FINAL DOCUMENT

Title: Framework for AHWP Safety Alert Dissemination System (SADS)

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Date: 23 January 2008

1. Objectives

The objectives of this document are

(a) To define a structure for disseminating medical device safety alerts among AHWP members;

(b) To define the roles and responsibilities of regulatory authorities in receiving and disseminating safety alerts; and

(c) To define the roles and responsibilities of manufacturers or their representatives in case of safety alerts.

2. Definitions

2.1 Safety Information

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.

2.2 Safety Alert

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.

3. Scope of SADS

In order to avoid flooding of safety information and safety alerts, participants should only disseminate through the SADS serious cases or cases causing serious public health threat or concern. Please refer to the document ***AHWP/WG2/SADS/002- Safety Alert Disseminating System: Safety Alert Dissemination Criteria, Procedures and Form*** for the general guidance on determining when and how a SADS alert should be disseminated.

4. Structure of the SADS

4.1 Regulatory authorities of AHWP member economies could join the SADS as participants in order to share the safety alerts with other regulatory authorities. Participants must nominate a representative and an alternate representative as the contact points of SADS.

4.2 Manufacturers or their representatives could provide support to the SADS by setting up a communication channel with the local regulatory authorities for the exchange of safety information.

4.3 All the information exchanged under SADS shall be in English and communicated through emails.

5. Dissemination Mechanism of SADS

5.1 Regulatory authorities communicate with the medical device manufacturers or their representatives on safety information related to medical devices as part of the post-market surveillance activities. Please refer to ***Fig 1: Communication between regulatory authorities and manufacturers*** appended in Appendix 1.

5.2 When there is any safety alert falls within the scope of SADS, manufacturers should work with the regulatory authority together and provide all the necessary information including a list of the AHWP member economies where the affected product has been distributed.

5.3 The regulatory authority originating the safety alert should disseminate it to all the AHWP SADS participants through emails directly. Please refer to ***Fig 2: Dissemination of Safety Alerts under SADS*** appended in Appendix 2. Unless otherwise specified, the originating regulatory authority would be the co-ordinator of this case and SADS participants may contact the co-ordinator for further information.

5.4 Regulatory authorities should involve the manufacturers or their representatives in the investigation of adverse incidents and resolution of issues and actions. The manufacturers should be consulted before the safety alerts are disseminated.

6. Roles and Responsibilities of Regulatory Authorities

6.1 Regulatory authorities originating a SADS alert should:

- Communicate with the manufacturer or its representative on the latest safety information;
- Confirm that the safety information falls within the scope of SADS;
- Discuss with the manufacturer or its representative about the intended actions and seek their comments on the information to be disseminated;

- Prepare the safety alert in the format specified under the document ***AHWP/WG2/SADS/002 - Safety Alert Disseminating System: Safety Alert Dissemination Criteria, Procedures and Form*** and then disseminate it to all SADS participants through emails;
- Co-ordinate the investigations of the case in conjunction with the manufacturer or its representative if appropriate; and
- Provide further information to other SADS participants regarding the case.

6.2 Regulatory authorities receiving a SADS alert should:

- Limit the circulation of the alert and related safety information, in particular the investigatory ones, to only those who really need to know (e.g. related authorities, affected hospitals and healthcare professionals and the manufacturer's representatives);
- Understand from the manufacturer or its local representative about the distribution of the affected product in the local market and any field safety corrective actions already or planned to be taken;
- Consult the manufacturer or its local representative on intended actions to be taken; and
- Inform the manufacturer or its local representative prior to taking any actions in particular disseminating the safety alert to the public.

7. Roles and Responsibilities of Manufacturers or their Representatives

7.1 Manufacturers should:

- Cooperate with the regulatory authority in conducting investigations on adverse incidents, performing remedial actions and disseminating safety information;
- Develop and implement a procedure for communicating with the regulatory authorities on adverse incidents and safety information;
- Maintain the distribution records of their products in all the AHWP member economies so that remedial actions can be effectively taken when needed; and
- Develop an efficient communication channel among all the offices in different AHWP member economies for ensuring concerted remedial actions together, if appropriate.

8. Joining SADS

8.1 Regulatory authorities of AHWP member economies could apply to join the SADS as participants by nominating a representative and an alternate representative with email addresses for communication purposes. At least one of the representatives should have attended the appropriate training organized by AHWP. Please refer to Appendix 3 for the application form.

8.2 If the applicant has not attended the appropriate training, the Work Group 2 (WG2) Chair will circulate the application to all WG2 members and seek their views. The application will be accepted if not more than 10% of the WG2 members object the application.

8.3 Upon the acceptance of the nomination of representatives, the WG2 Chair will confirm to the applicant and update the list of SADS participants.

8.4 The SADS participants shall immediately inform both the WG2 Chair and Co-chair of any changes in representatives or email addresses so that the list of participants can be updated accordingly.

9. References

9.1 AHWP Paper for Discussion: Formalization of a Post Market Alerts Dissemination Framework among AHWP Member Economies

9.2 GHTF SG2-N79R8:2006 – Medical Devices: Post Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form

9.3 GHTF SG2-N38R15:2005 - Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program

9.4 GHTF/SG2/N9R11:2003 – Global Medical Devices Competent Authority Report

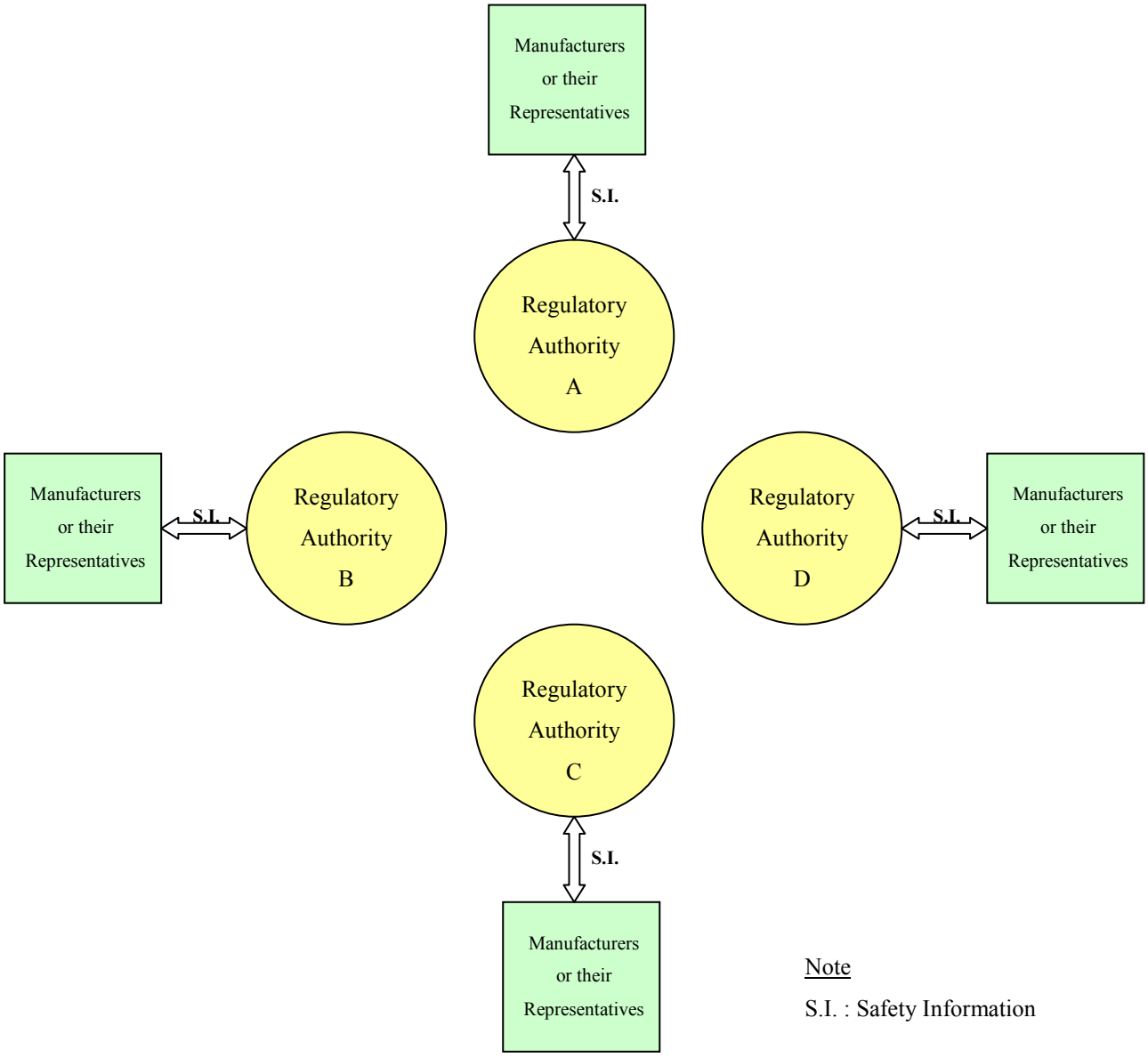
9.5 GHTF/SG2/N20R10:2002 – Medical Devices: Post Market Surveillance: National Competent Authority Report Exchange Criteria

9.6 GHTF-SG2-N8R4 - Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices

Appendix 1

Fig 1: Communication between Regulatory Authorities and Manufacturers

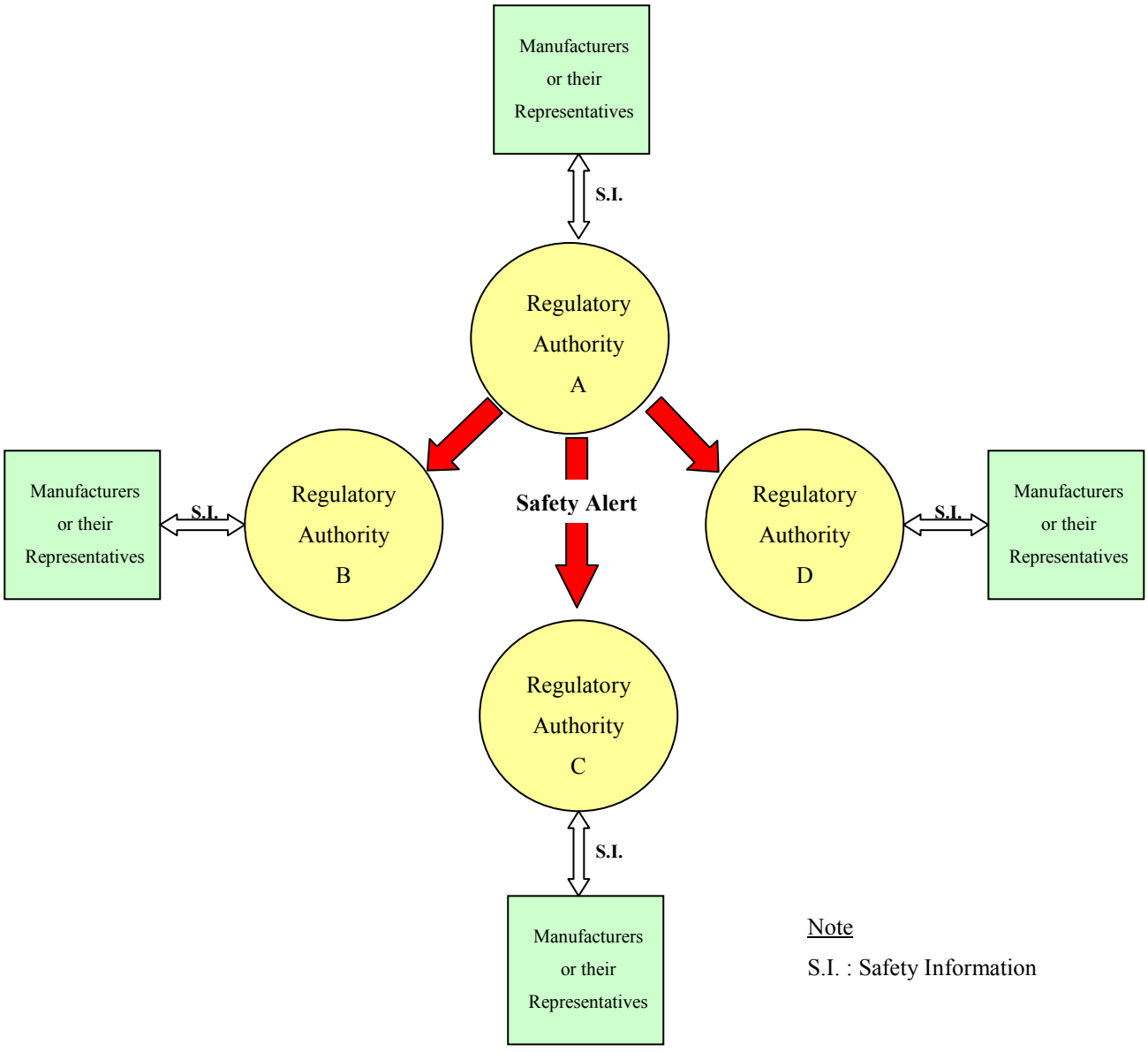
Regulatory Authorities communicate with the medical device manufacturers or their representatives on safety information related to medical devices as part of the post-market surveillance activities.



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.



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

Being 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 _____.

☐ we have not attended any related AHWP training.

We hereby agree to observe and comply with all the requirements of the AHWP Safety Alert Dissemination System and propose to use _____ (a 2-letter code) for numbering the safety alerts to be originated by us.

Signature: _____

Name: _____

Post: _____

Organization: _____

Economy: _____

Email Address: _____

Address: _____