NB: This document was developed by Legislative Renewal staff as a working document for internal purposes, with a focus on content rather than presentation. However, it is being made available to the public to provide background information.

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Executive Summary

Confidential commercial information is information that is supplied to the department by a third party and is treated consistently in a confidential manner by the third party. Currently, a fair amount of information is considered confidential even after a product has been approved. Free trade agreements impose on governments the obligation to protect confidential commercial information. Other jurisdictions have found ways to disclose information once the product is approved, some even before the product's approval.

Currently, the *Food and Drugs Act* is silent on the management of information received or generated by the Health Department. During the public national consultation on health protection legislative renewal, it was made clear by interested parties that government actions should be more transparent. The report of the committee of the Science Advisory Board which looked into the issue of the Drug Review Process indicated that new standards of access to information at all stages of the drug review process are necessary to enhance transparency and public confidence. The Therapeutic Products Programme has also instituted a Transparency Strategy in order to establish a coherent plan throughout the programme to improve transparency.

What is required is a balanced legislative approach, where the Act would provide the legislative authority to allow access to pertinent information for public health purposes while safeguarding commercial confidential information to the extent reasonably possible.

1. ISSUE

The purpose of this Issue Analysis Summary is to determine whether Health Canada should manage confidential commercial information differently than it does at the present time, and if so how and what provisions should be included in the legislation to that effect.

To help focus discussion, the issue is approached from the perspective of the drug approval process, but principles discussed hereunder would apply generally to any commercial information provided in confidence.

It is noted that the expression "third party" is used in the context of its definition in the *Access to Information Act*, i.e., any person, group of persons or organization other than the person who made the request or a government institution.

2. BACKGROUND AND ISSUE ANALYSIS

2.1 Current Situation

Confidential commercial information is information that is supplied to the department by a third party and is treated consistently in a confidential manner by the third party. It is

usually financial, commercial, scientific or technical information, the disclosure of which could result in financial loss. The *Food and Drugs Act* is silent on the management of information received or generated by the Department of Health.

At the moment, information such as the fact that a new drug submission is under review, the stage of review, the contents of a submission, the submission filing date, the ongoing clinical trials, parts of the Product Monographs (even after approval), the data the approval was based on, drugs released under the Special Access Program, etc., is considered to be confidential. This information is protected by common law and by international trade agreements. It can be requested under the *Access to Information Act* although some of the information listed above would in most cases be exempted under section 20 of the *Access to Information Act*:

> *20. (1) Subject to this section, the head of a government institution shall refuse to disclose any record requested under this Act that contains*
>
> *(a) trade secrets of a third party;*
> *(b) financial, commercial, scientific or technical information that is confidential information supplied to a government institution by a third party and is treated consistently in a confidential manner by the third party;*
> *(c) information the disclosure of which could reasonably be expected to result in material financial loss or gain to, or could reasonably be expected to prejudice the competitive position of, a third party; or*
> *(d) information the disclosure of which could reasonably be expected to interfere with contractual or other negotiations of a third party.*

The requirements of this section have led to awkward situations. For example, the Department is forced to deny knowledge of a filed new drug submission even when the information is already in the public domain, e.g., the submission filing dates appeared in the company's annual report. Another example would be the impossibility for the Department to respond to inquiries about a product once it is on the market when this information is in the submission data but not in the product monograph. This adds to the appearance of secrecy in the Department despite its objective to work in an open and transparent environment. At the same time, there is a demand for more openness on the part of the department and for information sharing.

2.2 Issues to Consider

When examining this subject, the following issues are raised:

2.2.1 Need for More Transparency/ Consumer's Right to Information

In the past, governments often took a paternalistic role. More and more, however, consumers want to take charge of their own health, to be informed and make their own health decisions or at least, to participate in the decision making regarding their health. The right of consumers to be informed is now well established.

During the Canada-wide public consultations held in the Fall of 1998 (see 2.3 below), one of the consistent and strong messages heard was that the lack of public confidence in Health Canada cannot be fully addressed until the activities of the Department are made more transparent and the public and the interested parties can play a more significant role in the decision making process. The way information is managed by the Department may lead to this perception of lack of transparency and even secrecy.

The Therapeutics Product Programme has conducted a consultation on the issue of improving the transparency in the drug approval process. The Programme asked if Industry would consent to make public the submission filing dates and the drugs available under the Special Access Program. At the moment, this information is considered confidential, and could not be disclosed unless the owner of the information consents to the disclosure, as provided under section 20. (5) of the *Access to Information Act*. Consumer groups, healthcare associations and patient groups agreed that this information should be public. Industry on the other hand, was receptive to the disclosure of the Special Access Programme drugs as it is recognized to be in the public interest, but strongly opposed the disclosure of submission filing dates, since they consider it would put the companies at a competitive disadvantage.[1]

2.2.2 Accountability to Canadians

Another strong message received during the consultations is that Health Canada should be made more accountable to Canadian citizens and that when decisions are made, Health Canada should consider the needs of consumers rather than the economic/competitive impact on Industry. For example, the right of Canadians to be informed should prevail over the right of Industry to have confidential commercial information protected when disclosure of this information is necessary for the protection of public health.

2.2.3 International Harmonization

In terms of international harmonization, some people are of the opinion that if Canada is the only jurisdiction where confidential commercial information is released, manufacturers may choose not to market products here to avoid the disclosure of trade secrets. Or they may decide to file only after their product has been approved in other major markets, which might delay the access of potentially beneficial products to Canadians. In cases where a submission for a Notice of Compliance (NOC) is filed, the free flow of information could be restricted because of the fear of disclosure. Also, the more information is available regarding pending applications, the more attempts to influence the decision for other considerations are likely.

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[1] Therapeutic Products Programme Issue Analysis Summary “Submission Filing Date Disclosure”, October 1998.

2.2.4 International Agreements

Free trade agreements impose on governments the obligation to protect confidential commercial information provided in support of a new drug/ agricultural chemical product submission.

2.2.4.1 North American Free Trade Agreement (NAFTA)

Article 1711 (5) of NAFTA provides for the protection of confidential data:

> *"If a party requires, as a condition for approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the party shall protect against disclosure of the data of persons making such submissions, where the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use."*

The definition section of Chapter 17 of NAFTA defines "confidential information" as including "trade secrets, privileged information and other materials exempted from disclosure under the Party's domestic law";

Subsections 1711 (1) and (3) of NAFTA prohibits the parties from relaxing the protection to that information.

2.2.4.2 TRIPS Chapter to the World Trade Organization

TRIPS ("Agreement on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods" commonly known as the "TRIPS" Agreement) is a chapter to the World Trade Organization Agreement (formed as a successor of the General Agreement on Tariffs and Trade) and its article 39 contains a similar provision to protect the confidentiality of confidential commercial information:

"*1. In the course of ensuring effective protection against unfair competition as provided in article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 3.*

2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices[2] so long as such information:

(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

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[2] For the purpose of this provision, "a manner contrary to honest commercial practices" shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.

(b) has commercial value because it is secret; and
(c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

Would NAFTA and TRIPS also apply to devices, novel foods, and natural health products? A definition of "pharmaceuticals" that was presented by Health Canada to a panel of the World Trade Organization reads as follows:

> *"Pharmaceuticals" is a contraction of "pharmaceutical preparations". In the present context, the term refers to products that contain medicines (i.e., drugs with therapeutic uses), which would include diagnostic and biological products."*

Medicine is defined by subsection 79(2) of the *Patent Act* as:

> *"Medicine" means a substance intended or capable of being used for the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or the symptoms thereof."*

If the panel adopts this definition to interpret the TRIPS Agreement, it is likely that the TRIPS and NAFTA obligations would apply to any device, food or natural health product that was intended for the diagnosis, treatment or prevention of a disease or disorder, or their symptoms.

There is also little doubt that the obligation not to disclose the information submitted in connection with regulatory approval would continue even after that approval has been granted or denied, unless, of course where the disclosure would be necessary to protect the public, or unless steps would be taken to ensure that the data is protected against unfair commercial use.

2.2.5 Submission Filing Dates

One important matter to clarify is what kind of information is in the interest of public health. What can be of interest to the public and what is in the interest of public health are two different matters. How could information about submission filing dates be considered in the interest of public health? It appears that this information is more useful to competitors than to the public. More generally, information about a product that is not yet on the market is not considered to be in the interest of public health as the general population is not exposed to the product, although some people argue it is because they may have an interest in knowing if or when a given product will come on the Canadian market.

For example, patients who are interested in knowing what submissions are under review may have participated in a clinical trial testing a particular product and have benefitted from the treatment, and thus they may have an interest in being able to have access to this product as soon as possible.

Then there are those who think that even the information about the products that do not make it to the market, i.e. the products that are refused, should be made public. They contend that, after all, part of the review is paid with taxpayers money.

The Health Action International Europe organization and the Dag Hammarskjöld Foundation jointly convened an International Working Group[3] to seek ways of promoting openness and accountability in drug regulation. Their report provides examples of information to which access is needed, and indicates that the information should be available from the date of marketing anywhere in the world, onwards. This position confirms the view that the disclosure of confidential information relating to a product prior to its approval/marketing not only challenges the international trade agreements, but it also appears to be of limited value in terms of public protection and public health.

It has been argued that the Department should focus on making information available on a product once it has reached the market. This is when the information is truly beneficial to the consumer, (i.e. is both of interest to the public and in the interest of public health) and does not violate international trade agreements (except "test data").

2.2.6 Impact on Department

There is a potential for decreasing the workload by diminishing the number of ATI requests the Department receives.

2.3 CONSULTATIONS

Here is a sample of what was heard during the national consultations on the issue of confidential commercial information:

"To ensure ability for transparency/public scrutiny of confidential information, we must have a provision in statute to prevail over the Access to Information and Privacy Acts."

"Our sense is that US is more transparent, with no apparent justification for the different situation in Canada. For example, data that could not be accessed in Canada because it was considered "trade secret", was public and readily accessible in the United States."

"We should move to the United States transparency, notwithstanding that Europeans or others

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[3] Statement of the International Working Group Transparency and Accountability in Drug Regulation, Health Action International, Dag Hammarskjöld Foundation, Uppsala, Sweden, 11-14 September 1996, p. 15-16.

are less transparent. Europeans are more transparent than Canada but less than the United States."

"We need clear rules regarding conflict of interest and disclosure."

"We need a "right to know" legislation."

"Trade secrets deserve consideration/protection, but must be clearly defined."

"Health and safety information should not be a trade secret."

"If its not a secret in the United States or elsewhere, it should not be a secret here."

"Canada Gazette not good enough."

"The law must require transparency."

"The transparency of process is more important than trade secrets."

"We have expressed concerns about the lack of consent required for drugs used for un-approved uses, lack of population-based research prior to approval of drugs, the secret nature of the drug approval system and the lack of public access to information about drugs."

"Public health should prevail over industrial secrets."

"Consumers' right to know what is in the food they eat is more important than industry's need to keep secret "proprietary" information."

2.4 International Comparison

2.4.1 United States

In the United States, as long as a drug has not been approved, as a general rule, the information is not releasable. The following statement appears on the United States Food and Drug Administration (USFDA) website: "FDA cannot comment about drugs that are in the review process. We cannot answer a question about when a drug will be approved or not approved." Similarly, before the approval of a drug, nothing would be available under the *Freedom of Information Act*.

The United States have public hearings or "Advisory Committee Meetings" as part of the drug approval process for some new drug applications (at the discretion of the USFDA) and over-the counter drug monographs. The recommendations of the Advisory Committee are not binding in that the USFDA considers them, but makes the final decision. If a drug is subject to an Advisory Committee Meeting, notice of the meeting will be published in the Federal Register (published almost daily) at least 15 days before the scheduled date of the meeting. For example, the notice would say:

> "The Committee will consider the safety and efficacy of new drug application (NDA) 20825, Zeldox™ (Ziprasidone Hydrochloride capsules, Pfizer Inc.) proposed for the management of psychotic disorders."

An organization called Public Citizens sued the USFDA because they felt the public could not make representations during public hearings since they did not have access to the information the Advisory Committee had. As a result of the lawsuit, the Court ordered the USFDA to develop and implement a policy to allow disclosure of information provided to the Advisory Committee. This policy is entitled "Guidance for Industry - Disclosing Information Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Related to the Testing or Approval of New Drugs and Convened by the Center for Drug Evaluation and Research" and has been in effect since January 2000. In short, it requires the sponsor to prepare an information package that is then given to the Advisory Committee for review.

Interestingly, this policy lists the materials that are typically disclosable and those that are not typically disclosable. Information that will usually be considered disclosable in advisory committee packages includes the summary tables of safety and effectiveness data, summaries of clinical or non-clinical safety or effectiveness data, summaries of suspected adverse drug reaction data, statistical summaries of safety and effectiveness data, clinical or preclinical protocols, copies of slides to be presented by the sponsor at the advisory committee meeting, names of the principal investigators, proposed indications for usage, dosage and administration, safety sections of product labelling, and any other information that has been previously publicly disclosed by the sponsor.

Although some of the material above might be considered confidential commercial information at earlier stages of the drug development process, the USFDA believes that it is appropriate to make them available at the time of an advisory committee meeting if they are germane to the issues being discussed.

Usually, the following materials would be considered to be trade secret or confidential commercial information and exempted from disclosure: product formulation and other chemistry, manufacturing, and controls information, full reports of raw clinical or preclinical data (raw data is data presented by individual subject) and reports of unpublished studies.

The sponsor can either provide the USFDA with an information package that is suitable for public release, with the mention "Fully Releasable Sponsor Submission" or submit an information package which will have to be redacted (purged from confidential commercial information and personal information) by the USFDA. Most sponsors choose the first option.

Twenty-four (24) hours before the Advisory Committee Meeting, the USFDA will post on its website the sponsor package or the Center for Drug Evaluation and Research

redacted package.

Advisory Committee Transcripts are posted on the website within 30 days after the meeting. They are also available 15 days after the meeting from the Freedom of Information office.

Once a drug has been approved, the letter of approval will appear on the USFDA website along with the labelling. The letter of approval mentions the date the submission was submitted, the date it was approved, the indications approved, the dosage form and the concentration. A substantial approval package is also eventually posted on the website. It contains the medical, chemistry, pharmacology, statistical, microbiology, clinical pharmacology biopharmaceutics and bioequivalence reviews, administrative documents and correspondence between the sponsor and the USFDA. A quick browse through the database of approved new drugs (http://www.fda.gov/cder/approval/index.htm) reveals that for many products, the approval package has not been posted yet. The reason given for this deficiency is that the USFDA has a large backlog in terms of the approval packages that have to be redacted by the Freedom of Information office.

2.4.2 E.M.E.A. (European Agency for the Evaluation of Medicinal Products)

Information on final Opinions, whether positive or negative, in relation to initial applications for marketing authorization, is now made available 60 days after adoption of the Opinion by the Committee for Proprietary Medicinal Products (CPMP). Opinions are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the Opinion.

In case of positive Opinions, the Summary of Product Characteristics (SPC), which is the information destined for health professionals, will be attached. As an example, one strength/ pharmaceutical form will be selected in case of multiple strengths/ pharmaceutical forms. In case of negative Opinions, the grounds for refusal of the marketing authorization will be annexed.

Once medicinal products are authorized by the European Commission, the trade name, package Leaflet and labelling will be published in the European Public Assessment Report (EPAR). See http://www.emea.eu.int/index/indexh1.htm . In case of Opinions adopted by majority vote, the divergent position will be included in the European Public Assessment Report. This information, as well as the chronological history of the submission, is not publicly available before completion of the review.

2.5 Science Advisory Board- Report of the Committee on the Drug Review Process

The Science Advisory Board, made up of recognized experts in public health from different disciplines and with different perspectives, was established in 1997 to provide independent advice to the Minister on the renewal of the Health Protection Program.

As lack of transparency is also a frequent public criticism when it comes to the Drug Review Process of the Branch, a Science Advisory Board Committee was created to examine the Drug Review Process and to propose recommendations for action. Here are a few of its findings:

- The current drug review process is unnecessarily opaque. Health Canada persists in maintaining a level of confidentiality that is inconsistent with public expectation and contributes to a public cynicism about the integrity of the process.

- Much more transparent practices are quite feasible within existing legislation; further, given the legislative renewal now being undertaken for Health Canada, there is little barrier to introducing any such legislative amendments as might be required.

- Transparency is essential to public confidence. It is believed that the Branch should set new standards of access to information at all stages of the drug review process, enhancing transparency and public confidence.

2.6 The Transparency Strategy of the Therapeutic Products Programme

The Transparency Strategy is an initiative of the Therapeutic Products Programme to enhance programme transparency and is part of a department-wide objective of increasing transparency for Health Canada operations and policy making. As a high priority, the Therapeutic Products Programme will cohesively link its plans and actions to enhance programme transparency into a well documented, easily understandable and widely accepted strategy. The Transparency Strategy and accompanying action plan will be used:

- to determine which gaps need to be filled
- to articulate what is already being done throughout the Therapeutic Products Programme,
- to inform interested parties, both within Health Canada and among stakeholder groups about what the Therapeutic Products Programme is doing to enhance transparency,
- to enable the Therapeutic Products Programme to ensure that interested parties needs are being accommodated.

3. OPTIONS ANALYSIS

3.1 Option 1: Status Quo

The current *Food and Drugs Act* is silent on the issues of confidential commercial information management. Under this option, the proposed legislation would also abstain from addressing these issues, and the disclosure of information would continue

to be subject to the common law rules, the *Access to Information Act*, and to international trade agreements.

However, the global trend of providing more information to the public and Health Canada's objective to make its activities more open and transparent support the proposition that the proposed legislation should contain a policy directive on confidential commercial information management. A major disadvantage of the status quo is that it perpetuates the appearance of secretive operations and the lack of open communication by the Department.

3.2 Option 2: Balanced Legislative Approach.

The Act could provide the legislative authority to allow access to pertinent information for public health purposes while safeguarding commercial confidential information to the extent reasonably possible. The Act would be complemented by regulations and administrative guidelines as described hereunder.

As to confidential commercial information, the proposed Act would provide that:

- The purpose of the proposed Act would be to protect the health of the people of Canada. Access to pertinent information would be required to achieve that public purpose. However, this would need to be balanced against the need to safeguard privacy and commercial confidentiality to the extent reasonably possible.

- One of the values underlined at the beginning of the Act would be openness and would be described in these terms: public scrutiny of government actions relating to health and safety and public engagement in the decision making process shall be encouraged.

The proposed Act would:

- Authorize the collection, use and disclosure of information by Health Canada, including information with commercial value such as financial, scientific or technical information (hereafter called "commercial information"), to the extent necessary, in the opinion of the Minister, to promote and preserve the health of the people, subject to what follows.

  One must remember that the circumstances in which Health Canada could actually "compel" the production of information would be more limited than the circumstances in which Health Canada could "collect" information (provided voluntarily).

  The Hazardous Materials Information Review Act would continue to apply.

- Establish restrictions and safeguards to protect the confidentiality and security of the information, particularly as it relates to "identifying personal health information" and confidential commercial information.

Commercial information of a confidential nature obtained by the Minister of Health in the course of the administration of this proposed Act could not be disclosed except in so far as:

- consent to the release of the information was given explicitly or implicitly;

  For example, the person was informed that the information would be disclosed and chose to provide it anyway.

- The information already is legally in the public domain;

- The disclosure is authorized by the proposed Act or the regulations or some other lawful authority; or

- the Minister believes on reasonable grounds that:

  - the disclosure is required to address a significant risk to the health and safety of the public;

  - there is no other reasonably practical means of addressing the risk; and

  - the public interest as it relates to public health and safety clearly outweighs in importance any prejudice to the person or organization concerned.

In any situation where the Minister intends to disclose confidential commercial information, the Minister would be required to:

- inform the person who provided the information of the intention to release the information and provide the person a reasonable opportunity in the circumstances to make representations;

  The process would be similar to the one found in the Access to Information Act.

- take reasonable measures to limit the content of the disclosure to what the Minister believes on reasonable grounds is required to promote and preserve the health of the people.

How should the issue be resolved when the Minister intends to disclose commercial information and there is a disagreement as to whether the information actually constitutes confidential information? More specifically:

- *Should it be left for the Minister to decide, subject to judicial review by the Federal Court?*

- *Should an independent "commission" decide on the validity of the claim for confidentiality and if the claim is valid determine what information could be used to advise the public of a health risk without unduly infringing on business confidentiality or trade secrets? Is this a realistic solution when a significant health risk requires immediate action?*

- *The Hazardous Materials Information Review Commission (created under the Hazardous Materials Information Review Act) already performs a somewhat similar function under Part 2 of the Hazardous Products Act, in the context of the Workplace Hazardous Materials Information System (WHMIS). Should the mandate of this Commission be extended?*

In any civil action, even when a settlement involving a confidentiality agreement has been reached between the plaintiff and the defendant and has been confirmed in a court order, the Minister of Health could have access to health and safety information contained in court records. Unless otherwise available through other sources, information obtained in this manner:

- could only be used by Health Canada for the purpose of assessing and addressing health risks and taking preventive measures to protect the public;

  For example, it could be used to determine whether a product should be ordered out of the market but it could not be used in proceedings of a punitive or compensatory nature such as criminal prosecutions or actions in damages.

- would be protected against disclosure by Health Canada in accordance with the rules described above; and

- could not be used in legal proceedings or otherwise, by a party other than the government of Canada.

Provided that Health Canada has the authority to collect personal or commercial information according to the rules described above (i.e. receive information provided on

a voluntary basis), it would also compel the production of information (i.e. force someone to provide the information) in the following cases:

- where prescribed in the Act or regulations;

  For example, manufacturers would be required to monitor and report serious adverse health effects associated with their products, including those pertaining to safety and efficacy.

  Should the Minister have the authority to require that a person provide Health Canada with information needed for health surveillance and research purposes, by way of a formal notice published in the Canada Gazette or in some other manner, an easier process than having to adopt regulations? This would be similar to section 46 of the Canadian Environmental Protection Act.

- to administer or enforce the legislation; or

  For example, Health Canada could inspect the records of a manufacturer or require a supplier to provide the results of tests or clinical trials regarding a product. This could also be used to obtain from the Customs and Revenue Agency information regarding the importation in Canada of a non-compliant product, in order to be able to trace it back and operate a recall.

- where the Minister believes on reasonable grounds that:

  - the information is required to address a significant risk to the health and safety of the public;

  - there is no other reasonably practical means of addressing the risk; and

  - the public interest as it relates to public health and safety clearly outweighs in importance any prejudice to the individual or party concerned, or compelling the production of the information would clearly benefit the individual or party to whom the information relates.

    For example, an airline company could be required to produce the list of passengers who travelled on the same flight as a person later found to suffer from a dangerous contagious disease, so that the people exposed can be

contacted and precautionary measures can be taken.

Regulations could be adopted respecting matters such as:

- the activities involving the collection, use or disclosure of information that Health Canada is authorized to conduct in support of its mandate;
- circumstances and conditions under which a person, organization or government institution may be compelled to produce personal or commercial information or record to the Minister of Health for the purposes of the proposed Act;
- who in Health Canada is authorized to have access to confidential information, for what purposes and under what conditions;
- safeguards that Health Canada must put in place to ensure the protection of confidentiality;
- internal procedures and review mechanisms;
- cooperation agreements and protocols with other governments or organizations concerning the collection, use or disclosure of information;
- what constitutes valid informed consent in specific circumstances;
- the disposal of the information once it is no longer required for the purpose for which it was collected, subject to the provisions of the *National Archives Act* and the *Privacy Act*;
- the information systems, facilities and monitoring stations to be established, maintained and operated and the information to be exchanged, searched and matched with other information;
- the class of individuals who may act on behalf of minors, incompetents, deceased persons or any other individuals under the proposed Act and regulating the manner in which any rights or actions of individuals under the proposed Act may be exercised or performed on their behalf;
- determining the extent to which this proposed Act or other Acts and regulations will apply to a program or activity involving the collection, use or disclosure of identifying personal health information;

With respect to the product review process of health products, the proposed legislation could provide authority to:

- render the process of reviewing submissions for market authorizations more transparent, respecting matters such as:

    - conducting public hearings where appropriate;

        (Along the line of what is being done in other countries such as the United States.)

    - facilitating public access to relevant information including:

        - status of pending submissions for market approval;
        - summary of data presented by the manufacturer to demonstrate the safety of a new product (and its effectiveness in the case of a new drug);
        - summary of Health Canada's evaluation of the safety and effectiveness of the product;
        - reports of adverse effects to both safety and efficacy;
        - other non-proprietary information;
        - enforcement actions taken by Health Canada

Proper legal authorities coupled with the necessary resources would facilitate progress towards opening the review process while protecting the confidentiality of commercial information.