Frequently Asked Questions
Adverse Drug Reaction (ADR) Reporting Module of CHARMS
October 2008

Where can I learn more about the ADR module?
http://www.scribd.com/doc/7540115/CHARMS-AE

What is CHARMS?
CHARMS is the Canadian Hemophilia Assessment and Resource Management information System (http://www.ahcdc.ca/charms.html), developed by the Association of Hemophilia Clinic Directors of Canada (AHCDC http://www.ahcdc.ca/). It is a computer program, which serves as a distributed database in each of the hemophilia clinics in Canada, to track the distribution and use of coagulation products by patients with inherited coagulation disorders.

What is the ADR reporting module?
This is a module of CHARMS developed to answer problems with the communication of Adverse Events in Canada. It assures that all the key groups and people are notified about an Adverse Drug Reaction and have equal access to the information.

How does the module work?
This module works as follows: Someone in a hemophilia clinic, who has noticed an Adverse Drug Reaction, fills in a form in the ADR module of CHARMS which populates the Adverse Drug Reaction form of Health Canada.

When completed with all required fields, the reporter clicks on submit and it is posted on a secure website. At the same time, an email notification about the posting on the secure website goes out to:
pharmacovigilance email address at the company involved,
Health Canada,
the transfusion transmitted disease group at the Public Health Agency of Canada,
Canadian Blood Services,
Hema Quebec, and
the directors of the clinic involved.

The people who have been notified can then sign on to the secure website and retrieve the information.
The company can only see ADRs for their products.
The clinic can only see the ADRs for their clinic.
Access to the website is logged.

Are all AE reports received by a company also automatically reported to Health Canada?
Yes, Health Canada gets the same notification as the company. Pharma should report this event as a duplicate.

Does the AE report include contact information from the reporting healthcare professional so that if further information is required that our regulatory people would know whom to contact?
Yes, this is one of the required fields before the event is reported.

Do all emailed AE reports from CHARMS come from a common CHARMS email address so that those on the receiving end can readily identify the report as coming from CHARMS.
Yes, the report will come from: CHARMS Web Notifier <notifier@ahcdc.ca>

Could you please kindly provide additional information on this initiative, including the address of this website, log-on requirements and such?
This is described in a powerpoint presentation visible at:
http://www.scribd.com/doc/7540115/CHARMS-AE

Who will have access to the website?
The signon and password will be sent to the adverse event reporting email address that has been provided. It is up to the organization to maintain that email and who is able to access it. It is also up to the company to decide who will be in charge of administering the password, changing it, and notifying the key people of any changes.

What if I have technical questions about this module?
Contact notifier@ahcdc.ca

What if I lose my password?
Contact notifier@ahcdc.ca