Health Canada | Santé Canada

Health Products and Food Branch | Direction générale des produits de santé et des aliments

September 6, 2005

NOTICE

Re: Extension of Consultation Period - Mandatory Reporting of Adverse Reactions

Further to announcements about improving the drug safety monitoring system made by the Minister of Health, the Honourable Ujjal Dosanjh, Health Canada wishes to inform you of its public consultation plan on implementing an effective mandatory adverse reaction reporting system for health professionals.

This Notice serves to advise that this issue is presently under review, and to describe the multi-phased consultation which is planned on how to proceed with a mandatory reporting scheme in Canada. Health Canada will consult with health professionals, the provincial and territorial governments who regulate health professionals and other interested parties.

Health Canada is committed to increasing adverse reaction reporting and is confident that a well-designed and properly administered mandatory reporting system could ultimately result in higher reporting rates. That, in turn, could furnish Health Canada with a more complete picture on the real-world safety of the health products available to Canadians.

Please find attached, a Discussion Paper: Designing a Mandatory System for Reporting Serious Adverse Reactions, containing background information on the current reporting system, the known barriers to reporting and other factors that may be considered in developing options for a mandatory reporting system. This paper initiates the formal consultation process with stakeholders on the development of a mandatory reporting system.

The Health Products and Food Branch (HPFB) is targeting to host a consultative workshop this fall/winter for stakeholders and the public, to provide input on detailed options with a view to enhancing policy positions and facilitating their implementation.

Should you wish to provide comments on the Discussion Paper you are requested to do so by **October 1, 2005.** Your comments and interest in receiving an invitation to the consultative workshop should be forwarded, preferably in electronic format, to:

Derek Wade
Policy and Regulatory Affairs
Marketed Health Products Directorate
Tunney's Pasture, A.L. #0701C, Ottawa, Ontario K1A 0K9
Tel: (613) 948-2573
Fax: (613) 948-7996
Email: mhpd_dpsc@hc-sc.gc.ca

Canada

DISCUSSION PAPER

Designing a Mandatory System for Reporting Serious Adverse Reactions

1. INTRODUCTION

Health Canada is committed to increasing adverse reaction (AR) reporting by Canadian health professionals which, in turn, would furnish us -- governments, health professionals and consumers -- with a more complete picture on the real-world safety of the health products available to Canadians. Accordingly, the Department is examining different models for implementing a well-designed and properly administered mandatory reporting system for health professionals and is carrying out consultations with provincial counterparts and stakeholders to inform its efforts.

Health Canada recognizes that mandatory reporting, on its own, is not the complete solution to the well known international problem of reporting of adverse reactions to marketed health products. The potential enhancement to signal detection capabilities and the resulting patient safety benefit that could result from approaches to increase reporting, such as the requirement for mandatory reporting by health professionals, will require a multi-faceted approach that would encompass a range of other promotional and educational strategies, more user-friendly reporting methods and close cooperation with the provinces and territories who regulate health professionals. An aggressive program is also underway to upgrade and modernize the Department's system architecture to receive and organize adverse reaction reports, including provisions for online public query capacity (launched on May 25, 2005 http://www.hc-sc.gc.ca/dhp-mps/medeff/databasdon/database-basedon_annou-annon_e.html), integration of foreign safety data, automated signal detection and eventually electronic filing. The Department will also continue to pursue, in collaboration with its health system partners, innovative report generating activities such as targeted (active) surveillance, educating health professionals and consumers on recognizing and submitting quality adverse reaction reports and social marketing programs.

2. THE INTENT OF THIS PAPER:

This paper sets out basic information that will facilitate a broad discussion of objectives, constraints, considerations and design principles as a basis for developing options for a mandatory reporting system, and is intended to:

- inform interested and affected parties about mandatory reporting and encourage public participation in the current policy development process;
- ensure accuracy and completeness of the preliminary issues identified during the course of our work so far;
- demonstrate an ongoing commitment to build relationships with affected parties; and
- identify subsequent phases of implementation that will require future consultation.

This paper and the consultations on creating an obligation for Canadian health professionals to report ARs are not intended to address wider issues such as consumer reporting. We acknowledge that discussions need to take place on other important AR reporting issues but they are beyond the scope of this consultation.

We welcome comments on the issues raised in this paper and on any other issues relevant to mandatory reporting. In several sections below we pose specific questions to stimulate discussion and critical comment. We would be interested in comments from all sources and particularly from health professionals.

As follow-up to the release of this paper, we will also be holding face-to-face consultations later this summer which will be designed to seek feedback from interested and affected parties on detailed options for a mandatory reporting system.

3. BACKGROUND

What is the problem?
It is believed that adverse reaction reports received by Health Canada represent only a small percentage of adverse reactions that have occurred. Some international studies estimate reporting rates to be as low as 1 - 10%[1,2,3]. The effectiveness of the monitoring system and signal detection is compromised by low reporting rates: under-reporting may cause an underestimation of a safety problem.

The Minister of Health has committed to moving forward on a number of drug safety initiatives including the implementation of a mandatory requirement to encourage reporting of adverse reactions, and Health Canada is in the process of determining how best to achieve this objective in a fair, balanced and responsible way.

Who currently reports adverse reactions?
The Canadian reporting system consists of two components: reporting by manufacturers on a mandatory basis (regulatory requirement)[4]; and, reporting by Canadian health professionals and patients/consumers on a voluntary basis, through either the drug manufacturer or directly to Health Canada. The success of both reporting systems depends heavily on the participation of health professionals who, although strongly encouraged to do so, are not obligated by regulation to report.

It is important to remember that market authorization holders can generate AR reports without waiting for a spontaneous report from health professionals through their field officer contacts with health professionals and institutions.

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[1] Kessler DA. Introducing MedWatch: A New Approach to Reporting Medication and Device Adverse Effects and Product Problems. JAMA 1993; 269:2765-2768.

[2] Bäckström M, Mjörndal T and Dahlqvist R. Under-reporting of serious adverse drug reactions in Sweden. Pharmacoepidemiology and Drug Safety 2004; 13: 483-487

[3] Begaud B, Martin K, Haramburu F, Moore N. Rates of reporting of adverse drug reactions in France. JAMA 2002; 288:1588.

[4] Under section C.01.016 of the Food and Drug Regulations, manufacturers are required to report all information with respect to any serious AR that has occurred in Canada and any serious unexpected AR (unexpected because it is not listed in a product's labelling) that has occurred outside Canada within 15 days after receiving the information.

The other departmental systems for post-market monitoring of health products (e.g. natural health products and medical devices) are all modeled on the same combination mandatory/voluntary reporting system as is currently in place for drugs.

The reporting of suspected adverse reactions by patients and health care professionals, through either the product manufacturer or directly to Health Canada, is the most common source of safety data, and in some cases may be the only source of information concerning rare or serious adverse reactions to new and older marketed health products.

What does Health Canada mean by Mandatory Reporting?
Apart from the unique role played by the patients themselves and their family members, health professionals are in the best position to observe any adverse reactions experienced by their patients and report them in clear, scientific terms. The reporting of adverse reactions by health professionals is presently done on a voluntary basis. An approach to address the problem of under-reporting would be to increase the likelihood that health professionals report suspected adverse reactions by making it mandatory by law. While a mandatory requirement may not achieve 100% compliance it may prompt a significant number of health professionals to report who would not have otherwise reported. This should not to be confused with the mandatory reporting (regulatory requirement) of adverse reactions by manufacturers which already exists.

Health Canada suggests that a well-designed and properly administered mandatory system could result in higher reporting rates by health professionals. That, in turn, could furnish us -- governments, health professionals and consumers -- with a more complete picture on the real-world safety of the health products available to Canadians.

Does mandatory reporting for Health Professionals exist elsewhere?
Ten other countries[5], notably France, Sweden, Norway, Austria and Italy, already have mandatory systems in place for adverse reaction reporting by health professionals.
In Canada there are no examples of federal laws for mandatory reporting by health professionals.

Although there is little evidence available regarding the success of these programs, at a provincial level there are mandatory reporting requirements for suspected child abuse, chemical intoxication and certain infectious diseases.

Why do we need adverse reaction data for marketed health products?
Health Canada authorizes health products for sale in Canada based on controlled clinical trial data demonstrating a product's safety and efficacy. However, because there are relatively few patients participating in these clinical trials and they are a select, homogeneous group who meet specific criteria, the clinical trials do not represent the product's use in the real world setting. This inherent limitation means that some adverse reactions may not become evident until the health product is marketed widely and used under real life conditions. After marketing approval, Health Canada continues to monitor the safety and effectiveness of health products.

Post-market assessments rely on information received through adverse reaction reports. Health

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[5] National Pharmacovigilance Systems. Country Profiles and Overview. 2nd ed. Uppsala, Sweden: Uppsala Monitoring Centre; 1999.

Canada collects reports of suspected adverse reactions to health products marketed in Canada, including prescription, non-prescription, herbal, and homeopathic health products. Monitoring adverse reactions to preventive vaccines is a responsibility of the Public Health Agency (PHA). The purpose of the reporting system is to provide data from which signals of potential problems which require further investigation to determine a product-reaction association can be detected.

In addition to these reports, information regarding health product safety and effectiveness can also be obtained through:

- post-market studies conducted by manufacturers or health care institutions;
- targeted (active) surveillance activities which include the regular periodic collection of case reports from health professionals and health facilities;
-publications in scientific journals;
-collaboration with patient groups, academic institutions, professional associations in Canada and internationally;
- risk-communications and shared commutative case series from regulatory agencies in other countries and health organizations (e.g., WHO Drug Monitoring Programme).

How many domestic reports does Health Canada receive annually?
Health Canada received 10 238 reports of suspected adverse reactions in 2004. Of the AR reports received, 7 000 (68.4%) were classified as serious. There has been a steady increase in the reporting of ARs in Canada over the past 6 years, with 11.2% more reports in 2004 than in 2003.

The ARs were reported for the most part by health professionals (pharmacists, physicians, nurses, dentists, coroners and others), either directly to Health Canada or indirectly through another source (Table 1). A further analysis of the total number of reports by reporter type (originator) is outlined in Table 2.

Table 1: Source of reports of adverse reactions (ARs) received by Health Canada in 2003 and 2004

Source	No. (and %) of reports received			
	2003		2004	
Manufacturer	6125	(66.5)	6114	(59.7)
Regional centre	2671	(29.0)	3617	(35.3)
Other*	413	(4.5)	507	(5.0)
Total	9209	(100.0)	10238	(100.0)

*Includes, but not limited to professional associations, nursing homes, hospitals, physicians, pharmacists, Health Canada regional inspectors, coroners, dentists and patients.

Table 2:	Number of AR reports by type of reporter (originator)			
	No. (and %) of reports			
Reporter	2003		2004	
Pharmacist	2369	(25.7)	3011	(29.4)
Physician	2176	(23.6)	2667	(26.2)
Health professional*	1974	(21.4)	1499	(14.6)
Consumer/patient	1628	(17.7)	1928	(18.8)
Nurse	689	(7.5)	873	(8.5)
Other	373	(4.1)	260	(2.5)
Total	9209	(100.0)	10238	(100.0)

*Type not specified in report.

What is a "serious" adverse reaction?

In practice, an adverse reaction is considered to be any harmful and unintended reaction to a health product that may occur under normal use conditions. Reactions may be evident within minutes to years after exposure to the health product and can range from minor reactions like a rash to severe and life-threatening ones such as a heart attack or liver failure. The Canadian Food and Drug Regulations define a **serious adverse drug reaction** as "a noxious and unintended response to a drug, that occurs at any dose and that requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death". Adverse reactions that require significant medical intervention to prevent one of these outcomes are also considered to be "serious". Proof (causality) that a health product has actually caused an adverse event is not a requirement for reporting. Adverse reaction reports are, for the most part, only suspected associations. Inclusion of a particular report in the database does not necessarily mean that it was caused by the suspected health product(s).

What is Signal Detection?

In a clinical trial, one needs to distinguish the clinical evidence of a health product's efficacy from the background noise of placebo effects. Similarly, post-market monitoring of health products requires analyzing the full set of available adverse reaction data and pulling out signals that there may be a potential health product-associated adverse event[6].

More specifically, a signal is considered to be the preliminary indication of a product-related safety issue. The identification of a signal is not by itself proof of the association between an adverse reaction and a health product, but it may trigger the need to further investigate a potential association. Signals must be carefully evaluated in order to confirm or to disprove the potential association between the product and the adverse reaction. Not all potential signals can or will be investigated and are prioritized based on available resources and perceived risk acceptability (e.g., nausea and vomiting may be seen as an "acceptable" AR in cancer

[6]Due to under-reporting, the lack of adverse reaction data limits the extent to which signals can be detected.

chemotherapy but not with medication used to treat symptoms of an upper respiratory tract infection i.e. a "cold").

Health Canada evaluators review the information from the adverse reaction reports and decide if further investigation is necessary to determine a product-reaction association. Additional scientific investigations are required to validate signals and to establish a previously unrecognized cause and effect relationship between a health product and an adverse reaction. Assessment of causality must include other factors such as temporal associations, the possible contribution of concomitant medication or therapies, the underlying disease, and the previous medical history.

4. DESIGN FEATURES FOR SUCCESS

The following is a discussion of proposed design features to be considered in developing options for a mandatory adverse reaction reporting system.

4.1 Address known barriers to reporting

Designing a mandatory reporting regime requires a clear understanding of the reasons for not reporting. For example, legislation in this area could be drafted to encourage reporting by also providing explicit protection to health professionals from liability for making a report in good faith (concern about legal liability and breaching patient confidentiality have been cited as barriers to reporting).

The proportion of cases reported may vary for a number of reasons. In addition to a lack of training in recognizing ARs, these factors include i) a lack of awareness of the existence and benefits of a reporting program, ii) the time and effort required to complete the reports, which competes with other work of a busy health professional, and iii) a reluctance to report by physicians who may view AR reporting as opening their prescribing practices to outside scrutiny. These barriers are a widely acknowledged international reality in the field of adverse reaction reporting. Several studies conducted in foreign jurisdictions explored attitudes about AR reporting and barriers to reporting[7,8,9,10]. These studies surveyed various health care professionals including pharmacists and doctors practising in various settings. The results are aggregated below in Table 3.

While the reporting scheme relies on a potential reporter making the connection between a symptom and a therapy, the importance of these additional barriers is supported by evidence that even for serious, very recognizable adverse reactions there is a high degree of under-

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[7] Belton KJ, Lewis SC, Payne S, Rawlins MD, Wood SM. Attitudinal survey of adverse drug reaction reporting by medical practitioners in the United Kingdom. Br J Clin Pharmacol 1995; 39: 223-226

[8] Green CF, Mottram DR, Rowe, PH, Pirmohamed M. Attitudes and knowledge of hospital pharmacists to adverse drug reaction reporting. Br J Clin Phamracol 2001; 51: 81-86

[9] Generali JA, Danish MA, Rosenbaum SE. Knowledge of and attitudes about adverse drug reaction reporting among Rhode Island Pharmacists. Ann Pharmacother 1995; 29: 365-9

[10] Eland IA, Belton KJ, Van Grootheest AC, Meiners AP, Rawlins MD, Stricker BH. Attitudinal survey of voluntary reporting of adverse drug reactions. Br J Clin Pharmacol. 1999;48:623-627

reporting[11]. Mandatory reporting and other supporting initiatives are meant to address these barriers.

Mandatory reporting could raise awareness of the value of reporting simply by virtue of the public debate which will accompany such an initiative. Once enacted into law, mandatory reporting would provide a focus for reminding health professionals of their duty to report suspected adverse reactions and promote awareness of any related program activity. Legal sanctions may also help encourage the provinces to integrate the topic of adverse reaction reporting into their health professional academic programs and courses.

Table 3: List of reasons, commonly cited in the literature examining AR reporting, as to why health professionals do not voluntarily report ARs.

Barriers to reporting
Perceptions - heavy workload - apathy - considered to be an 'additional' duty - negative attitude toward form-filling
Convenience and awareness - no form, phone or fax number for reporting - lack of information on how to report - no knowledge of the program
Confidence - lack of confidence in recognizing ARs (related to experience - studies show senior staff more likely to report). - tendency to report only *proven* ARs, as opposed to *suspected* ARs. - no training in recognizing or reporting ARs. - fear of 'appearing foolish' for suggesting an event is a suspected AR
Motivation - inadequate feedback - misconceptions about the purpose and usefulness of reporting - no financial incentive
Legal - concern about legal liability - fear of breaching patient confidentiality
Personal - ambition to collect and publish a personal series of cases

On April 2004, results of the Public Opinion Survey on Key Issues Pertaining to Post-market Surveillance of Marketed Health Products in Canada, Final Report were released. The report, which is available on Health Canada's website (http://www.hc-sc.gc.ca/dhp-mps/medeff/research-recherche/decima_2003_final_rep-rapp_e.ht

[11] Mittmann, N, Knowles S, Gomez M, et al. Under-reporting of Toxic Epidermal Necrolysis. Drug Safety 2004; 27(7): 477-487

ml), presented findings on the effectiveness of Health Canada's risk communication methods and included Canadians' views and opinions on reporting of adverse reactions.

Not only do Canadian health professionals believe that under-reporting is common, they also consider this to be a fairly serious problem. More than eight in ten naturopaths (91%), nurses (88%) and pharmacists (83%), and more than seven in ten physicians (74%) and dentists (71%) say that under-reporting of ARs is a very or somewhat serious problem in Canada today. The seriousness of under-reporting (by indicating "very serious") is most concerning to naturopaths (56%) and nurses (47%).

When it comes to health professionals reporting ARs, lack of familiarity with how to report is an issue for many. While more than nine in ten (92%) pharmacists say they know how to report an AR, this is the case for less than two-thirds (63%) of physicians, fewer than one in two (44%) nurses, and only a minority of naturopaths (19%) and dentists (13%). Even fewer members of each profession are familiar with where to find the AR reporting form. When asked about situations in which they would not report an AR, the most common circumstances are those in which an AR is already known, or is considered too trivial to report. While very few (3%) specifically mentioned they would not report an AR because they did not know how, the overall results clearly demonstrate that awareness of how to report is an obstacle that needs to be addressed in order to improve the rate of AR reporting in Canada.

Health professionals were also asked for their suggestions on how current AR reporting methods could be improved, in terms of making it easier, faster, or more accurate. The most frequent suggestion was to make the process easier for health professionals, by improving access to the form (27%), making it easier to submit a report (6%) and making the whole process less time consuming (3%). It is noteworthy that a few individuals suggested developing awareness among health professionals of the reporting process (14%).

1. *Should legislation in this area provide health professionals with legal protection against criminal or civil liability?*
2. *Should health professionals be compensated for participating in the reporting system (i.e. completing a report and follow-up)?*
3. *What other barriers can be directly addressed by legislation? Please suggest other complementary strategies, in addition to a legal obligation to report, that would be useful in addressing these known barriers.*

4.2 Maintain or improve report quality

A mandatory reporting system designed to increase the volume of reports by itself might not lead to success. The program's ability to identify potential problems also relies heavily on the contextual richness of the information in the case report describing the event and the circumstances, however, reports vary widely in quality, accuracy, and completeness.

An adverse reaction report must include the following four attributes: 1) an identifiable patient, 2) a suspected health product, 3) an identifiable reporter and 4) a reaction. However, reporters are encouraged to include other pertinent information that enhances the quality and usefulness of an AR report (see Table 4). For example, medical history and concomitantly used health products are important details often missing in submitted reports.

Table 4: List of detailed information items that enhance the quality and usefulness of the adverse reaction report.

Patient Details Identifier Age Sex Weight/height	**Relevant Medical History** Allergy Drug or alcohol abuse/Tobacco use Hepatic/renal dysfunction Previous reaction(s) Disease states (e.g., diabetes), etc.
Suspected Health Product(s) Trade name/common name Dosage form and strength Treatment start and stop dates Dose, frequency & route of administration	**Other health products being used at the same time** Any prescription and non-prescription drugs, natural health products, or other therapies Dosage, treatment dates, etc.
Details of suspected reaction Date of reaction Full description Tests, treatment, or hospitalization required	**Outcome** Information on recovery and any related outcomes In case of death, state cause of death and date
Reporter Information Name Address Telephone number Profession (speciality)	

A generally accepted pharmacoepidemiological principle is that it is better to make decisions based on fewer reports with high quality data than on many reports with poor quality data. This should be taken into consideration in developing and assessing options for mandatory reporting. For example, a strengthened legal authority could be designed to make it easier for Health Canada officials to contact the reporter in order to obtain missing data, request further pertinent details or follow-up on outcome, thereby increasing the quality of the information used to support decisions about safety problems. Moreover, referencing specific reporting requirements in regulation will encourage more complete reporting in the first instance.

An examination of different means of improving the quality of incoming data through a mandatory reporting requirement or other means should include a consideration of the regulatory burden on health professionals (see below).

1. *How might a mandatory reporting requirement affect quality of reporting?*
2. *How should a mandatory reporting system mitigate any impact on quality? Please suggest other measures that would support quality reports.*
3. *Should legislation in this area prescribe quality standards?*

4.3 Minimize administrative burden on health professionals

Typically, most health professionals would prioritize focussing on the direct care of their patients over filling out a Health Canada form. A misunderstanding of the product safety and subsequent patient safety benefits of a reporting program may contribute to a health

professional's reluctance to dedicate effort to reporting. As well, increased stress and reduced resources may also contribute to not reporting. Faced with a busy schedule, health professionals will become frustrated under a mandatory reporting system if their time is diverted away from providing patient care to reporting, if the reporting process is inefficient.

To make the reporting process more user-friendly, Health Canada is assessing the feasibility of using wireless technology (e.g. palm pilots) as a tool for the reporting of adverse reactions and for broadcasting new health product safety information at the point of care. This technology is expected to provide customized forms and drop-down lists that enable health professionals to promptly and more completely report information.

Health Canada is also developing a single window web site to centralize the collection of adverse reaction information and disseminate new health product safety information such as advisories and warnings to the health care community as well as consumers. It will be modeled after the well known US FDA web site, MedWatch. The Health Canada site will be called MedEffect Canada (MedEffet Canada) and is expected to be launched this year.

In designing options for a mandatory reporting system, consideration must be given to the need to minimize the regulatory burden on health professionals by making the system user-friendly, non-complex and, if possible, integrated within the paperwork already associated with typical patient care.

Health Canada will conduct a cost-benefit analysis of options to measure the potential impact of mandatory AR reporting on health professionals and the health care system. This would include costs associated with technology improvements, training, staff time etc.

1. *What other considerations would be relevant regarding the impact of a mandatory reporting requirement on health professionals?*
2. *How should a mandatory reporting requirement balance the interests of product safety and the practicalities of the regulated health professionals?*
3. *How can reporting under a mandatory system "fit"within the regulatory paperwork associated with typical patient care in private practice or health facility?*
4. *What actions may be required to adjust to a mandatory requirement?*
5. *What further measures might reduce the impact on health professionals?*

4.4 Minimize over-reporting

Another source of potential difficulty in the collection of AR data on a mandatory basis may be the reporting of certain kinds of ARs more readily than others (e.g. known ARs as opposed to unexpected or newly observed ones; less serious as opposed to serious ones). A mandatory reporting system might have the unintended effect of stimulating reporting of well documented, **non**-serious adverse reactions (i.e. information that would not contribute substantially to health product safety monitoring). The management (e.g., screening, data entry, coding etc) of these types of reports will also consume resources.

Health Canada wants to know about all suspected adverse reactions, but especially if they are:

- unexpected adverse reactions, regardless of their severity (not consistent with product information or labelling);
- serious adverse reactions, whether expected or not; and
- adverse reactions related to recently marketed health products (on the market for less than 5 years).

A mandatory reporting system may have the greatest impact on product safety if it is designed to encourage reporting of serious adverse reactions while ensuring that over-reporting of non-serious or well known adverse reactions does not dilute the overall efficiency of the signal detection process (i.e. the most critical trends become easier to identify in the absence of numerous, less critical reports).

1. *How can a mandatory reporting system be designed to limit overreporting?*
2. *What types of reactions should be reportable under a legal obligation?*
3. *Are changes to the regulatory definitions for reportable reactions required?*

4.5 Match assessment capacities

If reporting rates increase, the Department must be positioned to match this with increased ability to organize the data and evaluate reported reactions. These activities include data entry and scientific/medical coding of the incoming information.

Current Health Canada capacity for post-market monitoring, evaluation and dissemination of safety and therapeutic effectiveness information is insufficient to meet the expectations of Canadians. Mandatory reporting legislation will require additional resources to support the infrastructure for collecting, managing and evaluating the increased number of reports. Health Canada will conduct a cost projection of its report processing activity based on estimated levels of increased reporting.

4.6 Respect privacy

Measures for the protection of personal information will be a core consideration of a mandatory reporting system and communicated to health professionals and the public. Health Canada will work to ensure that the collection of data and its use is restricted to what is strictly required to achieve program objectives.

Health Canada also needs to be cognizant of how health organizations and health care professionals may interpret their responsibilities under privacy legislation and should facilitate their efforts to comply with privacy requirements. Mandatory reporting provisions could assuage concerns about breaching patient confidentiality and reporting without consent from the patient, as required by federal and provincial privacy legislation and professional ethical standards: the minimal intrusion of privacy rights (i.e. disclosure without consent) is warranted if disclosure is considered legitimate and compelled by statute.

1. *What impacts are health professionals facing now due to a patient privacy issue which could impact on the success of a mandatory reporting system?*

4.7 Promote compliance through sanctions

Design considerations and the scope of mandatory reporting (i.e. broad vs selective) should be linked with an ability to meaningfully enforce. For most, their professional duty to public health will be the main motivation in their decision to report, but the success of a mandatory reporting system may still be contingent on a strong compliance mechanism. Provisions for monitoring compliance would help ensure that the legislation is effective and that the regulator has a mechanism to help ascertain compliance with the law. The provisions could authorize or require inspections or investigations to be conducted. However, these mechanisms would need to be mindful of the need to minimize the costs for both the regulated professions and government.

The cross-jurisdictional nature of this issue and the potentially high cost of running a compliance program are some of the obstacles to compliance monitoring and enforcement activity. Penalties associated with failure to report might be difficult to apply since it is not easy to judge whether the health professional suspected an adverse effect which could be attributable to a health product. Case law for other mandatory reporting programs suggest that health professionals may argue that they were not able to identify a reportable reaction. Alternatively, a focus on demonstrating knowledge of the reporting system and having the means to report in place (e.g. copies of reporting forms, contact information etc) may be a more realistic strategy.

1. *What kind of compliance mechanism should be established?*
2. *Who should conduct the compliance activities and prescribe the circumstances under which they may be conducted?*
3. *What type of penalty (e.g., fines, professional consequences etc.) should be provided for in cases where health professionals do not comply with the law?*

4.8 Recognize a shared responsibility

Health Canada will collaborate closely with other parties to address any mandatory reporting implementation problems whose solutions can best be found in a cooperative, multi-jurisdictional approach in order for them to be implemented consistently and effectively. It is important to remember that market authorization holders (manufacturers) have primary responsibility under the Food and Drugs Act and Regulations regarding monitoring the safety of the use of their products.

Health Canada has made significant progress with respect to strengthening the way in which new health product safety information is collected and communicated to health care professionals and the general public. However, many different organizations and individuals contribute to health care in Canada including Health Canada, provincial and territorial governments, health care providers, manufacturers and consumers.

Many improvements to the reporting system can be implemented in a collaborative way involving all parties in the health care delivery system. Because health care services and products are delivered through the provincial and territorial programs, these initiatives must be carefully integrated across and between jurisdictions.

1. *How could the various parties contribute to the success of a mandatory reporting system?*

5. CONCLUSION

Upon completion of discussions on these preliminary issues, Health Canada plans to work with licensing bodies, health professional associations, provincial and territorial governments and health facilities to develop an Option Analysis Paper.

For example, rather than an all-inclusive requirement, targeted mandatory reporting may be advantageous in particular circumstances. More qualified or selective uses of the mandatory tool could be explored in the context of criteria based on: product characteristics (e.g., new chemical entity); nature of hazard (e.g., exceptionally rare or unexpected reaction); or vulnerable population (e.g., selected categories of paediatric adverse reactions). Or, the

requirement might be restricted to certain health professionals (physicians, pharmacists *etc.*) or to health care facilities rather than as a blanket requirement for all health professionals.

In developing options, Health Canada will consult with other programs and international jurisdictions on lessons learned from implementation of a mandatory reporting system. Representatives from France, Sweden, and Italy have shared their experiences in implementing mandatory AR reporting systems. While some countries have had limited success with mandatory reporting[12] we intend to learn from the experiences of those countries, and develop a uniquely Canadian regime that truly meets our needs in the context of the Canadian health system. In the end, the reason that these international mandatory reporting systems were not as successful as originally envisioned may lie in their design and implementation rather than their mandatory nature. There are also examples of provincial laws for mandatory reporting by health professionals in other areas, such as suspected child abuse and certain infectious diseases, that may provide further insight on the limitations and success factors of such a provision.

Health Canada officials expect to meet face-to-face with a variety of interested parties in late summer 2005 to assess and refine practical options for a mandatory adverse reaction reporting system for health professionals, and identify further opportunities for collaboration. The appropriateness of these options will then be assessed against alternatives for increasing reporting rates.

[12] Moride Y, Haramburu F, Requejo A, et al. Under-reporting of adverse drug reactions in general practice. Br J Clin Pharmacol 1997; 43: 177-81