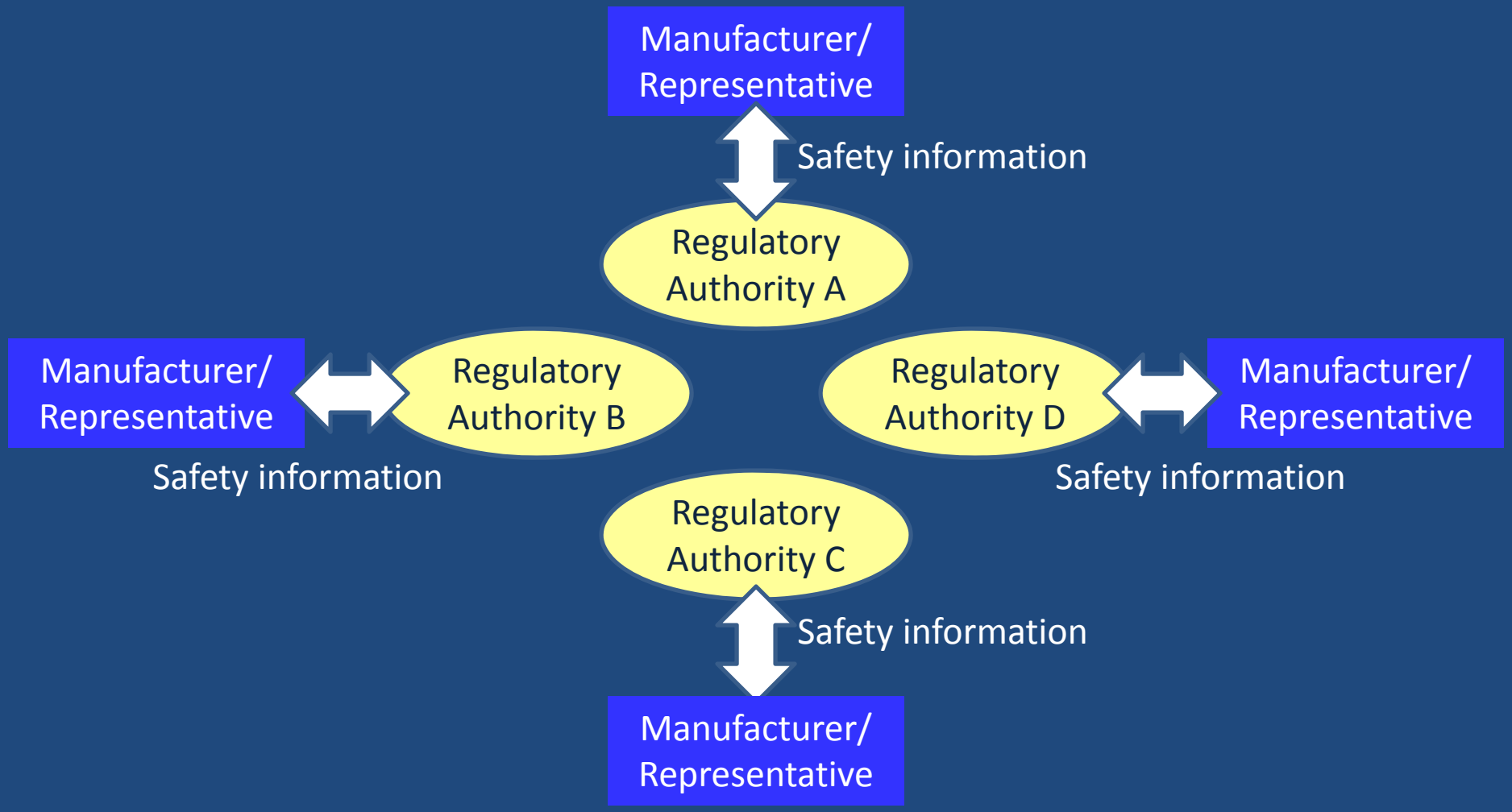
- Framework for AHWP Safety Alert Dissemination System (SADS)
- Safety Alert Dissemination System: Safety Alert Dissemination Criteria, Procedures and Form

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

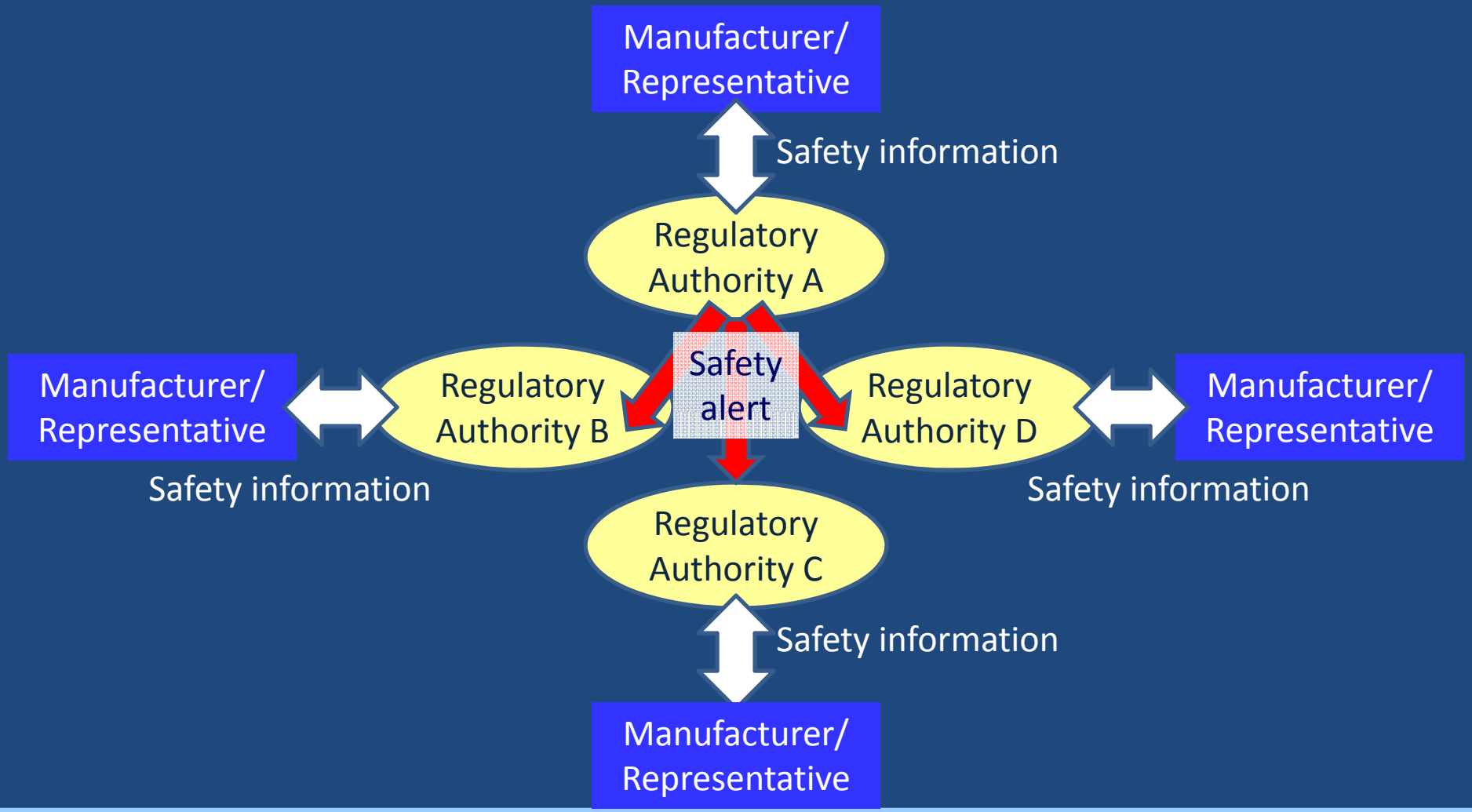
Contents

- 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.

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



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



Roles & Responsibilities of Originating Regulator

- Communicate with the manufacturer on latest safety information;
- Confirm the safety information falls within the scope of SADS;
- Discuss with the manufacturer about the intended actions and seek their comments;
- 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 action; 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 and implement a procedure for communicating with the RA on adverse incidents and safety information;
- Maintain the distribution records in all the AHWP member economies so that remedial actions could be effectively taken; and
- Develop an efficient communication channel in different AHWP member economies for ensuring concerted remedial actions together.

AHWP/WG2/SADS/002: Safety Alert Dissemination System: Dissemination Criteria, Procedures, 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.
- Cases causing serious public health threat or concern should always be disseminated.
- A single-event case should not be disseminated unless its cause is unknown and that may occur elsewhere with serious consequences.

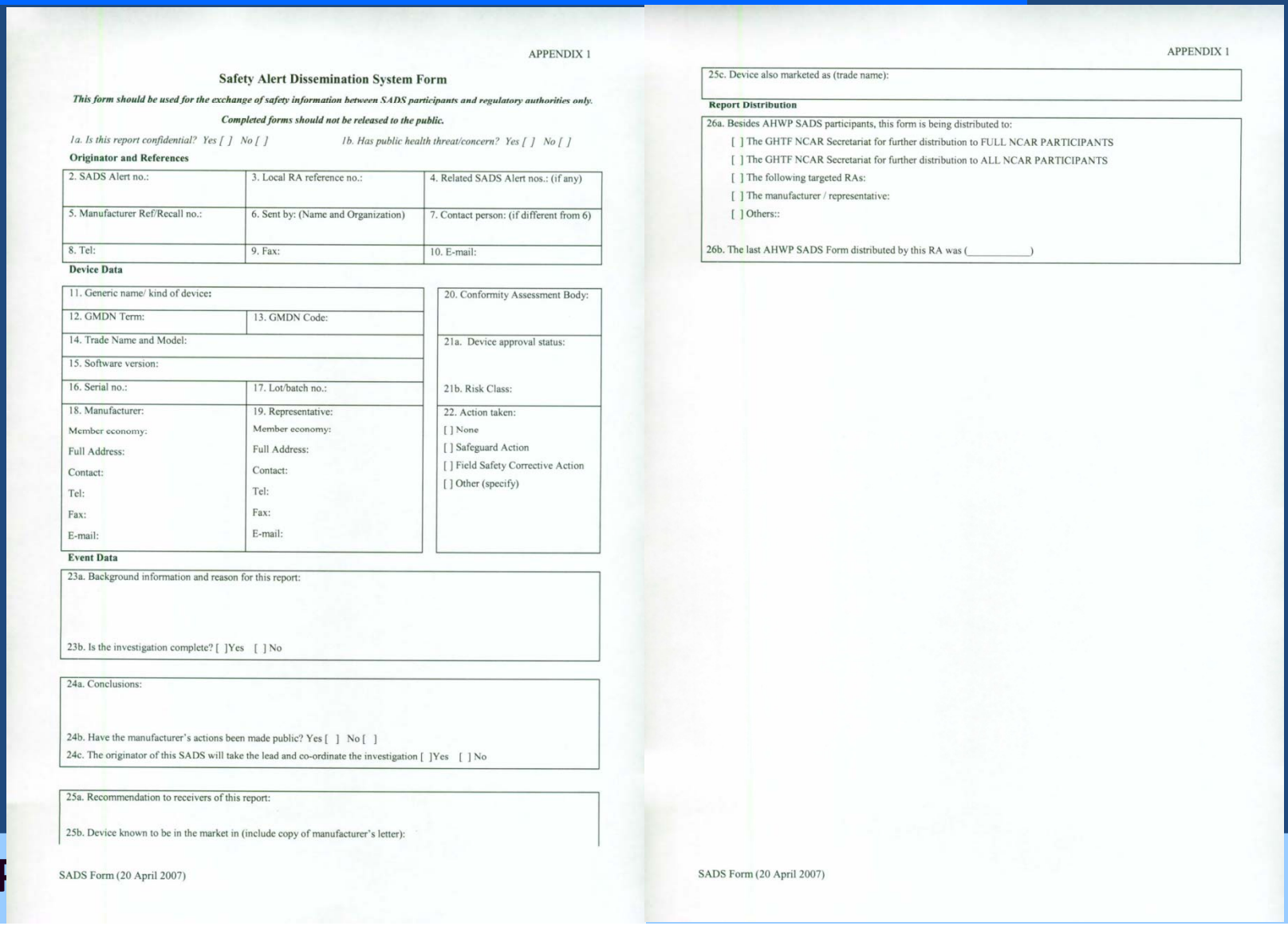
AHWP/WG2/SADS/002: Safety Alert Dissemination System: Dissemination Criteria, Procedures, Form

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.

AHWP/WG2/SADS/002: Safety Alert Dissemination System: Dissemination Criteria, Procedures, Form

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:		21b. Risk Class:
16. Serial no.:	17. Lot/batch no.:	
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):

SADS Form (20 April 2007)

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)

What Next?

- Encourage participation
- Review and fine-tune SADS
- Collaborate with GHTF NCAR Exchange Program to work towards one harmonized system

Thank you for your attention!