Information and Privacy Commissioner,
Ontario, Canada

Commissaire à l'information et à la protection de la vie privée,
Ontario, Canada

ORDER PO-3503

Appeals PA13-362 and PA14-50

Ministry of Health and Long-Term Care

June 29, 2015

Summary: The Ministry of Health and Long Term Care (the ministry) received a request under the *Freedom of Information and Protection of Privacy Act* (*FIPPA*) for access to a pharmaceutical company's (the affected party) submission to the ministry and the Committee to Evaluate Drugs (CED) for listing of a drug on the Ontario Drug Benefit Formulary.

This order finds that the responsive information in the letters to and from the ministry is not exempt by reason of the mandatory third party information exemption in section 17(1), as the information was either not supplied or did not meet the harms test.

This order also finds that the information for which the discretionary advice or recommendations exemption in section 13(1) has been claimed is not exempt by reason of the mandatory exception in section 13(2)(k) (committee report).

Statutes Considered: *Freedom of Information and Protection of Privacy Act*, R.S.O. 1990, c. F.31, as amended, sections 17(1)(a), 17(1)(c), 13(1), 13(2)(k).

Orders and Investigation Reports Considered: Orders PO-1988, PO-2681, and PO-2773.

OVERVIEW:

[1] The Ministry of Health and Long Term Care (the ministry) received a request under the *Freedom of Information and Protection of Privacy Act* (*FIPPA* or the *Act*) for access to a pharmaceutical company's (the affected party) submissions to the ministry

to demonstrate the compliance of a specific drug product (the drug) with section 12(9) of Ontario Regulation 201/96 under the *Ontario Drug Benefit Act*, R.S.O. 1990, Chapter O.10.

[2] The requester later provided the following clarification:

> Requesting information for the [drug] submissions and any documented correspondence relating to the [drug] submissions, subject to any statutory exemption barring disclosure.
>
> …
>
> By correspondence, I mean any written correspondence relating to a submission by [the affected party] and the Ministry in relation to [drug], which I expect would include, for instance, cover letters and emails.
>
> By table of contents or list of documents, I am referring to a table of contents or a list of documents relating to a [drug] submission that is either present within the submission itself or provided separately in separate correspondence.

[3] The ministry's search identified four responsive records. The ministry provided notice to the affected party under section 28(1)(a) of the *Act* in order to offer it an opportunity to provide submissions respecting the disclosure of the records. After receiving those submissions, the ministry issued an access decision on July 15, 2013 granting partial access to Records 1 and 4 and full access to Records 2 and 3. The ministry claimed the mandatory third party exemption in section 17(1) to deny access to the severed portions of Record 1 and sections 13(1) (advice or recommendations) and 17(1) for Record 4.

[4] The affected party appealed the ministry's access decision and this office opened Appeal PA13-362 to address the issues. The requester also appealed the ministry's access decision, resulting in this office opening Appeal PA14-50.

[5] In Appeal PA13-362, the affected party disputes the ministry's decision respecting Records 2, 3 and 4, asserting that Records 2 and 3 should be severed, rather than disclosed in full, and that Record 4 should be subject to further severances under section 17(1). Appeal PA13-362 does not involve Record 1. The affected party provided a copy of the records that were severed in a manner acceptable to it.

[6] On February 27, 2014, the ministry disclosed to the original requester severed copies of Records 2 and 3 as submitted by the affected party and a copy of Record 4 as severed by both the ministry and the affected party. Record 1, severed as the ministry intended originally, was also provided to the requester.

[7] Regarding Appeal PA14-50, the requester confirmed that he wishes to pursue access to the information withheld from all of the records.

[8] It was not possible to resolve the appeals by mediation and they were transferred to the adjudication stage of the appeal process for an inquiry. Representations from the ministry, the affected party, and the appellant were sought by the adjudicator previously assigned to these appeals. These representations were exchanged between the parties in accordance with section 7 of the IPC's *Code of Procedure* and *Practice Direction 7*.

[9] In this order, I find that the information at issue is not exempt under sections 13(1) and 17(1), other than certain information that the requester is not interested in obtaining.

RECORDS:

[10] At issue are the following records:

- Record 1 - Letter from the affected party to the ministry's Ontario Public Drug Programs branch director (OPDP) - September 15, 2011 (4 pages)
- Record 2 - Table of Contents to the affected party's drug submission (1 page)
- Record 3 - Letter from OPDP to the affected party - October 13, 2011 (2 pages)
- Record 4 - Letter from the OPDP to the affected party - January 4, 2012 (3 pages)

ISSUES:

A. Does the mandatory third party information exemption at section 17(1) apply to the records?

B. Does the discretionary advice or recommendations exemption in section 13(1) apply to the records?

DISCUSSION:

A. Does the mandatory third party information exemption at section 17(1) apply to the records?

[11] The affected party is relying on paragraphs (a) and (c) of section 17(1), which read:

> 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;
>
> (c) result in undue loss or gain to any person, group, committee or financial institution or agency.

[12] Section 17(1) is designed to protect the confidential "informational assets" of businesses or other organizations that provide information to government institutions.[1] 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.[2]

[13] For section 17(1) to apply, the institution and/or the third party 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), (c) and/or (d) of section 17(1) will occur.

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[1] *Boeing Co. v. Ontario (Ministry of Economic Development and Trade)*, [2005] O.J. No. 2851 (Div. Ct.), leave to appeal dismissed, Doc. M32858 (C.A.).
[2] Orders PO-1805, PO-2018, PO-2184 and MO-1706.

Part 1: type of information

[14] The affected party submits that the records contain commercial, scientific and technical information. These types of information have been discussed in prior orders, as follows:

> *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.[3]
>
> *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.[4]
>
> *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.[5] The fact that a record might have monetary value or potential monetary value does not necessarily mean that the record itself contains commercial information.[6]

[15] The affected party states that information in the records relates to its efforts to market its product through its inclusion in the Ontario Drug Formulary constitute commercial information and may also contain scientific and technical information in the form of a clinical study or manufacturing and chemistry data.

[16] The appellant did not provide representations on the application of section 17(1), other than to state that the public interest override in section 23 should apply.

Analysis/Findings

[17] Based on my review of the records, I agree with the affected party that the records reveal scientific and technical information about the drug, its uses and dosage.

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[3] Order PO-2010.
[4] Order PO-2010.
[5] Order PO-2010.
[6] Order P-1621.

The records also contain commercial information about the sale and marketing of the drug.

[18] Therefore, part 1 of the test under section 17(1) has been met.

Part 2: supplied in confidence

Supplied

[19] 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.[7]

[20] 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.[8]

[21] The affected party submits that Records 1 and 2 were directly supplied by it to the ministry as part of its submission to have the drug included in the Ontario Drug Benefit Formulary (the ODBF or the formulary).

[22] The affected party further submits that the information for which it claimed the section 17(1) exemption in Records 3 and 4 is based upon information that was directly supplied by it to the ministry for evaluation by the minister and the Committee to Evaluate Drugs (CED),[9] and disclosure of such information would permit the requester to draw inferences regarding the information provided by it as part of its efforts to have the drug listed on the ODBF.

Analysis/Findings

[23] Record 1 is a letter from the affected party to the ministry with detailed information about the drug. Record 2 is the table of contents of the affected party's submission to the ministry. There are three severances to Record 2. The requester does not seek disclosure of the first severance. I find that information at issue in Records 1 and 2 was supplied directly by the affected party to the ministry.

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[7] Order MO-1706.
[8] Orders PO-2020 and PO-2043.
[9] The affected party describes the CED as the ministry's independent expert advisory committee on drug related issues established by Order In Council under the authority of section 9 of the *Ministry of Health and Long Term Care Act*. It states that drug manufacturers cannot make any submissions directly to the CED, but rather must submit all materials in support of formulary listings to the ministry.

[24] Records 3 and 4 are both ministry letters to the affected party. The requester does not seek disclosure of the file numbers in these records; therefore, this information is no longer at issue.

[25] I do not find that the remaining information at issue in Record 3 was supplied by the affected party to the ministry. This information is a request from the ministry asking the affected party to provide further information that it has not received. It is a list of missing information from the ministry's files sent by the ministry to the affected party. I find that this information was not supplied by the affected party; nor does it reveal information supplied by the affected party. Instead it reveals information provided by the ministry to the affected party, concerning information missing from the ministry's files.

[26] The information at issue in Record 4 concerns the CED's evaluation of the drug. The requester seeks access to all of the information at issue in this record except for the information at bullets 8 and 9 as they concern pricing information. In addition, I note that the requester specifically states that he does not seek disclosure of pricing information of the drug. Bullet 6 is entirely about pricing information. As such, I will also remove this bullet from the scope of the appeal.

[27] The affected party did not provide evidence as to how disclosure of the particular information at issue in this record,[10] would reveal or permit the drawing of accurate inferences with respect to information supplied by it.

[28] The information at issue in Record 4[11] is similar to the information at issue in Order PO-2773. The records in that order were excerpts from CED minutes relating to the evaluation of a particular named drug. In Order PO-2773, I found that:

> Based upon my review of the information at issue in Records 9 and 10, I find that only certain specific information was supplied by the affected party to the Ministry. This information consists of information about the named drug at issue in this appeal and various studies of this drug conducted by the affected party, the drug manufacturer. The remaining information was not directly supplied to the Ministry by the drug manufacturer, nor would its disclosure reveal or permit the drawing of accurate inferences with respect to information supplied by the drug manufacturer [Orders PO-2020, PO-2043]. The information that was not supplied consists of the comments of the CED or its subcommittee regarding reviews or studies, such as comments on the expert pharma-economic and clinical reviews (Records 11 and 12), as well as discussions of various drug products and treatments.

[10] Or in Record 3.
[11] Other than the file numbers.

> Other than the specific information that was supplied, the remaining severances are not eligible for exemption under section 17(1), as this information does not meet part 2 of the test and, therefore, is not third party information. This information consists of the comments and expressions of opinion, about the sufficiency, quantity or even quality of the available clinical and economic literature and information and was not supplied by the affected party, originating from the CED or its subcommittee members. In addition, on my reading of this information, I find that it does not reveal or permit the drawing of accurate inferences with respect to information that may have been supplied.

[29] The information at issue in Record 4 is the following information on page 2:

- the second sentence of the first paragraph,
- a portion of bullets 2 and 5, and
- all of bullets 3, 4, and 7.

[30] The first severance is on page 2 and is about the purpose of the CED review. This information contains a brief statement about the affected party's request for listing the drug on the formulary. This severance does not reveal information that was supplied by the affected party.

[31] The remaining severances contain some of the comments made by the CED in its review. Certain severances do not reveal information that was supplied by the affected party. In particular:

- Bullet 5 – the information at issue in that bullet is a conclusion of the CED drawn from its review of a study and a guideline.
- Bullet 7 – this bullet mentions information not supplied by the affected party to the CED in its submission.

[32] The information at issue in bullets 5 and 7 is not in the affected party's submission to the ministry; nor is it about the CED's interpretation or position on the drug. I find that this information was not supplied by the affected party, nor does it reveal information supplied by the affected party.

[33] However, the severances at bullets 2, 3, and 4 of Record 4 concern information that reveals or permits the drawing of accurate inferences with respect to information that may have been supplied by the affected party.

[34] In conclusion, I find that all of the information at issue in Records 1 and 2 and the information at issue in bullets 2, 3 and 4 of Record 4 have been supplied by the affected party to the ministry. I will consider whether this information has been supplied in confidence.

[35] The information for which I found was not supplied, being the information at issue in Record 3 and the information at issue in the second sentence of the first paragraph and at bullets 5 and 7 of Record 4, does not meet part 2 of the test under section 17(1). As no other exemptions have been claimed for this information, I will order it disclosed.

In confidence

[36] 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.[12]

[37] 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.[13]

[38] The affected party submits that submissions in support of a formulary listing are made based on an explicit expectation of confidentiality that arises from the ministry's Ontario Guidelines for Drug Submission Evaluation. It refers to the ministry's Guidelines, which state in part:

> …To better inform the public and health care professionals, the status of submissions and the rationale supporting [the CED] and Ministry's

[12] Order PO-2020.
[13] Orders PO-2043, PO-2371 and PO-2497, upheld (cited above).

> decisions will now be released. ...All other submission information will continue to be held in confidence by the Ministry.

[39] The affected party states that only the CED recommendations and rationale are publicly available, while the information provided in the manufacturer's submission are not. It states that the ministry has released the status of listing of drug and the rationale for this decision. It states that the information that is sought to be severed by it in these proceedings reveals only the content of its submission.

[40] The affected party further states that implicit confidentiality also arises based on section 12(7) of Regulation 201/96 under the *Ontario Drug Benefit Act* (the *ODBA*), which relates to agreements entered between the Executive Officer for volume discounts relating to listed drugs. Section 12(7) mandates that where such an agreement is entered, only the name of the manufacturer, the subject matter of the agreement, and the fact of entering into or terminating the agreement may be released by the ministry.

Analysis/Findings

[41] Based on my review of the information at issue in Records 1 and 2 and the information I found supplied in Record 4, I agree with the affected party that this information was supplied in confidence. It reveals the information from the affected party's submission to the ministry in support of a formulary listing for the drug. This information was supplied by the affected party to the ministry on the basis that it was confidential and that it was to be kept confidential. It was also treated consistently in a manner that indicates a concern for its protection from disclosure prior to being communicated to the ministry, is not otherwise disclosed or available from sources to which the public has access, and was prepared for a purpose that would not entail disclosure.

[42] Therefore, part 2 of the test under section 17(1) has been met for the information at issue in Records 1 and 2 and the information I found to have been supplied in Record 4. I will now consider whether part 3 of the test has been met for this information.

Part 3: harms re: section 17(1)(a)

[43] 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.[14]

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[14] *Ontario (Workers' Compensation Board) v. Ontario (Assistant Information and Privacy Commissioner)*, cited above.

[44] 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.[15]

[45] The need for public accountability in the expenditure of public funds is an important reason behind the need for "detailed and convincing" evidence to support the harms outlined in section 17(1).[16]

[46] Parties should not assume that harms under section 17(1) are self-evident or can be substantiated by submissions that repeat the words of the *Act*.[17]

[47] The affected party provided both confidential and non-confidential representations on part 3 of the test. It relies on IPC orders and case law in support of its position under part 3.[18] It states that all of the redactions relate to confidential study data and/or manufacturing and chemistry data submitted to the ministry for the purposes of evaluating the listing submission.

[48] The affected party provided detailed representations concerning the information at issue in each record. It states that the information severed from Record 1 contains details with regard to its proprietary manufacturing process, study data, the precise formulation of the drug product as used in confidential studies, confidential clinical study information, and chemistry and manufacturing information.

[49] The affected party describes the information severed from Record 2 as specific pricing strategies and data.

[50] The affected party describes the information severed from Record 4 as the confidential and proprietary characterization of the rationale for the design of the drug, unpublished data, and pricing information.

[51] The affected party further states that Record 4 contains certain isolated comments or considerations taken into account by the CED, but does not accurately reflect its rationale for the recommendation, as well as non-summary information. It states that the release of these isolated considerations could reasonably be expected to be misconstrued.

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[15] Order PO-2020.
[16] Order PO-2435.
[17] Order PO-2435.
[18] The affected party relies on Orders PO-2097, PO-2273, PO-2528, *Janssen-Ortho Inc. v. Canada (Minister of Health)*, 2005 F.C. 1633, and *Rubin v. Canada,* 2001 FCT 929.

[52] The requester states that disclosure of the severed information in the records is unlikely to harm the affected party's competitive position because currently there is no competition with the drug as the affected party is the sole provider of this drug product in Canada.

[53] In reply, the affected party states that another drug company is currently seeking marketing approval in Canada for a generic version of the drug. It argues that this is a highly competitive market, particularly since public payers, including the ministry, will no longer reimburse this drug product if it does not have features that make the drug more tamper resistant than previous formulations. It states that the requester is attempting to gain access to confidential and proprietary, unpublished information submitted by the affected party to the ministry in confidence, which would be of commercial value to its competitors.

Analysis/Findings re: section 17(1)(a)

[54] The affected party has not provided representations to support its position that disclosure could reasonably be expected to interfere significantly with its contractual or other negotiations.

[55] It appears from the affected party's representations respecting section 17(1)(a) that it is claiming that disclosure of the information at issue could reasonably be expected to significantly prejudice its competitive position.

Record 1 - Letter from affected party to OPDP branch director dated September 15, 2011 (4 pages)

[56] Concerning Record 1, I do not agree with the affected party that disclosure could reasonably be expected to significantly prejudice its competitive position by providing competitors with commercially valuable information. In particular, with respect to each severance:

- Page 1, second paragraph, second sentence, - which the affected party states contains details with regard to the affected party's proprietary manufacturing process. I find that this type of information is apparent from the publicly available product monographs provided by the requester, which discuss this feature of the drug.[19] It is also apparent from the disclosed portions at page 3 of Record 1.

[19] See for example page 24 of 37 of the Product Monograph dated July 2014, at tab 38 of the requester's Book of Authorities. The requester provided copies of the drug product monographs with his representations. The most recent product monograph provided by the requester is dated July 2014. The ministry also quoted from a more recent product monograph in its representations dated October 2014.

- Page 1, fourth paragraph, page 2, first and third paragraphs, the first three sentences of fourth paragraph, and first three sentences of the first paragraph of page 3 - which the affected party states contain details of its confidential proprietary study data. However, I find that this information is general information about studies that were done on the drug prior to September 15, 2011.[20] This information reveals similar types of information about studies done on the drug as that found in the drug product monographs.[21] In addition, the information already disclosed from the records lists numerous studies. The affected party has not provided evidence as to why the study information that it wishes withheld comes within the harms set out in section 17(1)(a).

- Page 3, first paragraph, last two sentences, - while this refers a public study, the affected party does not want disclosed its reliance on this data as support for its submission is not public. As noted above, many studies were relied upon in the process leading up to the approval and listing of this drug. I find that the affected party has not demonstrated how reliance on this particular study could reasonably be expected to lead to the harms set out in section 17(1)(a).

- Page 3, third paragraph, - the affected party states that this reveals the formulation of the drug as used in confidential studies. Formulations of the drug as used in studies are listed in publicly available studies set out on page 4 of Record 1. The particular study that this formulation used is footnoted at the end of the third paragraph of page 3.

- Page 3, second to last sentence, - the affected party states that this statement discloses its strategy and positioning relating to listing of its product. This information contains the affected party's request as to how it wants the drug listed on the formulary. I do not see how this request could reasonably be expected to prejudice significantly the competitive position of the affected party as, according to the parties' representations, the drug has already been listed on the formulary.

- Page 4, the severance on this page lists the names of two studies, - the affected party states that this information was redacted since these published studies are not otherwise cited in its product monograph. Although these two studies are not listed in the product monograph, the affected party has not provided evidence as to the harm that could reasonably be expected to be incurred should this information be disclosed.

[20] September 15, 2011 is the date of affected party's letter to the ministry, which is Record 1.
[21] See for example pages 13, 14, and 27 to 30 of the Product Monograph dated July 2014.

Record 2 – Table of Contents to affected party's submission (1 page)

[57] There are three severances to Record 2. The requester does not seek disclosure of the first severance. The affected party describes the severances as the non-mandatory portions of the Table of Contents from its submission to the ministry. It submits that this information should be severed because it reveals specific pricing strategies and data as well as specific categories of data that the affected party chose to submit. I find that the two severances remaining at issue in this record do not reveal specific pricing strategies. In addition, I do not have sufficient evidence to determine how these two severances from the table of contents that comprises Record 2 comes within part 3 of the test under section 17(1)(a).

Record 4 – Letter from OPDP to affected party dated January 4, 2012 (3 pages)

[58] I found above that the information at bullets 2, 3, and 4 of Record 4 met part 2 of the test under section 17(1)(a). I do not agree with the affected party that disclosure of this information could reasonably be expected to significantly prejudice its competitive position by providing competitors with commercially valuable information. In particular, with respect to each severance:

- Bullet 2 - the affected party states that this information is taken from its submission and discloses its confidential and proprietary characterization of the rationale for the design of the drug. The affected party has not provided representations as to the harm under section 17(1)(a) that could reasonably be expected to occur should this information be disclosed, nor is this harm apparent from a review of this information. This information is about certain properties of the drug. Similar information about these properties of the drug has been discussed in the parties' representations.

- Bullet 3 - the affected party states that this information should be protected from disclosure as it refers to preliminary unpublished data. Although this bullet mentions unpublished data, it does not specifically state what this unpublished data is. Even if this unpublished data could be deduced from a reading of bullet 3, it is not apparent what harms could reasonably be expected to be incurred should the information in this bullet be disclosed. The affected party did not address this in its representations.

- Bullet 4 - the affected party states that this bullet represents unpublished data related to the CED Recommendation. It states that the ministry provided its acceptance of information from the CED Recommendations on February 29, 2013. It states that the only additional information that has been posted is that which is contained in a specific publication, which reflects the ministry and CED's final recommendations, rationales and decision regarding listing of the drug. It further states that the specific

> information that the affected party has redacted reflects certain isolated comments or considerations taken into account by the CED, but does not accurately reflect its rationale for the recommendation, which is based on a holistic review. It submits that the release of these isolated considerations could reasonably be expected to be misconstrued and to cause harm to the affected party.

[59] Based on my review of the information at issue in bullet 4, I do not agree that this information can be misconstrued such as to cause harm to the affected party within the meaning of section 17(1)(a). This type of information, which concerns the use of the drug, is apparent throughout the product monographs.

Conclusion

[60] Therefore, the information that I have found to meet part 2 of the test in Records 1, 2, and 4, did not meet part 3 of the test under section 17(1)(a). I will now consider whether it meets part 3 of the test under section 17(1)(c).

Part 3: harms re: section 17(1)(c)

[61] The affected party states that its reliance on particular proprietary data and analytical results of product testing represents the extensive work that it undertook to comply with regulatory requirements. It states that release of this information will provide a significant competitive advantage to its competitors and a competitive disadvantage to it associated with the loss of this competitive information.

[62] The affected party states that disclosure of this information at issue could reasonably be expected to result in material financial loss to it and would prejudice its competitive position by:

> (a) enabling competitors to avoid considerable expenditures of personnel and financial resources in designing and conducting clinical studies and designing reimbursement strategies;
>
> (b) enabling competitors through the cost savings achieved, to market their products at lower prices, thereby securing additional market share at the affected party's expense; and
>
> (c) enabling competitors to obtain regulatory or reimbursement approvals and launch their products sooner or on more favourable terms, thereby depriving the affected party of those sales.

[63] The affected party further states that disclosure of confidential information contained in the records would provide competitors with insight into its confidential

business strategy. Further, it states that isolated comments made in the CED Recommendations can be easily taken out of context and misused to cause damage to its reputation.

Analysis/Findings re: section 17(1)(c)

[64] I have considered each of the affected party's concerns with respect to the information at issue in Records 1, 2, and 4. These records consist of a cover letter and list of enclosures from the affected party to the ministry seeking listing of the drug on the formulary dated September 2011,[22] along with a letter from the ministry to the affected party regarding the CED Recommendation dated January 2012.[23]

[65] Any of the information related to pricing is no longer at issue as the requester has indicated that he does not seek access to this information; therefore, the affected party's concern under point (b) about pricing is not at issue. For the same reasons, the affected party's concern under points (a) and (c) about reimbursement strategies or approvals is not at issue.

[66] In addition, relying on my findings concerning section 17(1)(a), I find that the information at issue could not reasonably be expected to enable competitors to avoid considerable expenditures of personnel and financial resources in designing and conducting clinical studies under point (a) raised by the affected party. The records contain the titles of some studies. Although there is some brief mention of some of the details of studies in the records, this information is not more detailed than that in the product monographs, which are public documents.

[67] Point (c) is about enabling competitors to obtain regulatory approvals and launch their products sooner or on more favourable terms, thereby depriving the affected party of those sales. I find that in the absence of representations as to how competitors could use the specific information at issue to obtain regulatory approvals, I cannot determine that section 17(1)(c) applies.

[68] In making this determination under section 17(1)(c), I acknowledge that the affected party is concerned about the requester or others using the information at issue in a bid to have approval or registration of a generic brand of the drug. However, I cannot ascertain from my review of the records how disclosure of the particular information at issue could result in undue loss or gain to the affected party. Accordingly, I find that section 17(1)(c) does not apply and, as no other exemptions apply to the information at issue in Records 1, 2 and 4, I will order this information disclosed.

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[22] Records 1 and 2.
[23] Record 4.

B. Does the discretionary advice or recommendations exemption in section 13(1) apply to the records?

[69] 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.

[70] The purpose of section 13 is to preserve an effective and neutral public service by ensuring that people employed or retained by institutions are able to freely and frankly advise and make recommendations within the deliberative process of government decision-making and policy-making.[24]

[71] "Advice" and "recommendations" have distinct meanings. "Recommendations" refers to material that relates to a suggested course of action that will ultimately be accepted or rejected by the person being advised, and can be express or inferred.

[72] "Advice" has a broader meaning than "recommendations". It includes "policy options", which are lists of alternative courses of action to be accepted or rejected in relation to a decision that is to be made, and the public servant's identification and consideration of alternative decisions that could be made. "Advice" includes the views or opinions of a public servant as to the range of policy options to be considered by the decision maker even if they do not include a specific recommendation on which option to take. [25]

[73] "Advice" involves an evaluative analysis of information. Neither of the terms "advice" or "recommendations" extends to "objective information" or factual material.

[74] Advice or recommendations may be revealed in two ways:

- the information itself consists of advice or recommendations
- the information, if disclosed, would permit the drawing of accurate inferences as to the nature of the actual advice or recommendations.[26]

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[24] *John Doe v. Ontario (Finance)*, 2014 SCC 36, at para. 43.
[25] See above at paras. 26 and 47.
[26] Orders PO-2084, PO-2028, 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.), aff'd [2005] O.J. No. 4048 (C.A.), leave to appeal refused [2005] S.C.C.A. No. 564; see also Order PO-1993, upheld on judicial review in *Ontario (Ministry of Transportation) v. Ontario (Information and Privacy Commissioner)*, [2005] O.J. No. 4047 (C.A.), leave to appeal refused [2005] S.C.C.A. No. 563.

[75] The application of section 13(1) is assessed as of the time the public servant or consultant prepared the advice or recommendations. Section 13(1) does not require the institution to prove that the advice or recommendation was subsequently communicated. Evidence of an intention to communicate is also not required for section 13(1) to apply as that intention is inherent to the job of policy development, whether by a public servant or consultant.[27]

[76] Section 13(1) covers earlier drafts of material containing advice or recommendations. This is so even if the content of a draft is not included in the final version. The advice or recommendations contained in draft policy papers form a part of the deliberative process leading to a final decision and are protected by s. 13(1).[28]

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

- factual or background information[29]
- a supervisor's direction to staff on how to conduct an investigation[30]
- information prepared for public dissemination[31]

[78] The ministry has applied section 13(1) to two severances on page 3 of Record 4, which are a portion of bullet 10 and the paragraph entitled "CED Recommendation". It states that this information:

> …reveal the recommendations of a body whose purpose is to provide recommendations to the ministry on the issues described in that record. As the IPC explained in [Order] PO-2773, the CED is an advisory body to the Minister and is an entity intended to be covered by section 13(1). Records at issue comprise the CED reviewers' recommendations concerning the economic and clinical feasibility of the named drug. …The disclosure of any of the information in …would reveal the advice or recommendations made by the reviewers to the CED and are, therefore, exempt.

[79] The requester states that the severed information is directed to a factual, scientific and economic review of the drug and related advice and/or recommendations, which falls outside of section 13(1). In the alternative, he states that section 13(1) is found to be engaged by the severed information, any severed information engaged by section 13(1) must be limited to a recommendation by the CED that the drug should be

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[27] *John Doe v. Ontario (Finance)*, cited above, at para. 51.
[28] *John Doe v. Ontario (Finance)*, cited above, at paras. 50-51.
[29] Order PO-3315.
[30] Order 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.).
[31] Order PO-2677.

considered for funding and/or listed on the formulary and information that would permit one to accurately infer that recommendation.

[80] The requester relies on the mandatory exception to section 13(1) in section 13(2)(k), which reads:

> Despite subsection (1), a head shall not refuse under subsection (1) to disclose a record that contains,
>
> > a report of a committee, council or other body which is attached to an institution and which has been established for the purpose of undertaking inquiries and making reports or recommendations to the institution.

[81] The requester also takes issue with the section 13(1) findings in Order PO-2773. He states that this order incorrectly decided that the CED Reviewer Reports were engaged by section 13(1), as these reports contain factual, scientific and economic information regarding a third party's drug product that had no bearing on the ministry's deliberative decision-making or policy making processes. He states that disclosure would not adversely affect the ministry's ability to formulate and justify its policies, unfairly pressure the ministry to take actions or make decisions, harm the ministry's credibility or impair the ministry's effectiveness.

[82] The requester provided extensive representations as to why he believes that Order PO-2773 was incorrectly decided, including the finding that the CED Reviewer Reports did not fall within the section 13(2)(k) exception, as this order did not explain why the CED Reviewer Reports fail to meet that test. He submits that the finding that the CED Reviewer Reports fall within section 13(2)(k) is, in fact, consistent with prior orders.[32] He states Order PO-2773 wrongly characterized the CED Reviewer Reports as "reviews" instead of "reports" because the CED Reviewers prepared the reports instead of the CED and that the use of the word "Review" or "Reviewer" in the title "CED Reviewer Report" is not determinative of whether that document is a "report" for the purposes of section 13(2)(k) of the *Act*. The requester states the ruling in Order PO-2773 is silent on whether the second and third requirements of the section 13(2)(k) exception were met and that those requirements were met because:

> a) the CED is "attached" to the ministry, for it is an independent expert advisory committee of the Ministry, … and a body may be considered "attached" to an institution even if it maintains some degree of independence from that institution; and

[32] The requester relies on Orders MO-1192, MO-1238, MO-1337-I, MO-1767, MO-2303-I, PO-1884, PO-2211, and PO-1709.

> b) the CED was established 'for the purpose of undertaking inquiries and making reports or the CED was established 'for the purpose of undertaking inquiries and making reports or recommendations to the institution' because, …the functions of the CED are to evaluate drug products and recommend to the Executive Director of the OPDP of the ministry whether those drug products should be considered for funding and/or listed on the formulary.

[83] The requester submits that if any of the severed information is found to be engaged by section 13(1), such information must be limited to a recommendation by the CED that the drug should be considered for funding and/or listed on the formulary and information that would permit one to accurately infer that recommendation. In addition, he submits that comments of a clinical reviewer concerning a drug product that does not suggest a course of action with respect to consideration of the drug product for funding or listing of the drug product on the formulary falls outside of section 13(1).

[84] Concerning the first section 13(1) severance, the requester submits that information concerning the misuse or abuse deterrent potential of the drug would not permit one to draw an accurate inference that the CED recommended that the drug should or should not be considered for funding or be listed on the formulary. Further, he states that such information does not fall within section 13(1) and, in any case, would be mandatorily disclosed under the exception in section 13(2)(a).[33]

[85] Concerning the second section 13(1) severance, the requester submits that information exempted under section 13(1) must be limited to a recommendation by the CED that the drug should be considered for funding and/or listed on the formulary and any information that would permit one to accurately infer that recommendation.

[86] In reply, the ministry states that Record 4, the ministry letter, which has two paragraphs paraphrasing the CED's recommendations do not constitute "a report", as this term is used in section 13(2)(k) and as defined in IPC orders.

[87] The ministry submits that the appellant's argument that the CED's recommendations are not engaged by section 13(1) because their disclosure "would not adversely affect the ministry's ability to formulate and justify its policies, unfairly pressure the ministry to take actions and make decisions…" is irrelevant, as section 13(1) is not a "harms based" exemption like section 17. It states that although the effect of the disclosure on the ministry's ability to formulate and justify its policies informs the rationale for and interpretation of the exemption itself, it is not determinative of whether a given record is subject to the exemption.

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[33] Section 13(2)(a) states that:

> Despite subsection (1), a head shall not refuse under subsection (1) to disclose a record that contains factual material.

Analysis/Findings

[88] Based on my review of the information at issue in Record 4, I agree with the ministry that this information reveals the CED's recommendation to the ministry with respect to the funding and listing of this particular drug.

[89] Specifically, the second severance contains the CED's recommendation as it relates to a suggested course of action that will ultimately be accepted or rejected by the person being advised. The first severance information contains advice, as well as containing other information, that if disclosed, would permit the drawing of accurate inferences as to the nature of the actual recommendation in the second severance.

[90] Section 13(2) creates a list of mandatory exceptions to the section 13(1) exemption. If the information falls into one of these categories, it cannot be withheld under section 13.

[91] The exceptions in section 13(2) can be divided into two categories: objective information, and specific types of records that could contain advice or recommendations.[34] The first four paragraphs in section 13(2), paragraphs (a) to (d), are examples of objective information. They do not contain a public servant's opinion pertaining to a decision that is to be made but rather provide information on matters that are largely factual in nature.

[92] The remaining exceptions in section 13(2), paragraphs (e) to (l), will not always contain advice or recommendations but when they do, section 13(2) ensures that they are not protected from disclosure by section 13(1).

[93] The requester relies on the exceptions in sections 13(2)(a) and (k). In particular, he relies on section 13(2)(a) for the first severance and section 13(2)(k) for both severances.

[94] Section 13(2)(a) applies to factual material, which refers to a coherent body of facts separate and distinct from the advice and recommendations contained in the record.[35] Where the factual information is inextricably intertwined with the advice or recommendations, section 13(2)(a) may not apply.[36]

[95] I find that the information at issue does not come within the exception in section 13(2)(a) as it is not a coherent body of fact separate and distinct from the advice or recommendations.

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[34] *John Doe v. Ontario (Finance)*, cited above, at para. 30.
[35] Order 24.
[36] Order PO-2097.

[96] Concerning section 13(2)(k), this exception has three essential requirements:

(1) the record must be a "report" of a "committee, council or other body";

(2) the committee, council or other body must be "attached to" an institution;

(3) the committee, council or other body must have been established "for the purpose of undertaking inquiries and making reports or recommendations to the institution".[37]

[97] Section 13(2)(k) applies to any entity, body or organization similar to a committee or council, as long as the other elements of paragraph (k) are met. A body may be considered "attached" to an institution, even if it maintains some degree of independence from the institution. If the body reports to a minister, it will be considered to report to an "institution".[38]

[98] This office has defined "report" as a formal statement or account of the results of the collation and consideration of information. Generally speaking, this would not include mere observations or recordings of fact.[39]

[99] I find that the CED is a committee attached to the ministry established for the purpose of undertaking inquiries. As described by the ministry, the CED is an advisory body to the Minister whose purpose is to review drug product submissions made by drug manufacturers who wish to have their drug product recommended for listing on the formulary. The CED evaluates the therapeutic value and cost effectiveness of drug products and recommends to the Executive Director of the OPDP whether a particular drug product should be considered for funding and/or listed on the formulary.

[100] In Order PO-2773, relied upon by the ministry, I found that the exception in section 13(2)(k) did not apply to the records, which were entitled "Pharmacoeconomic Review Template" and "Expert Review – [name of drug] … (2nd Review)". I found that these two records were reviews, not reports as neither document consisted of or set out a formal statement or account of the results of the collation and consideration of information. I found that these records in Order PO-2773 were reviews prepared for the CED and that the CED was the committee that would be issuing a report based on the information in these records. As such, I found that requirement 1 had not been met. As all three requirements must be met, I found that the exception in section 13(2)(k) did not apply and that section 13(1) applied to exempt both records.

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[37] Order PO-2681.
[38] Order PO-2681 and PO-1709, upheld on judicial review in *Ontario (Minister of Health and Long-Term Care) v. Goodis* [2000] O.J. No. 4944, Toronto Doc. 684/99 (Div. Ct.); Order PO-1823.
[39] Order PO-2681; Order PO-1709, upheld on judicial review in *Ontario (Minister of Health and Long-Term Care) v. Goodis*, [2000] O.J. No. 4944 (Div. Ct.).

[101] However, in these appeals, Record 4 is not a review prepared for the CED, but is instead a report on the drug submission. This record is in the form of a report and is addressed to the affected party's Director, Federal and Provincial Regulatory Affairs, and is from the ministry's Ontario Public Drug Programs Division, Drug Program Services Branch. Record 4 is titled, "CED Recommendation", and page 1 of this record states that it was copied to the Assistant Deputy Minister and Executive Officer of the ministry, as well as to the affected party's President.

[102] The record's introduction states that the ministry and the CED have reviewed the affected party's submission.

[103] The first severance is in the section of Record 4 is entitled "CED Review". This section contains 10 detailed bullet point comments which contain the CED's evaluation of the affected party's submission for listing of the drug on the formulary. The ministry has claimed section 13(1) for a portion of the 10th bullet.

[104] The second severance is in the section entitled "CED Recommendation". The portion entitled "CED Recommendation" contains the ultimate recommendation of the CED concerning the listing of the drug. The ministry has claimed section 13(1) for the entire CRD recommendation.

[105] The ministry submits that two paragraphs of a ministry letter paraphrasing the CED's recommendations do not constitute "a report", as this term is used in section 13(2)(k), and as defined in IPC Orders.

[106] However, I note that in Order PO-2681 the records at issue included a cover letter to the Minister of Culture, which summarized and set out a specific report's findings and recommendations, and added further recommendations about a particular property. In that order, Senior Adjudicator John Higgins determined from the contents of this record that it was the institution's response to the Minister's request for an evaluation, and that it formed an integral part of the institution's reporting back to the Minister on its findings. He stated that the cover letter:

> … clearly represents a formal statement of the results of the collation and consideration of information. Its purpose is not "to describe, rather than to evaluate", and its contents do not "consist essentially of observations and facts rather than evaluations of those observations and facts", as discussed in Order PO-1988. I am satisfied that the cover letter is a "report" for the purposes of section 13(2)(k).

[107] Adopting the findings in Order PO-2681, and the order referred to therein, Order PO-1988, and considering Record 4 as a whole, I find that this record is a report within the meaning of section 13(2)(k) of *FIPPA*. Record 4 is a formal statement or account of the results of the collation and consideration of information by the CED. The CED is a

committee attached to the ministry established for the purpose of undertaking inquiries and making reports or recommendations to it.

[108] Record 4's contents consist of evaluations of observations and facts. Even though the ministry did not apply the discretionary exemption in section 13(1) to the entire record, the record is still a report within the meaning of section 13(2)(k). Accordingly, I find that the exception in section 13(2)(k) applies to the information in Record 4 that the ministry has claimed is subject to section 13(1).

[109] Therefore, as the two severances at issue in Record 4 are not exempt under section 13(1) by reason of section 13(2)(k), and as no other exemptions apply, I will order this information disclosed.

Conclusion

[110] Other than the information in the records that the requester is not interested in receiving access to, I have found that the information in the records is not exempt under *FIPPA*

ORDER:

1. I order the ministry to disclose to the requester all of the information in the records, by **August 5, 2015** but not before **July 31, 2015**, except for:

    a. the first severance in Record 2;

    b. the drug file numbers in Records 3 and 4; and,

    c. the information at bullets 6, 8, and 9 of Record 4.

2. In order to verify compliance with this order, I reserve the right to require the ministry to provide me with a copy of the records as disclosed to the requester.

Original Signed by: June 29, 2015
Diane Smith
Adjudicator