

**EXECUTIVE
SUMMARY**

**Adverse Reaction Reporting –
Survey with Health Professionals**

Prepared for:

Health Canada
por-rop@hc-sc.gc.ca

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ENVIRONICS
RESEARCH GROUP

336 MacLaren Street
Ottawa, ON K2P 0M6

pn6080

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Research purpose and objectives

Currently, drug companies are required to report adverse drug reactions (ADRs) brought to their attention, but health professionals and consumers provide such reports on a voluntary basis. Previous research by Health Canada estimated that health professionals report less than 10 percent of ADRs, representing a threat to the effectiveness of this monitoring system.

Given this issue, Health Canada has a need to understand the attitudes and behaviours of Canadian health professionals regarding adverse reaction reporting. Environics Research Group was commissioned to conduct a telephone survey of health professionals about their knowledge of, and opinions about, the drug safety system in Canada, their experience with using sources of new drug safety information and with ADR reporting. The findings of this research will support the development of a social marketing campaign designed to encourage increased reporting.

Key findings

The following are the key findings from this survey of doctors, dentists, pharmacists, and naturopaths. For the purpose of this report, these four groups are collectively referred to as health professionals.

Health professionals continue to be at least generally confident in the existing drug safety system, to have some measure of confidence in the roles of various stakeholders, and to feel that drug and natural health products are safe. Naturopaths differ considerably from other health professions in that they express more scepticism about the safety of traditional drug products, and less confidence in the roles of the federal government and other health professionals in the drug safety system. A majority of health professionals, regardless

of profession type, believe that drug companies should be shouldering full responsibility for drug safety.

While nine in ten health professionals feel it is very important to stay current about new drug safety information, somewhat fewer – about six in ten – say they seek out this type of information frequently. Those who do seek out such information usually do so using medical journals, on-line resources, medical compendia, drug companies and some Health Canada sources, and are generally satisfied with the information sources they use. There has been a notable increase in the proportion of health professionals who, when prompted, indicate that they are familiar with the Dear Health Care Professional letters from Health Canada, and this increase is noted across profession types.

Health professionals continue to believe that the ADR under-reporting problem in Canada is serious, and half feel it has become more problematic in the past five years. Only three in ten have ever reported an adverse reaction, most often pharmacists and physicians, and only about one in seven practitioners say they have reported such a reaction in the past 12 months. The survey results suggest that much under-reporting may be due to health professionals believing many ADRs to be well-known and/or trivial.

While half (49%) of health professionals (again, most often physicians and pharmacists) claim they are familiar with how to report an ADR, somewhat fewer (37%) say they know where to obtain the form to do so. Overall, three in ten say they are aware of the on-line reporting option. These results point to a need for additional efforts to educate professionals on ADRs in general, and a need for increased awareness about ADR reporting procedures specifically.

The following are key findings presented by subject.

Perceptions about drug and health product safety

- Over eight in ten health professionals consider prescription and non-prescription drugs to be generally or very safe (83% - 88%), and two-thirds (65%) feel the same way about natural health products. These overall results, however, mask a major distinction between naturopaths and other health professionals. A large majority of naturopaths consider natural health products (89%) to be safe but are less sure about prescription (45%) and non-prescription drugs (67%). However, naturopaths are more likely than in 2003 to feel that these last two types of products are at least generally safe.
- The majority of health professionals express confidence in how the members of their own profession stay informed about the safety of the drugs and products they administer (85%), and also have at least some confidence in the respective roles played by the federal government (83%), drug companies (78%) and other health professionals (80%). While overall confidence levels remain similar to those observed in 2003, there has in fact been a reduction in the proportion of health care professionals who are *very* confident in each of these stakeholders, and this lessening in confidence is most notable among dentists and pharmacists.
- A polarization of opinion between naturopaths and other health professionals is evident in several aspects of the drug safety system. They are less likely than other health professionals to express confidence in:
 - The systems and safeguards in place to ensure the safety of drugs available in Canada today (46% v. 93% - 97% of other professionals);
 - How drug companies research the safety and effectiveness of products (29% v. 86% - 91%);
 - How the federal government regulates and monitors the safety of drugs (45% v. 89% - 94%);
 - How health professionals in general stay informed about the drugs they administer (60% v. 79% - 87%).

- When asked to consider the amount of responsibility that different stakeholders should have for ensuring drug safety, nine in ten or more assign at least “significant” responsibility to each of drug companies, the federal government and health professionals, but fewer than half assign that level of responsibility to consumers and patients. When it comes to assuming full responsibility, two-thirds of health professionals see this as the role of drug companies.

Use and awareness of new safety information about drugs

- Nearly all health professionals (89%) say it is very important for them to stay current about new drug safety information; however, fewer (56%) indicate that they frequently seek out such information. The sources professionals most often consult include medical journals (28%), pharmaceutical compendia (24%), manufacturers (19%), medical reference websites (15%), and professional associations (13%), among others. The Health Canada/*MedEffect* website was mentioned unprompted by 12 percent.
- There has been a notable increase in the proportion of health professionals who when prompted say they are familiar with the Dear Health Care Professional letters from Health Canada. Over two-thirds (69%) are now at least somewhat familiar of this source, compared to 42 percent in 2003, and increases are noted across all professions. In the case of physicians and pharmacists, the increases are predominantly in the proportion saying they are very familiar with these letters. The Health Canada electronic mailing list has also seen a modest increase in overall familiarity (19%, up 8 points).
- Most health professionals want new product safety information fairly frequently: a majority of each group wishes to receive the information as soon as it is available (52%-75%), with others saying at least once a month (23%-45%, weekly or monthly). When it comes to preferred methods for receiving new product safety information, health professionals are divided between e-mail (38%), regular mail (29%) and fax (18%).

- Health professionals report being *very likely* to read information received from Health Canada (83%) and from professional associations to which they belong (87%). Only half say this about drug companies (49%). Sources of information are considered satisfactory if they are a good source of relevant information, and if that information is timely and up-to-date. Sources lose points for being out of date, lacking clarity and for poor organization.

Adverse reactions/reporting

- More than eight in ten professionals consider the adverse reaction problem in Canada to be either somewhat (51%) or very serious (35%). Half feel that these types of reactions have become more of a problem over the past five years (49%), another four in ten see things as unchanged, and only one in twenty note a reduction in this problem. Naturopaths (71%) are far more likely than other health professionals (26%-28%) to consider adverse reactions a *very serious* problem.
- Overall, only half of health professionals claim familiarity with how to report an adverse reaction (ranging from 16% of dentists, through 39% of naturopaths and 51% of physicians, to 87% of pharmacists). One-third (37%) say they know where to obtain the form for reporting adverse drug reactions (including 9% of dentists, 23% of naturopaths, 37% of physicians, and 75% of pharmacists).
- Three in ten, overall, have reported an ADR during their careers (5% of dentists, 7% of naturopaths, 43% of physicians and 63% of pharmacists). In the past 12 months, more than eight in ten practitioners have *not* reported any ADRs. Pharmacists are the most likely to have reported an ADR in the past year (14% one reaction, 11% two, and 9% three or more). Reports are most often made to Health Canada by fax, followed by contacting a drug manufacturer.
- The following are considered to be major reasons for *not* reporting ADRs:
 - A reaction is “well-known or expected” (56% overall, and 68% for physicians and pharmacists) or “minor/trivial” (47%, including 61% of physicians but only 35% of naturopaths);
 - It is not clear that the reaction was caused by a drug (48% overall, including 55% of physicians);
 - The definition of what to report is not clear or ambiguous (31% overall, including 38% of physicians);
 - The form is not easy to complete (17% overall, 24% of physicians);
 - The process is time-consuming (23% overall, 30% physicians and 18% naturopaths); and
 - There is no financial compensation for the time spent (7% overall, including 9% of physicians, and 11% of pharmacists).
- Two-thirds of health professionals believe that fewer than 30 percent of all ADRs are reported, including one-third saying that less than 10 percent are reported. Overall, eight in ten health professionals (83%) indicate that under-reporting of ADRs is a somewhat or very serious problem in Canada today; ranging from three-quarters of physicians to 96 percent of naturopaths.
- When asked what steps could be taken to ensure more complete reporting of ADRs, health professionals mention five main themes:
 - Efforts to educate professionals and/or raise awareness about how to report ADRs (47%);
 - Simplifying the process and/or making it less time-consuming (28%);
 - Making the public more aware of reporting (12%);
 - Providing financial compensation for the time spent (10%); and
 - Making reporting mandatory (8%).

Recommendations

In broad terms, these results substantiate the need for an ongoing information and education campaign to encourage adverse reaction reporting. Key messages for that campaign include:

- The *importance* of reporting – in order to convince professionals that the effort of reporting is worthwhile;
- The *reasons* to report – in order to counter certain myths in terms of reasons not to report – and raising awareness of the different *methods/media* available for reporting.

In the case of *physicians*, the results suggest that a particular focus on promoting an easy-to-use on-line reporting mechanism may go some way to increasing AR reporting among this audience. A follow-up or feedback mechanism may also lead to repeat reporting among this audience, by confirming the value of the information they report.

Increased promotion to *pharmacists* of on-line AR reporting options and the availability of HC information resources should help to augment their participation in the AR process.

Dentists need to be encouraged to become more of an integral part of the ADR system. Increased promotion of the ADR problem and the resources available to them should encourage participation. Information directed at dentists should also include clear instructions on reporting procedures.

In the case of *naturopaths*, continued education and outreach efforts may help them to feel they are more a part of the process and potentially aid in increasing their reporting of ADRs.

Finally, it may be that outreach efforts to the various professional associations will be of assistance in the distribution of drug safety information, as these are generally considered to be credible among members of the professions, and materials distributed by these associations tend to get read.

Methodology

The 2007 Adverse Reaction Reporting Survey with Health Professionals was based on telephone interviews conducted between March 6th and March 27th, 2007 with a sample of 1,108 Canadian health professionals. In order to ensure that the views of different types of health professionals are fairly represented, the sample was stratified according to area of practice/specialization. This included representative samples of physicians (300), dentists (300), pharmacists (301) and naturopaths (207). The physician, dentist and pharmacist samples at $n \approx 300/301$ provide results that are accurate to within plus or minus 6 percentage points in 19 out of 20 samples. The naturopath sample, at $n \approx 200$, is accurate to within plus or minus 7 percentage points at the 95% confidence level. A more detailed description of the methodology used in conducting this study is presented as an appendix to the report, along with the questionnaire.