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BARRISTERS & SOLICITORS

# Client Update

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## **CETA's Impact on Pharmaceutical and Medical Devices Procurement in Canada**

In September 2014 the Government of Canada announced it had successfully concluded negotiations with the European Union (“EU”) in respect of the Canada-EU *Comprehensive Economic and Trade Agreement* (“CETA”), with a final agreement having been provided to the parties for legal review. Ratification is expected in 2015.<sup>1</sup>

The CETA introduces numerous provisions that may substantially transform the Canadian pharmaceutical and medical devices landscape and impact Canadian companies and stakeholders.

This article explores the impact that CETA's chapter on government procurement may have on the manner in which government entities purchase pharmaceutical and medical devices.

## **The CETA's government procurement chapter makes provincial drug and device purchases subject to review**

The CETA includes a commitment by all provincial governments in Canada to open their procurement markets and to ensure the majority of procurements by government institutions are conducted in accordance with the CETA's requirements.

This means that upon ratification of the CETA, provincial government entities, including hospitals and health care institutions, must now make their purchases of drug products and medical devices compliant with established standards found in the CETA.

Eligible procurements will be those falling within the definition of “covered procurements”, which are defined as procurements of goods and services for which the value equals or exceeds established thresholds. The *Canadian Government Procurement Market Access Offer* annexed to the text of the CETA provides that the threshold for procurement of goods and services is \$315,000 for provincial government entities, including hospitals. For arms-length entities and provincial

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<sup>1</sup> The timing of ratification may hinge upon the EU's interpretation of CETA's scope, namely whether it deals solely with matters over which the EU has exclusive jurisdiction, in which case ratification will be by the European Parliament and the Council of the EU, or whether the CETA is a “mixed agreement” in which ratification of the agreement may be required by each of the 28 EU member states. Provisional implementation of certain items is also possible in the interim.

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Crown corporations (including for example Cancer Care Ontario) the threshold is \$560,000.<sup>2</sup>

CETA permits companies that have an interest in a bid or government tender may bring a complaint where the manner in which a government entity (including hospitals and listed Crown corporations) contravenes the terms of the CETA.

A complaint can be brought by a domestic supplier who has “an interest in the procurement”, even where no foreign parties have participated in the bid process or tender. That is, Canadian suppliers will benefit from the bid challenge provisions of CETA. In addition, the obligations found in the CETA benefit the suppliers, and not just the goods and services originating within the territory of a party. Consequently, the benefit of the CETA’s procurement provisions will be extended to both Canadian manufacturers and suppliers, as well as foreign companies located in Canada that have an established place of business in Canada through which its goods or services are supplied.

Procurement complaints may be brought on numerous grounds, including the following examples:

- The tender was not conducted fairly or impartially.
- The tender documentation did not include all information necessary to permit suppliers to prepare and submit responsive tenders. This necessary information includes all evaluation criteria that the entity will apply to determine which bidder will be awarded the contract, and the relative importance of such criteria.
- A procuring entity prescribed technical specifications that refer to a particular trademark or trade name, patent, copyright, design, type, specific origin, producer or supplier. Rather, the CETA requires that a procuring entity must set out the technical specification in terms of performance and functional requirements or base the technical specification on proper standards.
- The procuring entity adopted qualification procedures with the purpose or effect of creating unnecessary obstacles to the participation of a supplier.
- A procuring entity included conditions for participation in a procurement that were not essential to ensure that a supplier has the legal and financial capacities and the commercial and technical abilities to undertake the relevant procurement.

Numerous other requirements and grounds of complaint are included in the CETA, all of which may lead to a successful complaint by an affected supplier.

Where provincial government entities, including hospitals and government buying groups, are purchasing drugs, vaccines or medical devices these will fall under the scope of the CETA. The

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<sup>2</sup> In valuing procurement for the purpose of determining whether it is a covered procurement, a procuring entity may not divide procurement nor select a valuation method aimed at excluding it from the application of the CETA.



CETA does not provide any significant additional protections in relation to solicitations conducted by the federal government or federal entities. This is because existing trade agreements, including the NAFTA, the *Agreement on Internal Trade* (“**AIT**”) and various bilateral trade agreements already cover federal solicitations and are similar to those protections contained in the CETA.

Though purchases by government or hospital buying groups are covered by CETA, the full scope of the CETA’s sub-national application will require judicial interpretation. One particular area of potential contention relates to provincial formulary listings and whether these may fall within the parameters of the CETA’s government procurement chapter. This issue arises because, under a formulary listing, companies do not supply medicines to the provinces themselves and provinces do not take title or possession of medicines; rather they act as public insurers who reimburse eligible patients for the cost of their drugs.<sup>3</sup> Nonetheless, the government procurement chapter applies to “any *measure* regarding covered procurement...” A measure is defined as including “any law, regulation, procedure, administrative guidance or practice, or any action of a procuring entity relating to a covered procurement”. As

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<sup>3</sup> See for example *Pfizer Canada Inc. v. Canada (Attorney General)*, 2009 FC 719).

formularies may fall within this broad definition and scope, and as the maintaining of a supplier list is specifically covered under the agreement, there is still the potential for a challenge to be brought by a pharmaceutical company whose formulary listing was discriminatorily denied by a provincial entity.<sup>4</sup>

While the full scope of the CETA’s application may require judicial interpretation, drugs and medical devices purchased directly by provinces, Crown corporations and municipalities, municipal organizations, school boards and publicly-funded academic, health and social service entities and entities owned or controlled by the preceding (“**MASH sector entities**”), *will* be covered under the CETA and will be subject to procurement complaints, as they are under existing federal agreements.<sup>5</sup>

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<sup>4</sup> This particular issue is rendered more complex by recent developments in respect of product listing agreements (“PLAs”) and the pan-Canadian Pharmaceutical Alliance (“PCPA”), through which provinces have agreed to assign a lead province to negotiate prices for publicly covered drugs. Where an agreement is reached with the manufacturer, the lead province will sign a Letter of Intent with the manufacturer, which is shared with the other jurisdictions in the PCPA.

<sup>5</sup> Examples of procurement complaints brought to the Canadian International Trade Tribunal in respect of federal procurements include *Complaint by Sanofi Pasteur Limited*, (CITT), PR-2011-006, Reasons issued 26 May 2011, in which Sanofi alleged that PWGSC failed to disqualify the proposal of one of its competitors, Novartis Pharmaceuticals Canada

