GHTF

FINAL DOCUMENT

Title: Medical Device Postmarket Vigilance and Surveillance: Timing of Adverse Event Reports

Authoring Group: Study Group 2

Endorsed by: The Global Harmonization Task Force

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The document herein was produced by the Global Harmonization Task Force, a voluntary group of representatives from medical device regulatory agencies and the regulated industry. The document is intended to provide *non-binding* guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development.

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Preface

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1.0 Introduction

It is acknowledged in the issuance of this guidance that various national jurisdictions have current adverse event report timing requirements that differ from the recommendations contained herein. Consequently, establishment of harmonized reporting times has been controversial within Study Group 2 and the wording in this document represents the most reasonable compromise that has been produced to date. Due to differences in laws and regulations in different regions it may not be possible to harmonize all these current differences without changes that are beyond the authority of the National Competent Authorities to implement administratively. However, it is the view of GHTF Study Group 2 that issuing this guidance will nevertheless serve as a useful model in the development of adverse event reporting requirements in national jurisdictions that currently do not have a reporting system. This guidance is also considered a model for future change of existing reporting systems as they continue to evolve.

An examination of adverse event report timing requirements in Europe, USA, Canada, Australia, and Japan reveals a diversity of requirements ranging from 2 days to 30 days depending on the nature of the reportable event.

Study Group 2 has examined data provided by member manufacturers to determine the amount of time involved to conduct an investigation of adverse events for different types of devices. There was a wide spread in the distribution of investigation times. The median investigation time required for diagnostic imaging devices was approximately two weeks (15 days) and even longer for several other types of devices. More than 50 % of device events required more than two weeks to complete an investigation of the event. Thus, it is concluded that reporting of adverse events within the first two weeks is likely to be based on an incomplete investigation and may require a subsequent follow-up report as well.

This conclusion is consistent with the experience at FDA where reporting requirements have been in effect the longest. FDA has received a large number of follow-up reports and subsequently changed the reporting timing from 5 days (death & serious injury) and 15 days (malfunction) to 30 days for most reports. While it is desirable that adverse event reports be timely, it is also desirable that the information be accurate.

2.0 Scope

The Global Harmonization Task Force (GHTF) Study Group 2 (SG2) has developed a regulatory guidance document for manufacturers regarding adverse event reporting. This guidance is referenced as SG2 N21R8. It includes guidance for the regulatory authorities about reporting of adverse events that result in death or serious injury or certain types of near incidents. It does not stipulate timeframes for submitting adverse event reports. It is therefore proposed that a statement of reporting timing is included in SG2 N21R8 and it include the wording recommended in this guidance.

3.0 References

Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative, GHTF SG2 N21R8

4.0 Definitions

Immediately:

For purposes of adverse event reporting, immediately means as soon as possible, but not later than 10 elapsed calendar days following the date of awareness of the event.

Serious public heath threat:

Any event type, which results in imminent risk of death, serious injury, or serious illness that may require prompt remedial action.

Unanticipated:

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.

5.0 Report Times

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

Adverse events that result in unanticipated death or unanticipated serious injury or represent a serious public health threat must be reported immediately by the manufacturer.

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

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

All report times refer to when the NCA must first be notified. This notification may be in the form of an initial report, final report or trend report as defined in GHTF N32, "Manufacturer Universal Data Set". The choice of report type depends on whether all the applicable data specified in N32 is available within the appropriate report time. If additional information is required, the manufacturer should provide a follow-up or final report as soon as the information is available or as requested by the NCA.