Federal Court  Cour fédérale

Date: 20110502

Docket: T-1172-10

Citation: 2011 FC 507

Toronto, Ontario, May 2, 2011

PRESENT: The Honourable Mr. Justice Campbell

BETWEEN:

TEVA CANADA LIMITED

Applicant

and

THE MINISTER OF HEALTH AND SANOFI-AVENTIS CANADA INC.

Respondents

REASONS FOR ORDER AND ORDER

[1] The present Application raises three issues important to the innovator and generic drug manufacturer industries in Canada: what is the content of the authority provided to the Minister of Health (the Minister) as the entity charged with maintaining a Register of Innovative Drugs (the Register) pursuant to C.08.004.(9) of the *Food and Drug Regulations* (C.R.C., c. 870) (the *Regulations*); is judicial review available to hold the Minister accountable for decisions made in

exercising the authority; and what is the correct interpretation of the term “approved” in the definition of “innovative drug” in C.08.004.1(1) of the *Regulations*?

[2] In maintaining the Register, the Minister extends an open invitation to innovators and generics to make a request of the Minister with respect to the Register, and commits to supply a response to each request. Given this invitation, by letter dated March 19, 2010, the generic manufacturer Teva Canada Ltd. (Teva) wrote to the Minister requesting that the June 15, 2007 authorization issued to the innovator manufacturer sanofi-aventis Canada, Inc. (Sanofi) pursuant to C08.004.1 to sell the “innovative drug” ELOXATIN be deleted from the Register. The definition of this term is stated in C08.004.1(1) :

“innovative drug” means a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph. (drogue innovante)	« drogue innovante » S’entend de toute drogue qui contient un ingrédient médicinal non déjà approuvé dans une drogue par le ministre et qui ne constitue pas une variante d’un ingrédient médicinal déjà approuvé tel un changement de sel, d’ester, d’énantiomère, de solvate ou de polymorphe. (innovative drug)

Thus, to be authorized to sell ELOXATIN as an innovative drug it was necessary for Sanofi to establish that the drug does not contain a medicinal ingredient that has been “previously approved” by the Minister. The history with respect to approval of ELOXATIN is that on June 15, 2007, the Minister issued a “Notice of Compliance” (NOC) for the drug and, in a separate decision on or about that date, the Minister listed ELOXATIN on the Register. Prior to that time, ELOXATIN had neither an NOC nor a Drug Identification Number (DIN). In granting Sanofi the authorization to sell ELOXATIN as an innovative drug, the Minister determined that the medicinal ingredient in the drug, being oxaliplatin, had not been previously approved in a drug, meaning that the safety and

efficacy of oxaliplatin had not been established by the rigorous testing process dictated by the *Regulations*. In the present Application, Teva's primary argument is that ELOXATIN had been the subject of a previous "approval" on a factual basis prior to June 15, 2007 and the Minister's failure to include this form of approval in reaching the decision of June 21, 2010 constitutes an error in law.

[3] In 1999, Sanofi was authorized to sell ELOXATIN for the treatment of life-threatening colorectal cancer pursuant to the "Sale of New Drug for Emergency Treatment" provision found in C.08.010(1) of the *Regulations*, which is known in the pharmaceutical industry as the "Special Access Program" (the SAP). A drug authorized for sale under the SAP is exempt from the requirements of C08.004.1 of the *Regulations* meaning that the safety and effectiveness of ELOXATIN was not required to be established pursuant to the *Regulations* prior to an SAP authorization being granted.

[4] It is the evidence of Sanofi's wide-scale and high volume sale of ELOXATIN under the SAP between 1999 and 2005 that grounds Teva's arguments that, by authorizing those sales, the Minister approved the safety and efficacy of the drug, and, thus, the Minister erred in law in granting Sanofi the innovative drug status. After providing procedural fairness to Sanofi, in June 2010, the Minister rejected Teva's request on a finding that no error in law had been made.

[5] To challenge the Minister's decision, on July 22, 2010, Teva launched the present judicial review Application. Prior to the hearing of the Application the positions taken by Sanofi on the one hand, and Teva and the Minster on the other, were diametrically opposed on the preliminary issues of: whether the Minister has the authority to make the decision in issue; whether the decision is

subject to judicial review; and whether Teva has standing to bring the present Application. As a result, interlocutory motions were filed by the parties on each issue. At the hearing of the present Application, Teva and the Minister argued in favour of a positive result on each of the preliminary issues which would allow the judicial review Application to proceed to hearing, a position which Sanofi opposed. As to whether the Minister was correct in the legal finding made in rejecting Teva's request, assuming the Application would proceed to hearing, Sanofi and the Minister argued that the Minister was correct in finding no error of law was made, a position which Teva opposed. Determination of the motions is merged into the present reasons.

[6] For the reasons which follow, I agree with Teva and the Minister on each preliminary issue to find no impediment to reaching the present decision on the Application, and with respect to the merits, I agree with Sanofi and the Minister that the decision was not made in reviewable error.

I. What is Content of the Minister's Authority as the Person Charged with Maintaining the Register?

[7] With respect to this issue, C.08.004.1(9) of the *Regulations* expresses the delegation of authority:

(9) The Minister shall maintain a register of innovative drugs that includes information relating to the matters specified in subsections (3) and (4). SOR/95-411, s. 6; SOR/2006-241, s. 1.	(9) Le ministre tient un register des drogues innovantes, lequel contient les renseignements relatifs à l'application des paragraphes (3) et (4). DORS/95-411, art. 6; DORS/2006-241, art. 1.

[8] At the operational level, in maintaining the Register, the Minister invites innovator and generic manufacturers to engage in the dialogue as outlined in the Minister's "Guidance Document on Data Protection" (Guidance Document):

> […] a drug is eligible for listing on the Register of Innovative Drugs if it meets the definition of an innovative drug. Protection for the innovative drug applies only where an innovative drug has received an NOC and is marketed in Canada. If the listing is questioned on either of these grounds, the letter of inquiry should provide details. The OPML will confirm to both the originator of the inquiry and in innovative company that the drug's status has been questioned. […] The OPML will provide the results of the assessment to both parties and will provide 30 days to each party to make representations. After consideration of any representations received, the OPML will endeavour to make its decision available to both parties within 30 days.
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> (Application Record of the Applicant, p. 913)

With respect to the scope of the Minister's authority to provide the response of June 21, 2010 to Teva's request of March 19, 2010, the Minister takes the following firm position with which Teva agrees:

> As to the first subject, the Minister regards Health Canada's letter to the parties of June 21, 2010 as constituting the decision here under review. That letter was essentially a refusal of the Applicant's request to remove ELOXATIN from the Register of Innovative Drugs. The refusal was <u>not</u> based on any position that the Minister had no authority to remove it. Rather, it was based on the fact that notwithstanding Teva's representations, the Minister's officials were not persuaded that ELOXATIN is not an "innovative drug". It therefore qualified for continued inclusion on the Register.
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> Had the Minister's officials been persuaded that ELOXATIN is not an "innovative drug", no explicit authority would have been required for its removal from the Register. The Minister has a duty to "maintain" the Register under subsection C.08.004.1(9) of the *Food and Drugs Regulations*. Such a duty clearly implies a power both to add and to delete information from the Register, as appropriate.

> Further, the initial decision to include information on the Register does not represent the kind of situation in which *functus officio* principles have any place. Those principles concern the finality of judgments, and the jurisdiction of a Court or administrative tribunal to reopen a matter in which it has made a final ruling. Such is not the situation here. Rather than a process involving anything akin to a hearing and a resulting final decision, this matter involves ongoing dynamics. Under subsection C.08.004.1(3), the Minister has a continuing duty, for the specified time period, not to accept or approve a generic drug submission made on the basis of a comparison to an "innovative drug". If, for example, the Minister becomes aware of circumstances indicating that in a particular case the comparison is made to a drug that is not an "innovative drug", the Minister must (assuming all other requirements are satisfied) accept and approve the submission (under sections C.08.002.1 and C.08.004).
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> In this regard, it should be noted that parties other than the innovator, including other drug manufacturers, have no opportunity to participate in the initial decision to place information on the Register of Innovative Drugs. Indeed, any interest that those parties have may not even arise until well after that decision.
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> Thus, the Minister may, for example, entertain a request to remove a drug from the Register. Similarly, if the request is refused, and was made by a person who would have standing under the *Federal Court Act*, the refusal may be subject to judicial review.
>
> [Emphasis in the original]
>
> (The Minister's Supplemental Argument, April 5, 2011)

[9] As mentioned, Teva's concern in making the March 19, 2010 request was directed to the correctness of the 2007 decision in which the Minister authorized ELOXATIN to be placed on the Register as an "innovative drug" based on its own interpretation of the meaning of the word "approved". Teva did not challenge the 2007 decision by way of judicial review but, in the present Application, has challenged the June 21, 2010 decision as a "fresh decision" on the correctness of the 2007 authorization. The Minister accepted the obligation to answer the request, and takes the

position that it is a fresh decision subject to judicial review. Sanofi makes the following broad and detailed objection to the Minister's "fresh decision" position:

> The Minister's letter of June 21, 2010 does not constitute a "fresh decision" with respect to any previous actions taken by the Minister.
>
> The eligibility of Eloxatin for listing on the register was determined by the Minister's June 15, 2007 decision. The June 15, 2007 decision has not been challenged by way of a proper application for judicial review to the Federal Court.
>
> In its letter of March 19, 2010, Teva did not assert that it had identified any new facts subsequent to the June 15, 2007 decision by which a "fresh decision" was said to be required or authorized. A "fresh decision" cannot be triggered merely because a party writes a letter to a decision maker in order to provoke a reply, with the intention that the reply will thereby be reviewable on the very issue considered in the original decision. At minimum, new facts other than the mere exchange of correspondence is required.
>
> To hold otherwise would permit for the circumvention of the finality of administrative decisions outside of the usual judicial review framework and time limits.
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> Moreover, a "fresh decision" can only be found where the Minister had the authority to issue one. A clear grant of statutory authority is required to give the Minister the power to revisit or reopen her decision of June 15, 2007 in relation to the grounds asserted by Teva. No such grant of authority exists in relation to the request of Teva by its letter of March 19, 2010.
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> While the Minister has a broad jurisdiction over matters pertaining to the health and safety of the public, Teva's letter is not said to relate to this authority.
>
> As regards the data protection regime of section C.08.004.1 of the *Food and Drug Regulations*, the legislative grant describes situations where the Minister could be seen to be authorized to render a "fresh decision" in the face of new facts. By way of example, support could be found for the removal of a drug from the register if the drug is no longer marketed in Canada (section C.08.004.1(5)).
>
> However, there is no provision in the *Food and Drugs Act* and the *Food and Drug Regulations* that would provide the Minister with the

authority to revisit or reopen the June 15, 2007 for the reasons asserted by Teva and in the absence of new facts.

The Health Canada *Guidance Document on Data Protection* does not provide a legislative grant of jurisdiction, although it describes a mechanism by which a party may make an inquiry. As noted in the Foreword to the *Guidance Document on Data Protection* "Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach."

A broad authority to reopen the June 15, 2007 decision for the reasons asserted by Teva does not arise from section C.08.004. 1(9) that provides that the Minister "*shall maintain a register of innovative drugs that includes information relating to the matters specified in subsections (3) and (4)*".

Such authority cannot be found by analogy with the legislative regime of the *Patented Medicines (Notice of Compliance) Regulations ("PMNOC Regulations"),* which provides a clear grant of statutory authority to the Minister to revisit an earlier decision to list a patent on the Patent Register. Section 3(2) of the *PMNOC Regulations* authorizing the Minister to maintain a patent register states that "*To maintain the register, the Minister may refuse to add or may delete any patent or other information that does not meet the requirements of that section.*" That language was added to the *PMNOC Regulations* by amendments introduced in 1998.

No such language is found in section C.08,004.1 of the *Food and Drug Regulations*, notwithstanding that this section was introduced some eight years after the amendments to the express scope of the Minister's powers to "maintain" under section 3(2) of the *PMNOC Regulations*. Had the Legislator intended to provide for such broad authority with regard to data protection, similar language would have been used.

In addition, the application of Teva raises matters which are not justiciable at the request of Teva.Whether the problem is expressed as a lack of standing by Teva to challenge the decision, or rather that the decision raises issues which are not justiciable at the request of Teva, the outcome is the same: Teva cannot raise these matters in an effort to attack the decision of the Minister.

[Emphasis in the original]

(Sanofi's Supplemental Argument, April 5, 2011)

The Minister's response specifically with respect to Sanofi's argument that no legislative approval exists to substantiate the Minister's position draws a parallel to the conduct of the patented medicines regulatory regime:

> In its supplementary representations, Sanofi refers to the specific language used in subsection 3(2) of the *Patented Medicines (Notice of Compliance) Regulations*, permitting the Minister to add or delete information to or from the Patent Register "maintained" under those Regulations. Sanofi notes that the language is not repeated in section C.08.004.1(9) of the *Food and Drug Regulations.*
>
> That language was added to the *PM(NOC) Regulations* in 1998. However, as Teva has noted, the Federal Court had previously decided (in *Merck Frosst Canada v. Canada* (1997), 74 C.P.R. (3d) 307) that the duty to "maintain" the Register implies authority both to add and to delete information to or from the Register. The amendment in 1998 was clearly made simply for greater certainty.
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> (The Minister's Supplemental Argument, April 7, 2011)

[10] I find that, because by statutory authority the *PMNOC Regulations* detail the content of the authority provided to the Minister to maintain the Patent Register and the *Regulations* presently under consideration do not, the *PMNOC Regulations* are not a comparator for interpreting the Minister's authority under the *Regulations*. However, I also find that no basis exists in the present record to support Sanofi's argument that, because similar statutory authority does not appear in the *Regulations*, the *Regulations* should not be interpreted to provide the Minister with authority to add and delete from the Register. In my opinion, logic dictates the correct result.

[11] It is not logically possible for the Minister to maintain the Register without an open dialogue with the innovator and generic manufacturers based on the understanding that, in an appropriate case, the Minister would take action to amend the Register.

[12] In the April 7, 2011 supplemental argument advanced in opposition to the Minister's position, Sanofi makes the observation that the Guidance Document only describes a mechanism for making an inquiry, and, with one noted exception, implies that any reply that the Minister might give can lead to no action. I do not accept this general proposition because, if accepted, it establishes a situation which renders the Register a dead directory and the Minister a passive apologist. If this were the result, no matter how serious the concern about an entry, and how obvious it is that action should be taken with respect to the entry, it would be an exercise in futility to talk to the Minister about it because he or she would say that nothing can be done. In my opinion, this assertion does not allow for the proper maintenance of the Register.

[13] The one exception that Sanofi does acknowledge is that, if new facts are presented to the Minister which directly affects an authorization on the Register, then the Minister's consideration of the new facts and determination on them, is capable of being considered a "fresh decision" which can have legal force and effect in amending the Register. The example which exposes this possibility as reasonable is new evidence that an entry made on the Register was gained by fraud. It seems that Sanofi would not object to the removal of the entry if the new evidence is accepted by the Minister as establishing new facts. In my opinion, the principle of what is required to maintain the Register should not be limited to this obvious example; the same logic can be applied, at the very least, to an argument that an entry on the Register is contrary to law as is argued by Teva in the present case.

[14] As a result, I agree that the Minister had authority to issue the "fresh decision" of June 21, 2010.

II. Is Judicial Review Available to Hold the Minister Accountable for the Decision of June 21, 2010?

[15] In its letter of March 19, 2010, Teva made a request for a legal determination, and the Minister made a determination; but not the determination that Teva requested. Given that the Minister has the authority to make the legal finding expressed in the decision of June 21, 2010, the issue is whether judicial review is available to Teva to question the decision, and whether Teva can take advantage of it if it is available. The Minister does not object to being held accountable before this Court (see: Minister's Letter, March 21, 2011, p. 2).

[16] Teva is not a passive observer of the Register. It is a generic manufacturer which has a public as well as an economic interest in selling generic drugs into the marketplace in Canada. In bringing the Application, Teva advances the former interest and does not deny the latter interest. In its letter of March 19, 2010, Teva asserts that "to maintain ELOXATIN on the Register not only undermines the purpose and intent of the Data Provisions, but also imposes a significant hardship on Canada's health care system with a corresponding unjust enrichment of Sanofi" (Application Record of the Applicant, p. 716). The hardship that Teva is referring to is that, by the registration of ELOXATIN as an "innovative drug" pursuant to C.08.004.1(1), Sanofi is protected from generic competition by operation of the "Data Protection Provisions" of C.08.004.1(3) of the *Regulations* (see paragraph 21 of these reasons for a full description of the "data protection" operation of C.08.004.1(3)). This enduring obstacle placed in Teva's path towards entering the marketplace with

its generic version of ELOXATIN, is, understandably, of utmost interest to it. The question is whether this interest is sufficient to give Teva standing to bring the present Application.

[17] Generally, there is no disagreement among the parties to the present Application that judicial review is available to provide the opportunity to question a decision of the Minister made within authority. However, in the initial arguments of the parties filed in November and December 2010, the Minister and Sanofi objected to Teva's "standing" to bring the present Application essentially for the reason that Teva is not someone "directly affected by the matter in respect of which relief is sought" which is a requirement to bring the present Application pursuant to s. 18.1(1) of the *Federal Courts Act*. Both the Minister and Sanofi took the position that in order to prove that it is directly affected, Teva must have justified its interest in the decision presently under review by having made an attempt to enter the market by filing an Amended Abbreviated New Drug Submission (ANDS). This argument was made even though the ANDS would most certainly be rejected because of the protection provided by C.08.004.1(3).

[18] Nevertheless, it is important to note that, well prior to the hearing of the present Application, on January 17, 2011, Teva did attempt to file an ANDS which was rejected by the Minister. As a result of the attempt to file, the Minister formally abandoned the objection to Teva's standing to bring the present Application (see: Minister's Letter, March 21, 2011, p. 2). However, at the hearing of the present Application, Sanofi maintained the argument that in order for the ANDS to have effect on Teva's standing it must have been in place prior to the present Application being launched. Acceptance of this argument would mean that to challenge the Minister's decision, Teva would have to abandon the present Application and commence a new application with all the same

arguments being reintroduced, but for Sanofi's argument on standing. In my opinion, this course of action would do nothing to improve delivery of justice to any party to this Application, but would only produce delay and lost costs for no good purpose. Therefore, I dismiss Sanofi's objection, and find that, by attempting to file an ANDS, in any event of its rejection, Teva has perfected its standing to bring the present Application.

[19] One evidentiary issue initiated by Teva on which motions were crossed, and not otherwise dealt with in these reasons, concerns whether evidence not before the Minister can be added to the judicial review record. The additional affidavit evidence initially sought to be added by Teva included substantiations concerning Sanofi's activity in the SAP program which was intended by Teva to establish that ELOXATIN had gained widespread use. Since this evidence already existed in the contents of Teva's March 19, 2010 letter to the Minister, at the hearing of the Application, Teva abandoned its evidentiary motion, but with one exception. Teva continues to maintain that a "monograph" of ELOXATIN is relevant to the present review. Because this piece of evidence was not in the record upon which the Minister made the decision presently under review, and because the document is intended to prove the safety and efficacy of ELOXATIN and, therefore, is not background information, I dismiss the motion for its admission.

III. What is the correct interpretation of "approved" in the definition of "innovative drug" in s. C.08.004.1(1) of the *Regulations*?

[20] Sanofi supports the Minister's position on this issue.

[21] With respect to how C.08.004.1 works within the scheme of the *Regulations*, the Minister takes the position that safety and effectiveness are the considerations with respect to a drug approved for public use, and that proof that a drug meets these considerations guides the administration of the *Regulations*. The Minister provides the following summary of the factors in play:

> This application requires consideration of four aspects of the legislated framework within which drugs are regulated. They relate to drug submissions for new drugs, to submissions for Drug Identification Numbers ("DIN"), to the Special Access Programme, and to data protection.
>
> *Drug Submissions for New Drugs*
>
> A new drug may not be marketed in Canada unless its manufacturer has first obtained a notice of compliance ("NOC") pursuant to Part C, Division 8 of the Regulations. The manufacturer files a submission, and if the Minister finds that the information in it satisfies him that the drug is safe and effective, she issues an NOC.
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> A new drug submission ("NDS") is filed under section C.08.002, typically by a brand name drug manufacturer. It usually contains voluminous clinical trial data and detailed studies. These form the basis on which the drug is approved for sale.
>
> An abbreviated new drug submission ("ANDS") is available under section C.08.002.1 to generic drug manufacturers who wish to copy a marketed drug without having to provide clinical data demonstrating safety and effectiveness. The manufacturer must show instead that the generic drug is bioequivalent to a Canadian reference product, based on pharmaceutical and, where necessary, bioavailability characteristics.
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> Demonstrating bioequivalence by a comparison to a Canadian reference product permits a generic drug manufacturer to establish the safety and effectiveness of its product without making a direct assessment on the basis of clinical studies. In doing so, the generic drug manufacturer is relying on the information established about the Canadian reference product as filed in the NDS by the brand name drug manufacturer, which provides the primary knowledge about the safety and effectiveness of the drug and its conditions of use.

Drug Identification Number Submissions

No manufacturer may sell any drug unless a drug identification number ("DIN") has been assigned to it. A DIN is an eight-digit numerical code that identifies drug product characteristics including manufacturer, brand name, medicinal ingredient, strength of the medicinal ingredient, pharmaceutical form, and route of administration. Through the DIN, a drug can readily be tracked or recalled in the event of an adverse drug reaction in the population.

In the case of a new drug, a drug submission filed pursuant to Division 8 of the Food and Drug Regulations serves as an application for a DIN. When a drug is not "new" (as that term is defined), it is not subject to the requirements of Division 8. In that case, the application for a DIN is made through a DIN submission, and the drug is regulated primarily under Part C, Division 1 of the Regulations. To receive a DIN, a drug manufacturer must file sufficient data to allow the Minister to evaluate the safety and efficacy of the drug for its intended use, and the Minister may refuse to issue a DIN where he believes the drug to be unsafe or ineffective.

After receiving a DIN, a manufacturer may make changes to the drug or to the information associated with it by filing a new DIN submission or a notification for changes. The Minister will assess the proposed change and may require the filing of an NDS if the change is deemed to bring the drug within the definition of "new drug". In such cases, the requirements for an NOC under Division 8 of the Regulations must be met.

The Special Access Programme

The Special Access Programme, or "SAP", is provided for in the Regulations under the heading "Sale of New Drug for Emergency Treatment" [C.08.010 and C.08.011].

Thus, the SAP involves exceptional emergency situations, and is explicitly an exception to the requirements of the Regulations. A drug administered under the SAP is, when sold in accordance with its conditions, exempt from the requirements of the Regulations and, specifically, is exempt from the requirements of section C.08.002.

[…]

The operation of the SAP has recently been summarized by the Federal Court of Appeal [in *Hospira Healthcare Corp. v. Canada (Attorney General)*, 2010 FCA 345] as follows:

> ¶4 …the Director (Assistant Deputy Minister, Health Products and Food Branch, Health Canada) may authorize the sale of a new drug to a physician under the Special Access Programme ("SAP") for the emergency treatment of a patient
>
> ¶10 When requesting Health Canada for an authorization under the SAP, a physician must: (i) describe the patient's medical condition; (ii) explain why the medicine is the best choice for treating the condition; and (iii) provide data on the use, safety and efficacy of the medicine requested. If granted, an SAP authorization authorizes, but does not require, a manufacturer to sell a specified quantity of the medicine to the requesting physician for the emergency treatment of a specified condition of a named patient under the care of the physician. The physician must report to Health Canada on the use of the medicine, including any adverse effects.
>
> ¶11 SAP authorizations…are normally granted for serious or life-threatening conditions when conventional treatments have proved ineffective or are not suitable for the particular patient. Typically, medicines authorized under the SAP are treatments of last resort and are not subject to the same level of scrutiny for safety and efficacy as medicines for which an NOC has been issued. Nonetheless, Health Canada reviews the SAP request and any other available data on the new medicine in order to "manage the risk" of its use.

Data Protection

The amended "data protection" provisions in section C.08.004.1 of the *Food and Drug Regulations* came into force on October 5, 2006.

As specified in subsection C.08.004.1(2), these provisions apply to the implementation of Article 1711 of the *North American Free Trade Agreement* and of paragraph 3 of Article 39 of the *Trade Related Aspects of Intellectual Property Rights Agreement*. Under these commitments, generally speaking, where a person submits undisclosed data for approval of a pharmaceutical product, and the product utilizes a new chemical entity, signatories are to prevent other persons from making "unfair commercial use" of the data and (for a reasonable time) from relying on the data in their own applications for approval.

> Accordingly, to summarize section C.08.004.1, a generic drug manufacturer may not file a submission on the basis of a comparison to an "innovative drug" within the first six years of the eight-year period after the drug has received an NOC. In addition, the Minister may not issue an NOC to the generic drug manufacturer before the end of the eight-year period'. It is these prohibitions that result in what is known as "data protection".
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> An "innovative drug" is defined in subsection C.08.004.l(1) as "a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph."
>
> The administration of the data protection provisions by the Office of Patented Medicines and Liaison ("OPML") is outlined in Health Canada's guidance document entitled Data Protection under C.08.004.1 of the *Food and Drug Regulations*.
>
> When determining if a drug is an "innovative drug", the OPML first considers whether the medicinal ingredient was previously approved in a drug by the Minister, including a drug that received a DIN. If it was, the drug is not an "innovative drug", and is not eligible for data protection.
>
> [Emphasis in original]
>
> (The Minister's Memorandum of Fact and Law, paras. 5 - 21)

[22] Prior to ELOXATIN being approved as an innovative drug, Sanofi obtained an NOC for the drug on the basis of an NDS. As a result, the details of the new drug provisions of the *Regulations* are important to consider. A quotation of C.08.004.(1) is next provided, followed by the opening to C.08.002 to which it refers. The balance of C.08.002, C.08.002.1, C.08.003, and C.08.005.1 are quoted in the ADDENDUM to these reasons:

C.08.004. (1) Subject to section C.08.004.1, the Minister shall, after completing an examination of a new drug submission or abbreviated new drug submission or a	C.08.004. (1) Sous réserve de l'article C.08.004.1, après avoir terminé l'examen d'une présentation de drogue nouvelle, d'une présentation abrégée de drogue nouvelle ou

supplement to either submission,

(a) if that submission or supplement complies with section C.08.002, C.08.002.1 or C.08.003, as the case may be, and section C.08.005.1, issue a notice of compliance;

or

(b) if that submission or supplement does not comply with section C.08.002, C.08.002.1 or C.08.003, as the case may be, or section C.08.005.1, notify the manufacturer that the submission or supplement does not so comply.

d'un supplément à l'une de ces présentations, le ministre :

a) si la présentation ou le supplément est conforme aux articles C.08.002, .08.002.1 ou C.08.003, selon le cas, et à l'article C.08.005.1, délivre un avis de conformité;

b) si la présentation ou le supplément n'est pas conforme aux articles C.08.002, C.08.002.1 ou C.08.003, selon le cas, ou à l'article C.08.005.1, en informe le fabricant.

C.08.002. (1) No person shall sell or advertise a new drug unless

(a) the manufacturer of the new drug has filed with the Minister a new drug submission or an abbreviated new drug submission relating to the new drug that is satisfactory to the Minister;

(b) the Minister has issued, pursuant to section C.08.004, a notice of compliance to the manufacturer of the new drug in respect of the new drug submission or abbreviated new drug submission;

(c) the notice of compliance in respect of the submission has not been suspended pursuant to

C.08.002. (1) Il est interdit de vendre ou d'annoncer une drogue nouvelle, à moins que les conditions suivantes ne soient réunies :

a) le fabricant de la drogue nouvelle a, relativement à celle-ci, déposé auprès du ministre une présentation de drogue nouvelle ou une présentation abrégée de drogue nouvelle que celui-ci juge acceptable;

b) le ministre a, aux termes de l'article C.08.004, deliver au fabricant de la drogue nouvelle un avis de conformité relativement à la présentation de drogue nouvelle ou à la présentation abrégée de drogue nouvelle;

section C.08.006; and	c) l'avis de conformité relatif à la présentation n'a pas été suspendu aux termes de l'article C.08.006;
(d) the manufacturer of the new drug has submitted to the Minister specimens of the final version of any labels, including package inserts, product brochures and file cards, intended for use in connection with that new drug, and a statement setting out the proposed date on which those labels will first be used.	d) le fabricant de la drogue nouvelle a présenté au ministre, sous leur forme définitive, des échantillons des étiquettes — y compris toute notice jointe à l'emballage, tout dépliant et toute fiche sur le produit — destinées à être utilisées pour la drogue nouvelle, ainsi qu'une déclaration indiquant la date à laquelle il est prévu de commencer à utiliser ces étiquettes.
(2) A new drug submission shall contain sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug, including the following:	(2) La présentation de drogue nouvelle doit contenir suffisamment de renseignements et de matériel pour permettre au ministre d'évaluer l'innocuité et l'efficacité de la drogue nouvelle, notamment :
[Emphasis added]	[Non souligné dans l'original]

The list of what must be included in a new drug submission pursuant to C.08.002.(1) is exhaustive and includes: a list of the ingredients of the new drug; details of the tests to be applied to control the potency, purity, stability and safety of the new drug; detailed reports of the tests made to establish the safety of the new drug for the purpose and under the conditions of use recommended; and substantial evidence of the clinical effectiveness of the new drug for the purpose and under the conditions of use recommended.

[23] There is ample support for the Minister's position that, with the exception of approvals under the SAP, proof of safety and effectiveness is at the base of the approval process under the *Regulations*.

[24] Teva's first argument to the Minister was that safety and effectiveness can be proved by conduct and not by a formal authorization process:

> As at June 15, 2007, Eloxatin was not an "innovative drug" (as defined in the Food and Drug Regulation) because oxaliplatin had been previously approved by the Minister through the widespread authorization of the drug under the Special Access Programme ("SAP"). Eloxatin therefore did not meet the requirements for listing on the Register (Page 2).
>
> […]
>
> The Minister would not have permitted such pervasive use of Eloxatin (and other drugs containing oxaliplatin) under SAP if she were not satisfied as to the safety and efficacy of Sanofi's oxaliplatin products and generic oxaliplatin products. The safety and efficacy of Sanofi's oxaliplatin products had been established through the worldwide approval of Sanofi's oxaliplatin products, sold under the brand name Eloxatin, at the relevant time as well as the worldwide approval of generic oxaliplatin products (Page 6).
>
> [Emphasis added]
>
> (Letter of March 19, 2010)

The Minister rejected this argument:

> […] Contrary to Teva's submission, the OPML did not proceed on the assumption that the term "innovative drug' is tied to the issuance of a notice of compliance, but rather, the OPML proceeded on the basis that the term 'innovative drug" is defined by reference to the approval of a drug containing the medicinal ingredient, whether by notice of compliance or otherwise. More specifically, the OPML is of the position that under the definition of an "innovative drug", drugs that contain medicinal ingredients that have been previously approved in Canada—including drugs that have previously received a notice of compliance and/or a drug identification number—will not be afforded data protection.

> […] Drugs sold under the SAP have not undergone full regulatory review and, therefore, have not received market authorization by the Minister. As such, for the purposes of subsection C.08.004.1(1) of the Regulations, the OPML was of the view that it could not be said that a medicinal ingredient authorized for sale under the SAP, such as oxaliplatin, had been previously approved in a drug by the Minister. The OPML remains of this view.
>
> […]
>
> Notwithstanding Teva's submissions, the OPML must, in determining the eligibility for data protection under section C.08.004.1 of the Regulations, determine whether a drug contains a medicinal ingredient previously approved in a drug in Canada under the Regulations. As indicated above, drugs sold under the SAP have not received market authorization (i.e. approval) by the Minister under the Regulations and, as such, oxaliplatin, despite having been authorized for sale under the SAP, had not been previously approved in a drug by the Minister prior to the issuance of the first notice of compliance for ELOXAT1N on June 15, 2007.
>
> [Emphasis added]
>
> (Decision, p. 3)

.

[25] Teva's request to the Minister to remove ELOXATIN from the Register depends on the Minister's acceptance of the proposition that Sanofi's sales under the SAP can constitute a finding by the Minister that the medicinal ingredient oxaliplatin is safe and effective, and that this finding itself is an "approval". The Minister did not accept this proposition, which is a result with which I agree. In my opinion, there is no merit to Teva's argument given the demands of the *Regulations*.

[26] Under the *Regulations* the granting of market approval for a drug involves a two-part decision-making process conducted by the Minister: the evidence presented by an innovator as proof of the fact that a drug is safe and effective must be accepted by the Minister as proving that fact, and then, as a result of that proof, the drug is given market authorization by the Minister. That

is, the drug is “approved” for sale by the issuance of a formal legal determination. Thus, the factual finding is required as a condition precedent to the making of the legal determination.

[27] The issue to which this analysis is applied is whether, in Teva’s argument advanced to the Minister in the letter of March 19, 2010, it had discharged the evidentiary burden to prove that the medicinal ingredient oxaliplatin had been previously approved in a drug by the Minister. To succeed in this argument it was necessary for Teva to prove that the Minister had made the factual finding that oxaliplatin is safe and effective. There is no evidence that such a factual finding was made; attempting to put words in the Minister’s mouth does not discharge the burden. In my opinion, the SAP sales record proves nothing about oxaliplatin’s safety and effectiveness; it proves that many seriously ill people were willing to take the unapproved ELOXATIN in a hope of getting well.

[28] Teva’s second argument to the Minister expressed by letter dated June 2, 2010 was as follows :

> The term “innovative drug” in the Data Provisions must be interpreted and applied by the Minister with a view to the purpose of the provisions, which has been stated by the Federal Court in *Canadian Generic Pharmaceutical Assn. v. Canada (Minister of Health)* 2007 FC 725 to be as follows:
>
> > The balancing of commercial considerations between the protection of art innovator drug manufacturer’s investments in preparing the NOS information in order to obtain an NOC for a new drug arid the eventual NOC approval of generic drug manufacturer’s ANDS for a lower cost generic version of the new drug.
>
> The granting of two periods of exclusivity to Sanofi (as detailed in Teva’s March 19, 2010 letter) distorts the intended balance between the two competing objectives underlying the Data Provisions.

> Therefore, the proposed interpretation of "innovative drug" by OPML in its March 30, 2010 letter is inappropriate.
>
> It is "a well established principle of statutory interpretation that the legislature does not intend to produce absurd consequences" (Ruth Sullivan, Sullivan on the Construction of Statutes, 5th ed. (Markham: LexisNexis Canada Inc., 2008) at 303 -304). In its March 30, 2010 letter, the OPML fails to address the following absurd result produced by listing Eloxatin on the Register of Innovative Drugs, as set out in Teva's March 19, 2010 letter:
>
> > (i) The listing of Eloxatin on the Register has resulted in two periods of exclusivity being granted to sanofi-aventis Canada Inc. ("Sanofi") in respect of Eloxatin: 1999-2005, under the Special Access Programme ('SAP") and 2007-2015, post-NOC for 8.5 years. This absurd result is contrary to, and undermines the intent of, the Data Provisions.
> >
> > (ii) To maintain Eloxatin on the Register not only undermines the purpose and intent of the Data Provisions, but also imposes a significant hardship on Canada's health care system with a corresponding unjust enrichment of Sanofi.
>
> Teva states that based on the above, Eloxatin cannot be correctly designated an 'innovative drug".
>
> (Application Record of the Applicant, pp. 747 - 748)

The Minister dismissed this argument by the statement that "ELOXATIN was properly added to the Register for a term of eight and one-half years from the date of the issuance of its first notice of compliance" (Decision, p. 4). It is obvious that the Minister could not respond to Teva's "absurd result" argument except to say that the Data Protection Provisions of the *Regulations* were applied to ELOXATIN as a matter of course as required by a finding that the drug is an "innovative drug". In my opinion, Teva's argument is, in essence, an attack on the Data Protection Provisions themselves because they are considered to have a negative impact on generic manufacturers such as Teva. I find that this argument is misplaced in the present Application because it is extraneous to the

issue of the meaning of the term “approved” which is the issue for determination. Thus, it is dismissed.

[29] In the course of oral argument during the hearing of the present Application, Teva raised a second purposive approach argument. Teva argues that the purpose of the Data Protection Provisions is to comply with Article 1711 of the *North American Free Trade Agreement* and Article 39, paragraph 3, of the *Trade Related Aspects of Intellectual Property Rights Agreement* as stated in C.08.004.1(2), and, thereby, to protect “trade secrets”. Teva argues that this purpose was not taken into consideration when ELOXATIN was authorized as an innovative drug. The argument relies on the assertion that, since C.08.004.1 is designed to protect undisclosed data, given that the data sought to be protected by the innovative drug authorization of ELOXATIN is data arising from Sanofi’s participation in the SAP, and given that that data was publicly disclosed and published at the time the authorization was issued in 2007 by the “monograph” referred to in paragraph 19 of these reasons, the Minister did not apply the correct legal test in granting the authorization (see Hearing Transcript pp. 73 – 78).

[30] In the present Application the 2007 decision is not under review. The review is confined to the Minister’s decision of June 21, 2010, and, because Teva’s second purposive argument just addressed was not advanced to the Minister for decision, I find it is irrelevant to the present Application.

[31] Therefore, I find that the Minister is correct that, both the factual condition precedent of a finding that a drug is safe and effective, and a market authorization approved accordingly, are

required for a drug to be “approved” as that term is used in the definition of an innovative drug in C.08.004.1(1) of the *Regulations.*

[32] Two final comments are necessary.

[33] The Federal Court of Appeal’s decision in *Hospira Healthcare Corp. v. Canada (Attorney General)*, 2010 FCA 345 requires consideration because both the Minister and Sanofi rely on it in argument. In *Hospira* the Minister’s discretion to accept evidence to prove safety and effectiveness was in issue. In the course of finding that the Minister has discretion, the Court of Appeal made the following statement at paragraph 6:

> In our view, the Minister has a discretion as to the nature and form of the information that will be accepted as meeting the requirements of paragraphs C.08.002(2)(g) and (h). It may well be that in the vast majority of cases, the requirements of those provisions would and should be met by pre-clinical and clinical data from clinical trials performed by the party seeking the notice of compliance. However, the Minister has the discretion to permit the requirements of these provisions to be met by some other means including, for example, reports of clinical trials conducted by others. At the same time, we accept the submission of counsel for the Minister that the safety and efficacy of a drug cannot be established solely on the basis that its use has been permitted under the Special Access Programme, even if permission has been given thousands of times as is the case with the drug in issue.

In my opinion this statement is not relevant to the present Application because it deals with an issue that is not directly in play. The statement is with respect to the kind of evidence that the Minister can accept upon which to find that a drug is safe and effective. On the basis of Teva’s primary argument, the issue in the present case is whether a finding of safety and effectiveness <u>was made</u> by the Minister.

[34] Following completion of the hearing on the present Application, the decision in *CGPA v. Minister of Health and Glaxosmithkline Inc.*, 2011 FC 465 has been released. In that case, Justice de Montigny held that the Canadian Generic Pharmaceutical Association was not "directly affected" by the Minister's decision to maintain the listing of fluticasone furoate on the Register of Innovative Drugs and, therefore, did not have standing to challenge the decision by judicial review. The ratio of the decision is that the CGPA did not have standing, and could not obtain standing, because it is an association which represents generic drug manufacturers, and, as such, could never file an ANDS which would either be accepted or rejected by the Minister. Thus, because Teva is not in this same position, I find that the decision is not relevant to the present Application.

IV. Conclusion

[35] As stated in *Dunsmuir v. New Brunswick*, 2008 SCC 9, [2008] 1 S.C.R. 190 at paragraph 50, normally questions of law are reviewed on the standard of correctness:

> […] When applying the correctness standard, a reviewing court will not show deference to the decision maker's reasoning process; it will rather undertake its own analysis of the question. The analysis will bring the court to decide whether it agrees with the determination of the decision maker; if not, the court will substitute its own view and provide the correct answer. From the outset, the court must ask whether the tribunal's decision was correct.

In *Epicept Corp. v. Canada (Minister of Health)*, 2010 FC 956, with respect to questions of statutory interpretation of the *Regulations*, while acknowledging that in some circumstances the standard of reasonableness is the appropriate standard to apply even to a question of law, and deference to a decision-maker may be required where the question of law is within the decision-

maker's specialized area of expertise and is not of central importance to the legal system generally, Justice Near determined that the Minister is not to be accorded such deference (paragraph 40).

Therefore, on the basis of the analysis provided in these reasons, I find that the Minister was correct in determining the meaning of “approved”, and, as a result, the Minister’s decision is not made in reviewable error.

ORDER

For the reasons provided, the present Application is dismissed.

The issue of costs will be determined in a separate order following submissions by Counsel.

"Douglas R. Campbell"
Judge

ADDENDUM

Food and Drug Regulations (C.R.C., c. 870)

C.08.002 states as follows:

C.08.002. (1) No person shall sell or advertise a new drug unless	C.08.002. (1) Il est interdit de vendre ou d'annoncer une drogue nouvelle, à moins que les conditions suivantes ne soient réunies :
(a) the manufacturer of the new drug has filed with the Minister a new drug submission or an abbreviated new drug submission relating to the new drug that is satisfactory to the Minister;	a) le fabricant de la drogue nouvelle a, relativement à celle-ci, déposé auprès du ministre une présentation de drogue nouvelle ou une présentation abrégée de drogue nouvelle que celui-ci juge acceptable;
(b) the Minister has issued, pursuant to section C.08.004, a notice of compliance to the manufacturer of the new drug in respect of the new drug submission or abbreviated new drug submission;	b) le ministre a, aux termes de l'article C.08.004, deliver au fabricant de la drogue nouvelle un avis de conformité relativement à la présentation de drogue nouvelle ou à la présentation abrégée de drogue nouvelle;
(c) the notice of compliance in respect of the submission has not been suspended pursuant to section C.08.006; and	c) l'avis de conformité relatif à la présentation n'a pas été suspendu aux termes de l'article C.08.006;
(d) the manufacturer of the new drug has submitted to the Minister specimens of the final version of any labels, including package inserts, product brochures and file cards, intended for use in connection with that new drug, and a statement setting out the proposed date on which those labels will first be used.	d) le fabricant de la drogue nouvelle a présenté au ministre, sous leur forme définitive, des échantillons des étiquettes — y compris toute notice jointe à l'emballage, tout dépliant et toute fiche sur le produit — destinées à être utilisées pour la drogue nouvelle, ainsi qu'une déclaration indiquant la date à laquelle il est prévu de
(2) A new drug submission shall contain sufficient	

information and material to enable the Minister to assess the safety and effectiveness of the new drug, including the following:

(a) a description of the new drug and a statement of its proper name or its common name if there is no proper name;

(b) a statement of the brand name of the new drug or the identifying name or code proposed for the new drug;

(c) a list of the ingredients of the new drug, stated quantitatively, and the specifications for each of those ingredients;

(d) a description of the plant and equipment to be used in the manufacture, preparation and packaging of the new drug;

(e) details of the method of manufacture and the controls to be used in the manufacture, preparation and packaging of the new drug;

(f) details of the tests to be applied to control the potency, purity, stability and safety of the new drug;

(g) detailed reports of the tests made to establish the safety of the new drug for the purpose and under the conditions of use recommended;

(h) substantial evidence of the

commencer à utiliser ces étiquettes.

(2) La présentation de drogue nouvelle doit contenir suffisamment de renseignements et de matériel pour permettre au ministre d'évaluer l'innocuité et l'efficacité de la drogue nouvelle, notamment :

a) une description de la drogue nouvelle et une mention de son nom propre ou, à défaut, de son nom usuel;

b) une mention de la marque nominative de la drogue nouvelle ou du nom ou code d'identification projeté pour celle-ci;

c) la liste quantitative des ingrédients de la drogue nouvelle et les spécifications relatives à chaque ingrédient;

d) la description des installations et de l'équipement à utiliser pour la fabrication, la préparation et l'emballage de la drogue nouvelle;

e) des précisions sur la méthode de fabrication et les mécanismes de contrôle à appliquer pour la fabrication, la préparation et l'emballage de la drogue nouvelle;

f) le détail des épreuves qui doivent être effectuées pour contrôler l'activité, la pureté, la stabilité et l'innocuité de la drogue nouvelle;

clinical effectiveness of the new drug for the purpose and under the conditions of use recommended;

(i) a statement of the names and qualifications of all the investigators to whom the new drug has been sold;

(j) a draft of every label to be used in conjunction with the new drug;

(k) a statement of all the representations to be made for the promotion of the new drug respecting

(i) the recommended route of administration of the new drug,

(ii) the proposed dosage of the new drug,

(iii) the claims to be made for the new drug, and

(iv) the contra-indications and side effects of the new drug;

(l) a description of the dosage form in which it is proposed that the new drug be sold;

(m) evidence that all test batches of the new drug used in any studies conducted in connection with the submission were manufactured and controlled in a manner that is representative of market production; and

(n) for a drug intended for administration to food-

g) les rapports détaillés des épreuves effectuées en vue d'établir l'innocuité de la drogue nouvelle, aux fins et selon le mode d'emploi recommandés;

h) des preuves substantielles de l'efficacité clinique de la drogue nouvelle aux fins et selon le mode d'emploi recommandés;

i) la déclaration des noms et titres professionnels de tous les chercheurs à qui la drogue nouvelle a été vendue;

j) une esquisse de chacune des étiquettes qui doivent être employées relativement à la drogue nouvelle;

k) la déclaration de toutes les recommandations qui doivent être faites dans la réclame pour la drogue nouvelle, au sujet

(i) de la voie d'administration recommandée pour la drogue nouvelle,

(ii) de la posologie proposée pour la drogue nouvelle,

(iii) des propriétés attribuées à la drogue nouvelle,

(iv) des contre-indications et les effets secondaires de la drogue nouvelle;

l) la description de la forme posologique propose pour la vente de la drogue nouvelle;

m) les éléments de preuve

producing animals, the withdrawal period of the new drug.

(3) The manufacturer of a new drug shall, at the request of the Minister, provide the Minister, where for the purposes of a new drug submission the Minister considers it necessary to assess the safety and effectiveness of the new drug, with the following information and material:

(a) the names and addresses of the manufacturers of each of the ingredients of the new drug and the names and addresses of the manufacturers of the new drug in the dosage form in which it is proposed that the new drug be sold;

(b) samples of the ingredients of the new drug;

(c) samples of the new drug in the dosage form in which it is proposed that the new drug be sold; and

(d) any additional information or material respecting the safety and effectiveness of the new drug.

SOR/85-143, s. 1; SOR/93-202, s. 24; SOR/95-411, s. 4.

[Emphasis added]

établissant que les lots d'essai de la drogue nouvelle ayant servi aux etudes menées dans le cadre de la présentation ont été fabriqués et contrôlés d'une manière représentative de la production destinée au commerce;

n) dans le cas d'une drogue nouvelle destinée à être administrée à des animaux roducteurs de denrées alimentaires, le délai d'attente applicable.

(3) Le fabricant de la drogue nouvelle doit, à la demande du ministre, lui fournir, selon ce que celui-ci estime nécessaire pour évaluer l'innocuité et l'efficacité de la drogue dans le cadre de la présentation de drogue nouvelle, les renseignements et le matériel suivants :

a) les nom et adresse des fabricants de chaque ingredient de la drogue nouvelle et les nom et adresse des fabricants de la drogue nouvelle sous sa forme posologique proposée pour la vente;

b) des échantillons des ingrédients de la drogue nouvelle;

c) des échantillons de la drogue nouvelle sous sa forme posologique proposée pour la vente;

d) tout renseignement ou matériel supplémentaire se

rapportant à l'innocuité et à l'efficacité de la drogue nouvelle.

DORS/85-143, art. 1; DORS/93-202, art. 24; DORS/95-411, art. 4.

[Non souligné dans l'orginal]

C.08.002.1 states:

C.08.002.1. (1) A manufacturer of a new drug may file an abbreviated new drug submission for the new drug where, in comparison with a Canadian reference product,

(a) the new drug is the pharmaceutical equivalent of the Canadian reference product;

(b) the new drug is bioequivalent with the Canadian reference product, based on the pharmaceutical and, where the Minister considers it necessary, bioavailability characteristics;

(c) the route of administration of the new drug is the same as that of the Canadian reference product; and

(d) the conditions of use for the new drug fall within the conditions of use for the Canadian reference product

(2) An abbreviated new drug submission shall contain

C.08.002.1. (1) Le fabricant d'une drogue nouvelle peut déposer à l'égard de celle-ci une présentation abrégée de drogue nouvelle si, par comparaison à un produit de référence canadien :

a) la drogue nouvelle est un équivalent pharmaceutique du produit de référence canadien;

b) elle est bioéquivalente au produit de référence canadien d'après les caractéristiques pharmaceutiques et, si le ministre l'estime nécessaire, d'après les caractéristiques en matière de biodisponibilité;

c) la voie d'administration de la drogue nouvelle est identique à celle du produit de référence canadien;

d) les conditions thérapeutiques relatives à la drogue nouvelle figurent parmi celles qui s'appliquent au produit de référence canadien.

sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug, including the following:

(a) the information and material described in paragraphs C.08.002(2)(a) to (f) and (j) to (l);

(b) information identifying the Canadian reference product used in any comparative studies conducted in connection with the submission;

(c) evidence from the comparative studies conducted in connection with the submission that the new drug is

(i) the pharmaceutical equivalent of the Canadian reference product, and

(ii) where the Minister considers it necessary on the basis of the pharmaceutical and, where applicable, bioavailability characteristics of the new drug, bioequivalent with the Canadian reference product as demonstrated using bioavailability studies, pharmacodynamic studies or clinical studies;

(d) evidence that all test batches of the new drug used in any studies conducted in connection with the submission were manufactured and controlled in a manner that is representative of market production; and

(2) La présentation abrégée de drogue nouvelle doit contenir suffisamment de renseignements et de materiel pour permettre au ministre d'évaluer l'innocuité et l'efficacité de la drogue nouvelle, notamment :

a) les renseignements et le matériel visés aux alinéas C.08.002(2)a) à f) et j) à l);

b) les renseignements permettant d'identifier le produit de référence canadien utilisé pour les études comparatives menées dans le cadre de la présentation;

c) les éléments de preuve, provenant des études comparatives menées dans le cadre de la présentation, établissant que la drogue nouvelle :

(i) d'une part, est un équivalent pharmaceutique du produit de référence canadien,

(ii) d'autre part, si le ministre l'estime nécessaire d'après les caractéristiques pharmaceutiques et, le cas échéant, d'après les caractéristiques en matière de biodisponibilité de celle-ci, est bioéquivalente au produit de référence canadien selon les résultats des études en matière de biodisponibilité, des etudes pharmacodynamiques ou des études cliniques;

d) les éléments de preuve

(e) for a drug intended for administration to food-producing animals, sufficient information to confirm that the withdrawal period is identical to that of the Canadian reference product.

(3) The manufacturer of a new drug shall, at the request of the Minister, provide the Minister, where for the purposes of an abbreviated new drug submission the Minister considers it necessary to assess the safety and effectiveness of the new drug, with the following information and material:

(a) the names and addresses of the manufacturers of each of the ingredients of the new drug and the names and addresses of the manufacturers of the new drug in the dosage form in which it is proposed that the new drug be sold;

(b) samples of the ingredients of the new drug;

(c) samples of the new drug in the dosage form in which it is proposed that the new drug be sold; and

(d) any additional information or material respecting the safety and effectiveness of the new drug.
SOR/95-411, s. 5.

établissant que les lots d'essai de la drogue nouvelle ayant servi aux études menées dans le cadre de la présentation ont été fabriqués et contrôlés d'une manière représentative de la production destinée au commerce;

e) dans le cas d'une drogue destinée à être administrée à des animaux producteurs de denrées alimentaires, les renseignements permettant de confirmer que le délai d'attente est identique à celui du produit de reference canadien.

(3) Le fabricant de la drogue nouvelle doit, à la demande du ministre, lui fournir, selon ce que celui-ci estime nécessaire pour évaluer l'innocuité et l'efficacité de la drogue dans le cadre de la présentation abrégée de drogue nouvelle, les renseignements et le materiel suivants :

a) les nom et adresse des fabricants de chaque ingredient de la drogue nouvelle et les nom et adresse des fabricants de la drogue nouvelle sous sa forme posologique proposée pour la vente;

b) des échantillons des ingrédients de la drogue nouvelle;

c) des échantillons de la drogue nouvelle sous sa forme posologique proposée pour la vente;

	d) tout renseignement ou matériel supplémentaire se rapportant à l'innocuité et à l'efficacité de la drogue nouvelle. DORS/95-411, art. 5.
[Emphasis added]	[Non souligné dans l'orginal]

C.08.003 states:

C.08.003. (1) Notwithstanding section C.08.002, no person shall sell a new drug in respect of which a notice of compliance has been issued to the manufacturer of that new drug and has not been suspended pursuant to section C.08.006, if any of the matters specified in subsection (2) are significantly different from the information or material contained in the new drug submission or abbreviated new drug submission, unless	C.08.003. (1) Malgré l'article C.08.002, il est interdit de vendre une drogue nouvelle à l'égard de laquelle un avis de conformité a été délivré à son fabricant et n'a pas été suspendu aux termes de l'article C.08.006, lorsqu'un des éléments visés au paragraphe (2) diffère sensiblement des renseignements ou du matériel contenus dans la présentation de drogue nouvelle ou la presentation abrégée de drogue nouvelle, à moins que les conditions suivantes ne soient réunies:
(a) the manufacturer of the new drug has filed with the Minister	a) le fabricant de la drogue nouvelle a déposé auprès du ministre :
(i) a supplement to that new drug submission, or	(i) soit un supplément à la présentation de drogue nouvelle,
(ii) a supplement to that abbreviated new drug submission;	(ii) soit un supplément à la présentation abrégée de drogue nouvelle;
(b) the Minister has issued a notice of compliance to the manufacturer of the new drug in respect of the supplement;	b) le ministre a délivré au fabricant un avis de conformité relativement au supplément;
(c) the notice of compliance in respect of the supplement has	c) l'avis de conformité relatif au supplément n'a pas été

not been suspended pursuant to section C.08.006; and

(d) the manufacturer of the new drug has submitted to the Minister specimens of the final version of any label, including any package insert, product brochure and file card, intended for use in connection with the new drug, where a change with respect to any of the matters specified in subsection (2) is made that would require a change to the label.

(2) The matters specified for the purposes of subsection (1), in relation to the new drug, are the following:

(a) the description of the new drug;

(b) the brand name of the new drug or the identifying name or code proposed for the new drug;

(c) the specifications of the ingredients of the new drug;

(d) the plant and equipment used in manufacturing, preparation and packaging the new drug;

(e) the method of manufacture and the controls used in manufacturing, preparation and packaging the new drug;

(f) the tests applied to control the potency, purity, stability and safety of the new drug;

suspendu aux termes de l'article C.08.006;

d) le fabricant de la drogue nouvelle a présenté au ministre, sous leur forme définitive, des échantillons de toute étiquette — y compris une notice jointe à l'emballage, un dépliant et une fiche sur le produit — destine à être utilisée pour la drogue nouvelle, dans le cas où la modification d'un des éléments visés au paragraphe (2) nécessite un changement dans l'étiquette.

(2) Pour l'application du paragraphe (1), les elements ayant trait à la drogue nouvelle sont les suivants:

a) sa description;

b) sa marque nominative ou le nom ou code sous lequel il est proposé de l'identifier;

c) les spécifications de ses ingrédients;

d) les installations et l'équipement à utiliser pour sa fabrication, sa préparation et son emballage;

e) la méthode de fabrication et les mécanismes de contrôle à appliquer pour sa fabrication, sa preparation et son emballage;

f) les analyses effectuées pour contrôler son activité, sa pureté, sa stabilité et son innocuité;

g) les étiquettes à utiliser pour la drogue nouvelle;

h) les observations faites relativement :

(g) the labels used in connection with the new drug;

(h) the representations made with regard to the new drug respecting

(i) the recommended route of administration of the new drug,

(ii) the dosage of the new drug,

(iii) the claims made for the new drug,

(iv) the contra-indications and side effects of the new drug, and

(v) the withdrawal period of the new drug; and

(i) the dosage form in which it is proposed that the new drug be sold.

(3) A supplement to a new drug submission or to an abbreviated new drug submission, with respect to the matters that are significantly different from those contained in the submission, shall contain sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug in relation to those matters.

(i) à la voie d'administration recommandée pour la drogue nouvelle,

(ii) à sa posologie,

(iii) aux propriétés qui lui sont attribuées,

(iv) à ses contre-indications et à ses effets secondaires,

(v) au délai d'attente applicable à celle-ci;

i) sa forme posologique proposée pour la vente.

(3) Le supplément à la présentation de drogue nouvelle ou à la présentation abrégée de drogue nouvelle doit contenir, à l'égard des éléments qui diffèrent sensiblement de ce qui figure dans la présentation, les renseignements et le matériel nécessaires pour permettre au ministre d'évaluer l'innocuité et l'efficacité de la drogue nouvelle relativement à ces éléments.

DORS/85-143, art. 2; DORS/93-202, art. 25; DORS/95-411, art. 6.

C.08.005.1 states:

C.08.005.1. (1) Every manufacturer who files a new drug submission, an

C.08.005.1. (1) Le fabricant qui dépose une présentation de drogue nouvelle, une

abbreviated new drug submission, a supplement to a new drug submission, a supplement to an abbreviated new drug submission or a submission for the clinical testing of a new drug for veterinary use shall, in addition to any information and material that is required under section C.08.002, C.08.003 and C.08.005, include in the submission or supplement

(a) a copy of all clinical case reports respecting any subject of a study included in the submission or supplement if that subject has died, suffered a serious adverse reaction or an unexpected adverse reaction, or the study, insofar as it relates to this subject, has not been completed;

(b) a sectional report in respect of each human, animal and in vitro study included in the submission or supplement;

(c) a comprehensive summary of each human, animal and in vitro study referred to or included in the submission or supplement; and

(d) a submission certificate in respect of all information and material contained in the submission or supplement and any additional information or material filed to amend the submission or supplement.

(2) A sectional report referred to in paragraph (1)(b) shall

présentation abrégée de drogue nouvelle, un supplément à l'une de ces presentations ou une présentation pour l'essai clinique d'une drogue nouvelle pour usage vétérinaire doit, en plus des renseignements et du matériel exigés aux articles C.08.002, C.08.003 et C.08.005, y inclure :

a) une copie des rapports d'observations cliniques relatifs à chaque sujet ayant participé à une étude comprise dans la présentation ou le supplément si celui-ci soit est mort, soit a subi une réaction indésirable grave ou une réaction indésirable imprévue, ou si l'étude, dans la mesure où elle a trait au sujet, n'a pas été complétée;

b) un résumé de section pour chaque étude sur l'homme, sur l'animal et in vitro comprise dans la presentation ou le supplément;

c) une synthèse globale de chaque étude sur l'homme, sur l'animal et in vitro qui est comprise dans la presentation ou le supplément ou à laquelle il est fait renvoi;

d) une attestation concernant les renseignements et le matériel que contient la présentation ou le supplément, ainsi que les renseignements ou le matériel supplémentaires déposés, le cas échéant, aux fins de la modification de la présentation ou du supplément.

include

(a) a summary of each study included in the submission or supplement;

(b) a summary of any additional information or material filed to amend the submission or supplement; and

(c) where raw data is available to the manufacturer in respect of a study,

(i) a summary of the data,

(ii) a cross-referencing of the data to the relevant portions of the sectional report,

(iii) a description of the conditions under which the experiments from which the data were obtained were conducted,

(iv) the details of the data treatment process, and

(v) the results and conclusions of the study.

(3) The comprehensive summary referred to in paragraph (1)(c) shall include a summary of the methods used, results obtained and conclusions arrived at in respect of all studies referred to or included in the submission or supplement and shall be cross-referenced to the relevant portions of the sectional reports.

(4) The submission certificate

(2) Le résumé de section visé à l'alinéa (1)b) doit comprendre:
a) un résumé de chaque étude comprise dans la presentation ou le supplément;
b) un sommaire des renseignements ou du materiel supplémentaires déposés, le cas échéant, aux fins de la modification de la présentation ou du supplément;
c) lorsque le fabricant dispose des données brutes d'une étude :
(i) un sommaire de ces données,
(ii) les renvois aux parties pertinentes du résumé de section,
(iii) la description des conditions dans lesquelles se sont déroulées les expériences desquelles les données ont été obtenues,
(iv) les détails du mode de traitement des données,
(v) les résultats et les conclusions de l'étude.

(3) La synthèse globale visée à l'alinéa (1)c) doit comprendre un sommaire des méthodes utilisées, des résultats obtenus et des conclusions émises pour les etudes qui sont comprises dans la présentation ou le supplement ou auxquelles il est fait renvoi, et doit indiquer les renvois aux parties pertinentes des résumés de sections.

(4) L'attestation visée à l'alinéa (1)d) doit :
a) attester que les renseignements et le matériel compris dans la présentation ou

referred to in paragraph (1)(d) shall

(a) certify that all information and material included in the submission or supplement and any additional information or material filed to amend the submission or supplement are accurate and complete, and that the sectional reports and the comprehensive summary correctly represent the information and material referred to or included in the submission or supplement; and

(b) be signed and dated by

(i) the senior executive officer in Canada of the manufacturer filing the submission or supplement, and

(ii) the senior medical or scientific officer of the manufacturer.

(5) No person shall sign a submission certificate if a sectional report, comprehensive summary or any information or material included in the submission or supplement, or any additional information and material filed to amend the submission or supplement,

(a) is false or misleading; or

(b) contains omissions that may affect its accuracy and completeness.

(6) Every manufacturer who has filed a new drug submission, an abbreviated new

le supplément et tout renseignement ou matériel supplémentaire déposé aux fins de la modification de la présentation ou du supplement sont exacts et complets, et que les résumés de sections et la synthèse globale représentent fidèlement les renseignements et le matériel qui sont compris dans la présentation ou le supplément ou auxquels il est fait renvoi;

b) être datée et signée à la fois par:

(i) le premier dirigeant au Canada du fabricant qui dépose la présentation ou le supplément,

(ii) le directeur médical ou scientifique du fabricant.

(5) Il est interdit de signer une attestation si un résumé de section, la synthèse globale ou tout renseignement ou matériel compris dans la présentation ou le supplément, ou tout renseignement ou matériel supplémentaire déposé aux fins de la modification de cette presentation ou de ce supplément :

a) soit est faux ou trompeur;

b) soit comporte des omissions qui peuvent avoir une incidence sur son exactitude et son intégralité.

(6) Le fabricant qui a déposé une présentation de drogue

drug submission, a supplement to a new drug submission, a supplement to an abbreviated new drug submission or a submission for the clinical testing of a new drug for veterinary use, and has any relating clinical case reports or raw data that were not included therein, shall keep those reports or data and shall, within 30 days after receiving a written request from the Minister, submit them to the Minister.

nouvelle, une présentation abrégée de drogue nouvelle, un supplément à l'une de ces présentations ou une présentation pour l'essai clinique d'une drogue nouvelle pour usage vétérinaire sans y inclure les fiches d'observations cliniques ou les données brutes y ayant trait doit conserver ces fiches ou ces données et les soumettre au ministre, s'il en fait la demande par écrit, dans les trente jours suivant la réception de celle-ci.

DORS/85-143, art. 5; DORS/92-543, art. 1; DORS/94-689, art. 2(F); DORS/95-411, art. 8; DORS/2001-203, art. 7.

And, C.08.010 and s. C08.011 state:

C.08.010. (1) The Director may issue a letter of authorization authorizing the sale of a quantity of a new drug for human or veterinary use to a practitioner named in the letter of authorization for use in the emergency treatment of a patient under the care of that practitioner, if

C.08.010. (1) Le Directeur général peut fournir une lettre d'autorisation permettant la vente d'une certaine quantité d'une drogue nouvelle d'usage humaine ou vétérinaire à un praticien nommé dans la lettre d'autorisation pour le traitement d'urgence d'un malade traité par ledit praticien, si

(a) the practitioner has supplied to the Director information concerning

a) le praticien a fourni au Directeur général des renseignements concernant

(i) the medical emergency for which the drug is

(i) l'état pathologique urgent pour laquel la drogue

required,
(ii) the data in the possession of the practitioner with respect to the use, safety and efficacy of that drug,
(iii) the names of all institutions in which the drug is to be used, and
(iv) such other data as the Director may require; and

(b) the practitioner has agreed to
(i) report to the manufacturer of the new drug and to the Director on the results of the use of the drug in the medical emergency, including information respecting any adverse reactions encountered, and
(ii) account to the Director on request for all quantities of the drug received by him.

(2) The Director shall, in any letter of authorization issued pursuant to subsection (1), state
(a) the name of the practitioner to whom the new drug may be sold;

(b) the medical emergency in respect of which the new drug may be sold; and
(c) the quantity of the new drug that may be sold to that practitioner for that emergency.

est requise,

(ii) les données que possède le praticien à propos de l'usage, de l'innocuité et de l'efficacité de ladite drogue,

(iii) le nom de tous les établissements où la drogue doit être utilisée, et

(iv) les autres renseignements que le Directeur general pourrait lui demander; et

b) le praticien a consenti à
(i) faire part au fabricant de la drogue nouvelle et au Directeur général des résultats de l'usage de la drogue au cours de l'urgence, y compris les renseignements se rapportant à toute réaction défavorable qu'il aura observée, et

(ii) rendre compte au Directeur général, sur demande, de toutes les quantités de la drogue qu'il aura reçues.

(2) Le Directeur général doit, dans toute lettre d'autorisation fournie conformément au paragraphe (1), spécifier

a) le nom du praticien auquel la drogue nouvelle peut être vendue;

b) l'état pathologique urgent pour lequel la drogue

nouvelle peut être vendue; et

c) la quantité de la drogue nouvelle qui peut être vendue audit praticien pour ledit cas urgent.

C.08.011. (1) Notwithstanding section C.08.002, a manufacturer may sell to a practitioner named in a letter of authorization issued pursuant to section C.08.010, a quantity of the new drug named in that letter that does not exceed the quantity specified in the letter.

C.08.011. (1) Nonobstant l'article C.08.002, un fabricant peut vendre à un praticien mentionné dans une lettre d'autorisation fournie conformément à l'article C.08.010, une quantité de la drogue nouvelle nommée dans ladite lettre qui n'excède pas la quantité spécifiée dans la lettre.

(2) A sale of a new drug made in accordance with subsection (1) is exempt from the provisions of the Act and these Regulations.

(2) La vente d'une drogue nouvelle faite en conformité du paragraphe (1) n'est pas soumise aux dispositions de la Loi et du présent règlement.

FEDERAL COURT

SOLICITORS OF RECORD

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