Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

PROPOSED FINAL DOCUMENT

Title: Adverse Event Reporting Timelines Guidance for Medical Device Manufacturer and its Authorised Representative

Authoring Group: Working Group 4: Post-Market

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1. Objectives

This document was developed by Work Group 4 of AHWP to provide guidance and information to Regulatory Authorities (RAs) and the Medical Device Industry (Industry) on the AE reporting timelines.

Work Group 2 acknowledged that different jurisdictions have their own adverse event (AE) reporting timeframe, due to differences in regulatory environment, where the current reporting timeframe ranges from 2 days to 30 days, depending on the nature and local regulatory requirements of the reportable event. Therefore, this document only represents the most reasonable compromise that has been produced to date.

This document should be read together with the following AHWP guidance documents

(i) Medical Device Adverse Event (AE) Report Form (AHWP/WG2/F001:2012)

(ii) Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorised Representative (AHWP/WG2/F001:2013)

2. Definitions

2.1 **Authorised Representative (AR)** means any natural or legal person[1] established within a country or jurisdiction who has received a written mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's obligations under that country or jurisdiction's legislation.

2.2 **Manufacturer (or legal manufacturer or known as *"product owner"* in some countries)** means any natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s).

2.3 **Immediately**, for the purpose of AE reporting, means as soon as possible but not later than 10 elapsed calendar days following the date of awareness of the event.

2.4 **Serious injury (also known as "*serious deterioration in state of health*")** means either

(i) Life threatening illness or injury; or

(ii) Permanent impairment of body function or permanent damage to a body

[1] The term "person" includes legal entities such as a corporation, a partnership or an association.

structure; or

(iii) A condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.

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

2.6 **Unanticipated death or unanticipated serious injury** means a death or serious injury is considered unanticipated if the condition leading to the event was not considered in a risk analysis performed during the design and development phase of the device. There must be documented evidence in the design file that such analysis was used to reduce the risk to an acceptable level.

3. Timing for Reporting

3.1 Upon becoming aware that an event has occurred and is associated with one of its devices, the medical device manufacturer or the AR must determine whether it is an adverse event.

3.2 Adverse events that represent a serious public health threat shall be reported within 48 hours, following the date of awareness of the event by the manufacturer or its AR to the relevant regulatory authority(ies).

3.3 Adverse events that result in unanticipated death or unanticipated serious injury must be reported immediately, following the date of awareness of the event by the manufacturer or its AR to the relevant regulatory authority(ies).

3.4 All other reportable events must be reported as soon as possible by the manufacturer or its AR, but not later than 30-elapsed calendar days following the date of awareness of the event.

3.5 If after becoming aware of a potentially reportable adverse event, there is still uncertainty about whether the event is reportable, the manufacturer or its AR must submit a report within the timeframe required for that type of event.

3.6 All reporting timeframes refer to when the relevant regulatory authority(ies)[2] must

[2] In some countries, the regulatory authority may require the manufacturers or ARs to report adverse events of registered devices occur in a foreign country.

be first notified. This notification may be in the form of

(i) ***Initial report***, which is defined as the first information submitted by the manufacturer or its AR about a reportable event. Any information which is not available upon submission of the initial report or differs from information submitted on the initial report will need to be submitted in the type of documentation to the RA as soon as the information is available OR within the timeframe specified by the RA. The types of documentation include safety notification, follow-up report and final report.

(ii) ***Final report,*** which is defined as the last report that the manufacturer or its AR expects to submit about the reportable event. A final report may also be the first report if the information is complete; or

(iii) ***Trend report***, which is defined as information supplied as a result of trending upon request of the relevant regulatory authority(ies).

The choice of report types depends on whether all the applicable data specified in the Medical Device Adverse Event (AE) Report Form (AHW/WG2/F001:2012) and/or local regulatory requirements is available within the appropriate report time. If addition information is required, the manufacturer or its AR should provide a follow-up[3] or final report as soon as the information is available OR as requested by the relevant regulatory authority(ies), e.g. within the timeframe indicated for such report on the Medical Device Adverse Event (AE) Report Form by the regulatory authority.

4. References

4.1 Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorised Representative (AHWP/WG2/F001:2013)

4.2 Medical Device Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices (GHTF/SG2/N54R8:2006)

[3] Follow-up report is defined as a report that provides supplementary information about a reportable event that was not previously available.