

# Annual Report to the Minister

**To:** Canada Vigilance Program  
Marketed Health Products Safety and Effectiveness Information Bureau  
Marketed Health Products Directorate  
Health Products and Food Branch  
Health Canada  
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**From:** **Name of Investigating Facility:** \_\_\_\_\_

*[Subject to Blood Regulations section 116, at the end of each year, an establishment must prepare an annual report that summarizes all of the final reports that it filed in the year, including a concise critical analysis of the investigations that were the subjects of those reports, and must file it with the Minister on request.]*

*[Document as applicable:]*

**Executive Summary:**

*[Report summary]*

**Relationship of Adverse Reactions to the Transfused Blood:**

*[As applicable, the relationship the reaction(s) to the transfused blood]*

**Analysis and Assessment of New Safety Signals:**

*[New safety signals based on the year's reports]*

**Summary Analysis of Adverse Reactions:**

*[The summary of the reporting year]*

**Cumulative Year over Year Trend Analysis:**

*[Review of adverse reactions over time]*

**Lookback and Traceback Summary and Statistics:**

*[As applicable]*

**Conclusions and Opportunities for Improvement:**

*[Report conclusions]*

**Attachment: Establishment Annual Hemovigilance report**

<b>Report Prepared By:</b>	<b>Date:</b>
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