Glia
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London, ON

Complaint Handling Protocol

1.0 Introduction

Glia's **Complaint Handling Protocol** is informed by Health Canada's **Medical Device Regulations (SOR/98-282)**[1], and follows the requirements for complaint handling outlined in Sections 57 and 58a.

2.0 Complaint Handling Protocol

As per **Section 57**:

(1) The manufacturer, importer and distributor of a medical device shall each maintain records of the following:

(a) reported problems relating to the performance characteristics or safety of the device, including any consumer complaints, received by the manufacturer, importer or distributor after the device was first sold in Canada: and

(b) all actions taken by the manufacturer, importer or distributor in response to the problems referred to in paragraph (a).

Glia is a manufacturer and distributor of medical devices, and thus creates and maintains complaints records reported on any of its manufactured medical devices. This includes items that are sold, donated, or given away for the purposes of use, research, and/or demonstration.
Glia retains its distribution records in a secure, password protected computer located at Glia's headquarters.

As per **Section 58(a)**:

(a) The manufacturer, importer and distributor of a medical device shall each establish and implement documented procedures that will enable the manufacturer, importer or distributor to carry out an effective and timely investigation of the problems referred to in paragraph 57(1)(a)

As per Health Canada guidelines, in the event of a complaint, Glia's complaint handling protocol will be followed as outlined in Appendix A of this document. All complaints will be handled in a timely way to ensure quick resolution of any complaints.

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1. Health Canada: Medical Devices Regulations (SOR/98-282). (2011). Retrieved from: http://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/page-12.html#h-40

The time to resolution of complaints will be handled according to a risk assessment by the primary receiving officer as indicated in Appendix A and following guidance in GUI 65-6.4.4, *Risk-based time constraints*.

3.0 Document References

Health Canada: Medical Devices Regulations (SOR/98-282). (2011). Retrieved from: http://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/page-12.html#h-40

Health Canada: Guidance on Investigation of Reported Medical Device Problems (GUI-0065). (2011). Retrieved from: https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/problem-reporting/guidance-investigation-reported-medical-device-problems-0065.html

Appendix A: Procedure for handling complaint

1. Complaints may be received by any methods, including but not limited to email, personal interactions, social media or others. Standardize complaint by entering it into the complaint record.

2. Decide complaint completion timeline depending on risk analysis:

a. Is device currently resulting in death, disease or injury to users or patients? If so, contact Dr. Tarek Loubani immediately (target within 8 hours) of receiving complaint to initiate immediate response.

b. Does the device have a flaw that may result in death, disease or injury to users or patients? If so, contact Dr. Tarek Loubani within 24 hours of receiving complaint for further risk assessment and investigation.

c. Does the device have an issue that may result in mild or moderate harm to users or patients that does not threaten life or serious injury? If so, proceed with complaint entry and refer to Glia Medical Officer within 24 hours.

d. Does the device have a usability or comfort-related issue? If so, proceed with complaint error and refer to Glia Medical Officer within 72 hours.

3. Once relevant medical officer receives complaint, severity reassessment should occur.

4. The complaint should be investigated by collecting the device (or photos if not available), further information and any collateral history.

5. Does the device meet the standard for mandatory reporting to Health Canada? If so, initiate reporting process.

6. Does the complaint warrant a recall of the device or other devices? If so, initiate recall process

7. Communicate findings to complainant and complete record of complaint with findings.