



FINAL DOCUMENT
Global Harmonization Task Force

Title: Medical Devices: Post Market Surveillance:
National Competent Authority Report Exchange Criteria

Authoring Group: Study Group 2

Date: 21 May 2002

A handwritten signature in black ink, which appears to read 'Rita Mac lachlan'.

Rita Mac lachlan, GHTF Chair

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.

There are no restrictions on the reproduction, distribution or use of this document; however, incorporation of this document, in part or in whole, into any other document, or its translation into languages other than English, does not convey or represent an endorsement of any kind by the Global Harmonization Task Force.

Copyright © 2002 by the Global Harmonization Task Force

Preface

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.

There are no restrictions on the reproduction, distribution or use of this document; however, incorporation of this document, in part or in whole, into any other document, or its translation into languages other than English, does not convey or represent an endorsement of any kind by the Global Harmonization Task Force.

Table of Contents

1.0 Introduction.....	4
2.0 Scope.....	4
3.0 Reporting Guidance.....	4
4.0 Report Exchange Method	4

1.0 Introduction

This document was developed by Study Group 2, GHTF, to provide guidance and procedures for the exchange of reports concerning medical devices between National Competent Authorities (NCA).

2.0 Scope

This document should be used to determine when to exchange information with other national competent authorities. It provides suggested criteria that can be used to make this decision. Countries participating in the exchange of GHTF National Competent Authority Reports (NCAR) are encouraged to use this guidance and follow the procedure outlined. Requirements for participating in the GHTF National Competent Authority Report exchange programme are contained in a supplementary document N38. SG 2 document N8 provides general guidance on the public release of information. SG2 N9 is the report format for the exchange of information between NCA's.

In this document, “recall” is when there is a significant risk of death or serious injury resulting in:

- the return of a medical device to the manufacturer or its representative;
- modification to device, labeling or recommendations on clinical management by the manufacturer or its representative;
- the exchange of the device;
- the destruction of the device;

in accordance with the instructions contained in an advisory notice.

3.0 Reporting Guidance

Figure 1 (Appendix A) should be used to determine the route for information exchange between NCAs. At this time, no information is being exchanged under the “Passive Exchange”. “Passive Exchange” is a concept for a future database available to exchange participants to view at their discretion, whereas the e-mail is an active exchange and the current means for exchanging high risk issues.

- a) If the investigation is complete, and a decision has been made by the NCA or manufacturer that action is required, then the NCA should consult the following ten criteria to determine the degree of public health threat or concern related to the issue. The public health threat or concern should be categorized as either High and sent to the immediate attention of the other NCA's, or Low and added to the passive exchange database.

- Seriousness
- Unexpectedness of the incident/event
- Population Vulnerable (pediatric/elderly)
- Preventability (can useful recommendations be made?)
- Public Concern / Outrage (ex: lead aprons containing radioactive material)
- Benefit/Risk - State of the art? Alternatives?
- Lack of Scientific Data (especially long term effects)
- Repeated device problems that re-surface (ex: heating pads, O.R. fires)
- Class I recall or equivalent
- Written notifications by the NCA to the public (hospitals, physicians, etc.)

Competent Authorities should involve the manufacturer in the investigation of incidents and resolution of issues or actions and consult with the manufacturer before sending out notices to other NCA's. 'Seriousness' should be linked with many of the other criteria. For example, an unexpected but non-serious event is unlikely to be exchanged.

- b) If the investigation is not complete but a decision has been made to take action or action is likely, the public health threat or concern must be assessed and if high, a report should be sent. If such reports are exchanged, questions to the manufacturer should be directed to the lead NCA whenever possible.
- c) If the Investigation is complete and no action is required, then the report should not be exchanged.

4.0 Report Exchange Method

- 1) The Competent Authority Reporting Form (N9) should be used. Comments may be added to the report to maintain its confidentiality or to prevent public disclosure. For example, "Still under investigation, do not disclose through access to information", or "Do not release to public". Also, send electronically any background information such as a "Dear Doctor" letter or company letter.
- 2) Send forms to mdv@hc-sc.gc.ca. (Canada). A note indicating receipt of the form will be returned to the sender.
- 3) In order to minimize the risk of confusion, Canada, on behalf of GHTF, will review the form for completeness, the correct sequential references and track the reports. Content is not edited. The form will then be forwarded by e-mail to countries participating in the exchange (see note).
- 4) In rare circumstances, such as when there are time critical issues of significant public health threat or concern, NCA's may send reports directly to countries participating in the exchange. In such circumstances, the issuing NCA should ensure that the form is completed fully and contains the correct sequential reference, preferably by contacting MDV Canada.

- 5) The lead NCA is the originator of the report unless the report says otherwise. The manufacturer must be notified of the intention to exchange information internationally.
- 6) Countries can contact the source country of the report for more information if they wish. This should be the first point of contact for incidents “still under investigation”.

Note: This reporting procedure provides a centralized GHTF facility enabling NCAs participating in GHTF to check that they have received all forms sent for exchange. In the longer term this role may be transferred to the GHTF Secretariat and the form references posted on the GHTF website.

\\P012100L\share\CO\TGA\TDB\GHTF\SG2\N20R10.final.doc

APPENDIX A

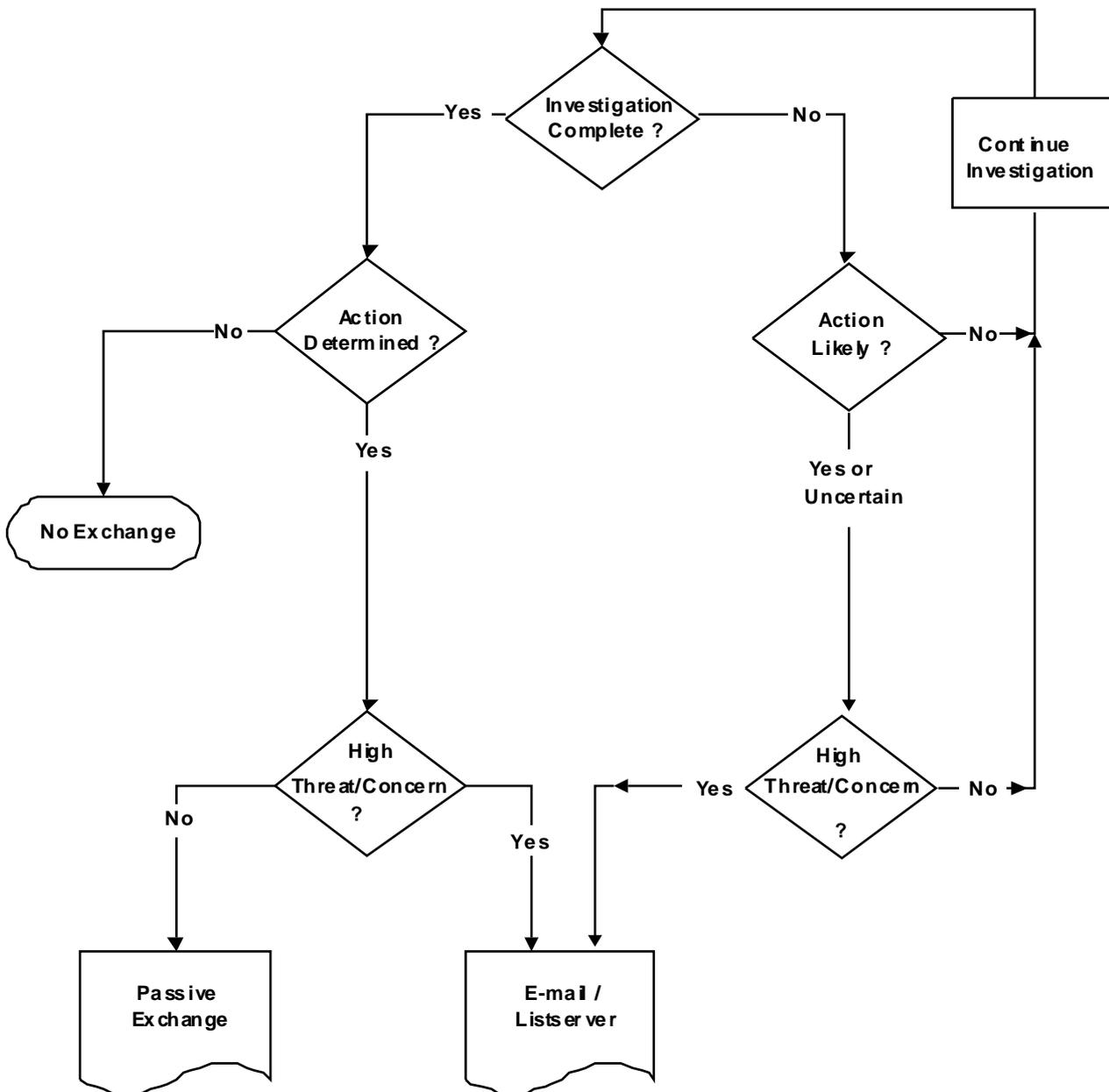


Figure 1 - Competent Authority Reporting Flowchart