# ORDER PO-2262

## Appeal PA-030180-1

## Ministry of Health and Long-Term Care

## NATURE OF THE APPEAL:

The Ministry of Health and Long-Term Care (the Ministry) received a request under the *Freedom of Information and Protection of Privacy Act* (the *Act)* for access to the following information:

1. Copies of any and all cover letters from the applicant company for their submission(s) to the Ontario Drug Benefit Formulary (ODBF), (Ministry of Health and Long Term Care, Drug Programs Branch, Health Services Division) since January 1, 2002 for the products listed in [an appended table]

2. Copies of any and all correspondence (including NDSS) related to the submission(s) in 1. issued by the Ministry of Health and Long-Term Care, Drug Programs Branch, Health Services Division to the applicant company since January 1, 2002 for the products listed in the appended table1.

The Ministry located the responsive records and denied access to them, claiming the application of the following exemptions contained in the *Act*:

- Advice or recommendations - section 13(1);
- Third party information - sections 17(1)(a), (b) and(c); and
- Economic and other interests – sections 18(1)(c) and (d)

The Ministry provided the requester with an index of records containing a description of the records and the exemptions claimed for each.

The requester (now the appellant) appealed the Ministry's decision.

During the mediation stage of the appeal, the appellant narrowed the scope of the request and clarified that he is seeking access only to the initial letters from the applicant company, as described in part 1 of the original request and the final responses from the Ministry as described in part 2 of the original request. As a result, a number of responsive records were removed from the scope of the appeal (Records 2, 3, 6, 9, 12 to15, 18 to 22, 25, 26, 29, 32, 35 to 40, 43 to 46, 49, 52 to 55, 58 to 63, 65, 67 to 70, 73, 76, 77, 80, 83 to 85, 88, 89, 92 to 95, 98 to 100, 103 to 112, 115 to 119, and 122 to 125).

Further mediation was not possible and the appeal was moved into the adjudication stage. I initially sought the representations of the Ministry and eight parties whose interests may be affected by the disclosure of the records (the affected parties). I received representations from the Ministry and three affected parties. The non-confidential portions of the affected parties' submissions and the complete representations of the Ministry were provided to the appellant, along with a Notice of Inquiry.

One of the affected parties made extensive submissions with respect to a portion of one document (Record 82) but did not address the application of the exemptions claimed to the other records containing information about it.

I received submissions from the appellant. The appellant indicates that while he wishes to obtain access to all of the non-exempt information in the records, the primary focus of the request and subsequent appeal is on the name of the Applicant Company, the name of the product that is the subject of the application, the date the application was submitted and the date of the Ministry's recommended approval.

I then provided a copy of the appellant's representations to the Ministry and invited it to make further representations by way of reply. The Ministry submitted additional reply representations.

## RECORDS:

The following records, consisting of correspondence, remain at issue in the appeal:

> Records 1, 4, 5, 7, 8, 10, 11, 16, 17, 23, 24, 27, 28, 30, 31, 33, 34, 41, 42, 47, 48, 50, 51, 56, 57, 64, 66, 71, 72, 74, 75, 78, 79, 81, 82, 86, 87, 90, 91, 96, 97, 101, 102, 113, 114, 120, 121, and 126.

These records consist of 24 Applicant Cover letters and 24 Ministry Approval letters covering the period January 1, 2002 to the date of the request.

## DISCUSSION:

### THIRD PARTY INFORMATION

The Ministry and the affected parties submit that the mandatory exemption in section 17(1) applies to the records as they contain trade secrets, as well as commercial, financial, scientific or technical information provided to the Ministry with an expectation that they would be treated confidentially.

### General principles

Section 17(1)(a), (b) and (c) state:

> A head shall refuse to disclose a record that reveals a trade secret or scientific, technical, commercial, financial or labour relations information, supplied in confidence implicitly or explicitly, where the disclosure could reasonably be expected to,
>
> > (a) prejudice significantly the competitive position or interfere significantly with the contractual or other negotiations of a person, group of persons, or organization;

> (b) result in similar information no longer being supplied to the institution where it is in the public interest that similar information continue to be so supplied;
>
> (c) result in undue loss or gain to any person, group, committee or financial institution or agency; or

Section 17(1) is designed to protect the confidential "informational assets" of businesses or other organizations that provide information to government institutions. Although one of the central purposes of the *Act* is to shed light on the operations of government, section 17(1) serves to limit disclosure of confidential information of third parties that could be exploited by a competitor in the marketplace [Orders PO-1805, PO-2018, PO-2184, MO-1706].

For section 17(1) to apply, the institution and/or the affected parties must satisfy each part of the following three-part test:

1. the record must reveal information that is a trade secret or scientific, technical, commercial, financial or labour relations information; and

2. the information must have been supplied to the institution in confidence, either implicitly or explicitly; and

3. the prospect of disclosure of the record must give rise to a reasonable expectation that one of the harms specified in paragraph (a), (b) and/or (c) of section 17(1) will occur.

In Order PO-2097, I addressed the application of section 17(1) to a number of similar records which related to an application by a pharmaceutical company for the inclusion of its products on the Ontario Drug Formulary. In that decision, I made certain findings with respect to the application of section 17(1) to records that are similar to those under consideration in this appeal. I intend to adopt many of the findings and conclusions reached in that decision in the adjudication of the issues before me in this appeal.

***Part 1: type of information***

The types of information listed in section 17(1) have been discussed in prior orders:

> *Trade secret*
>
> Trade secret means information including but not limited to a formula, pattern, compilation, programme, method, technique, or process or information contained or embodied in a product, device or mechanism which
>
> (i) is, or may be used in a trade or business,

(ii) is not generally known in that trade or business,

(iii) has economic value from not being generally known, and

(iv) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy [Order PO-2010].

*Scientific information*

Previous orders have determined that scientific information is information belonging to an organized field of knowledge in the natural, biological or social sciences, or mathematics. In addition, for information to be characterized as scientific, it must relate to the observation and testing of a specific hypothesis or conclusion and be undertaken by an expert in the field [Order PO-2010].

*Technical information*

Technical information is information belonging to an organized field of knowledge that would fall under the general categories of applied sciences or mechanical arts. Examples of these fields include architecture, engineering or electronics. While it is difficult to define technical information in a precise fashion, it will usually involve information prepared by a professional in the field and describe the construction, operation or maintenance of a structure, process, equipment or thing [Order PO-2010].

*Commercial information*

Commercial information is information that relates solely to the buying, selling or exchange of merchandise or services. This term can apply to both profit-making enterprises and non-profit organizations, and has equal application to both large and small enterprises [Order PO-2010]. The fact that a record might have monetary value or potential monetary value does not necessarily mean that the record itself contains commercial information [P-1621].

*Financial information*

Financial information refers to information relating to money and its use or distribution and must contain or refer to specific data. Examples of this type of information include cost accounting methods, pricing practices, profit and loss data, overhead and operating costs [Order PO-2010].

**Findings with respect to part 1**

The Ministry submits:

> as a general proposition, applicant manufacturers' covering letters necessarily fall within section 17 because the fact alone of *making* a listing application is confidential propriety [sic] information.

It goes on to add that:

> The Ontario Guidelines for Drug Submission and Evaluation, dated September 2000, at page II-4, states that manufacturers are required to provide the following information in their covering letters:
>
> - The brand name, generic name, strength, dosage form, and various package sizes to be considered for reimbursement;
> - The regulation under which the submission is being made;
> - If a generic drug, the name of the original product to which an interchangeability designation is being sought;
> - The type of listing sought (i.e. General Benefit or Limited Use);
> - Any exempting regulations being applied for (i.e. additional strength, format, pseudogeneric or aqueous solution);
> - A fast track request, if applicable.
>
> The MOHLTC submits that this information consists of either trade secret, commercial or financial information, and that the 24 covering letters contain this listed information. The drug name, strength and dosage alone constitute a manufacturer's trade secret and commercial information; proposed pricing is clearly financial information as well, since it reflects the unit price for the named drug at a given dosage.

One of the affected parties submits that the information contained in the records constitutes a "trade secret" as it "discloses which drug products [it] was (secretly) planning to market in Ontario" and "[its] secret marketing, regulatory and technical/scientific plans relating to these new products." This affected party also makes reference in its confidential representations to the commercial, scientific, technical and financial information included in the records which relate to its applications.

Another affected party makes similar arguments in favour of a finding that the records contain information that qualifies as its "trade secret." It submits that information relating to the contractual relationships it has with other manufacturers represents a "confidential strategy" and ought to be characterized as a trade secret for the purposes of section 17(1).

In Order PO-2097, I made the following finding in response to the submissions of the Ministry and an affected party that the records contained information which satisfied the definition of "trade secret" for the purposes of section 17(1). I determined that:

> In my view, the types of information contained in the records at issue in this appeal do not constitute "trade secrets" for the purposes of section 17(1). Despite the evidence tendered by the affected party, I find that the strategies and the methodologies relating to governmental relations which are included in the records are common throughout the pharmaceutical industry and are not in any way unique to the affected parties. The Guidelines referred to by the appellant set the ground rules for the submission of new drug products and describe the process to be employed by all manufacturers. The records do not describe the processes or formulas for the manufacturing of the drug produced by one of the affected parties, rather they relate strictly to the company's efforts to have the drug included in the Ontario Formulary. In my view, this information cannot qualify as a "trade secret" for the purpose of section 17(1) as it is generally known in the pharmaceutical industry and is common to all manufacturers.

In the present appeal, I find that this reasoning is also applicable. The covering letters and responses from the Ministry do not contain information about the actual processes or formulas involved in the manufacturing of drug products. Rather, the information relates to the efforts of the affected parties to secure a listing in the Drug Formulary for their products. As a result, adopting the rationale from Order PO-2097, I find that the information does not qualify as "trade secrets" for the purposes of section 17(1).

All of the records at issue are concerned with the marketing of drug products by the affected parties. Each record refers to a particular product, its pricing and so on. The records include information about the prices to be charged for the drug products. Record 82 contains information about a particular contractual arrangement entered into by a manufacturer that also qualifies as "commercial information" about this particular affected party. As a result, I have no difficulty in finding that all of the records, in whole or in part, contain information that qualifies as "commercial information" for the purposes of section 17(1).

In addition, many of the records also include a description of their therapeutic value or, in the case of generic drugs, their brand name equivalent. In some cases, the application letters from the manufacturers contain detailed information pertaining to the clinical trials performed and the results of those trials. I find that this information qualifies as "scientific information" within the meaning of section 17(1).

In conclusion, I find that all of the records contain some information that satisfies the requirements of the definition of "commercial information" and that others contain "scientific information" for the purposes of section 17(1).

***Part 2: supplied in confidence***

*Supplied*

The requirement that it be shown that the information was "supplied" to the institution reflects the purpose in section 17(1) of protecting the informational assets of third parties [Orders MO-1706 and PO-2097].

Information may qualify as "supplied" if it was directly supplied to an institution by a third party, or where its disclosure would reveal or permit the drawing of accurate inferences with respect to information supplied by a third party [Orders PO-2020, PO-2043].

The contents of a contract involving an institution and a third party will not normally qualify as having been "supplied" for the purpose of section 17(1). The provisions of a contract, in general, have been treated as mutually generated, rather than "supplied" by the third party, even where the contract is preceded by little or no negotiation [Orders PO-2018, MO-1706].

The Ministry and the affected parties submit that the information contained in the initial letters from the manufacturers to the Ministry was "supplied" within the meaning of section 17(1). They also argue that the disclosure of the references to the supplied information that are contained in the Ministry's final approval letters would reveal the substance of the supplied information and also meets the requirements of section 17(1).

In my view, the commercial and scientific information contained in the initial submissions from the manufacturers was supplied by the affected parties to the Ministry for the purposes of section 17(1). Further, I find that the disclosure of the commercial and scientific information in the responses from the Ministry would allow the drawing of accurate inferences with respect to the information actually supplied by the affected parties.

*In confidence*

In order to satisfy the "in confidence" component of part two, the parties resisting disclosure must establish that the supplier had a reasonable expectation of confidentiality, implicit or explicit, at the time the information was provided. This expectation must have an objective basis [PO-2020].

In determining whether an expectation of confidentiality is based on reasonable and objective grounds, it is necessary to consider all the circumstances of the case, including whether the information was

- communicated to the institution on the basis that it was confidential and that it was to be kept confidential

- treated consistently in a manner that indicates a concern for its protection from disclosure by the affected person prior to being communicated to the government organization

- not otherwise disclosed or available from sources to which the public has access

- prepared for a purpose that would not entail disclosure [PO-2043]

The Ministry submits that its' *Ontario Guidelines for Drug Submission and Evaluation* indicates to drug manufacturers that their submissions will "be held in confidence" by the Ministry. It also states that some of the initial submissions made by the manufacturers contain explicit statements of confidentiality and that there is an implicit expectation of confidentiality surrounding this type of information, due to its proprietary nature.

This point is reiterated by several of the affected parties, one of which points out that:

> It is the standard practice of both federal and provincial Canadian pharmaceutical authorities not to disclose submissions from any manufacturer seeking regulatory approval. For example, Health Canada does not disclose the existence or contents of New Drug Submissions or Abbreviated New Drug Submissions. The fact that the Ministry has refused complete disclosure of the Second Party Information confirms that both the Ministry and the Second Party regarded the Second Party Information as confidential when it was supplied to the Ministry.

In my view, the information contained in the initial submissions by the affected parties was provided to the Ministry with a reasonably-held expectation that it would be treated in a confidential fashion. The Ministry's *Guidelines* referred to above confirm that the parties making submissions for a listing in the formulary do so with an expectation that the information they supply will be treated confidentially by the Ministry. In addition, I find that the disclosure of some of the information contained in the Ministry's responses to those submissions would also reveal the substance of the confidential information supplied directly by the manufacturers. As a result, I find that portions of this correspondence also contain information that was provided to the Ministry in confidence. In this regard, I find specifically that the information described in the response letters as "Drug Benefit Price(s)" was provided to the Ministry with an expectation that it would be treated confidentially.

***Part 3 – harms***

*General principles*

To meet this part of the test, the institution and/or the third party must provide "detailed and convincing" evidence to establish a "reasonable expectation of harm." Evidence amounting to speculation of possible harm is not sufficient [*Ontario (Workers' Compensation Board) v. Ontario (Assistant Information and Privacy Commissioner)* (1998), 41 O.R. (3d) 464 (C.A.)].

The failure of a party resisting disclosure to provide detailed and convincing evidence will not necessarily defeat the claim for exemption where harm can be inferred from other circumstances. However, only in exceptional circumstances would such a determination be made on the basis of anything other than the records at issue and the evidence provided by a party in discharging its onus [Order PO-2020].

*Analysis*

***Section 17(1)(a)***

One of the affected parties and the Ministry suggest that the disclosure of the information contained in the records could reasonably be expected to "lessen competition in the pharmaceutical marketplace." The affected party argues that the appellant would be able to gain an undue advantage "to minimize their regulatory costs of entering the respective markets for the named pharmaceutical products" and would "almost certainly invest additional resources in challenging the declaration of equivalence issued by the federal government respecting [its] products and attack the Ministry's decision on interchangeability and inclusion on the Formulary of [its] products."

The manufacturer referenced in Record 82 provided detailed representations expressing its objections to the disclosure of the information contained therein. Because of the confidential nature of those representations, I am unable to describe them further in this decision.

The Ministry's submissions focus primarily on the disclosure of pricing information, relying on the decision in Order 47. The Ministry also indicates that information relating to the timing of a submission for inclusion in the Formulary is also a "highly guarded valuable secret in the pharmaceutical industry." It suggests that, if released, the affected parties "would be placed at a competitive disadvantage since this information would be public whereas none of its competitors' similar information is public." It then goes on to argue that having this information available would assist a competitor in bringing a similar product to market sooner. How exactly this might occur, however, is not explained.

With respect to the information in the records which relates to "scientific testing, manufacturing procedures and methods, sales or marketing projections, etc.", the Ministry submits that the disclosure of this type of information "would assist a competitor to bring a drug similar to theirs onto the market more quickly than would otherwise be the case" and that "this would have an extremely adverse effect on the competitive position of the affected third party."

The appellant submits that the information contained in the submissions and responses cannot qualify for exemption under section 17(1) because:

> . . . the fact that the Applicant Company has applied [for] and received the Ministry's recommended approval for their product to be listed in the ODBF is already public knowledge, and the information relating thereto is currently

> published on Health Canada's Notice of Compliance (NOC) website. No breach of confidential information is therefore made via the disclosure of [the] Requested Information.
>
> . . .
>
> The disclosure of the date of submission and dates of approval for products already listed on the ODBF (i.e. the Requested Information) has no impact on the competitive position or contractual negotiations of the Applicant Companies or products in question. This disclosure would also not result in any undue loss or gain to any person whatsoever, as the approval process for the products in question is already complete and disclosed in the current ODBF.

In Order PO-2097 I reached the following conclusion regarding the application of section 17(1)(a) to information found in similar records. I determined that:

> Generally, I find favour with the positions expressed by the Ministry and the affected parties with respect to the harms which could reasonably be expected to follow the disclosure of the information which I have found to be subject to Parts I and II of the section 17(1) test. I find that the affected parties in particular have provided me with convincing and detailed evidence of a reasonable expectation that disclosure of this information would result in harm to their competitive position in what is clearly a very competitive industry. It is clear from the evidence provided to me by all of the parties that pharmaceutical companies view their marketing strategies and the information they provide to the Ministry in support of a Formulary listing application as information worthy of protection from their competitors. These principles have assisted me in making the findings set out below.

In my view, the disclosure of certain information contained in the initial letters provided by the affected parties to the Ministry in support of their applications for an ODBF listing could reasonably be expected to result in harm to their competitive position. I refer specifically to information relating to the marketing or manufacturing of their products, as well as any other commercially unique information, such as that contained in Record 82. I further find that the disclosure of the pricing information contained in both the initial correspondence and the Ministry's responses could reasonably be expected to result in harm to the affected parties' competitive position and that this information also qualifies for exemption under section 17(1)(a).

Much of the information in the records is included in the ODBF and the equivalent listing maintained by Health Canada, which are publicly available databases. This includes information relating to equivalencies and interchangeability, dosages and the therapeutic value of the drug. In my view, the disclosure of such information cannot give rise to a reasonable expectation of harm to the affected parties' competitive position.

In addition, I cannot agree with the position taken by the Ministry that the disclosure of the dates of the applications and approvals could reasonably be expected to lead to the harms contemplated by section 17(1)(a). In my view, the affected parties and the Ministry have not provided me with the kind of detailed and convincing evidence required to make such a finding. Accordingly, I find that this information does not qualify for exemption under section 17(1)(a).

I have provided the Ministry with a highlighted copy of the records indicating those portions which qualify for exemption under section 17(1)(a). Those portions of the records that are not highlighted are to be disclosed.

***Section 17(1)(b)***

In support of his argument that section 17(1)(b) has no application to the information contained in the records, the appellant submits that:

> Finally, there is little risk that the disclosure of the Requested Information would result in similar information no longer being supplied to the institution. Generic drug companies must submit their products to the Ministry for listing on the publicly disclosed ODBF, in order to permit these products to be interchanged by pharmacists as generic substitutions in Ontario. This is the only method available to Applicant Companies who wish to market their products in this way. The disclosure of the Requested Information would therefore not impede Applicant Companies from submitting similar information to the Ministry in the future.

In its reply submissions, the Ministry refutes this position as follows:

> . . . the disclosure of the applicants' cover letters could reasonably be expected to result in fewer ODBF applications from drug companies generally. They may choose not to apply at all, rather than have their proprietary information disclosed to their competitors, particularly if that information could also be of use in a private sector competitive context. Furthermore, it is in the public interest that such applications continue to be made; the greater the number of listed drugs, the greater the medical and financial benefit to the vulnerable population that is eligible to receive reimbursement for such drugs under the Ontario Drug Benefit Program.

I accept the arguments of the appellant with respect to the application of section 17(1)(b) to the information in the records. In my view, the affected parties will continue to make application to the Ministry for inclusion of their products on the Formulary because it is profitable for them to do so. I find that the Ministry has not provided me with the kind of detailed and convincing evidence required to demonstrate that the harms contemplated by sections 17(1)(b) could reasonably be expected to flow from the disclosure of the information contained in the records. In my view, there are commercial imperatives driving the affected parties to continue to make

applications for inclusion in the Formulary which will not be impeded by the disclosure of the information which is not exempt under section 17(1)(a).

***Section 17(1)(c)***

The Ministry argues that the disclosure of the information contained in the records could reasonably be expected to result in the an undue loss on the part of the affected parties because:

> . . . the information was developed solely from the work and experience of the affected third party drug manufacturers staff, totally at the companies' own expense, exclusively as a result of their own efforts. Release of any or all of the Records could 'jump-start' a competitor by providing extremely valuable information relating to technical pharmaceutical issues, manufacturing methods, and sales/marketing strategies. In addition disclosure of the records could provide a competitor with information with respect to how best to present data for regulatory and governmental approval. Thus, the competitor could address and avoid all the problems they encountered during the submission process, without having expended any time, effort or expense of its own. The Ministry submits that this scenario is patently unfair to them, and thus satisfies the criteria for 'undue loss' as presented by both the IPC of Ontario and the Nova Scotia Supreme Court [in *Re: Appeal Pursuant to Section 41 of the Freedom of Information and Protection of Privacy Act*]

The appellant submits that:

> The disclosure of the date of submission and the dates of approval for products already listed on the ODBF (i.e. the Requested Information) has no impact on the competitive position or contractual negotiations of the Applicant Companies or products in question. This disclosure would also not result in any undue loss or gain to any person whatsoever as the approval process is already complete and disclosed in the current ODBF.

In its reply representations, the Ministry makes the following submissions:

> . . . the undue advantage to competitors would be increased significantly if the Ministry Approval Letters were also disclosed, particularly in cases where the Ministry's recommendation, or the government's decision, is not to approve the drug product for listing in the Formulary. Knowing that a company producing a similar drug applied for a listing based on a specific strength, format or listing (i.e. general benefit or limited use) and was ultimately approved on a different basis (as evidenced by the Approval Letter or in the published Formulary), would provide an advantage to a competing manufacturer.

In my view, the disclosure of information relating to the type of listing sought by the affected parties in their applications could reasonably be expected to result in an undue loss to them. As has been repeated in previous orders and the representations of the parties many times, the pharmaceutical industry is extremely competitive. Drug companies make use of every advantage available to them to increase their market share or product visibility. This includes the publication of unfavourable comments or peer reviews about each others products. In my view, the disclosure of information relating to the types of listings sought, particularly if the final approval granted is for a different type of listing, could reasonably be expected to result in an undue loss to that manufacturer through the publicizing of that fact by a competitor. For this reason, I agree with the position taken by the Ministry with respect to information relating to the type of listings sought and, ultimately, determined by the Ministry.

In my findings under section 17(1)(a), I determined that information relating to pricing, marketing and manufacturing that is contained in the records was also exempt from disclosure. For reasons similar to those addressed above, I find that this information also qualifies for exemption under section 17(1)(c).

However, I find that the disclosure of information relating to the dates of the applications, the products for which a Formulary listing is sought and the dates of approvals from the Ministry could not reasonably be expected to result in the harms contemplated by section 17(1)(c). I find that I have not been provided with the kind of detailed and convincing evidence required under the exemption to establish that the harms in section 17(1)(c) could reasonably be expected to follow the disclosure of this information.

As noted above, I have provided the Ministry with a highlighted copy of the records indicating those portions which are exempt under sections 17(1)(a), and now (c), and are, therefore, **not** to be disclosed.

## ADVICE OR RECOMMENDATIONS

### General principles

Section 13(1) states:

> A head may refuse to disclose a record where the disclosure would reveal advice or recommendations of a public servant, any other person employed in the service of an institution or a consultant retained by an institution.

The purpose of section 13 is to ensure that persons employed in the public service are able to freely and frankly advise and make recommendations within the deliberative process of government decision-making and policy-making. The exemption also seeks to preserve the decision maker or policy maker's ability to take actions and make decisions without unfair pressure [Orders 24, P-1398, upheld on judicial review in *Ontario (Minister of Finance) v. Ontario (Information and Privacy Commissioner)* (1999), 118 O.A.C. 108 (C.A.)].

"Advice" and "recommendations" have a similar meaning. In order to qualify as "advice or recommendations", the information in the record must suggest a course of action that will ultimately be accepted or rejected by the person being advised [Orders PO-2028, PO-2084, upheld on judicial review in *Ontario (Ministry of Northern Development and Mines) v. Ontario (Assistant Information and Privacy Commissioner)*, [2004] O.J. No. 163 (Div. Ct.)].

Advice or recommendations may be revealed in two ways:

- the information itself consists of advice or recommendations

- the information, if disclosed, would permit one to accurately infer the advice or recommendations given

[Orders PO-2028, PO-2084, upheld on judicial review in *Ontario (Ministry of Northern Development and Mines) v. Ontario (Information and Privacy Commissioner)*, [2004] O.J. No. 163 (Div. Ct.)]

Examples of the types of information that have been found *not* to qualify as advice or recommendations include

- factual or background information
- analytical information
- evaluative information
- notifications or cautions
- views
- draft documents
- a supervisor's direction to staff on how to conduct an investigation

[Orders P-434, PO-1993, PO-2115, P-363, upheld on judicial review in *Ontario (Human Rights Commission) v. Ontario (Information and Privacy Commissioner)* (March 25, 1994), Toronto Doc. 721/92 (Ont. Div. Ct.), PO-2028, upheld on judicial review in *Ontario (Ministry of Northern Development and Mines) v. Ontario (Information and Privacy Commissioner)*, [2004] O.J. No. 163 (Div. Ct.)].

**Analysis**

The Ministry takes the position that the records contain "advice or recommendations" within the meaning of section 13(1) as they "relate to suggested courses of action that will ultimately by accepted or rejected by its recipient during the process of deliberation." It argues that the records contain advice relating to "pharmaceutical interchangeability and generics" and that it is possible to "deduce accurate inferences with respect to advice and recommendations to list the products in the Formulary/CDI."

In its reply representations, the Ministry expanded somewhat on these submissions, arguing that the Ministry "approval letters" "reflect *recommendations* made by the DQTC to the Minister, and by the Minister to Cabinet." The Ministry points out that the "approval letters" do not "constitute or reflect a decision by the Ministry to list a drug product on the Formulary. Only the LGIC [the Lieutenant Governor in Council] has the power to decide whether or not to designate a drug product as a listed drug product under the *Ontario Drug Benefit Act* and must do so by way of a regulation." The Ministry further explains:

> . . . drug manufacturers' listing applications are presented to the DQTC for review. One of the DQTC's main functions is to make recommendations to the Minister on the applications, regarding the listing of the product on the Formulary. This recommendation is clearly referred to in the records at issue.

The appellant indicates that he is not seeking access to any "advice or recommendations" that may be included in the records.

I have carefully reviewed the contents of the "approval letters" and have concluded that the "approval letters" do not contain any indication that the DQTC has made a "recommendation" or provided any "advice" to either the Ministry or the LGIC. The letters simply indicate that the DQTC does not have any further questions about the application and that the applicant is asked to confirm the DIN and prices with a Ministry official. I cannot agree with the position taken by the Ministry that the disclosure of the records would somehow "reveal" the recommendation of the DQTC. The inclusion of the product in the Formulary would also verify the fact that it had received the approval of the DQTC.

As a result, I find that section 13(1) has no application to the "approval letters" at issue in this appeal.

**ECONOMIC INTERESTS**

The Ministry has also applied the discretionary exemptions in sections 18(1)(c) and (d) to the information contained in the records. These sections state:

> A head may refuse to disclose a record that contains,
>
> (c) information where the disclosure could reasonably be expected to prejudice the economic interests of an institution or the competitive position of an institution;
>
> (d) information where the disclosure could reasonably be expected to be injurious to the financial interests of the Government of Ontario or the ability of the Government of Ontario to manage the economy of Ontario;

The purpose of section 18 is to protect certain economic interests of institutions. The report titled *Public Government for Private People: The Report of the Commission on Freedom of Information and Individual Privacy 1980*, vol. 2 (Toronto: Queen's Printer, 1980) (the Williams Commission Report) provides the following description of the rationale for including a "valuable government information" exemption in the *Act*:

> In our view, the commercially valuable information of institutions such as this should be exempt from the general rule of public access to the same extent that similar information of non-governmental organizations is protected under the statute . . . Government sponsored research is sometimes undertaken with the intention of developing expertise or scientific innovations which can be exploited.

For sections 18(1)(c) or (d) to apply, the institution must demonstrate that disclosure of the record "could reasonably be expected to" lead to the specified result. To meet this test, the institution must provide "detailed and convincing" evidence to establish a "reasonable expectation of harm." Evidence amounting to speculation of possible harm is not sufficient [*Ontario (Workers' Compensation Board) v. Ontario (Assistant Information and Privacy Commissioner)* (1998), 41 O.R. (3d) 464 (C.A.)].

The purpose of section 18(1)(c) is to protect the ability of institutions to earn money in the marketplace. This exemption recognizes that institutions sometimes have economic interests and compete for business with other public or private sector entities, and it provides discretion to refuse disclosure of information on the basis of a reasonable expectation of prejudice to these economic interests or competitive positions [Order P-1190].

Given that one of the harms sought to be avoided by section 18(1)(d) is injury to the "ability of the Government of Ontario to manage the economy of Ontario", section 18(1)(d), in particular, is intended to protect the broader economic interests of Ontarians [Order P-1398].

The Ministry provided a great deal of background information describing the process whereby drug products are added to the Formulary and the financial checks and balances in place to ensure that taxpayer dollars are spent in the most cost-effective manner. It summarizes its position as follows:

> . . . the disclosure of the records would prejudice [the Ministry's] economic interests in that the operation of the drug submission and Formulary listing system would be impeded and compromised. Pharmaceutical companies typically submit all of the necessary Records to the DPB [the Drug Programs Branch] of the Ministry in the strictest confidence and rely on the fact that this confidence will not be breached. If these Records were to be disclosed, pharmaceutical companies would lose trust in the good faith of the government with respect to the maintenance of confidentiality.

> . . . there is information in some of these Records that, if publicly disclosed, could be deliberately misused in order to create the impression that the drug product is unsafe or ineffective. In addition, some of the dates in the Records, if taken out of context or presented in isolation by an unscrupulous competitor, could be used to infer that the marketing campaign for some of the drugs was fraudulent or misleading.
>
> It is reasonable to expect that disclosure of these Records would result in damage to both the tangible and intangible assets (i.e. its reputation in the industry) of the affected third party drug manufacturers. As a result, it is highly unlikely that a company would desire to participate in the Formulary/CDI drug submission process of the MOHLTC in the future. It thereby follows, that if a pharmaceutical company suffers a serious breach of confidentiality, resulting in the loss of valuable trade secret and sensitive scientific/technical, commercial and financial information, few if any other pharmaceutical companies will be willing to be involved in dealings with the Ontario Government.
>
> The MOHLTC submits that this scenario described above would be extremely injurious to the financial interests of the Government of Ontario and to the Government's ability to manage the economy of the province. For example, the listing of the drug products on the Formulary is expected to result in significant cost savings to the Government of Ontario.
>
> On its own, a savings loss of this magnitude would be injurious to the provincial government, especially in the light of the present climate of fiscal restraint. However, as previously noted, it is likely that disclosure of the confidential information of one drug company would lead to a 'ripple effect' throughout the industry, whereby few if any pharmaceutical companies would be willing to commit the time, money and resources necessary to complete the drug Formulary submission process. The MOHLTC submits that such a resulting outcome would be extremely injurious to the financial interests of the Government of Ontario and to the ability of the Government to manage the economy.

I note that in my discussion above, I have found that the scientific and commercial information that was supplied to the Ministry by the applicant companies with an expectation that it would be treated confidentially is exempt from disclosure under section 17(1). In my view, the disclosure of the remaining information, particularly that relating to the dates of the applications and approvals cannot reasonably be expected to result in the harms contemplated by sections 18(1)(c) and (d). The disclosure of this information will not have a "chilling effect" on the submission of new listing applications from pharmaceutical companies. They have an interest in marketing their products in Ontario and inclusion in the Formulary is an important part of that strategy. I am not convinced that the disclosure of the non-exempt (under section 17(1)) information remaining at issue will have that result.

Accordingly, I find that sections 18(1)(c) and (d) have no application to the information still at issue.

## ORDER:

1. I uphold the Ministry's decision to refuse access under sections 17(1)(a) and (c) to those portions of the records which I have highlighted on the copy of the records provided to the Ministry's Freedom of Information Co-ordinator.

2. I order the Ministry to provide the appellant with copies of those portions of the records which are **not** highlighted in the copy of the records provided to the Ministry's Freedom of Information Co-ordinator by **May 21, 2004** but not before **May 14, 2004**.

3. In order to verify compliance with the terms of Order Provision 2, I reserve the right to require the Ministry to provide me with copies of the records that are disclosed to the appellant.

April 16, 2004

Donald Hale
Adjudicator