

Reconsideration Order PO-2680-R

Appeal PA-040044-1

Order PO-2528

Ministry of Health and Long-Term Care

BACKGROUND:

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:

All documentation including communications to or from the Ministry, internal memoranda of the Ministry, correspondence, technical or other reports or data, submissions, opinions, contracts and other relevant information relating to the application for the listing and the listing of the drug [a specific drug] in the Special Drugs Program [SDP] of the Ministry.

The Ministry granted the requester access in part to the responsive records, but denied access to the remaining information pursuant to sections 13(1) (advice to government), 17(1)(a), (b), (c) (third party information), 18(1)(c), (d), (g) (economic and other interests), 19 (solicitor-client privilege), and 21(1) (personal privacy) of the Act. In addition, the Ministry charged the requester a fee of \$143.90 for search, preparation and copies of the responsive records.

The requester, now the appellant, appealed the Ministry's decision in part.

Following mediation, the application of the exemptions in sections 13(1), 17(1)(a), (b) and (c), 18(1)(a), (c), (d) and (g) and 23 to the records remained at issue. The Adjudicator previously assigned to this file commenced the inquiry and completed the representations stage. The file was subsequently transferred to me to complete the adjudication process.

I concluded the initial inquiry by issuing Order PO-2528. In that decision, I found that the vast majority of the records were exempt pursuant to one or more of the exemptions claimed for them. I determined, however, that Records 17, 19, 20 and 34 were not exempt, and ordered the Ministry to disclose these records to the appellant.

The Ministry submitted a reconsideration request in relation to the order provision requiring the disclosure of provision 6 of Record 34, and provided detailed representations in support of its request. I granted a stay of the order provision for Record 34 in its entirety.

RECORD:

The record subject to the reconsideration request comprises a facsimile cover and a four-page "Letter of Intent" signed by representatives of the Ministry and the affected party. This document sets out the terms and conditions of an agreement reached between the Ministry and affected party. Although the record contains a number of provisions, the Ministry has asked that I reconsider my decision only with respect to provision 6.

DISCUSSION:

THE RECONSIDERATION PROCESS

Section 18 of the IPC's *Code of Procedure* (the *Code*) sets out the grounds upon which the Commissioner's office may reconsider an order. Sections 18.01 and 18.02 of the *Code* state as follows:

18.01 The IPC may reconsider an order or other decision where it is established that there is:

- (a) a fundamental defect in the adjudication process;
- (b) some other jurisdictional defect in the decision; or
- (c) a clerical error, accidental error or omission or other similar error in the decision.

18.02 The IPC will not reconsider a decision simply on the basis that new evidence is provided, whether or not that evidence was available at the time of the decision.

GROUNDS FOR THE RECONSIDERATION REQUEST

Fundamental defect in the adjudication process

The Ministry submits that I should reconsider the application of the section 18(1)(c) and (d) exemptions to provision 6 of Record 34 as there was a two-year delay between the date that submissions were made in this appeal and the date the decision was rendered, and that in the intervening time, the government developed, introduced and passed the *Transparent Drug System for Patients Act* (the *TDSPA*), which the Ministry claims has fundamentally changed the Formulary/CDI Listing process. The Ministry contends that my failure to consider the application of sections 18(1)(c) and (d) to Record 34 in light of the *TDSPA*, which received Royal Assent on June 20, 2006, constitutes a fundamental defect in the adjudication process.

In this regard, the Ministry notes that the TDSPA significantly amended the two statutes that formed the basis of the Ministry's original submissions: the Ontario Drug Benefit Act (ODBA) and the Drug Interchangeability and Dispensing Fee Act (DIDFA). The Ministry states that its representations would therefore have been substantively different if written after the passage of the TDSPA on the basis that the disclosure of the information in provision 6 now has greater financial consequences for the Ministry and Government precisely because of the new Formulary/CDI listing process under the TDSPA. The Ministry submits that given the fact that the law regarding the Formulary/CDI listing process changed completely since the Ministry wrote its original submissions in 2004, I should have taken notice of the new legislation and given the Ministry an opportunity to make supplementary representations on the law's potential impact on the records at issue.

Analysis and Finding

In effect, the Ministry has asked that I consider new factual information that it says I should have taken notice of, even though that information was available at the time of the decision. I issued my decision in Order PO-2528 on November 22, 2006. As I noted above, the *TDSPA* received

Royal Assent on June 20, 2006. Pursuant to section 53 of the *Act*, where an institution refuses access to a record or part of a record, the burden of proof that the record or part of the record falls within one of the specified exemptions in the *Act* lies upon the institution. More particularly, previous orders of this office clearly identify that the onus is on an institution to demonstrate that disclosure of the records at issue "could reasonably be expected to" lead to the harms specified in sections 18(c) or (d). To meet this test, the institution must provide "detailed and convincing" evidence to establish a "reasonable expectation of harm". This applies at the time that the representations are sought from the parties.

Where information regarding newly enacted legislation that might have an impact on the records at issue in the appeal came to the Ministry's attention prior to the issuance of the decision, it was the Ministry's responsibility to draw that legislation to my attention, if it wished to do so. I do not agree that it is the responsibility of this office to actively and/or routinely scan legislation relating to institutions under the *Act* in the course of adjudicating an appeal, and invite representations on the possible impact such legislative changes might have on a particular record at issue in that appeal, absent some notice from the institution. As I noted above, section 53 of the *Act* clearly places the onus of establishing the application of an exemption, particularly a discretionary exemption, on the institution.

Although the Ministry's initial representations on the possible harms under section 18(1) were made in December of 2004, the representations stage of the appeal continued for another eight months. The Ministry was given an opportunity to provide reply representations in May of 2005 (and did so with its representations dated June 15, 2005). The appellant was provided with the opportunity to provide sur-reply representations in August of 2005. The Ministry did not indicate when it became aware of the pending legislation, however, it was certainly aware of its enactment at least six months before the decision was issued, as the *TDSPA* received Royal Assent in June 2006, and the Ministry cannot now rely on its own lack of diligence in putting this information before me in a timely manner to generate a ground for reconsideration of the decision.

Therefore, I find that failure to consider the possible implications resulting from the *TDSPA* at the time the order was issued does not constitute a defect in the adjudication process. Moreover, in accordance with section 18.02 of the *Code*, the Ministry's request technically does not fall within the reconsideration policy.

While that is sufficient to dispose of the reconsideration request, I have decided to also address the merits of this argument for the reasons that follow. Unlike other types of information that might support a particular argument, the enactment of legislation can have a direct and significant impact on a government program and records created under that program, and in particular, whether records fall within the purview of the *Act* and/or a particular exemption. Accordingly, I have decided to consider the Ministry's submissions with respect to the potential impact of this new legislation on provision 6 of Record 34. However, after doing so, I conclude that my findings in Order PO-2528 should not be varied.

ECONOMIC AND OTHER INTERESTS

As I indicated above, the Ministry has asked that I reconsider the application of sections 18(1)(c) and (d) only to the information contained in provision 6 of Record 34, although at first instance it had also claimed the additional exemptions in sections 18(1)(a) and (g) to this record. As explained below, the Ministry submits that the consequences of disclosure are different now that the *TDSPA* has been enacted. Sections 18(1)(c) and (d) 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;

Broadly speaking, section 18 is designed 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) explains 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.

Section 18(1)(c) and (d) take into consideration the consequences that would result to an institution if a record was released [Order MO-1474].

Section 18(1)(c) provides institutions with a discretionary exemption which can be claimed where disclosure of information could reasonably be expected to prejudice an institution in the competitive marketplace, interfere with its ability to discharge its responsibilities in managing the provincial economy, or adversely affect the government's ability to protect its legitimate economic interests. (Order P-441)

To establish a valid exemption claim under section 18(1)(d), the institution must demonstrate a reasonable expectation of injury to the financial interests of the Government of Ontario or the ability of the Government of Ontario to manage the economy of Ontario. (Orders P-219, P-641 and P-1114)

For sections 18(c) and/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 Ministry's position

The Ministry takes the position that the disclosure of provision 6 of record 34 would prejudice the Ministry's (and the Government's) economic/financial interests because it would undermine the Ministry's ability to freely negotiate similar agreements with other drug companies (as provided for under the new legislation) and, more specifically, would actively interfere with the negotiation of pricing agreements that are currently being conducted with drug companies under the new system initiated through the new legislation.

Referring to its original submissions, the Ministry stated that when it made those submissions, the focus was on the potential impact of disclosure on the Special Drugs Program (SDP). The Ministry points to a portion of one of the reasons I gave for rejecting its submissions. That portion of my decision, in its entirety, provides:

Moreover, the agreement which comprises Record 34 was clearly the result of extensive negotiation and is specifically geared to the unique components of the particular drug. It is not at all clear to me, nor have I been provided with any evidence as to how such an agreement could be replicated in the future by a different (or the same) company for a different drug.

The Ministry submits that because of the *TDSPA*, disclosure of the information in provision 6 of Record 34 today will have a much broader and more significant impact on the Ontario Drug Benefit Program (ODBP) as a whole, than it would have had in 2004 (when it made its original submissions). The Ministry submits further that the passage and implementation of the *TDSPA* have increased the likelihood and extent of the prejudice that would result from disclosure. The Ministry acknowledges that the use of letters of intent, such as Record 34, was uncommon in 2004, however, as a result of the *TDSPA*, such agreements will be commonplace and in many cases a condition for listing on the Formulary/CDI.

The Ministry explains that the *TDSPA* made significant changes to the *ODBA*, the *DIDFA* and their respective regulations. These changes include the creation of an Executive Officer, whose responsibilities include the negotiation of agreements with manufacturers regarding the drug benefit price of listed drug products.

The Ministry also identifies that new regulatory provisions deal with these agreements, and include possible limitations on the information in these agreements which may be made public. The Ministry states that these restrict the public information to information about:

- 1. The name of the manufacturer.
- 2. The subject-matter of the agreement.
- 3. The fact of entering into or terminating the agreement.

The Ministry also states that one of the primary goals in introducing the *TDSPA* was to control ODBP costs and to manage the economy. It also identifies the amount of anticipated savings the changes are expected to bring, and the importance of these changes for all Ontarians.

After providing this information, the Ministry then identifies how, in its view, sections 18(1)(c) and (d) apply to the information in provision 6 of Record 34. The Ministry states that disclosure would prejudice the Ministry's (and the Government's) economic/financial interests:

... because it would undermine the Ministry's ability to freely negotiate similar agreements with other drug companies (as provided for under the new legislation) and, more specifically, would actively interfere with the negotiation of pricing agreements that are currently being conducted with drug companies under the new system. It is the proximity of the current, ongoing negotiations in respect of pricing agreements that will trigger the financial prejudice to the Ministry, and the Government as whole. Had the record been disclosed in 2005, before any of these negotiations had begun, the prejudice would not have been as acute.

The Ministry then refers specifically to the information in provision 6 and identifies that the amount in the agreement was agreed to by the parties. It then identifies that the Ministry is "currently negotiating similar pricing agreements with various drug companies" and states:

... If record 34 is disclosed now, no drug company will agree to enter into an agreement with the Ministry under the *TDSPA* if they think there is a likelihood that the terms and conditions of the agreement will be disclosed, particularly to a competitor.

The Ministry expands on this point later in its representations when it states:

... drug companies fully expect their pricing agreements under the *TDSPA* to remain confidential; they would not expect their competitors to know the details of the savings they guarantee to the Ministry. During the consultation period on the *TDSPA*, drug manufacturers were very adamant about this issue; they wanted assurances that information about guaranteed savings (and other pricing issues) would be kept confidential. Ministry staff confirmed that on many occasions drug manufacturers stated that they would not be willing to enter into *TDSPA* agreements with the Ministry if the terms of those agreements would be disclosed.

The Ministry again refers to the limitations on the types of information that is to be made public under the new regulations, and states that, with this in mind, the disclosure of provision 6 at this point in time "may sidetrack its negotiations with drug companies concerned that the details of their pricing agreements with the Ministry will be made public and thus available to their competitors." The Ministry states that drug companies will be far more reluctant to enter into agreements with the Ministry under the new *TDSPA* system because of the confidentiality issue, and that this will threaten the financial savings the Ministry and Government anticipated and counted on in its reform of the ODBP as a tool to manage the economy. The Ministry also states that disclosure will "undermine the broader systemic drug reforms the Government hoped to implement and achieve through the new legislation."

In addition, the Ministry refers to provision 6 of Record 34 and states that, as it is currently negotiating similar pricing agreements with various drug companies, that provision may be regarded by those companies as the "standard to be followed and met." The Ministry then states:

The Ministry concedes that drug companies are highly motivated to be listed on the Formulary/CDI, and that the Ministry can take a "hardline" approach in its negotiations with these companies by simply dismissing record 34 as an old, irrelevant agreement.

Nevertheless, the Ministry submits that the public interest is not served by the Ministry engaging in acrimonious and protracted negotiations with drug companies The Ministry respectfully submits that in order to avoid delays in listing drugs that eligible recipients need (another stated goal of the new legislation), it must do all it can to encourage smooth negotiations. Consequently, to achieve this important social policy goal, the Ministry may be forced to concede to pressure from drug companies presenting record 34 as the standard to be followed and met. This will, in many cases, lead to lower savings rates, and the Ministry and the Government will suffer direct economic/financial prejudice as a result, because it will be paying higher than anticipated prices for current and new drugs listed on the Formulary/CDI. That financial prejudice will ultimately have an impact on taxpayers as well.

Ministry staff confirm that currently, negotiations are underway with brand and generic drug manufacturers for pricing agreements, to negotiate the raising (or lowering) of drug benefit prices of manufacturers' drug products that are proposed to be listed, or are currently listed, on the Formulary, as well as conditional listing agreements, which set the terms and conditions for listing of new drug products, including the drug benefit price of those products on the Formulary. The disclosure of the information in record 34 at this critical and sensitive point in time will have a direct, prejudicial impact on the Ministry's current discussions with manufacturers.

Based on the above, the Ministry submits that provision 6 of record 34 is exempt under sections 18(1)(c) and (d), and requests that I reconsider my decision and order the severance of provision 6.

Analysis and Findings

I have carefully considered the Ministry's arguments that the legislative changes now support a finding that provision 6 of Record 34 is exempt under sections 18(1)(c) and (d). In my view, the legislative changes do not impact my decision in Order PO-2528.

The Ministry makes two main arguments in support of its position that section 18(1)(c) and (d) now apply to provision 6.

The Ministry's first main argument is that, if Record 34 is disclosed now, drug companies will refuse to enter into an agreement with the Ministry under the *TDSPA* if they think that the terms and conditions of the agreement will be disclosed, particularly to a competitor. I reject the Ministry's argument.

Order PO-2528 clearly deals with the records that were at issue in that appeal. circumstances of the appeal, including the date of the request and those identified in this reconsideration decision, make it clear that the Order deals with records which pre-date the passage of the TDSPA, and that Record 34 is not an agreement entered into under the TDSPA. As identified by the Ministry, the representations and the Order refer to other legislation (not the TDSPA), and the findings are made on that basis. The Ministry's representations set out above identify that during the consultation period on the TDSPA, drug manufacturers were very adamant about wanting assurances that certain information in the agreements would be kept confidential, and that they "would not be willing to enter into TDSPA agreements with the Ministry if the terms of those agreements would be disclosed" [emphasis added]. It is clear from the representations that the Ministry and the drug companies understood that the changes to the legislation were establishing different standards for the disclosure of information in agreements made under the TDSPA. In my view, the disclosure or non-disclosure of information in agreements made prior to the implementation of the TDSPA would not affect the drug companies' willingness to enter new agreements made under the TDSPA. In the event that there is confusion by any party in that regard, the Ministry could make it clear to any party that may be under any misapprehension regarding whether the TDSPA applies to these records.

Accordingly, I do not accept the Ministry's position that, if Record 34 is disclosed now, drug companies will refuse to enter into an agreement with the Ministry under the *TDSPA* because of concerns that the terms and conditions of the agreement will be disclosed.

The Ministry's second main argument is that, if Record 34 is disclosed now, this may prejudice the Ministry's current discussions with manufacturers, and that the Ministry may be forced to concede to pressure from drug companies presenting Record 34 as the standard to be followed and met. I also reject this argument by the Ministry's.

Again, Order PO-2528 clearly deals with the records at issue in that appeal. Those records predate the passage of the *TDSPA*, and Record 34 is not an agreement entered into under the *TDSPA*. The Ministry's representations set out above support the view that the changes to the legislation established different standards and expectations for agreements made under the *TDSPA*. The Ministry concedes that drug companies are highly motivated to enter agreements under the *TDSPA*. It also recognizes that one position that it could take would be to view Record 34 as an "old, irrelevant agreement" made under previous legislation and involving different parameters.

In my view, the disclosure or non-disclosure of the information in Record 34, an agreement made prior to the implementation of the *TDSPA*, could not reasonably be expected to prejudice the economic interests of the Ministry or its competitive position. The parties are aware that different standards and expectations apply under the new legislation and, in these circumstances, I have not been provided with detailed and convincing evidence to satisfy me the Ministry may be "forced to concede to pressure from drug companies presenting Record 34 as the standard to be followed and met." This is particularly so in light of the Ministry's concession that drug companies are "highly motivated" to enter agreements under the *TDSPA*.

Accordingly, I do not accept the Ministry's position that, if Record 34 is disclosed now, the harms under section 18(1)(c) or (d) could reasonably be expected to result.

In summary, I am not satisfied that the grounds set out in the Ministry's reconsideration request support a finding that provision 6 of Record 34 is exempt under section 18(1)(c) and/or (d), and I uphold my decision in Order PO-2528. As the original date for disclosure in the order has passed, I order the Ministry to disclose the information ordered disclosed from Record 34 in Order PO-2528 by sending it to the appellant by **June 26, 2008.**

Original signed by:	June 5, 2008
Laurel Cropley	
Adjudicator	