COMMUNICATING DRUG SAFETY INFORMATION WORKSHOP

November 29 & 30, 2001

Hosted by

THERAPEUTIC PRODUCTS DIRECTORATE (TPD)

- SUMMARY REPORT -

Workshop Coordinated by

Bureau of Licensed Product Assessment (BLPA)
(now the Marketed Health Products Directorate - MHPD)

Introduction

The Therapeutic Products Directorate (TPD), Health Products and Foods Branch, Health Canada convened an invitational workshop on November 29 and 30, 2001 to undertake the following:

Objectives

• Explore issues and challenges respecting the communication of drug safety information;
• Identify potential partnerships and associated roles / responsibilities of collaborating parties with a view to promoting safe drug use; and
• Consider options for examining the efficacy of drug safety information dissemination.

Information Dissemination

A number of presentations set the context for discussions that took place during the two day workshop. The discussion on improving the dissemination of drug safety information led to the identification of barriers, suggestions on how they should be overcome, and who might collaborate to accomplish these tasks. The participants explored the question of partnerships and discussion led to the identification of partnership possibilities and how they might work.

Information Gathering

Proposed enhancements to TPD's active and passive surveillance approaches, and challenges to tracking products that are on the market were outlined. This led to discussion of issues related to improving the gathering of information on drug safety. From these discussions surfaced a number of challenges along with suggestions on how these could be overcome, identifying who might help strengthen the process.

Issues and Challenges

The *Communicating Drug Safety Information* workshop encouraged dialogue and cooperation among individuals and organizations involved in drug safety, and initiated new and open discussion. The following summary report identifies the issues and challenges that must initially be understood, and consequently addressed, if there is to be improvement in gathering of drug safety information and subsequently in communication of risk information.

Notes

1.   An "As-It-Was-Said" Report, prepared by Workshop facilitator, Raymonde D'Amour of Praxis Consultants, is available.

2.   Copies of the Workshop Agenda and List of Participants are appended to this Report.

3.   The text of this Report was prepared by Margaret Zimmerman, Manager - Paediatric Adverse Reaction Monitoring Project, Marketed Health Products Directorate (formerly Bureau of Licensed Product Assessment).

Dealing with Information Overload

Tailoring Information

Health care professionals are bombarded with information identified as critical to delivery of high quality patient care. Drug safety information in the form of Advisories and Dear Health Professional letters are two of the numerous communications crowding the "communication space" of health care providers in a busy patient care environment. Little time is available for sorting and assimilation of information in the daily or weekly schedule. It is thus critical to tailor information to the needs and workflow of the health care professional. In finding solutions to these challenges, it is important to explore collaboration and partnerships to ensure systems allow targeting of information specific to an applicable area of practice. Such an approach may minimize the information overload that occurs when safety information is disseminated to all parties.

Triaging Information

Discussion of possible solutions focussed on the need for a strategy to enable more focussed dissemination of drug safety information. Triaging of information was suggested as a step in this direction. It was felt triaging would allow dissemination of information to specific target audiences without overloading or desensitizing others. Triaging would include grading of risks associated with a drug product. It was noted that some triaging of information is currently occurring with Dear Health Professional letters. An example is anaesthetic drugs, where Health Canada focuses information dissemination on hospitals and other institutions most likely to administer such drugs.

Flagging Information

Flagging important safety information is also a potential solution in the effort to reduce information overload. This solution is aimed at making critical drug safety information more prominent and suggestive of material that requires timely attention. The mailing of new safety information (i.e., warnings and advisories) in an envelope with a clearly identified appearance (e.g., red box on an envelope with the message *Important New Safety Information on Drug Products*) is one strategy implemented to flag important safety information. It was acknowledged there is a need to evaluate this mechanism to better understand its ability to achieve the desired end result. Additional ideas will need to be generated , tested and evaluated.

Clarity

In addition, it was clear that to reduce concerns with information overload, there should be focus on the preparation of safety messages that are clear, action oriented, targeted to the intended audience and available at the point-of-care.

Source of Drug Safety Information

Credibility

Discussion identified a need to concentrate on establishing, or strengthening, an independent source of credible drug safety information. The

view expressed by the majority of participants was that Health Canada, as a regulatory agency, is an independent and unbiased source of information. These characteristics put Health Canada in the best position to be the provider of credible drug safety information for both the consumer and the health care community. However, the pros and cons of this option would have to be subjected to a more in depth assessment.

Leadership and Coordination

The consensus from participants was for Health Canada to take a leadership / coordination role in establishing a multi-sectoral process for standard setting with regard to dissemination of credible, objective safety information. The Canadian Task Force on Preventative Healthcare, characterised as a central source of credible and proactive information, was suggested as a good model.

How to Encourage Behaviour Change

Culture Change

This issue received considerable constructive discussion. It is an area that needs to be addressed if there is to be success in the gathering and communication of drug safety information. The underlying challenge is the apparent inability of drug safety information (or method in which it is disseminated), to bring about a culture change in the health care community that supports and takes full responsibility for drug safety issues.

Existing Mechanisms

To fully embrace a reporting culture requires that health care professionals be more aware of drug safety issues, and more educated on what needs to be done to contribute to safer medication use for patients. It was felt there is a need to make use of existing professional development mechanisms and opportunities to build more awareness of drug safety issues among professionals, and reinforce the crucial role they play in improving drug safety.

Language and Style

Participants noted it is critical that needs and interests of the target audiences involved in the exchange of such information be understood. What is intended and what is perceived should match. Choosing language and a style that are matched to the purpose of the communication and characteristics of the audience, and that allow the audience to understand and use the information effectively, requires a great deal of skill and understanding. Working collaboratively with health care professionals, consumers and organizations representing their needs will enable a better understanding of target audiences. It will allow development of more effective ways of connecting audiences with the information they need. Existing communication strategies need to be evaluated to answer the following questions: "Who is being targeted or influenced?", and "Will this approach be effective in engaging the target audience?".

Peer

Peer approval is viewed as a powerful motivator of change and an

Motivation important influence on culture change within a professional group. Comments from workshop participants consistently reinforced that drug safety messages need to reverberate through the community to gain momentum and strength. An initiative of the Canadian Paediatric Society was identified as an example of a member-based Society that has taken ownership and responsibility for the successful implementation of an active surveillance program. The paediatricians and many sub-specialists have bought into the program and are responsible for its on-going success and practical outcomes. A proposal is currently under consideration by Health Canada and the Canadian Paediatric Society for the inclusion of surveillance on serious adverse drug reactions (ADRs) in children.

Consumers as the Centre of Patient Care

Active Participant A great deal of attention was focussed on consumers, their role and needs in the post-market drug safety continuum. It was felt by many, particularly those whose mandate is to represent the patient, that the patient must be seen as an active participant in the drug safety process. They need to be viewed as an integral player on the health care team and in decisions about their drug therapy.

Shared Responsibility To facilitate full participation of the consumer on the health care team and in the decision making process, relevant information must be presented and disseminated effectively. It must also be accompanied by adequate support and assistance to ensure its proper use. Patients require sufficient information about health products to enable them to understand the benefits and risks; to be alert to symptoms that may point to potentially serious reactions; and to aid in safe and appropriate use of those products. It was also suggested there is a need to promote the fact that consumers are partners and as such have a shared responsibility in safe use of medications.

Efficient Dissemination There is a need to promote the availability of appropriate information to the consumer, and develop efficient dissemination vehicles, such as those utilized by many voluntary health organizations. Participant comments suggested that if appropriate drug safety information is currently available from government sources, most of the public does not know how to access that information.

Disseminating Information in a Timely and Effective Manner

Communication Loop Developing appropriate information is just one step in the information sharing paradigm. Ensuring mechanisms are in place to broadly disseminate the information to the intended audience in a timely and effective manner is the next challenge. Finally, measuring its effectiveness allows for the loop to be closed and continuously improved. The continuing challenge will be to develop and use effective communication channels to reach specified audiences, and then close the

loop by evaluating the impact and value of the communication.

Timely and Effective

Good decision making and provision of quality patient care is reliant on the ability to access critical drug safety information in a timely and effective manner. Attendees agreed that there are gaps to close to achieve a state where information is provided in a timely and effective manner. It was also agreed that improved communication will not come about through one solution, but rather a cluster of communication solutions tailored to the needs of the target audiences.

Action Oriented

At a practical level, the importance of Health Canada communicating concerns in a timely and effective manner was noted. It was felt that early recognition and awareness of a problem places the health care professionals in a better position to provide patients with an effective response and will help to prevent "crisis" situations. In addition to timely information dissemination, it was felt that emphasis needs to be placed on clarity of message, ensuring that the communication is action oriented. Unclear messaging that is not action oriented is making the role of communicating drug safety information to patients more challenging, and having less of the desired behavioural change impact.

Current Context

It was perceived by those in attendance that a number of options are currently available for consideration to improve the dissemination of drug safety information to target audiences. There was also acknowledgement of the need to focus resources on exploring solutions that are feasible in the current context/reality. With the longer term future in mind, other approaches can be piloted that are innovative and potentially viable, such as those made possible by technologies not currently widely utilized; e.g. the palm pilot.

Infrastructure

To quickly and effectively disseminate information in the immediate future, it is important to build and strengthen infrastructure capable of handling the increased need for information. The value to be gained by further exploring established networks for information transfer, such as those established by voluntary health organizations, was given serious consideration. These networks use repetition of the message from multiple sources to bring about improved communication. In addition, they have the capacity to expand the network of people taking action to improve drug safety. An example provided was the concept of a dissemination tree which might include the regional health authorities, pharmacy information systems, as well as networks supported by medical societies/organizations. It was also felt there may be benefit in exploring the services, expertise and networks that Communication Canada[1] provides.

Media Involvement

The involvement of the media in a more constructive role was discussed. It was apparent the media are viewed by many present at the Workshop with some scepticism. Regardless, the media are seen as a powerful communicator. It was

acknowledged that the media has the ability to inform and raise the level of debate at a local, national or international level. The media plays an important role in increasing public awareness and influencing use of health care interventions such as medication. It was suggested that developing effective relationships with the print and broadcast media makes good sense. This could include utilising a range of media tools to ensure the best chance of messages getting through. Approaches can be developed and fine-tuned that will enable the public and health professions to view the media as a credible source of drug safety information, and not merely (as expressed by some present) a source for scare tactics and sensationalism.

Industry

The role of pharmaceutical companies in information dissemination was also discussed. It was felt pharmaceutical companies need to improve their image as a respected and trustworthy source of information. A need was expressed to explore better mechanisms for industry to become more involved in dissemination of safety information.

New Technology

Computerized messages will almost certainly be used to disseminate drug safety information in the future. The potential of this vehicle to educate and better inform different groups about safety and health issues, and provide links to effective action is yet to be understood. The current challenge however, is to identify and develop mechanisms that enable dissemination of information in a timely and effective manner, until new technologies can be fully exploited.

Electronic Pharmacy Systems

Investigating use of electronic pharmacy systems (such as PharmaNet and WellNet) was noted as an example of an available technology that has significant potential in dissemination of drug safety information. The features of these systems allow for identification of drugs for which advisories or warnings have been issued, and for provision of consumer information. Discussion concluded that this could be considered as a feasible solution in the future provided finances were available to make necessary programming changes to these systems.

Strengthening the Collection of Drug Safety Information

The focus of the second day's discussions was on gathering of drug safety information. There are numerous barriers and challenges faced by health care professionals in reporting drug safety information. Those identified were:

Barriers and Challenges

1. Deciding on the diagnosis;
2. Attribution of a reaction to a product;
3. No model/methodology for patient care givers to follow to determine whether a reaction is worthy of reporting as an adverse event;
4. Physical act of reporting (complacency, fear of litigation, ambition to publish, ignorance, diffidence, lethargy, competing time pressures);

5. Perception that an adverse event is trivial or already known;
6. Lack of health professional and consumer awareness of the need for, and value of, adverse event data generation and collection;
7. The lack of useful feedback;
8. Actively engaging patients in adverse event reporting, either directly or indirectly, to establish shared responsibility for safe drug use;
9. The limited number of people in Canada who are trained to carry out adverse event data analysis;
10. The need for timely recognition and reporting of adverse events;
11. Balancing the volume of data collected with quality of data (signal generation challenges);
12. Finding the resources to get the critical information collected and assessed (quality and quantity challenge); and not allowing the collection to outweigh the analysis as a priority;
13. Difficulties with interdisciplinary communication/interaction including roles and responsibilities in adverse event data generation;
14. Technology for ease of reporting, data management, data analysis and information feedback to reporters in a timely manner; and
15. Relatively small population; i.e., it takes longer for rare reactions to be identified and confirmed if with only Canadian data.

How do We Drive Change in Practice?

Social Responsibility There is a need for heightened awareness and understanding of drug safety issues by health care professionals and consumers. There is also need for strategies that make it possible for these groups to make a difference. It was suggested it is possible to have many systems in place with simple reporting tools; however, if health care professionals and consumers do not have the knowledge, attitudes or belief that they are important contributors to a bigger system, that they have a social responsibility to report, then nothing will change.

Reporting Culture Creating a reporting culture requires the ability to change or form behaviours. A significant challenge will be encouraging health care professionals to assess their attitudes and behaviours with respect to reporting of adverse reactions, and to motivate adoption of behaviours that support and encourage reporting. The solutions developed should have the ability to educate, reinforce and encourage changes in attitudes and values, therefore providing the right foundation for behaviour modification. Tools and strategies, such as those successfully used by the health promotion field, may provide a valuable model or starting point. In addition to education, it was noted that supporting legislation has also helped to drive change in other jurisdictions; e.g., child abuse system.

Reality

No matter what the solutions, these need to be grounded in reality. As an example, the general medical practitioner works an average of 70 hrs/week and finds it almost impossible to add more to an already full schedule. It was their belief that adoption of reporting behaviours would require some form of reward or incentive program.

Ease of Reporting

From Health Canada's perspective, mechanisms that encourage a reporting culture among health care professionals should be put in place. Barriers should be removed. Reporting should be easy and less time consuming than it is on paper, and complimentary to, rather than intrusive with, the health professional's current workflow.

Educating the Healthcare Professional

Importance of Reporting

It was clearly felt by participants that whether the objective is to increase voluntary reporting or active reporting of adverse events, awareness of the importance of reporting needs to be raised. It is necessary to educate people with regard to why it is important to report, what should be reported, and how to report. It was noted that physicians may have difficulty in distinguishing in a single case whether the drug, the disease process or some other circumstances led to an adverse reaction. It was recognized that physician under graduate training may be limited due to full curricula. Additional emphasis on topics related to drug safety such as clinical pharmacology, drug development and benefit-risk issues may help to encourage a culture of reporting. This educational process would begin by going back into the curriculum of medical schools. In addition, it was felt academia needs to ensure that post graduate training of health professionals, as well as continuing health care professional medical education, covers all areas necessary for an understanding of drug action and adverse reactions. The development of a clinical decision making tool that would clearly identify what is a side-effect, what is a serious adverse reaction, and how to report, was also suggested as a mechanism for the education of health professionals.

The Role of the Consumer

Primary Responsibilities

In line with the move toward a more responsible and engaged patient, it was expressed by some that patients need opportunities to become actively engaged in adverse event reporting. The rationale being that they are the ones who take the medications and experience adverse events. Patients are seen as having four primary responsibilities: know the names of the medications they are taking, know why they are taking those medications, understand the potential side-effects, and know who to tell if there is problem. For this to happen, there is a responsibility to direct consumers to relevant information sources. There is a need for improved information on what reporting is about, why they need to be

involved, and what should be reported.

Although both pharmacists and physicians are in a position to educate patients, the role of pharmacists in information dissemination to the patient and consumer received considerable attention. Pharmacists have the opportunity to discuss issues related to adverse reactions with patients when medicines are dispensed. They can also assist the patient in understanding the type of information they need (and where to access it) to take their medications safely.

To whom the consumer or patient should report their adverse events, was an area that received some attention. It is felt by some that pharmacists are the front line and more accessible to patients for reporting an adverse reaction. Patients may see many doctors and therefore need a central point such as that provided by the community pharmacist. Others felt patients need to tell doctors, who can gather information on many patients and their medication side effects and then provide that information to the pharmacist. The majority of attendees expressed the need to have consumers go through a health care professional for the reporting of adverse event information. From a consumer perspective, it is important to acknowledge that the physician may perceive risks and adverse events differently than the patient. This is a major reason for the focus on greater opportunities for consumer reporting. Open to the possibility that many solutions are possible, there appears to be the desire and need for improved dialogue among health care professionals, consumer groups and the regulators to address consumer issues.

The Role of Industry

Industry was also identified as having a role in the gathering of drug safety information. It was felt that to improve their credibility and show a greater concern for patient care, industry should play a larger role in identifying adverse effects related to their drugs. Industry representatives expressed the desire to play a more constructive role, however cautioned they are not in the position to provide money for everything. The view, from industry's perspective, appears to be that nobody wants industry to make money but everybody wants them to give money. In fact, industry feels that "Synergy" is all about "my ideas and your money".

From an industry perspective, they have sympathy for those seeking resources to do this work, however they want it understand that there is not as much flexibility with resources as many would like to believe. Industry simply cannot do it all under current financial realities. However, industry is open and prepared to examine new ways of doing work. Rx&D would like to be a partner, however is not in a position to fund the whole process. Other attendees would like to see the redirection of industry funding into other initiatives.

Collection and Analysis of Data

*Quality
Vs
Quantity*

       The process for the collection and analysis of data was given considerable thought and consideration. It was recognized that increasing the volume of reports by itself would not necessarily lead to a more successful system. The ability to identify potential signals also relies on the quality of the information describing the reaction or adverse event, and the circumstances that support the reporter's assumptions. There is thus a need to discover how to improve the reporting rate, while recognizing the importance of increased quality of information and not just increased quantity of information.

*Increased
Reporting
Vs
Resource
Requirements*

       From evidence available, it is apparent that efforts to improve reporting of adverse events are paying off. Health Canada has gone from 7000 reports received in 2000 to almost 9,000 in 2001. Some practical concerns were expressed by Health Canada with regard to engaging new groups, including patients, to actively participate in the reporting of adverse reactions. Efforts to increase reporting rates are only useful if sufficient resources exist to enter the additional cases into the Canadian Adverse Drug Reaction Information System and investigate reported events. Unless additional resources are identified in the short term, efforts to increase the number of reports received will only increase the backlog. Resource issues include the ability to train/educate people to evaluate reports, work up issues, and contribute to the decision making process.

*Attribution
of
Event
to
Drug*

       It is also understood that there is a need to gather enough data to build a profile of critical information on any one product. However, there is the concern that the longer the process for collection and analysis of data, the longer it takes to get the critical information needed to ensure the safety of the patient. The quality of the information, and subsequent filtering of the information, are important in terms of attribution of whether this data has a serious relationship to a drug . There is also a need to distinguish progression of disease from failure of a drug; i.e., the background rate for a particular sign or symptom related to the disease. The question was asked as to what is the level of expertise required to do this work and how to ensure that the resources are in place to make this expertise available. Suggestions provided to improve this process and optimize use of currently available resources, focussed on the establishment of an expert group or advisory committee on management for post-market safety issues. The role envisaged for this group was completing an initial assessment of reports and making an assessment of the severity of the reaction reported.

*New
Vs
Established
Drugs*

       With regard to requirements for the reporting of information, it was felt that there are different needs depending on whether the drug is new to the market or well established. Those in attendance felt it was important to emphasize that when a drug is new to the market there is a danger in just looking for serious

adverse reactions. The collection of data should be simple and yet the net should be cast wide, even if the data is "noisy[2]". It has been out of "noisy" data that serious concerns have been identified, and regulatory actions taken, to either change labelling or remove a product from the market.

In addition to who should report and what should be reported, there was discussion of where reported information should be captured for future analysis. There appears to be limited or no value in decentralized system where individual or select groups deal with their own spontaneous reports. One or two confidential reports will not get to the seriousness of some background noise. It is clearly felt by participants that multiple spontaneous reports coming into a central location is the most powerful model. However, for this to model to function effectively, a process is needed with the end result being the report of an adverse reaction by anyone (i.e., consumer or health care professional). It was proposed that consideration be given to a computerized system that allows this to happen quickly and easily. With everyone able to report, and reports sent to a central location, evidence will build and signals end up on the "radar screen" in a more timely manner. With any model or system, the primary goal is to resolve issues for the individual patient regarding adverse reactions. Secondary, but also important, is to have a system in place that allows understanding of the issues, analysis and dissemination back to the health care community.

Where to go from Here

Opportunities

In his closing remarks, Dr. Robert Peterson, Director General for the Therapeutic Products Directorate, thanked everyone for their contribution and participation in the workshop and spoke to the tremendous opportunities to explore a number of issues. He identified linkages to be strengthened, and or created, among institutions/organizations offering continuing education programs, with a view to using this as a strategy to change cultures and ultimately improve the quality of reporting adverse events. He spoke to the greater potential for patient/consumer involvement by taking steps to encourage consumer reporting and linking patient reporting to prescribing practices. He suggested the need to explore various mechanisms and networks that would assist getting relevant information to the public. Below is a list of suggested next steps put forth from the workshop participants.

Participant Suggested Next Steps

1. Explore linkages with the colleges of medicine, dentistry, nursing and pharmacy, and with professional medical education programs/curricula;
2. Consider communicating reports, to provincial / territorial health care professional colleges, on statistics regarding adverse event reporting by region;
3. Pursue involvement of consumers in adverse event reporting (both passive

and active);

4. Undertake and pursue pilot projects with, e.g., Health Charities, Paediatrics;

5. Explore options for working with the media, including web links such that communication is established with consumers;

6. Evaluate the success and impact of Public Advisories as currently used;

7. Assess the regulatory role regarding signals from Adverse Reaction Reports (beyond the authority to approve, deny and revoke);

8. Investigate mandatory reporting in other countries with a view to assessing the advantages and disadvantages of these approaches;

9. Generate a report from these deliberations and circulate to participants for comment and review, with a view to making the document publicly available;

10. Explore how to improve partnerships between Health Canada and the health care professions for input on Advisories;

11. Assess the possibility of putting in place a national initiative on information management/information technology respecting pharmacotherapeutics, and establish linkages to health care professional education and practice;

12. Make this report available to the National Steering Committee on Patient Safety (led by The Royal College of Physicians and Surgeons of Canada);

13. Assess the results of current risk assessment and develop future risk communication models; e.g., target efforts to specialists, patient populations;

14. Explore the idea of making the post-approval process an "arms length mechanism" separate from the pre-approval process;

15. TPD endeavour to bring together partners, in the context of interdisciplinary cooperation, to initiate dialogue on patient safety (patient-centred) (e.g., CPhA, CMA, Colleges, CDA, CACDS, patients, industry (as observer)); and

16. TPD endeavour to reconvene the group in 6 months to report on what has been done to date and what else needs to happen.

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1. Communication Canada works with other government departments and agencies, as well as with the private sector and non-governmental organizations, on initiatives to inform Canadians about the services available to them from the Government of Canada.

2. The reference to "noisy" data, was a suggestion that one may receive a large volume of reports, many of which are already reported and/or appear in the product monograph.

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

AGENDA

**Therapeutic Products Directorate (TPD)
Workshop:**

Communicating Drug Safety Information

**November 29 & 30, 2001
Chaudière A, Château Cartier
Aylmer, Québec**

Purpose

Further to Health Canada's commitment to consider the jury's recommendations as a result of the Coroner's Inquest into the death of Vanessa Young, the purpose of the workshop is to:

- Explore issues and challenges respecting the communication of drug safety information
- Identify potential partnerships and associated roles / responsibilities of collaborating parties with a view to promoting safe drug use
- Consider options for examining the efficacy of drug safety information dissemination

Day 1

❑   **1.   INTRODUCTION**

09:00   1.1   Welcome and setting the context   Dr. Robert Peterson
          1.2   Group norms   Ms. Raymonde D'Amour
                     Take care of others
                     Take care of your self
          1.3   Expectations
          1.4   Review of the Agenda
          1.5   Introductions and information-sharing on current approaches to the dissemination of drug safety information

Desired outcome:
The participants will have an understanding of why they are here and what will take place during the workshop. They will have developed group norms, identified and clarified their expectations of the workshop and shared information on what is currently taking place in their organizations respecting the dissemination of drug safety information

10:15 Break

❏ **2. COMMUNICATING DRUG SAFETY INFORMATION**

10:30 2.1 Health Canada's Approach to Drug Safety Information Dissemination
Ms. Micheline Ho / Ms. Ann Sztuke-Fournier

11:00 2.2 Discussion on improving the dissemination of drug safety information

12:30 Lunch

13:30 2.3 Summation of suggested improvements to disseminate drug safety information

Desired outcome:
The participants will have discussed the challenges faced when disseminating information on drug safety and generated suggestions on how the challenges could be overcome. Potential collaborating parties and corresponding roles and responsibilities will have been proposed.

❏ **3. GATHERING DRUG SAFETY INFORMATION**

14:00 3.1 Presentation on Passive Surveillance Dr. Chris Turner

Current Adverse Drug Reporting (ADR) mechanisms and Health Canada's efforts to facilitate reporting by health professionals

14:15 3.2 Presentation on Active Surveillance Dr. Chris Turner

Health Canada's current approaches to actively seek out and gather drug safety information

14:30 3.3 Discussion on improving the gathering of drug safety information

15:15 Break

16:00	3.4	Summation of suggestions to improve the gathering of drug safety information

Desired outcome:
The participants will have discussed the challenges faced when gathering information on drug safety, and generated suggestions on how the challenges could be overcome. Potential collaborating parties and corresponding roles and responsibilities will have been proposed.

16:30		**Adjournment**

Day 2

❏   **GETTING UNDERWAY**

09:00   Caption of what we heard on Day 1
Review of the Agenda for Day 2

❏   **4.**   **EXAMINING THE EFFICACY OF DRUG SAFETY INFORMATION DISSEMINATION**

09:15	4.1	Setting the context	Dr. Robert Peterson

09:45	4.2	Consider options (such as the formation of a Joint Body) on how to examine the efficacy of drug safety information dissemination.

10:45		Break

11:00	4.3	Summation of proposed options to examine the efficacy of drug safety information dissemination.

Desired outcome:
The participants will have considered options re examining the efficacy of drug safety information dissemination.

❏   **5.**   **NEXT STEPS**

11:30	5.1	Identify what needs to happen further to this workshop
	5.2	Closing remarks
	5.3	Evaluation of the workshop

12:00		Invitation to lunch

13:00		The End

Workshop Participants / Observers & Resource persons

Dr. Richard Handfield-Jones	College of Family Physicians of Canada
Ms. Jacqueline Conant	Canadian Drug Manufacturers Association
Ms. Janet Cooper	Canadian Pharmacists Association
Dr. Isra Levy	Canadian Medical Association
Mr. Denis Morrice	Health Charities Council of Canada
Dr. Gary Johnson (30th only)	Federation of Medical Licensing Authorities of Canada
Dr. Chris Turner	Project Manager, Marketed Health Products Reorganization, Policy and Strategic Planning Directorate
Dr. John P. O'Keefe	Canadian Dental Association
Ms. Carol Repchinsky	Canadian Pharmacists Association
Mr. Robert White	Non-Prescription Drug Manufacturers Association of Canada
Mr. James Dunsmuir	Canadian Association of Retired Persons (Fifty-Plus)
Mr. Jacques Lefebvre	Canada's Research-Based Pharmaceutical Companies
Dr. John Parboosingh	Royal College of Physicians and Surgeons of Canada
Ms. Deb Saltmarche	Canadian Association of Chain Drug Stores
Ms. Ann Sztuke-Fournier	Unit Head, Advertising and Communications, Bureau of Licensed Product Assessment, TPD
Mr. Murray Elston (30th only)	Canada's Research-Based Pharmaceutical Companies
Ms. Juline Latrémouille (29th only)	Canada's Research-Based Pharmaceutical Companies
Ms Linda Levesque	Working Group on Women and Health Protection
Dr Francine Mathieu-Millaire	Collège des médecins du Québec
Mr. Pat Rich	Canadian Medical Association
Ms. Barbara Wells	National Association of Pharmacy Regulatory Authorities
Ms. Micheline Ho	Manager, Product Information Division, Bureau of Pharmaceutical Assessment, TPD
Dr. Robert Peterson	Director General, Therapeutic Products Directorate (TPD)
Mr. George Samiotis	Manager, Policy Operations Division, Bureau of Licensed Product Assessment, TPD

Resource / Observers

Ms. Stacey Gillis*	Policy Officer, Policy and Promotion Division, Biologics and Genetic Therapies Directorate (BGTD)
Dr. Judith Glennie*	A/Director, Risk Management Coordination Division, Policy and Strategic Planning Directorate
Ms. Jo-Ann Julien*	Program Consultant, Office of Consumer and Public Involvement, Health Products and Food Branch
Ms. Karolyn Lui*	Policy and Guideline Coordinator, Licensing Services Division, Medical Devices Bureau, TPD
Ms. Cathy Parker*	A/Manager, Policy and Promotion Division, BGTD

Mr. Jeffrey Pender*   Senior Communications Advisor, Health Products and
                                        Food Branch
Dr. Susan Robertson   A/Director, Bureau of Licensed Product Assessment, TPD

Ms. Kathy Vesterfelt   Regulatory Officer, Policy Division, Bureau of Policy and
                                        Coordination, TPD
Mr. Douglas Connors   Director of Communications, Natural Health Products
                                        Directorate

Workshop Support Team

Mr. Ross Duncan   Bureau of Policy and Coordination
Mr. Bill Leslie   Bureau of Licensed Product Assessment, TPD
Ms. Carolin Vaughn   Bureau of Policy and Coordination, TPD
Ms. Margaret Zimmerman   Bureau of Licensed Product Assessment, TPD

Ms. Raymonde D'Amour   Moderator, PRAXIS Consultants