OPENING STATEMENT—THE STANDING SENATE COMMITTEE ON SOCIAL AFFAIRS, SCIENCE AND TECHNOLOGY

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I am a Professor from the Faculties of Law and Medicine at Dalhousie University. All of my research concerns pharmaceutical law and policy and is geared towards one goal: improving access to essential medicines.

For that reason, I support the introduction of universal, single-payer, publicly funded and administered pharmacare in Canada. And I cannot imagine two more important classes of medicines than diabetes treatments and contraceptives to start building a system of national pharmacare around in Canada.

As written, however, I cannot support Bill C-64.

The proposed legislation is flawed in two fundamental ways. First, it does not include clear, consistent criteria or standards for implementing pharmacare. The closest the legislation comes is in section 6 of Bill C-64 where the federal Minister of Health is empowered to make payments to a province or territory to "provide universal, single-payer, first-dollar coverage" for drugs and related products for contraception and diabetes treatment. But those criteria are not defined within the four corners of the legislation; moreover, such coverage hangs on the Minister having already entered into a separate agreement with the province or territory in question.

That is, Bill C-64, as my colleague Dr. Morgan notes, sets up a series of bilateral agreements, to be negotiated in the future, between the Government of Canada and the provinces and territories, which is likely to lead to variations in—not universal access to—essential medicines across the country.

That kind of uneven, fragmented system is *not* the kind of system that the government's Advisory Council led by Dr. Eric Hoskins envisioned, nor one that is capable of reducing expenditures on prescription drugs, which are the fastest growing and second highest line item of provincial and territorial spending on healthcare in Canada.

Bill C-64's second fundamental flaw lies in its failure to articulate, within the four corners of the statute, the powers, functions, and governance structure of the Canadian Drug Agency or 'CDA'.

As drafted, the Bill simply refers to the CDA as a body from which the Minister of Health may seek advice about, for example, the cost-effectiveness of drugs and directs the Minister to request that the CDA help develop a national formulary and national bulk purchasing strategy. It does not give the CDA any real legal authority about which medicines to include in the formulary or to implement a bulk purchasing strategy.

In short, under Bill C-64 all of the authority to create and implement pharmacare remains in the hands of the political actors, in particular, the federal Minister of Health.

Yet, we know that decisions about which medicines should be a part of pharmacare must be informed by a careful appraisal of the safety, effectiveness, and relative value of prescription drugs to public health and/or unmet medical needs, including rare diseases.

It is the CDA, not political actors, that is most equipped with the necessary expertise. So the absence of any details in Bill C-64 about what the CDA's authorities and responsibilities are, and how it is to be governed so as to ensure that it is both protected from undue influence by political and other powerful outside actors, yet transparent and accountable to Canadians who will depend on its decision-making, is a troubling omission from the legislation.

In view of these two fundamental flaws in Bill C-64, I have drafted several amendments to the proposed legislation, which I have appended to my opening statement for your consideration.

At this stage in the legislative process, I'm sure that there will be little appetite for entertaining such a sweeping set of amendments to the Bill. My intention in sharing them is rather to show what a serious piece of pharmacare legislation needs to encompass in order to stand a chance of providing equitable and affordable access to essential medicines in Canada.

Further, in my view, it is open to this Committee to conclude that Bill C-64 was passed by the House of Commons in error by virtue of the fact that its provisions do *not* support a system of pharmacare characterized by universal access to essential medicines.

You can remedy this by integrating clear criteria standards directly into the statute about what pharmacare must look like in Canada and removing language in Bill C-64 that puts pharmacare off to future negotiations. I have highlighted these essential amendments to Bill C-64 in the appendix accompanying my statement and I hope the members of this Committee will give them strong consideration.

Thank you.

APPENDIX—PROPOSED AMENDMENTS TO BILL C-64, THE *PHARMACARE ACT*

This Appendix contains a set of proposed amendments to Bill C-64, which was passed by the House of Commons in June 2024. For clarity, new wording that I propose should be added to the provisions of Bill C-64 appears in **bold, underlined text**. Where deletions are suggested, I use ~~strikethrough text~~. As well, I have provided a rationale alongside each proposed amendment in the table below in an effort to explain why each of the proposed amendments is important.

Taken together, the amendments proposed herein aim to achieve two core changes to Bill C-64. First, they strengthen the legislation's overall commitment to building a universal, single-payer, publicly administered system of pharmacare. In line with the Adviosry Council's recommendations, they integrate clear criteria in the proposed Pharmacare Act and charge the federal Minister of Health with enforcing those criteria in order for provinces and territories to receive cash contributions to pay for essential medicines. Second, they create, within the four corners of the statute, the Canadian Drug Agency (CDA), setting out its powers, functions, and governance structure. In particular, the proposed changes to Bill C-64 would empower the CDA to create and over time update a list of essential medicines that would comprise a national formulary to which all Canadian citizens and residents would be entitled to access once in place.

I acknowledge that the proposed amendments are sweeping in scope. In laying out the full set of amendments that we believe are required to deliver an effective and fair system of national pharmacare, my intention is to demonstrate how poorly Bill C-64 has been drafted and why the Senate should *not* support the proposed legislation in the absence of major reform.

As noted in my opening statement, amendments that integrate clear criteria into the Act are the most essential at this stage. I have highlighted those amendments in yellow in the pages that follow.

Proposed Amendments Section-by-Section	***Accompanying Rationale***
Preamble Whereas the Government of Canada recognizes that quality health care, including access to prescription drugs and related products, is critical to protecting and promoting the health and well-being of Canadians; Whereas the Government of Canada plays an important role in ensuring that prescription drugs and related products are safe, effective and of high quality; Whereas the Government of Canada acknowledges that when Canadians do not have their prescriptions filled for financial reasons, their health may worsen, which can lead to increased use of the health care system and increased health care costs; Whereas the Government of Canada recognizes the role of the provinces, territories and Indigenous peoples in the provision of health care, including coverage for prescription drugs and related products, and is committed to collaborating and maintaining partnerships with them to support their efforts to improve the accessibility and affordability of prescription drugs and related products; Whereas the Government of Canada provides, within federal jurisdiction, health care services, including coverage for prescription drugs and related products, to certain populations; Whereas the Government of Canada recognizes that the Advisory Council on the Implementation of National Pharmacare as well as several studies have recommended establishing universal, single-payer, public pharmacare in Canada; Whereas the Government of Canada is committed to continued collaboration with the provinces, territories, Indigenous peoples and other partners and stakeholders on the step-by-step implementation of national universal pharmacare, which is to be guided by the *Canada Health Act* and carried out in accordance with the recommendations of the Advisory Council on the Implementation of National Pharmacare;	*Bill C-64 references the "Canadian Drug Agency" (CDA) but does not establish the agency by law, nor define its powers, functions, and governance structure. In keeping with the recommendations of the Advisory Council, it is critical that the new agency have powers, functions, and governance structure that is clearly defined in the law. This will help to improve the transparency of the CDA's decision-making, guard against interference from outside actors, and ensure a level of accountability to stakeholders, including, most importantly Canadian patients.*

Proposed Amendments Section-by-Section	***Accompanying Rationale***
Whereas the Government of Canada recognizes the importance of modernizing the health care system with standardized health data and digital tools, such as electronic prescribing, to support better health outcomes and greater efficiency of the health care system; Whereas the Government of Canada is collaborating with the provinces and territories and other partners and stakeholders to support the work of the Canadian Drug Agency to improve coordination within the pharmaceutical system in Canada and better prepare it for the future; **Whereas the Government of Canada recognizes that decision-making about coverage for essential medicines must be transparent, evidence-based, independent, and free from conflict-of-interests;** And whereas the Government of Canada has launched the National Strategy for Drugs for Rare Diseases to improve the accessibility and affordability of those drugs for Canadians; Now, therefore, His Majesty, by and with the advice and consent of the Senate and House of Commons of Canada, enacts as follows:	
2 The following definitions apply in this Act. ***Agency* means the Canadian Drug Agency continued by section 14. (*agence*)** ***Essential Medicines List* means the list of essential medicines that is publicly available on the website of the Agency.** ***Indigenous peoples*** has the meaning assigned by the definition *aboriginal peoples of Canada* in subsection 35(2) of the *Constitution Act, 1982*. (*peuples autochtones*) ***Minister*** means the Minister of Health. (*ministre*) ***pharmacare*** means a program that provides **public** coverage of **essential medicines** ~~prescription drugs and related products~~. (*régime d'assurance médicaments*)	*As noted above, it is critical to define the CDA's powers, functions, etc. within the four corners of Bill C-64. The proposed amendments use the term 'Agency' in several sections of the Act and therefore needs to be defined in section 2 of the Act.* *A national formulary should provide access to all pharmaceutical products, which are supported by strong evidence of safety, effectiveness and also have importance to public health and/or address an unmet medical need. Many pharmaceutical products, including some treatments for rare diseases, meet these criteria and are thus considered essential medicines by many national governments as well as international bodies such as the World Health Organization. Some pharmaceutical products offer only marginal clinical benefits or fail to improve public health*

Proposed Amendments Section-by-Section	***Accompanying Rationale***
essential medicine ~~***pharmaceutical product***~~ means a prescription drug or related product that is **listed on the website of the Agency and** funded, in whole or in part, through ~~a~~ pharmacare ~~agreement to which the Government of Canada is a party~~. (*produit pharmaceutique*)	*or do not address an unmet medical need. They should therefore not be considered essential medicines and also not included within the scope of a national formulary maintained by the CDA. Additionally, if the price of a medicine is too high in view of the evidence of its safety and effectiveness, the CDA should have the discretion to not to include the medicine on the list of essential medicines in the absence of a reduction in price.* *As envisioned in Bill C-64, the national formulary may initially only include products related to diabetes and contraception. However, over time the list of essential medicines included under pharmacare should expand. Similar to the Prescription Drug List that is maintained by Health Canada, the CDA would be tasked with creating, updating, and maintaining an 'Essential Medicines List' on the Agency's website. The CDA would also be required under an amended C-64 to publish its rationale for any changes made to the Essential Medicines List. The list will therefore provide a relatively efficient mechanism for adding essential medicines to the national formulary without having to seek an order made by the Governor in Council or a legislative amendment via Parliament to Bill C-64.* *The removal of the reference to an 'agreement to which the Government of Canada is a party' from the definition of an essential medicine is one of several amendments designed to integrate national standards or criteria in Bill C-64. Like the Canada Health Act, provinces and territories are eligible to receive cash contributions from the federal government in respect of health care provided they comply with the criteria of universality, accessibility, portability, comprehensiveness, and public administration as they are defined in that legislation. As outlined further below, Bill C-64 should be amended to establish its own criteria (tailored to pharmacare) that would*

Proposed Amendments Section-by-Section	*Accompanying Rationale*
	entitle provinces and territories to receive funding for pharmacare. This would obviate the need for bilateral agreements between the Government of Canada and each province and territory.
3 The purpose of this Act is to guide efforts to improve, for all Canadians, the accessibility and affordability of **essential medicines** ~~prescription drugs and related products~~, and to support their appropriate use, in collaboration with the provinces, territories, Indigenous peoples and other partners and stakeholders, with the aim of ~~continuing to work toward the implementation of~~ **creating a system of** national**,** universal**, publicly managed** pharmacare. Its purpose is also to support the development of a national formulary of essential **medicines** ~~prescription drugs and related products~~ and to provide for the development a national bulk purchasing strategy.	*The proposed amendments to section 3 follow from the shift to the 'essential medicines' terminology noted above and to emphasize the importance of creating not only a national and universal system of pharmacare, but also one that is publicly managed or administered. Evidence shows that the costs associated with administering public drug plans are a fraction of the costs of program administration incurred by private insurers. Public administration should therefore be a central commitment and feature of Bill C-64.*
4 **(1)** The Minister ~~is to consider~~ **shall apply** the following principles and the *Canada Health Act* when collaborating with provinces, territories, Indigenous peoples and other partners and stakeholders with the aim of continuing to work toward the implementation of national universal pharmacare: (a) improve the accessibility of **essential medicines**~~pharmaceutical products~~, including through their coverage, in a manner that is ~~more~~ consistent across Canada; (b) improve the affordability of **essential medicines** ~~pharmaceutical products~~, including by reducing financial barriers for Canadians; (c) support the appropriate use of **essential medicines** ~~pharmaceutical products~~ — namely, in a manner that prioritizes patient safety, optimizes health outcomes and reinforces health system sustainability — in order to improve the physical and mental health and well-being of Canadians; and (d) provide universal**, single-payer, first-dollar, public** coverage of **essential medicines included on the Essential Medicines List**~~pharmaceutical products~~ across Canada. **(2) In addition, and without limiting the importance of the foregoing principles, the Minister recognizes**	*Section 4 is broken down into two subsections. Subsection (1) mirrors the existing section 4, with changes to the language to be consistent with the shift to essential medicines and the creation of an Essential Medicines List as part of Bill C-64.* *Importantly, the proposed amendment to subsection(1)(d) also adds the language of 'single-payer, first-dollar, public' to national coverage. Currently, that language, which follows from the Advisory Council's recommendations as well as extensive evidence about the key features of pharmacare, is only contained in section 6 of Bill C-64, which is focused specifically on products intended for contraception or the treatment of diabetes. It should, however, extend to all essential medicines—not just those covered by section 6.* *Subsection(2) has been added to section 4 in order to emphasize that maintaining the institutional independence of the CDA should also be considered a key principle of the legislation. This is because decisions about access to pharmaceutical products can*

Proposed Amendments Section-by-Section	*Accompanying Rationale*
that the Agency, established under section 14, must operate as an arm's length, independent body.	*become highly politicized and the subject of intense lobbying and pressure from well-resourced companies.*
5 **(1) Subject to this Act,** the Government of Canada commits to maintaining long-term funding for the provinces, territories and Indigenous peoples to improve the accessibility and affordability of **essential medicines** ~~pharmaceutical products, beginning with~~**, including** those for rare diseases. ~~The funding for provinces and territories must be provided primarily through agreements with their respective governments.~~ **(2) For greater clarity, provinces and territories are eligible to receive a full cash contribution on an annual basis provided that the province or territory meet the criteria specified in sections 6 to 11 of the Act.**	*By adding the language of 'Subject to this Act', the amendments proposed in Section 5 are, taken together, designed to help create and enforce national standards for pharmacare. Rather than having to enter into bilateral agreements with each of the provinces and territories, the Government of Canada can simply point to standards articulated in sections 6-11 of Bill C-64; provinces and territories, which, in turn, meet those standards/criteria are entitled to a full cash contribution from the federal government.*
6 In order that a province or territory may qualify for a full cash contribution referred to in section 5 for a fiscal year, the province or territory must, throughout the fiscal year, satisfy the following criteria: **(a) public administration;** **(b) comprehensiveness;** **(c) universality;** **(d) portability; and** **(e) accessibility**	*The proposed new section 6 of Bill C-64 mirrors—almost word for word—the language of section 7 in the Canada Health Act. Again, the idea here is to set out standards in the legislation, as opposed to through bilateral agreements, that provinces and territories have to meet to be eligible for funding for pharmacare from the federal government.*
7 In order to satisfy the criteria respecting public administration, the pharmacare program of a province or territory providing coverage for essential medicines must be administered and operated on a non-profit basis by a public authority appointed or designated by the government of the province or territory.	*The proposed new section 7 outlines the criterion of public administration. Consistent with the Advisory Council report, section 7 requires that pharmacare is both publicly funded and publicly administered. However, pharmaceutical products that are not considered essential medicines and are not listed on the Essential Medicines List that would be maintained by the CDA can continue to be provided by private insurance providers. This parallels the Canada Health Act, which does not limit private insurance of services, such as cosmetic surgery, that are not considered medically necessary.*

Proposed Amendments Section-by-Section	*Accompanying Rationale*
8 In order to satisfy the criterion respecting comprehensiveness, the province or territory must provide coverage for all essential medicines listed on the Essential Medicines List on the website of the Agency.	*The proposed new section 8 simply requires provinces and territories to provide coverage for all essential medicines listed on the Agency's website. As explained further below, the CDA will be empowered to add to and make changes to this list over time. Diabetes treatments and contraceptives will, in keeping with the original spirit of Bill C-64 to make those medicines freely available to patients as soon as possible, be included on the CDA's Essential Medicines List as soon as practicable after the legislation is enacted by Parliament.*
9 In order to satisfy the criterion respecting universality, all residents of the province or territory must have access to all essential medicines on the Essential Medicines List on the website of the Agency.	*The language of this criterion mirrors the universality criterion contained in the Canada Health Act. The goal with this provision is to make sure that pharmacare extends not only to all essential medicines in a given province or territory, but also is available to all, rather than only some, residents within that province or territory.*
10 In order to satisfy the criterion respecting portability, the pharmacare program of a province or territory, **(a) must not impose any minimum period of residence in the province or territory, or waiting period, in excess of three months before residents of the province or territory are eligible for or entitled to access the pharmacare program of the province or territory;** **(b) must provide for and be administered and operated so as to provide for the payment of amounts for the cost of essential medicines provided to residents while temporarily absent from the province or territory on the basis that** **(i) where essential medicines are provided in Canada, payment for the essential medicines is at the rate that is approved by the pharmacare program of the province in which the essential medicines are provided, unless the provinces or territories concerned agree to apportion the**	*The language of the proposed new section 10 closely mirrors the language of the portability criterion found in section 11 of the Canada Health Act. However, unlike health care services, there are likely to be very few urgent, non-elective prescription drugs that would not be prescribed to a patient that is in a hospital in a province or territory in which they do not ordinarily reside. As such, the portability may be less important in the context of pharmacare relative to other health care services. Given, however, that the Advisory Council recommended that the criterion of portability should also be extended to pharmacare, we have added this provision to the list of proposed amendments.*

Proposed Amendments Section-by-Section	*Accompanying Rationale*
cost between them in a different manner, or **(ii) where the essential medicines are provided out of Canada, payment is made on the basis of the amount that would have been paid by the province or territory for similar essential medicines accessed in the province or territory,; and** **(c) must provide for and be administered and operated so as to provide for the payment, during any minimum period of residence, or any waiting period, imposed by the pharmacare program of another province or territory, of the cost of essential medicines provided to persons who have ceased to be residents by reason of having become residents of that other province or territory, on the same basis as though they had not ceased to be residents of the province or territory.**	
11 In order to satisfy the criterion respecting accessibility, the pharmacare program of a province or territory must provide essential medicines on the Essential Medicines List on the website of the Agency on uniform terms and conditions and on a basis that does not impede or preclude, either directly or indirectly whether by charges made to residents or otherwise, reasonable access to essential medicines by residents in the province or territory.	*The proposed new section 11 of Bill C-64 aims to ensure that residents of a province or territory do not encounter additional barriers to accessing an essential medicine. Unlike the analogous section in the Canada Health Act, which provides for reasonable compensation for health care services rendered by medical practitioners, that language is not included here because the Agency, through its decision-making about which products to include on the Essential Medicines List, will in effect ensure that manufacturers of essential medicines receive compensation for their products.*
12 In order that a province or territory may qualify for a full cash contribution referred to in section 5, the government of the province or territory shall, at the times and in the manner prescribed by the regulations, provide the Minister with such information, of a type prescribed by the regulations,	*In order to ensure that provinces and territories are meeting the criteria expressed in sections 6-11 of the Act, this section creates an information-sharing obligation between the provinces and territories and the federal Minister of Health.*

Proposed Amendments Section-by-Section	*Accompanying Rationale*
as the Minister may reasonably require for the purposes of this Act.	
13 ~~6~~ (1) The Minister may, ~~if the Minister has entered into an agreement with a province or territory to do so~~, make payments to the province or territory in order to **increase any existing public pharmacare coverage — and to** provide universal, single-payer, first-dollar**, public** coverage — for **essential medicines, beginning with** specific prescription drugs and related products intended for contraception or the treatment of diabetes **complications**.	*Consistent with the above changes, the amendments proposed for this section remove wording about bilateral agreements between the federal government and provinces/territories, and add the commitment to providing 'public coverage' (in line with the criterion of public administration) while also maintaining Bill C-64's promise of prioritizing access to contraceptives and diabetes related essential medicines.* *The addition of the word 'complications' has the potential to aid thousands more Canadians who suffer from conditions related to diabetes, such as hypertension.*
14 (1) The Agency is hereby continued, and shall consist of not more than seven members to be appointed by the Governor in Council, in consultation with the provinces, territories, and Indigenous peoples. **(2) Each member of the Agency shall hold office during good behaviour for a period of five years, but may be removed at any time by the Governor in Council for cause.** **(3) A member of the Agency, on the expiration of a first term of office, is eligible to be reappointed for one further term.** **(4) A person may continue to act as a member of the Agency after the expiration of the person's term of appointment in respect of any matter in which the person became engaged during the term of appointment.** **(5) The members of the Agency shall be paid such remuneration as may be fixed by the Governor in Council and are entitled to be paid reasonable travel and living expenses incurred by them in the course of their duties under this Act while absent from their ordinary place of residence.**	*This newly proposed section aims to create, by law, the CDA, and allow for the appointment of its governing members by the Governor in Council. As outlined below in a new section 15 of Bill C-64, appointments by the Governor in Council to the Agency must be informed by an advisory panel, which includes representatives of the provinces, territories and Indigenous peoples.* *Subsections (2)-(5) of the proposed section 14 are designed to provide security of tenure to individuals who are appointed to the Agency (they can only be removed from their position by the Governor in Council for cause), specify the term of their appointment, and allow for remuneration for their work.* *It is important to note that section 14 (and other new sections that follow) are modeled after the provisions in the Patent Act, which establish the Patented Medicine Prices Review Board and clarify its powers, functions, and governance structure.*

Proposed Amendments Section-by-Section	***Accompanying Rationale***
15 (1) The Minister shall establish an advisory panel to advise the Minister on the appointment of persons to the Agency, which panel shall include representatives of the provincial and territorial ministers of the Crown responsible for health, representatives of Indigenous peoples, representatives of consumer groups, and such other persons as the Minister considers appropriate to appoint. **(2) The Minister shall consult with an advisory panel established under subsection (1) for the purpose of making a recommendation to the Governor in Council with respect to the appointment of a person to the Agency.**	*In keeping with the obligation to consult with provinces/territories and Indigenous peoples articulated in section 14(1), the proposed new section 15 requires that the Minister establish an advisory panel for the purpose of informing the Governor in Council appointments to the Agency that includes representatives of provinces/territories and Indigenous peoples.*
16 (1) The Governor in Council shall designate one of the members of the Agency to be Chairperson of the Agency and one of the members to be Vice-chairperson of the Agency. **(2) The Chairperson is the chief executive officer of the Agency and has supervision over and direction of the work of the Agency, including** **(a) the apportionment of the work among the members thereof and the assignment of members to deal with matters before the Board and to sit at hearings of the Board and to preside at hearings or other proceedings; and** **(b) generally, the conduct of the work of the Board, the management of its internal affairs and the duties of its staff.** **(3) If the Chairperson is absent or incapacitated or if the office of Chairperson is vacant, the Vice-chairperson has all the powers and functions of the Chairperson during the absence, incapacity or vacancy.**	*The proposed new section 16 explains that the Agency will be governed by a Chairperson (chosen by the Governor in Council) who will be responsible for workload management, supervision and direction of the Agency. In the absence of a Chairperson, the Vice-Chairperson will assume such roles and responsibilities.*
17 (1) Such officers and employees as are necessary for the proper conduct of the work of the Agency shall be appointed in accordance with the *Public Service Employment Act*.	*The proposed new section 17 allows the Agency to hire employees and also engage, on a temporary basis, persons with technical or specialized knowledge that may assist with the Agency's functions.*

Proposed Amendments Section-by-Section	*Accompanying Rationale*
(2) Persons appointed under subsection (1) shall be deemed to be employed in the public service for the purposes of the *Public Service Superannuation Act*. **(3) The Agency may engage on a temporary basis the services of persons having technical or specialized knowledge to advise and assist in the performance of its duties and, with the approval of the Treasury Board, the Agency may fix and pay the remuneration and expenses of those persons.**	*Ensuring that the Agency's employees are civil servants within the meaning of the Public Service Employment Act is critical to the CDA's ability to attract and retain highly qualified persons to its offices. At present, employees of the CDA (formerly CADTH) do not have that status and thus lack various employment benefits that federal civil servants enjoy.*
18 (1) The principal office of the Agency shall be in the National Capital Region described in the schedule to the *National Capital Act*. **(2) The Agency may meet at such times and places in Canada as the Chairperson deems advisable.**	*The proposed new section 18 simply states that the CDA will be situated in Ottawa. With the current CDA already stationed in the capital region, this section does not require the CDA to change locations or take any other action. It only prevents the CDA from relocating outside the National Capital Region in the future.*
19 ~~7~~ **(1)** The **Agency** ~~Minister~~ **shall collect, analyse, and publicly disseminate data and information about** ~~may seek advice from the Canadian Drug Agency on~~ **(a)** the **safety,** clinical effectiveness and cost-effectiveness of prescription drugs and related products compared to other treatment options; ~~**(b)** the prescription drugs and related products that should be included in prescription drug coverage plans in Canada and the conditions of that coverage;~~ ~~**(c)** the collection and analysis of data on prescription drugs and related products;~~ **(d)** ~~information and recommendations to be provided to health care practitioners and patients on~~ the appropriate use of prescription drugs and related products; and **(e)** improvements to be made to the pharmaceutical system, including through greater coordination between health system partners, patients and other stakeholders. **(2) For the purposes of fulfilling the Agency's functions under subsection(1), manufacturers of**	*As originally drafted, Bill C-64 contains a passive obligation (in section 7) upon the Minister to 'seek advice' from the CDA regarding a number of matters. The amendments proposed here instead aim to vest the CDA with the power to collect data about prescription drugs directly from prescription drug manufacturers in order to inform its decision-making about which prescription drugs to deem to be essential medicines and thus eligible for listing on the Agency's website, which, as explained in section 20 constitutes the national formulary.* *The purpose of the changes contained here in the newly proposed section 19 (coupled with the new section 20 that follows) is to grant decision-making authority to the CDA, as opposed to the Minister, regarding which prescription drugs and related products should be included in the national formulary. In principle, vesting this power within the CDA has the potential to depoliticize decision-making about which prescription drugs are part of pharmacare.*

Proposed Amendments Section-by-Section	*Accompanying Rationale*
prescription drugs and related products shall, as required by and in accordance with the regulations, provide the Agency with the information and documents that the regulations may specify respecting **(a) the identity of the prescription drug or related product;** **(b) the price at which the prescription drug or related product is being or has been sold in any market in Canada;** **(c) the safety and effectiveness of the prescription drug or related product; and** **(d) other evidence regarding the impact of a prescription drug or related product upon public health and/or an unmet medical need.** **(3) For greater clarity, if a manufacturer does not provide information and documents in accordance with subsection (2) in respect of a prescription drug or related product, that prescription drug or related product shall not eligible for inclusion on the Essential Medicines List.**	*Subsection (2) of this new section 19 is intended to compel manufacturers to provide information and documentation that the CDA will need to evaluate the safety, effectiveness, cost-effectiveness, and impact of prescription drugs on public health and/or unmet medical needs. It should be noted, however, that the CDA, once established as a part of the federal government, will be eligible to receive such information from other government bodies, including Health Canada and the Patented Medicine Prices Review Board.*
20~~8~~ (1) The **Agency**~~Minister~~ **shall**~~must, after discussions with the provinces and territories, request that the Canadian Drug Agency prepare~~, **publish** no later than the first anniversary of the day on which this Act receives royal assent, a list of essential **medicines** ~~prescription drugs and related products~~ to **be included on the website of the Agency and serve as a** ~~inform the development of a~~ national formulary that will establish the scope of **essential medicines** ~~prescription drugs and related products~~ to which Canadians should have access under national universal pharmacare. (2) The **Agency**~~Minister~~ **may** ~~must~~, after the list referred to in subsection (1) has been prepared, ~~initiate discussions based on the list with provinces, territories, Indigenous peoples and other partners and stakeholders with the aim of continuing to work toward the implementation of national universal pharmacare.~~ **change the list, adding or removing prescription drugs and related products, at any time by providing public notice and reasons on the**	*In contrast to the current wording of section 8 of Bill C-64, the amendments proposed here are designed to give the Agency control over the list of essential medicines to be included in a national formulary. Subsection (2) gives the CDA the power to change and update the list over time, at its sole discretion, provided that it gives public notice of its decision to do so and a detailed rationale for the change. Historically, many organizations, including Health Canada as well as the CDA (formerly CADTH) provide public explanations of product approvals and recommendations about prescription drug coverage. Enshrining this power in the CDA and requiring transparency around its decision-making is thus consistent with existing best practices.*

Proposed Amendments Section-by-Section	*Accompanying Rationale*
website of the Agency for making such a change to the list.	
21~~9~~ The **Agency**~~Minister~~ **shall**~~must~~, after discussions with the provinces**,** ~~and~~ territories, **and Indigenous peoples** ~~request that the Canadian Drug Agency~~ develop, in collaboration with partners and stakeholders and no later than the first anniversary of the day on which this Act receives royal assent, a national bulk purchasing strategy for prescription drugs and related products to support the principles set out in paragraphs 4**(1)**(a) to (d).	*The new proposed section 21 is similar to the current version of section 9 of Bill C-64; however, it empowers the CDA—not the Minister—to develop a national bulk purchasing strategy.*
22~~10~~ (1) The **Agency** ~~Minister shall~~must, no later than the first anniversary of the day on which this Act receives royal assent, publish on the website of the **Agency** ~~Department of Health~~ a pan-Canadian strategy regarding the appropriate use of **essential medicines**~~prescription drugs and related products~~. (2) The **Agency** ~~Minister~~ may, after discussions with the provinces**,** ~~and~~ territories, **and Indigenous peoples,** ~~request that the Canadian Drug Agency~~ prepare **and publicly disseminate**, no later than the third anniversary of the day on which the strategy is published and no later than every three years following that anniversary, a report on the progress made in advancing that strategy.	*Similar to the previous amendments, the new section 22 aims to give the CDA the authority to develop and disseminate an appropriate use strategy.*
23~~11~~ (1) The Minister must, no later than 30 days after the day on which this Act receives royal assent, establish a committee of experts, and provide for its membership, **comprised of persons without any conflict-of-interests,** to make recommendations respecting options ~~for the operation and financing of national, universal, single-payer pharmacare~~ **to ensure that the Agency can function as an arm's length, independent body from the Government of Canada, without undue influence or interference from outside actors, and as free as possible from conflict-of-interests whether individual or institutional in character, but also maintaining a high degree of transparency and accountability to Canadian citizens and residents.**	*Having granted the CDA a number of new powers, such as the creation and maintenance of a national formulary through the foregoing proposed amendments, there is no need to charge a committee of experts with further studying how such a formulary should be financed and so forth.* *That said, while the CDA would be newly established by law if the proposed amendments were to be incorporated into Bill C-64, the Agency would not be created in a vacuum. On the contrary, the CDA (formerly CADTH) already exists and has several well-established practices as part of its operations. Some of these practices, such as publishing the reasons for its decisions, should—as noted*

Proposed Amendments Section-by-Section	***Accompanying Rationale***
(2) The committee must, no later than the first anniversary of the day on which this Act receives royal assent, provide a written report to the Minister setting out its recommendations. (3) The Minister must cause a copy of the report to be tabled in each House of Parliament on any of the first 20 days on which that House is sitting after the day on which the Minister receives the report.	*above—continue. However, others, for instance, the CDA's heavy reliance upon 'user fees' from prescription drug manufacturers to fund approximately 50 percent of its annual operations, warrant further examination to ensure they do not compromise the CDA's independence from undue influence by outside actors. It is therefore critical that the committee of experts envisioned in Bill C-64 be tasked with examining this and related issues in an effort to bolster the CDA's institutional integrity.*
24 (1) Subject to subsection (2), the Governor in Council may make regulations **(a) specifying the information that the government of the province or territory must provide to the Minister as the Minister may reasonably require for the purposes of this Act, in particular, for evaluating the compliance of a province or territory with the criteria outlined in sections 6-11 of the Act.** **(b) specifying the information and documents that shall be provided to the Agency by manufacturers of prescription drugs under subsection 19(2).**	*This new section 24 empowers the Governor in Council to make regulations in order to enable the Minister to enforce the criteria of public administration, comprehensiveness, portability, universality, and accessibility, expressed in the proposed amendments contained in sections 6-11 while also delineating the types of information that manufacturers must provide to the Agency to inform its decision-making.*