

# THE PROPOSED EU-CANADA TRADE AGREEMENT RAISES HEALTH CONCERNS IN BOTH CANADA AND EUROPEAN UNION

JUNE 26, 2011

**Meri Koivusalo, Ronald Labonte, Scott Sinclair<sup>1</sup>**

The European Union (EU) and Canada are currently negotiating a new Comprehensive Economic and Trade Agreement (CETA) (European Commission 2011). In early 2010, the negotiating text was leaked and posted to the Trade Justice Network website, raising a variety of red flags for European member states. The draft agreement, described as more far-reaching and ambitious than any of either party's previous free trade agreements, has already raised concerns in Canada. These focus on the extension of government procurement commitments to include local services (Sinclair 2010), the potential addition of investment protections (Sinclair 2011), and how EU demands in the field of intellectual property rights and enforcement will impact drug costs (Grootendorst and Hollis 2011). Issues arising from the draft agreement are of substantial importance for health policy-making within the EU. While concerns in the two jurisdictions are not necessarily the same, from a health policy perspective many of the issues raised by Canadians are also relevant to EU member states. Negotiations are expected to conclude by early 2012.

## **Background**

The 2007 Lisbon Treaty gives the European Commission (EC) stronger powers to negotiate trade agreements (Treaty of Lisbon 2007; TFEU 2010). This creates a crucial challenge for the multilevel governance that characterizes the EU. Decisions of the EC may strongly influence the scope and nature of regulation and cost-containment measures of member states, who remain responsible for the regulation and financing of health systems. The clear disconnect between the development of rules and the delivery of services make it critically important that the European Parliament and EU member states ensure that EC negotiators safeguard policy space for health and for regulation in the public interest. Further concerns stem from the potential for cost-containment measures retraction from costly commissioning tenders, and efforts to curb or reverse commercialisation of public sector services provision to all become vulnerable to trade disputes under the CETA.

In contrast to Canada, a federal state with relatively similar provincial health care service systems, the national health systems of EU member states vary substantially. The CETA implications for European health systems are likely to differ in relation to the bases and organisation of health system financing and provision within member states. However, EU member states have jointly excluded health services from the services directive and have agreed upon values and principles in European health systems (European Council 2006). These actions demonstrate the preference of member states for restraint and caution with respect to the liberalisation of health services.

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<sup>1</sup> Meri Koivusalo, senior researcher, National Institute for Health and Welfare, Helsinki, Finland, ([meri.koivusalo@thl.fi](mailto:meri.koivusalo@thl.fi)); Ronald Labonte, Canada Research Chair on Globalization and Health Equity, University of Ottawa, Institute of Population Health ([r.labonte@uottawa.ca](mailto:r.labonte@uottawa.ca)); and Scott Sinclair, senior researcher, Canadian Centre for Policy Alternatives ([scsinclair@pei.sympatico.ca](mailto:scsinclair@pei.sympatico.ca)).

## What is at stake?

The CETA negotiations are very **broad, covering not only trade in goods and services but also investment, government procurement, intellectual property rights and regulatory cooperation** matters. They thus extend much further into national policy space and governance than traditional trade agreements focussing primarily on border measures affecting trade in goods.

A major concern with respect to the negotiations is the option for a **negative listing approach** to services. Under negative listing, member governments must list those services and regulatory measures to which the agreement will not apply. This contrasts with the positive listing approach used in previous EU bilateral free trade agreements and in the General Agreement on Trade in Services (GATS) negotiations, where member states can decide which sectors they would prefer to further liberalise. Under the CETA, governments will need to anticipate current and future regulatory needs so as to expressly exclude sectors, services and potentially non-conforming regulatory measures from the agreement.

Furthermore, due to the strengthened EC mandate to negotiate investment protection, the CETA is likely to include substantive protections for foreign investors. These protections could include an extremely broad definition of investment, right of establishment, compensation for direct and indirect expropriation, minimum standards of treatment and prohibitions against performance requirements. The inclusion of these investment protection provisions, together with an **investor-state dispute settlement mechanism**, would greatly strengthen the position of investors and investor rights. For example, investors could claim compensation from regulatory measures that could be seen as expropriation or tantamount to expropriation, even if such measures were taken to enhance the access, affordability or quality of a health care system.

## Reversing privatisation - even failed privatisation - could become more difficult and costly

The inclusion of investor-state dispute settlement and strengthened investor protections in the CETA could have significant consequences for public policies, including health care. As of October 2010, there have been 28 investor-state claims against Canada, 19 against the U.S. and 19 against Mexico under the NAFTA's investment chapter. Canada has lost or settled four claims and paid damages of CAD \$157 million. Mexico has lost five cases, paying damages of US \$187 million. The U.S. has yet to lose a case. All three governments have incurred tens of millions of dollars in legal costs. (Sinclair 2010)

One of the best known cases is Ethyl Corporation vs Canada, which occurred after the Canadian government banned MMT, a gasoline additive and suspected neurotoxin. Canada settled the claim by reversing measures to control MMT, apologising to the investor and paying US \$13 million in compensation. (NAFTA 1998). More recently, Canada agreed to the largest NAFTA settlement to date (CAD \$130 million) involving the AbitibiBowater forestry company. The Newfoundland and Labrador government had expropriated the company's assets after it declared bankruptcy and closed its last remaining mill in the province. The NAFTA settlement, negotiated by the federal government, compensated the investor for the loss of water and timber rights on public lands, which are not usually considered compensable rights under Canadian law. The provincial government was left to cover the costs of severance and pensions for workers and environmental remediation.

The settlement raises jurisdictional issues that are similar to ones which are likely to occur within the EU. The province was acting legally within its own jurisdiction while the NAFTA settlement was agreed to by the federal government of Canada. Clearly, investor-state dispute settlement, while a valuable tool for corporations, is increasingly seen as a threat to progressive public policy in Canada. In 2008 the Canadian Environmental Law Association called for removal of the NAFTA's expropriation provisions due to their potential to undermine health and environmental policy (CELA 2008).

Although less pronounced in the EU to date, at least two cases where governments have sought to roll back privatisation policies have led to investor-state claims under European member states' bilateral investment agreements (Hall 2010). There is thus reasonable cause for concern that future government decisions to reduce the scope of services privatisation, contracting out or outsourcing could become difficult if not impossible unless these sectors are specifically excluded from the CETA. For example, if the National Health Service (NHS) was to engage in policies to contract with "any willing provider" (such as has been envisioned in NHS reform proposals), retraction at a later date from this policy could result in compensatory claims unless health and related management services were not fully and explicitly excluded from the CETA. Such an exclusion would also need to ensure provisions with respect to future measures that might be inconsistent with the CETA. During the NAFTA negotiations, for example, Canada included reservations protecting not only existing non-conforming measures, but also new measures that would have otherwise been inconsistent with the agreement (Sinclair 2011). Unfortunately, these reservations do not protect against claims under the NAFTA Article 1110 on expropriation, leading to concerns that the expansion of public health insurance into new areas could trigger claims for compensation from foreign insurers and/or health care providers (Johnson 2003).

The potential for investor-state provisions to be included in the CETA is of particular importance with respect to health services. Such services can be kept outside the agreement, but they need to be totally excluded and not only excluded on the basis of existing legislation. The so-called ratchet provisions in CETA could otherwise bring health services within the trade treaty (and do so without further negotiations) on the basis of countries' legislative reforms enacted after the treaty is agreed upon. This makes the situation difficult for member states, as they could be bound by the CETA without necessarily ever explicitly making this decision with regard to health care policy reforms they make in the future. This is a particular concern for public service sectors that are currently weakly regulated or where provision of services is significantly commercialised. Appropriate and necessary regulatory changes to contain costs, strengthen social solidarity or improve quality of the service could then become more difficult or, in the worst case, vulnerable to compensatory claims.

In order to maintain sufficient regulatory policy space, health services need to be fully excluded from all provisions of the CETA, protecting both existing and future policy measures. This means that the EU commitments for privately funded health services in the Cariforum-EC economic partnership agreement should not be precedents for other trade agreements. The boundary between privately and publicly funded services is often unclear or mixed, with providers operating in both publicly contracted and fully private services. From the perspective of protecting health care policy, the CETA's negative listing obliges the EU to retain regulatory policy space not only for publicly funded health services, but also for privately funded services.

### **European Union negotiators need to know what is not to be traded**

The choice and basis for agreed negotiation and priorities are naturally dependent on the policy priorities of member states and are likely to unfold further during this year. It is important, however,

that all member states are fully aware of and understand in which category their health services are likely to fall: i) in the agreement as any commercial service, ii) in the agreement on the basis of legislation on market access to be included as part of agreement if legislation changes, iii) excluded on the basis of current legislation, but without scope to make this more market restrictive in the future or iv) excluded without reference to existing legislation and providing for future regulatory needs. In terms of health systems, the fourth option is the only one which can secure future regulatory policy space. Canada has sought to exclude health services widely in the context of the NAFTA negotiations, so it is unlikely that they would strongly oppose this option.

Trade negotiators are expected to act on the basis of priorities conveyed to them by policymakers and member state administrations. It is thus of utmost importance that health policy concerns are raised loudly, so as to ensure that trade negotiators know and comply with all necessary limitations and exceptions. Standard forms of health impact assessments made by trade departments, in turn, are likely to be insufficient in detecting and understanding health policy needs and requirements (Stahl 2010; Smith et al 2010ab). The more specific Sustainability Impact Assessment (SIA) has its background in assessing environmental sustainability aspects in trade agreements. An SIA has been completed for CETA. Health concerns were taken up mainly due to the engagement of Canadian health groups and advocates. This assessment has included some aspects that relate to impacts on health care, most notably in Canada, however it remains insufficient in addressing key concerns that apply to European Union health systems.

European health policy groups and proponents are mostly absent from the list of organisations and industry that have been consulted. The focus of the SIA is also limited and does not deal comprehensively with implications to policy space in different health systems or with respect to government-procured health services. The SIA notes, for example, that in relation to implications to EU health care "On a very macro level, and only in the long term, competition as a result of CETA may result in reduction of prices of certain medical services, although this is not necessarily the case and prices may potentially rise. Among other issues, the percentage of healthcare contracts meeting CETA thresholds would have to be considered. A specific assessment herein depends on a number of factors and is beyond the scope of this analysis"(SIA 2011, p. 279). This vagueness and lack of specific assessment suggests that the SIA has not provided an adequate basis for EU decision-makers to anticipate the health policy implications of the CETA.

In order to assess priorities and required policy space for regulatory and cost-containment measures, member states will need to produce a more comprehensive assessment. This is particularly important if member states wish to ensure future policy space for cost-containment, regulation and cross-subsidising service provision for equity and solidarity. The Council Statement on common values and principles emphasises the common values of universality, access to good quality of care, equity and solidarity. In addition, it states that: "**We also believe that it will be important to safeguard the common values and principles outlined below as regards the application of competition rules on the systems that implement them.**" (European Council 2006) Including health services as part of trade agreements would run counter to this explicit statement of common values by the EU member states.

### **Does the corporate sector benefit at the cost of health sector?**

Despite the EU's commitment to the precautionary principle (European Commission 2000), it is important to recognise a gradual weakening of the basis for use of this principle for regulation in the public interest through negotiated international agreements. Compensatory claims under investor-state provisions are likely to affect, in particular, public health, safety and environmental regulatory

measures. Regulatory reform and policies seeking "better regulation" have already been influenced - if not introduced - by the tobacco industry and others in the corporate sector (Smith et al 2010ab). The further strengthening of investor rights, while limiting public regulation, will clearly not be in the best interest of EU citizens and consumers. It is possible, unless explicitly exempted, that investor expropriation claims could be utilised against government health care cost-containment policies that lower expected returns from investments.

The EU is making extensive demands on behalf of the brand-name pharmaceutical sector with respect to intellectual property provisions and negotiations concerning data exclusivity and enforcement. While the SIA notes that the level of piracy in Canada is not particularly high in comparison to many European member states (SIA 2011), its stance on Intellectual Property Rights (IPR) in the CETA negotiations is part of an effort to globalize enforcement measures with much broader implications for developing countries related to the generic medicine industry and access to medicines. The EU proposes language that would not only extend data exclusivity provisions in Canada, but will broaden their application to all new medicines. From a consumer and public health viewpoint, this compares poorly to previous requirements in Canada that such exclusivity should be applied only to innovative drugs (Grootendorst and Hollis 2011).

The Canadian generic drug industry commissioned an external analysis of the economic impacts of IPR requests by the European Union. The analysis by Grootendorst and Hollis suggests that shifts towards EU requests are likely to add in the magnitude of CAD \$2.8 billion annually to Canadian costs of medicines. While Canada might be responding with a proposal for more industry-friendly patent linkage that is not applicable in the European Union, the real question is whether further savings on costs of medicines could be achieved through opting for some Canadian policies within Europe. For example, with respect to limitations for data exclusivity which the EU is seeking to dismantle, adopting the existing Canadian model might save money for Ministries of Health. Rather than undermining Canadian policies in health-related fields, there should be further cooperation with Ministries of Health in exploring where and to what extent common interests in pharmaceutical policies on both sides of the Atlantic could be addressed (Koivusalo 2011).

### **How could health concerns be addressed?**

The European Union has, for the most part, been unwilling to make trade treaty commitments in health services. Additional security for member states has been provided in previous trade agreements, such as the GATS, on the basis of an exclusion that relates to services in the general economic interest. These decisions echo the concerns brought up in the context of European Council conclusions on common values. It is unlikely that the CETA will accommodate these concerns without explicit exclusion of health systems.

Outsourcing, commissioning and contracting out are part of health systems functions in most European member states, and the dividing lines between publicly and privately financed services are not explicit and clear. Health systems are thus likely to fall outside of the more narrow provisions that are required to fulfil requirements for exemption of services provided in the exercise of governmental authority or government procured services (Krajewski 2003; Fidler et al 2005).

Concern over expropriation and the inclusion of investor-state dispute settlement provisions, whose impact on public health regulations may not have been envisaged by European member states and Ministries of Health, extends beyond health systems. These provisions also influence the ways in which the EU and its member states can regulate in order to meet public health obligations under the CETA. Lisbon Treaty Article 168 on public health emphasises that: "A high level of human

health protection shall be ensured in the definition and implementation of all Union policies and activities" (Lisbon Treaty 2007; TFEU 2010). It is also feasible and possible to exclude public health, health systems and environmental policy-related regulations from the state-investor dispute settlement.

However, there is a danger that in spite of EU member state and Canadian health policy concerns, the CETA negotiations may be dominated by business interests more concerned with advancing the commercial interests of Canadian and European service providers and manufacturers than with broader public interests. While multinational industries might be the winners in such a deal, there is a risk that public policies, particularly in the areas of health and environment, could be losers on both sides of the Atlantic.

### **Conclusion: Excluding health and social security policies governance from commercial policy agreements must be a priority**

There are no convincing reasons why the EU and Canada could not or should not make broad exclusions from the agreement to safeguard policy space for health and public policies. EU member states and Canada have common interests in securing policy space for health and regulation in the public interest and should explicitly protect these interests. A broad exclusion for the health sector and health measures would likely be supported by a large majority of citizens in both jurisdictions.

It is important that measures to exclude health services are not superficial or too narrowly defined, leading to a false sense of security. Exclusions need to be sufficiently broad and explicit with due consideration, in particular, to ensuring that investor-state disputes and compensatory claims do not threaten appropriate public sector regulation. This would include safety requirements, cost-containment measures, and the securing of consumer rights and access to knowledge. Accordingly, the agreement should include an article or provision stating that nothing in the agreement shall be construed to apply to measures adopted or maintained by a party with respect to health care, public health insurance or maintaining a high level of health protection. Similar measures have been advocated by Canadian public health proponents (Canadian Health Coalition 2011). The EU is also committed as part of its Treaty obligations to maintain a high level of health protection in all policies (TFEU 2010).

It is important to emphasise that excluding health and social security from trade and investment agreements does not preclude market access or a role for the private sector in provision of care. It merely safeguards the right of democratically elected governments to maintain policy space for regulation, licensing, cost-containment and limiting or reversing commercialisation, where this is in the public interest.

In light of the negotiations and their purpose, a broad and explicit exclusion of health services, including for reasons of future regulation, is likely to be in the best interest of both EU member states and Canada. With respect to intellectual property rights, provisions should be adequately assessed in terms of their cost implications to public policies. The pharmaceutical industry should not be permitted to seek additional profits through trade agreements negotiated at the EU level by industrial and trade policy proponents, when these increased costs would come out of the budgets of local or national-level health administrations.

Ministries of Health within the EU should also assess the potential regulatory and health implications that would result from the introduction of investor-state compensatory mechanisms. This assessment should cover public health and environmental regulations as well as

pharmaceutical, health services, and social health insurance and social security policies. The challenge is to better understand the implications of investor-state dispute settlement mechanisms and strengthened investor rights from a public policy and public interest perspective. This applies as well to measures promoted under "smart regulation" or "regulatory cooperation". There are no grounds to dismiss or treat investor-state claims as irrelevant to the national health policy context. Appropriate limits to the utilisation of investor-state mechanisms and compensatory measures are necessary to ensure that high levels of health protection can be maintained within the European Union in future and to avoid narrowing the scope and basis for public policies.

**European Union member states and Canada should negotiate maximum protection for health care and the expansion of coverage of public health insurance, and ensure sufficient safeguards for regulatory policy space with respect to any negotiated investor-state compensatory mechanisms.**

It would be a tragedy for public health, health systems and public policies if the European Union and Canada negotiate a free trade agreement that, in the name of enhancing growth, erodes and undermines the scope and measures that can be applied as part of public policies, health systems governance and health protection by each party. It is possible to avoid this health policy erosion, while at the same time contributing to policies that would enhance trade and competitiveness. But trade policy cannot be left only to those whose commercial interests are served, with costs falling to consumers and citizens. It is a responsibility of each of the parties to ensure that policies pursued as part of trade and investment negotiations are not merely accommodating corporate needs, but also serve democratic accountability, protect public interests and address key concerns of citizens.

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