

# INSTITUTE FOR SAFE MEDICATION PRACTICES CANADA

## PRIVACY IMPACT ASSESSMENT (PIA) ON ANALYZE-ERR<sup>TM</sup> AND CURRENT DATA HANDLING OPERATIONS

**VERSION 3.0-2** 

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ISMP Canada

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#### History of this privacy impact assessment

This document is Version 3 of a privacy impact assessment (PIA) on Analyze-ERR™ and the information systems of ISMP Canada.

Version 1 of this PIA was developed in 2004 in conjunction with:

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and reviewed by:

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Version 1 was a lengthy and technical document intended to provide ISMP Canada with an in-house reference tool relevant to privacy, confidentiality and security of information in its custody.

Version 2 was an in-house, concise, reader-friendly edition of Version 1, with updates current to July 2005.

Versions 1 and 2 included recommendations made by the PIA consultants. ISMP Canada is currently working to examine and implement these recommendations so as to facilitate future updates to this PIA and ongoing upgrades to its privacy practices

Version 3 is being made available to the public as a demonstration of the integrity of ISMP Canada's information handling practices. Further information may be obtained from ISMP Canada's Chief Privacy Officer.

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## 1 Institute for Safe Medication Practices Canada (ISMP Canada): Introduction and Overview

The Institute for Safe Medication Practices Canada (ISMP Canada) understands the importance of respecting privacy by keeping health information in its care safe and confidential. To this end, ISMP Canada has undertaken to complete a privacy impact assessment (PIA) on its information systems, operations and processes to ensure that its data collection, use and disclosure activities meet current best practices.

ISMP Canada is an independent, non-profit, federally incorporated organization established for the collection and analysis of medication error reports and the development of recommendations for the enhancement of patient safety. ISMP Canada intends to serve as a national resource for promoting safe medication practices throughout the healthcare community in Canada.

ISMP Canada is dedicated to enhancing the safety of medication use through improvements in prescribing, distribution (including naming, packaging, labeling), dispensing, administration and monitoring. ISMP Canada works collaboratively with healthcare practitioners and institutions, schools and universities, professional organizations, pharmaceutical manufacturers, and regulatory and government agencies to provide education about adverse drug events and their prevention.

Identification of different factors contributing to medication error incidents, as well as safeguards and best practices for preventing them, are shared with the healthcare community through ISMP Canada's Medication Safety Bulletins.

#### 2 DESCRIPTION OF ISMP CANADA

#### 2.1 ISMP Canada Values

The values of ISMP Canada are:

- To provide a quality, high integrity, reliable system for reporting medication errors in healthcare settings.
- To enable practitioners to share information about system safeguards implemented as a result of learning from medication errors.
- To maintain and protect the confidentiality of individuals and organizations reporting medication errors.
- To empower healthcare providers, through knowledge and training, to enable them
  to prevent medication errors in their own organizations, minimize the impact of
  unavoidable errors and enhance patient safety.
- To lead research into the causes and prevention of medication errors (prevention of harm from errors) in healthcare settings.
- To ensure that funding of ISMP Canada is free of conflict of interest and preserves its non-profit, independent status.

#### 2.2 Goals and Objectives

In keeping with its corporate mandate, the goals and objectives of ISMP Canada are:

- To review medication errors submitted by practitioners to ISMP Canada and to make recommendations to reduce the probability that such errors will happen again.
- To publish and disseminate information to the health care community and practitioners through efficient electronic means in order to promote safe medication use and strategies for reduction of error-induced injury in Canada.
- To participate in co-operative programs with professional organizations in Canada in providing education about adverse drug events and their prevention.
- To act as consultants to institutions and other health care settings on safe medication use.
- To develop educational and quality improvement assessment tools for healthcare practitioners and institutions.
- To establish and maintain a strong partnership with the Institute for Safe Medication Practices (ISMP) in the US, and the other national and provincial patient safety initiatives.
- To provide educational programs for university and health professional constituents.

#### 2.3 Current and Intended Scope

Since 2000, ISMP Canada has received reports from health care practitioners and health service organizations describing medication errors that resulted in patient harms and nearmiss incidents and had potential to cause patient harm. The collection of this data enables ISMP Canada to investigate and analyze contributing factors and underlying causes of many of the medication error reports.

ISMP Canada is working in cooperation with Health Canada, the Canadian Institute for Health Information and other stakeholders to develop and implement the Canadian Medication Incident Reporting and Prevention System (CMIRPS), a national medication incident reporting and prevention system to assist health professionals, health organizations community-based pharmacies and governments to recognize potential problems before they occur and implement appropriate preventative strategies.

The data elements currently collected are sufficient and appropriate in scope for ISMP Canada's goals and objectives. The list of data elements were developed and evaluated on a trial basis and created in collaboration with interdisciplinary stakeholders.

#### 3 DATA COLLECTION

In accordance with its goals and objectives, ISMP Canada collects information about medication errors (also referred to as medication error incidents) from institutional and individual reporters. The focus of any one report is on the error itself and reports do not contain patient identifiers. Submission of incident reports by reporters is entirely voluntary.

#### 3.1 Categories of Reporting

Reports may be made using any one of three different categories of transmission:

- Analyze-ERR™ software system
- Web-based incident reporting
- Other mechanisms

#### 3.1.1 Analyze-ERR™ Reporting

Analyze-ERR™ is a PC based software tool developed to allow institutional reporters to streamline their medication incident reporting and analysis processes. In addition to providing an in-house tracking mechanism for medication errors, the software provides some analysis functionality and the optional ability to transmit de-identified data to ISMP Canada for aggregate analysis and reporting.

Analyze-ERR™ limits the scope of data elements that may be transmitted. ISMP Canada encourages reporters who submit medication error reports via other means to limit the data elements submitted to those using Analyze-ERR™.

The Analyze-ERR™ software allows a reporter to submit de-identified incident reports to ISMP Canada. Analyze-ERR™ transmissions contain no patient identifiers and are encrypted and protected during transmission to ISMP Canada.

In addition to providing institutional reporters with a mechanism for transmitting reports to ISMP Canada, Analyze-ERR™ provides these reporters with two other useful functions:

- Analyze-ERR™ Web-Based Query—Institutional reporters may use the web based Analyze-ERR™ to submit a query to ISMP Canada and compare its own incidents against aggregate data. Information about an incident is encrypted. Usernames and passwords are configured by the institutions themselves. The reports do not contain any patient identifiers or institution identifiers, consistent with ISMP Canada' practice of not storing patient or institution identifiers in the ISMP Canada Web Server.
- Medication Safety Self-Assessment (MSSA)—An institutional reporter may also perform an objective evaluation of its level of medication safety using the Medication Safety Self-Assessment. Completion of a questionnaire and reporting of an institution's results against the aggregate results takes place over a secure Web transmission. However, no patient information or institutional identifiers are submitted or reported by this assessment. Rather, these reports contain only general information, such as type of institution or size of institution.

#### 3.1.2 Web Incident Reporting

Individual reporters can interact with ISMP Canada via its Web site. The individual reporter may enter incident information into a reporting screen. The error report is then securely transmitted to ISMP Canada via the secure sockets layer protocol (an encrypted internet protocol.)

All activities take place in a secure Web environment. Information collected through the web incident reporting form is encrypted and protected during transmission to ISMP Canada.

The information collected on the Web incident reporting form contains no patient identifiers. For example, the form does not include provision for collecting patient names, addresses, telephone numbers, OHIP number, patient number, or any other information that could be used on its own to directly identify individual patients.

#### 3.1.3 Other Incident Reporting Channels

Medication error incidents may also be reported to ISMP Canada by other channels. These channels include telephone, fax, email, Canada Post regular mail and in person.

The information collected is stored securely either in hard copy format (for instance, a hard copy report, letter or fax), or in an electronic format (on the ISMP Canada Server.)

The information maintained is identical to the information contained in the Analyze-ERR™ software transmission. This stored information does not contain any personal identifiers of patients who were the subjects of medication errors.

Reporters may include their contact information in order to communicate further with ISMP Canada staff about the report.

The ISMP Canada staff member who receives the report is responsible for ensuring that any personal or institutional identifiers that are submitted in error are not retained.

## 3.2 Authorities for the Collection, Use, Retention & Disclosure Of Information

The collection of medication incident information is supported by and consistent with:

- The letters patent issued to ISMP Canada on the 14th day of July 2000 under the Canada Corporations Act (R.S. 1970, c. C-32).
- The goals and purposes of ISMP Canada.
- The broad objectives of the Canada Health Act (R.S. 1985, c. C-6).
- The broad objectives of various provincial health enabling legislation.

In Ontario, collection is also consistent the *Personal Health Information Protection Act, 2004* (PHIPA) at sub-section 40(1); see discussion at part 3.7 of this PIA.

#### 3.3 Information Collected for ISMP Canada

#### 3.3.1 Analyze-ERR™ Reporting

The Analyze-ERR™ software supports submission of incident reports to ISMP Canada using a secure transfer protocol. Data submission is a voluntary process done on an individual event basis. Each event can be marked for submission using a check box under the Event Tab.

The data entry screens in Analyze-ERR™ include a patient information tab that allows reporters to enter patient identifiers. There is also a hospital information tab that contains hospital identifiers. However, the entries in these fields are limited to use of Analyze-ERR™ software only at the reporting site. There is no sharing or transmission of this information to ISMP Canada. The data file is encrypted before the actual transmission; see Appendix A for a copy of these data entry screens.

#### 3.3.2 Web Incident Reporting

Information is collected directly from the reporter on the ISMP Canada web site. Submission of any data element is entirely voluntary. There is no requirement for the reporters to identify themselves.

There are no fields that contain patient identifiers or identifiable personal information. The only identifiable personal information is the identity of the reporter. This information is optional and will not be collected without the consent of the reporting individual; see Appendix B for a copy of the Web-form.

#### 3.3.3 Other Incident Reporting Channels

ISMP Canada cannot control the amount or type of data submitted by reporters via fax, email, by regular mail, or in person. However, the ISMP Canada staff member receiving an incident report other than via Analyze-ERR™ is responsible for ensuring that no identifiers are retained in the files or databases of ISMP Canada. The data retained are limited to the same data elements collected through Analyze-ERR™.

Contact information for the reporter may be retained for a period of up to nine months for the purpose of follow-up and confirming the content of a report.

#### 3.3.4 Web Based Query Capability

Reporters who wish to submit a Web-based query use a particular screen for this purpose; see Appendix C. The query produces a screen with a report resulting from the query; see Appendix D. The screen for inputting the query data and the resulting report do not include any categories that allow for patient or reporter identifiers. Transmission of query data and subsequent query results are encrypted.

#### 3.4 Limits on ISMP Canada Data Collection

ISMP Canada limits collection to specific data elements using technical and non-technical means. Technical limits include specific fields on web submission forms and in Analyze-

ERR™. Non-technical limits include statements in ISMP Canada's privacy policy. Patient identifiers are not solicited from the reporter.

#### 3.5 Location and Retention of ISMP Canada Data

ISMP Canada's data holdings are stored on a privately owned server located in Canada. Data may be transmitted from other locations by virtue of the location of the reporter and due to the international nature of the internet.

From time to time, ISMP Canada staff may possess information entrusted to them for the purpose of an active investigation (for example, notes, incident data, or email reports.) Staff may also travel to the location of an investigation or to consult with ISMP Canada staff located in other provinces.

All data is retained in facilities and systems owned or operated by ISMP Canada. A data cleansing process is used to review reports and ensure that patient identifiers or institution identifiers are removed. A purge process removes reporter information nine months or earlier from the date the report is received.

#### 3.6 Data Quality & Accuracy

By collecting directly from reporting individuals and institutions, ISMP Canada can ensure that the information received is accurate. Where reporter contact information is supplied, ISMP Canada is able to clarify elements of the drug incident with the reporter, as needed.

#### 3.7 Consent Issues

ISMP Canada relies on reporters to ensure that, when appropriate, reporters obtain consent from subject individuals to collect health information for the purpose of reporting medication error incidents to ISMP Canada.

In the home province of ISMP Canada's operations, the Ontario *Personal Health Information Protection Act*, 2004, sub-section 40(1) states:

40(1) A health information custodian may disclose personal health information about an individual if the custodian believes on reasonable grounds that the disclosure is necessary for the purpose of eliminating or reducing a significant risk of serious bodily harm to a person or group of persons.

This sub-section permits disclosures of personal health information by health information custodians in Ontario, such as ISMP Canada's institutional or individual reporters. In the case that a medication error report might lead to identification of an individual who was the subject of an error, sub-section 40(1) would permit the reporting because it is for the purpose of eliminating or reducing a significant risk of serious bodily harm to other patients. Under sub-section 49(1), the exemption from any requirement from consent is justified, provided that the information collected is used and/or disclosed only for the purpose for which the reporter disclosed the information to ISMP Canada.

ISMP Canada is in the process of confirming the existence of similar provisions in other provinces.

#### 4 USE AND DISCLOSURE OF ISMP CANADA INFORMATION

Data collected by ISMP Canada is used by ISMP Canada staff to issue drug reports and medication safety alerts, and perform root cause and other type of incident analysis.

#### 4.1 Use of ISMP Canada Information

ISMP Canada uses incident reports and databases to create drug reports and medication safety alerts for the broader healthcare community.

#### 4.2 Disclosures of ISMP Canada Information

ISMP Canada ensures that drug incident reports and medication safety alerts do not contain information that may identify a given individual or institution. These reports are reviewed with affected parties prior to public release.

ISMP Canada does not disclose reporters' identities. This information is only available to ISMP Canada staff.

In keeping with its goals and objectives, ISMP Canada may disclose aggregate data to similar organizations, reporters, or researchers.

#### 4.2.1 Drug Reports

Data outputs from ISMP Canada take a number of forms. For example, outputs include drug reports related to specific incidents, or a set of specific incidents or reports that relate to aggregate statistical information about medication errors. These may include specific incident analysis reports and medication safety alerts.

When a report or alert is written, no institutions or individuals are identified in the report. It is ISMP Canada's practice to review a report with the affected parties prior to release.

#### 4.2.2 Aggregate Reports

In keeping with its goals and objectives, ISMP Canada may disclose aggregate data to similar organizations, reporters, or researchers.

#### 4.3 Access to ISMP Canada information

#### 4.3.1 Access for patients to information held by ISMP Canada

To date, ISMP Canada has not received a request for access from a patient who was the subject of a medication error. Should such a request be made, ISMP Canada would act in accordance with its privacy policy and direct the person to their healthcare practitioner and institution. It is not possible for ISMP Canada to actually provide this access, as it does not

retain patient identifiers and consequently has no accurate, practical or possible means of providing access.

#### 4.3.2 Access for institutional reporters to information held by ISMP Canada

If the reporter has specifically chosen to submit incident data using Analyze-ERR™ then incident information previously transmitted is available via password-protected web query. De-identified aggregate data is also available via password-protected web query.

#### 4.3.3 Access for individual reporters to information held by ISMP Canada

It is not possible for ISMP Canada to actually provide access for individual reporters. ISMP Canada does not retain reporter identifiers for longer than nine months and consequently has no accurate, practical or possible means of providing access.

#### 5 PRIVACY STANDARDS: CONCERNS AND SECURITY MEASURES.

ISMP Canada protects <u>all</u> information in its custody and control, including de-identifed and aggregate data.

#### 5.1 Security Safeguards

- Firewall and internet routing services are supplied to ISMP Canada by its internet and facilities supplier.
- Technical and network management support is provided by ISMP Canada staff and outside agencies as required.
- Appropriate technical safeguards are used with respect to network access.
- Backups are performed regularly by ISMP Canada staff and stored at a secure offsite location.
- The ISMP Canada file server is owned by ISMP Canada and is located in Canada at a secure commercial data-centre. To ensure system availability the data-centre provides multiple internet connections and backup power generation.
- The ISMP Canada web servers are owned by ISMP Canada and located at secure commercial data-centres in the United States and Canada. To ensure system availability the data-centres provides multiple internet connections and backup power generation.
- All ISMP Canada servers are operated and maintained only by staff of ISMP Canada. These servers are used only by ISMP Canada. No other use, storage of data or access is allowed. A preliminary security review performed by the PIA consultants indicates that appropriate steps have been taken to secure access to the servers.

- Physical access controls are utilized to prevent physical access to ISMP Canada's offices by unauthorized persons; visitors must be escorted into the office by an ISMP Canada staff member.
- Filing and document storage cabinets at ISMP Canada's location are locked whenever the office is unoccupied.
- Although email and data may transit through other jurisdictions (due to the topology and architecture of the internet) no personally identifiable information is permanently stored outside of ISMP Canada's offices.
- Reporter identifiers are only stored when voluntarily supplied, and for a period of time no longer than nine months from the date of the report.
- Patient identifiers are not collected or retained.

#### 6 A PRIVACY REPORT CARD

#### 6.1 Analysis

After careful review of the data-flows, data collection and data usage practices, the following conclusions have been drawn:

- Data collection has been minimized.
  - Only the minimum required information is collected from the individual reporter or institutional reporter. This information represents the minimum necessary to properly perform an investigation while being mindful of the potential need to pose follow-up questions or requests for clarification.
  - This approach supports the professional obligations of reporters in a nonthreatening and pragmatic manner, allowing the reporter to choose to selfidentify without requiring them to.
- Data usage has been minimized.
  - Elements of incident information are only accessed by ISMP Canada staff with a specific need to know the information and authority to access the information.
  - Aggregate incident information is available generally to all reporters (via web query), but only once the reporter identifiers are removed and only if the reporter has specifically chosen to submit the incident using Analyze-ERR™.
  - Data protection safeguards have been utilized to protect data in the custody of ISMP Canada.
  - o Specific recommendations have been made (opportunistic encryption, pseudonymity, etc) to limit data usage even further within ISMP Canada.

- Data usage is consistent with ISMP Canada's stated goals and objectives.
- ISMP Canada does not use data for purposes other than those for which the data was collected.
- No covert or hidden data flows exist.
- Information is collected <u>directly</u> and with the knowledge and agreement of reporters.

#### 6.2 Summary

In order to fulfill its mandate ISMP Canada requires the free-flow of information about medication error incidents. At the same time, it is obliged to maintain a high level of protection for patient privacy and be sensitive to the concerns of institutional reporters and individual reporting professionals.

To overcome this challenge, ISMP Canada has decided <u>not</u> to collect any information which would identify the patient or data subject, it has also taken steps to ensure that this information is not accidentally collected. Where information as to the identity of the institutional or individual reporters <u>is</u> collected, it is collected <u>only</u> directly and openly from reporters with their full knowledge. Assurances of confidentiality are given to all reporters.

These collection and consent practices represent a pragmatic and privacy protective manner in which to achieve the goals and purposes of ISMP Canada.

#### 6.3 Privacy Principles

#### 6.3.1 Accountability

The ISMP Canada Privacy Policy provides a framework for privacy responsibility from the highest levels of the organization. ISMP Canada has developed an easy to read and understandable confidentiality agreement for all employees and associates.

ISMP Canada is responsible for any information that may be transferred to a third party. Contractual and other means are used to extend protection to information temporarily transferred to third parties.

#### 6.3.2 Identifying Purpose

Information regarding the purpose specification, goals and purposes of ISMP Canada is readily available to reporters and others.

#### 6.3.3 Limiting Collection

Information is collected by ISMP using fair and lawful means. Information collected is directly related to the primary identifying purpose and appears to be limited to a minimum dataset required to perform that primary identifying purpose.

ISMP Canada utilizes technical and non-technical means to ensure that no extraneous or unnecessary information is collected.

#### 6.3.4 Consent

Information is collected directly from institutional and individual reporters. ISMP Canada does not have a relationship with, nor is it able to directly identify, the patient to whom an incident relates.

To fulfill its mandate, ISMP Canada requires timely information about events that involve medication errors. It does <u>not</u> require information about individual patients who were the subjects of medication errors.

Nevertheless, it is possible that the circumstances of an event may make it reasonably foreseeable that an individual may be identifiable. Under many statutory schemes, collection, use or disclosure of identifiable personal information would call either for consent, or an exception to the requirement for consent.

Sub-section 40(1) of PHIPA permits disclosures of personal health information by health information custodians in Ontario, such as ISMP Canada's institutional or individual reporters, under the kind of circumstances specified in this sub-section. ISMP Canada is in the process of confirming the existence of similar provisions in other provinces.

#### 6.3.5 Limiting Use, Disclosure and Retention

ISMP Canada only discloses aggregate information in a manner that ensures that all individual and institutional identifiers are removed. A specific policy applies to extremely small datasets where the potential exists to identify the institution or individual reporter (special cases known as small cell data.)

Access to information at ISMP Canada is limited to authorized individuals on a 'need to know' basis.

Specific technical recommendations have been made to further limit inappropriate usage and disclosure.

#### 6.3.6 Accuracy

ISMP Canada obtains information directly from reporters. Provided that the reporter contact information is supplied, ISMP Canada contacts the reporter for clarification of further information, if required.

As a matter of policy, ISMP never issues a report or conducts a root cause analysis based on information that it considers to be less than totally accurate and that it cannot adequately correct or clarify.

#### 6.3.7 Safeguards

ISMP Canada employs a number of security safeguards to protect the data in its custody and control. These security safeguards protect information against loss, theft or other failure (availability) as well as against unauthorized access, disclosure, use or modification (access control and integrity.) ISMP Canada protects information regardless of the mechanism of storage and reporting channel.

In accordance with recommendations from an earlier version of this PIA:

- ISMP Canada uses strong encryption to protect the transmission of data by Analyze-ERR™, on the incident reporting webpage and on the web query webpage.
- ISMP Canada has placed a warning on the web incident reporting page to remind users that patient information must not be submitted.
- ISMP Canada has implemented a VPN (Virtual Private Network) to encrypt and protect remote access to the ISMP Canada office computer network.

#### 6.3.8 Openness

ISMP Canada collects information openly from reporting individuals and institutions.

#### 6.3.9 Individual Access

As previously noted, ISMP Canada has no means of providing individual access to incident information in response to a request from a patient.

While the patient may have a 'theoretical' right of access to this information; given the absence of patient identifiers, it is not possible to provide this access.

As a matter of policy ISMP Canada will advise patients to contact their healthcare practitioner and institution for access to their personal health information.

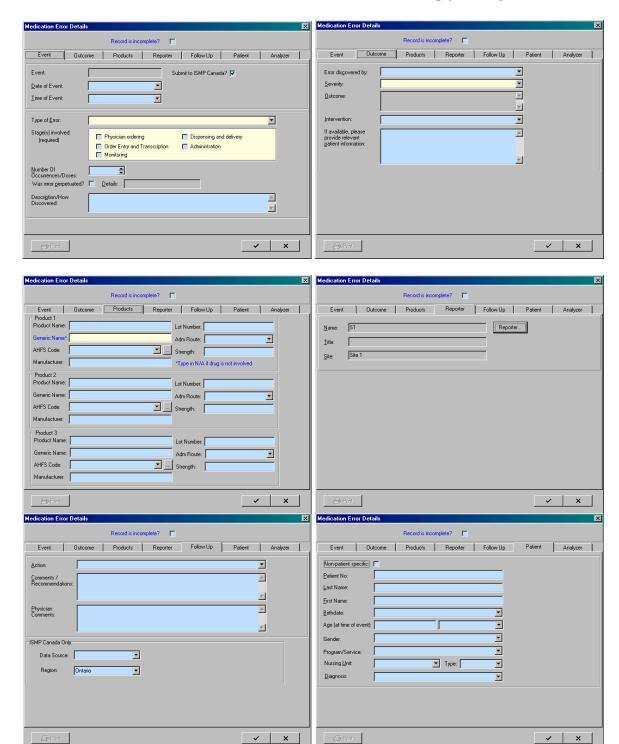
#### 6.3.10 Challenging Compliance

The Chief Privacy Officer at ISMP Canada receives any complaints or queries regarding its privacy policies and practices. ISMP Canada has a policy to make its complaint procedure easily accessible and simple to use.

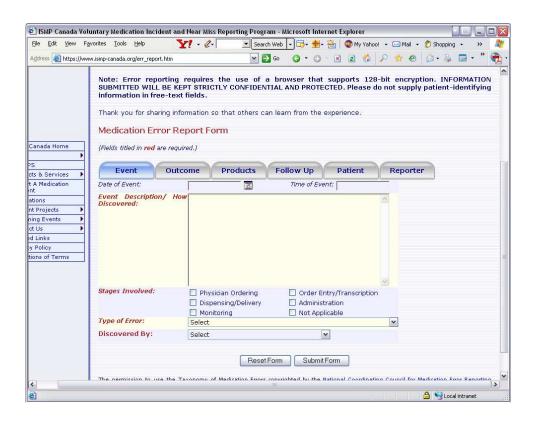
ISMP Canada has, as a matter of policy, indicated that it will investigate all complaints received and, if necessary, amend its policies and practices.

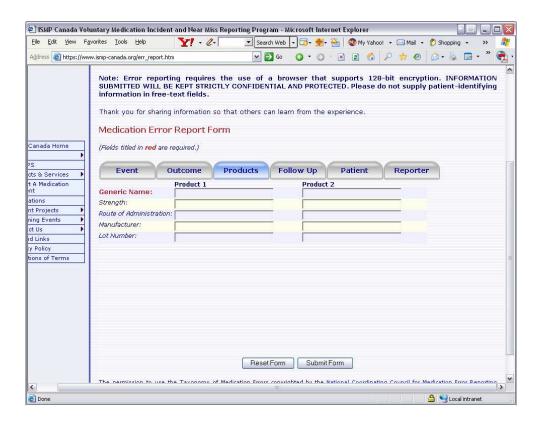
To date, ISMP Canada has not received any complaints about its information practices.

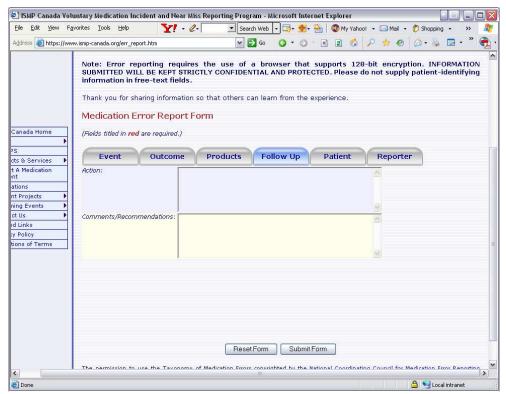
#### 7 APPENDIX 'A' – ANALYZE-ERR™ DATA ENTRY SCREENS

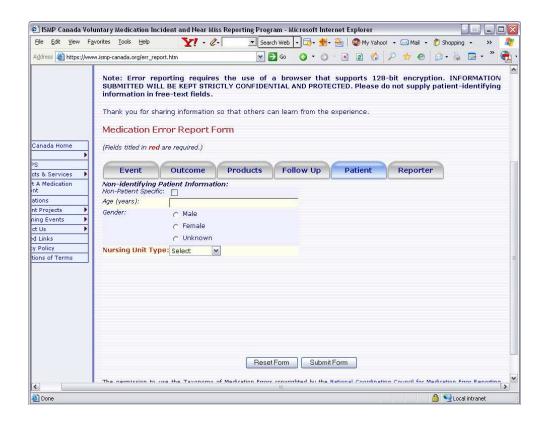


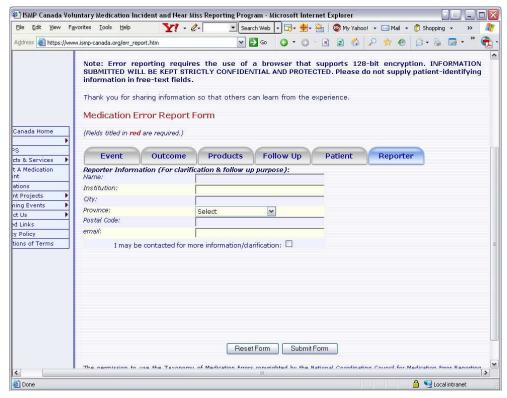
#### 8 APPENDIX 'B' - WEB INCIDENT REPORTING FORM



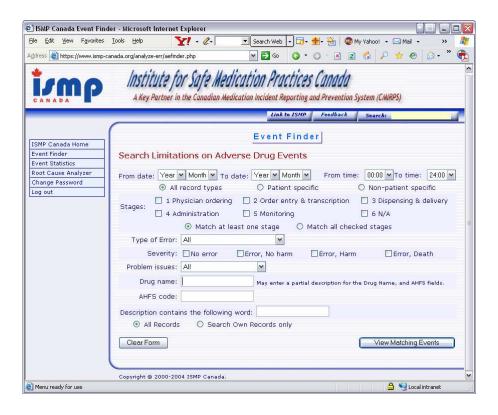








#### 9 APPENDIX 'C' - WEB-BASED QUERY SUBMISSION SCREEN



#### 10 APPENDIX 'D' - WEB-BASED QUERY RESULTS SCREEN

