Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

PROPOSED FINAL DOCUMENT

Title: Medical Device Adverse Event (AE) Report Form

Authoring Group: Working Group 2, Post-Market Surveillance and Vigilance

Date: November 1st, 2012

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Chair, Working Group 2

Reset the form

AR Report Ref

Report No. (Official Use Only)

Medical Device Adverse Event (AE) Report Form

For use by Authorised Representatives (AR) to report events that have taken place in:

_____

I. ADMINISTRATIVE INFORMATION

1. Report Type (select one):

☐ Initial ☐ Follow-up ☐ Final ☐ Trend

2. Classification of Event:

☐ Serious Public Health Concern ☐ Death

☐ Serious Injury ☐ Minor injury

☐ Other Reportable Event

3. Date of this report (dd-mmm-yyyy)	
4. Date of adverse event (dd-mmm-yyyy)	
5. AR awareness date (dd-mmm-yyyy)	
6. Expected date of next report (dd-mmm-yyyy)	

Particulars of the AR Submitting this Report:

7. Name	
8. Company	
9. Address	
10. Mobile Phone No	
11. Fax	
12. E-mail	

13. Other Regulatory Authorities to which this report was also sent

II. CLINICAL EVENT INFORMATION

1. Event Description:

2. No. of affected people involved		3. No. of devices involved	

III. HEALTHCARE FACILITY INFORMATION (OPTIONAL)

1. Name of the Facility			
2. Name of Contact Person			
3. Facility Report No.			
4. Address			
5. Phone		6. Fax	
7. E-mail			

IV. DEVICE INFORMATION

Device Information

1. Device Name	
2. Product License No.	
3. Product Registration No.	
4. Nomenclature System	AMDNS / UMDNS Code
	GMDN Code
5. Catalogue No.	
6. Serial No.	
7. Lot / Batch No.	

Legal Manufacturer Information

8. Name			
9. Contact Person			
10. Address			
11. Phone		12. Fax	
13. E-mail			

14. Operator of device at the time of the event

☐ Healthcare Professional ☐ Patient ☐ Other ☐ None

15. Usage of Device

☐ Initial Use ☐ Reuse of Single-Use Device

☐ Reuse of Reusable Device ☐ Refurbished

☐ Other, please specify:

16. Device Disposition / Current Location:

V. RESULT OF MANUFACTURER S INVESTIGATION

1. Manufacturer's Device Analysis Results:

2. Remedial Action / Corrective Action / Preventive Action:

VI. INFORMATION OF PATIENT (OPTIONAL)

1. Age at time of event (months, years)			
2. Gender (M/F)		3. Weight (kg)	

4. List of devices involved with the patient (see Section IV):

5. Corrective action taken relevant to the care of the patient:

6. Patient outcome:

VII. OTHER REPORTING INFORMATION (OPTIONAL)

Any events with this device with the same root cause?

☐ Yes, please specify the rate: _____ ☐ No

VIII. COMMENTS

IX. SUBMISSION OF REPORT

By Mail:

By Fax: ( ) By e-mail:

X. DISCLAIMER

Submission of this report does not constitute an admission of manufacturer, AR, user, or patient liability for the event and its consequences. It does not, in itself, represent a conclusion by the AR that the content of this report is complete or confirmed, that the device(s) listed failed in any manner. It is also not a conclusion that the device(s) caused or contributed to the adverse event.

GUIDANCE FOR FILLING IN THE ADVERSE EVENT REPORT FORM

GENERAL

All fields must be completed with appropriate information or "NA" if not applicable to the event or "unknown" when the data is not available.

"AR Report No." on the top right hand corner of the first page is the unique number assigned by the AR to identify the report in the AR's internal system.

Reasonable effort must be made to address all elements. However, failure or inability to do so is not justification for failing to submit a report within the establishment timeframes.

All AHWP documents referred to in this guidance are available at the AHWP homepage: http://www.ahwp.info/

I. ADMINISTRATIVE INFORMATION

1. Report Type

Initial: defined as the first information submitted by the AR about a reportable event, but the information is incomplete and supplementary information will need to be submitted. This includes immediate submission.

Follow-up: defined as a report that provides supplemental information about a reportable event that was not previously available.

Final: defined as the last report that the AR expects to submit about the reportable event. A final report may also be the first report.

Trend: defined as information supplied as a result of significant increase in the rate of (i) reportable events, (ii) non-reportable adverse events, or (iii) adverse events scheduled for periodic reporting. Please refer to the related AHWP guidance document(s).

2. Classification of Event

Adverse events that resulted in (i) serious public health concern shall be reported *within 48 hours*, (ii) death, (iii) serious injury shall be reported as soon as possible, but not later than *10 elapsed calendar days* following the awareness of the event.

All other reportable events shall be reported as soon as possible, but not later than *30 elapsed calendar days* following the awareness of the event.

Please note that the following use errors are reportable events

a. Use errors that result in death or serious injury or serious public health concern;
b. When the AR or manufacturer notes a change in trend or a change in pattern of an issue that can potentially lead to death or serious injury or public health concern;
c. When the AR or manufacturer initiates corrective action to prevent death or serious injury or serious public health concern.

Other use errors that do not result in death or serious injury or serious public health concern need not be reported.

For details on reportable and non-reportable events, please refer to the related guidance notes.

3 – 6. Date of this report, date of adverse event, AR awareness date, and expected date of next report

All dates must be formatted as follows: 2 digit day, 3 letter month, 4 digit year, e.g. 01-JAN-2001

Expected date of next report: the date when further information will be provided. This should be "NA" for final report.

7 – 12. Particulars of the AR Submitting this Report

Please fill in the contact details of the AE's reporter.

13. Other Regulatory Authorities to which this report was also sent

Please identify to what other regulatory authorities, such as the FDA (US), MHRA (UK), this report was also sent.

II. CLINICAL EVENT INFORMATION

1. Event Description

Clarification or relevant information that might impact the understanding or evaluation of the adverse event AND that is not included elsewhere in the report. E.g. "the patient was confused prior to becoming trapped in the bedsides", "the patient was a very low birth weight premature delivery and had a central line placed three days before onset of cardiac tamponade", "the X-ray machine was over 20 years old and had been poorly maintained at the time of the adverse event", etc.

2. No. of affected people

Please include any affected individual, e.g. user, patient, or third party.

3. No of devices

Please state the number of devices involved in this event.

III HEALTHCARE FACILITY INFORMATION

Please provide information about the place of the event. It could include home care, transport or emergency care site. Information in this section is optional.

IV. DEVICE INFORMATION

1-13. Device information:

Please provide information on the device involved. Please repeat this section for each device in separate sheets.

14. Operator of device at the time of the event

Please indicate the type of operator of the device at the time of the event. “None” means that the problem is noted prior to use.

15. Usage of Device

Please indicate the usage of the device involved

16. Device Disposition / Current Location:

Please provide information on whether and in what state the device is at the time of the report, e.g. “the device has been destroyed”, “the device remains implanted in patient”, “the device was returned to the manufacturer”, “the device remains under investigation”, etc.

V. RESULTS OF MANUFACTURER S INVESTIGATION

1. Manufacturer’s Device Analysis Results:

Specify, for this event, details of investigation methods, results and conclusions.

Alternatively, manufacturer’s device analysis report may be submitted

2. Remedial Action / Corrective Action / Preventive Action

Specify if action was taken by manufacturer and/or AR for the reported specific event or for all similar types of products. Include what action was taken by the manufacturer and/or AR to prevent recurrence. Clarify the timeframes for completion of various action plans.

VI. INFORMATION OF PATIENT (OPTIONAL)

Please provide individual patient information (including information of any affected individual, e.g. user, patient, or third party) for each element as appropriate. Please repeat this section for each patient involved in separate sheets. Please note that in some cases, the patient’s age, gender and weight might be irrelevant. In some cases, they are essential, e.g. the age and weight of the patient in regard to some implants. Some events are caused by the combined action of two or more devices, medical or non-medical. Please provide a brief list of devices involved.

Information in this section is **optional**.

VII. OTHER REPORTING INFORMATION (OPTIONAL)

If the manufacturer or the AR is aware of similar events with this device with the same root cause, please provide the number of such events. The number should be specified in terms of event per unit sold, or the number of event per unit sold / in use in a region, etc. Information in this section is optional, and is applicable for **final reports** only.

VIII. COMMENTS

Please provide any additional details that are relevant and not requested elsewhere in this report.