

**Health Canada**  
**UNDERUTILIZATION OF THE ADVERSE REACTION**  
**REPORTING SYSTEM**  
**HCPOR-06-83**

**June 20, 2007**

**EXECUTIVE SUMMARY**

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**PWGSC Contract Number: H1011-060066**  
**Contract Award Date: January 2007**

## **EXECUTIVE SUMMARY**

### **Research Objectives**

The purpose of this research initiative was to collect qualitative information to help Health Canada understand why less than 10% of adverse reactions are reported by health care professionals and to explore ideas to increase reporting.

### **Approach and Methodology**

Forty-eight one-on-one interviews were conducted with the following four groups: Medical doctors, Naturopathic doctors, Nurses, and Pharmacists. Twelve interviews were conducted with each of the target groups, each interview lasting approximately 30 to 40 minutes. The interviews were conducted between February 26 and March 12, 2007.

### **Sources of Post Market Drug Information**

The most common sources for post market drug information used by the interview participants include the College of Physicians and Surgeons (CPS), journals (such as the New England Medical Journal), and personal interaction with colleagues in the industry either within the office, at a seminar or at a conference.

Awareness of the MedEffect website is fairly low. Of those who have heard of the MedEffect site, just half have visited the site while one respondent actually subscribed to the MedEffect e-notice.

### **Responsibility, Awareness and Use**

Respondents were more likely to feel that physicians should be responsible for reporting adverse reactions over other health professionals in order to ensure the safety of the patient with the medication being administered. The main reason for this thinking is that the physicians are responsible for prescribing medication to patients and they are also the ones with the complete medical history of the patient.

Following physicians, pharmacists were the next most likely individuals to be identified as the person that should be responsible for post market drug safety. The key reason for believing pharmacists should be responsible is that they are the ones who bottle the medication and physically hand it to the patient. Very few participants felt that nurses are the health professionals who should be responsible for post market drug safety.

### **Reporting ADRs**

Based on all interviews conducted, just three respondents have ever reported an adverse reaction (two pharmacists and one medical doctor). The majority of the medical doctors interviewed felt that there are six major factors affecting their willingness or ability to report: time, lack of knowledge about the reporting program, (lack of) severity of the reaction, previously known side effects, difficulty of analyzing symptoms, and the feeling that it is someone else's responsibility.

Pharmacists and nurses who were interviewed felt there were five major reasons for not reporting adverse reactions: lack of severity of reaction, lack of time, lack of knowledge, report to the doctor or drug company, and previously known side effects.

The differentiation between a perceived adverse reaction and a normal side effect was not clear to the participants. It was felt by most that there is no need to report what they would classify as a normal side effect such as a snuffle or a cough.

Due to an overwhelming workload, it is very important to keep the reporting system simple, easy to use, and convenient. Most professionals are not opposed to spending the time to fill out a report as long as the process is quick and easy to understand.

Interview participants indicated that a variety of reporting methods should be available. For example, some participants no longer have a fax machine in the office while some have limited or no Internet access. The method preferred by most participants was the Internet; however, many preferred the telephone as they do not appreciate impersonal means of communicating this type of information as it deals with a person's health.

There is a lack of awareness of how, why, what, and who should be reporting adverse reactions to Health Canada. Many participants feel that if this information were to be more effectively communicated then there would be an increase in reporting rates by health professionals. Participants indicated that they will refuse to report adverse reactions "just for the sake of reporting". However, if they were able to understand the value of their time and that it was being used for a greater good then they would be more likely to report.

## **Conclusions**

There is a lack of awareness of the system in place for reporting adverse reactions to the Canadian Adverse Drug Reaction Monitoring Program. The positive news is that all health professionals interviewed agreed that there is some benefit in reporting adverse drug reactions to Health Canada for the better good of Canadians.

Health Canada needs to better communicate the definition of what constitutes an adverse reaction. Without the knowledge of what Health Canada defines as an adverse reaction and when they should be reported, health professionals can not be expected to increase their participation in the program.

Although there is no clear consensus on who should be reporting adverse reactions to Health Canada, it is clear that the physician who prescribes the medication is best suited to determine what is and is not an adverse reaction.

The majority of health professionals interviewed feel that appropriate communications will be enough to bolster their participation. It will be important for Health Canada to effectively explain the types of reactions that need to be reported, who should be reporting and when they should be reporting.

If the reporting process is kept simple and is easy to access, combined with effective communication, many of the interview participants indicated that they would likely start reporting adverse reactions on a more regular basis.

There are many health professionals that continue to prefer sending and receiving faxes or receiving letter mail, while others have become internet and computer savvy. Several interview participants feel that in-person communications at conferences or seminars is also a useful way of reaching health professionals. Since there is no single way to communicate with all health professionals, Health Canada should consider a multifaceted approach to any potential communications programs aimed at health professionals.