ADDENDUM TO INNOVATIVE MEDICINES CANADA SUBMISSION ON NATIONAL PHARMACARE

JUNE 1, 2023

Purpose

In light of the Federal Government's intent to table pharmacare legislation in 2023, this document is an update Innovative Medicines Canada's (IMC) position on National Pharmacare in Canada and to identify a collaborative path forward for consideration. It is also a supplement to our September 2018 submission to the Federal Government's *Advisory Council on the Implementation of National Pharmacare*, which is attached for reference.

The pharmaceutical environment in Canada

Pharmacare should address clear policy objectives that reflect the coverage, financial and legal realities of the Canadian pharmaceutical environment:

- **Mixed public-private market:** Canada's system of pharmaceutical coverage is a mixed public insurance (44% of prescription spending) and privately insured/funded (56% of prescription spending) regime.[1]
- **Private plans are more robust:** Employer-based coverage generally offers more timely and robust coverage than public plans.
    - 44% of new medicines available globally are launched in Canada but only 20% of new medicines available globally are available via public drug plans. Additionally, it can take up to two years following regulatory approval for medicines to be available to publicly insured patients.[2]
- **Single-payer options are unrealistic:** Efforts to nationalize the higher quality employer-based insurance plans or otherwise replace them with lower-quality single-payer, or 'publicly administered' options may be opposed by many Canadians concerned about the dilution or diminution of their drug coverage. Moreover, given that public plans are largely administered by provincial and territorial governments, single-payer options could only be implemented after a complex, difficult and protracted F/PT negotiation process.

[1] CIHI https://www.cihi.ca/en/trends-in-public-drug-program-spending-in-canada
[2] https://innovativemedicines.ca/wp-content/uploads/2022/10/20221007_FINAL_PreBudget_Consultation-1.pdf

- **Canada can fill the gaps:** 97.2% of Canadians already have access to pharmaceutical coverage and insurance gaps are concentrated in a small number of provinces.[3] This presents a clear, realistic and feasible opportunity to remedy existing coverage gaps in a fiscally responsible manner that would have meaningful health benefits for patients.

Recent pharmacare history

Despite significant discussion over many years, there is no consensus on the role or rationale for federal pharmacare legislation:

- **Advisory Council Report**: In 2018, an Advisory Council on the Implementation of National Pharmacare chaired by Dr. Eric Hoskins solicited feedback on potential directions for National Pharmacare. The main recommendation for a "universal, single-payer, public pharmacare in Canada" is unfeasible in light of the coverage, financial and legal realities noted above. Please see IMC's attached submission to the Advisory Council, which outlines key principles and positions that remain relevant today.
- **Bill C-213:** In 2020, the NDP tabled Bill C-213 -*An Act to Implement Pharmacare Act*. The bill was opposed by the government and defeated in Parliament on second reading in February 2021.[4]
    - C-213 attempted to nationalize drug coverage and would have effectively mandated public administration of pharmacare. This would have tied the hands of provincial and territorial governments, jeopardized pharmaceutical coverage, and exacerbated the current disarray and uncertainty in the Canadian pharmaceutical environment. The bill also raised significant constitutional concerns given the primary responsibility of provinces and territories for healthcare.
- **PEI Pharmacare as a template:** In 2021, the federal government advanced a more effective and practical approach through its pharmacare agreement with PEI to help fill pharmaceutical coverage gaps. This agreement represents a productive template for the federal government to work with other governments to make meaningful improvements to patient access and healthcare outcomes.
- **Pending Federal legislation:** As part of the March 2022 Supply and Confidence Agreement with the NDP, the Federal Government has signaled that it will pass a

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[3] In 2022, The Conference Board of Canada released a report quantifying current uninsurance gaps in Canada at only 1.1 million focused in select provinces. 97.2% of Canadians have coverage.

[4] 295 MPs voted against the Bill with 32 supporting.

Pharmacare Act in 2023, but the scope, purpose, and impact of such legislation is currently unclear.

Considerations regarding potential legislation

Given the limited information on the purpose and scope of pharmacare legislation, this topic merits more stakeholder dialogue before legislation is tabled. If a compelling case for legislation can be articulated, the Federal Government should ensure the following:

- **Enhance Access:** As an overarching principle, pharmacare must help to elevate standards of Canadians' access to prescription drugs while being respectful of the existing and effective mixed public/private systems.
- **Avoid imposing obligations on provinces and territories:** Federal legislative or regulatory "strings" attached to funding are not prudent and are unlikely be effective over time, and therefore should be avoided.
- **No "Public Administration" clauses or obligations:** A new pharmacare bill should avoid these elements of previous legislative proposals.
- **Public and private roles:** Legislation should define "private" and "provincial" drug insurance plans separately in order to make a clear distinction between the two and ensure an ongoing role for both.
- **Consistent with federal jurisdiction:** Healthcare is a largely a provincial responsibility. To succeed, pharmacare must respect the letter and spirit of Canada's constitutional framework.
- **Avoid "white elephant" institutions that will be difficult to change:** Legislation should not enshrine any particular agency on a near-permanent basis without a clear statutory purpose and mandate.

Proposed Path Forward

IMC suggests that the Federal Government engage in the following practical steps prior to tabling legislation:

1. **Determine the core policy objectives, alternatives to address, and impacts on other policy objectives:** Publish and consult with provinces and stakeholders on core objectives and scope of pharmacare legislation in advance of it being tabled (e.g., What are the objectives, and what alternatives have been considered to address those objectives?).
    - ➢ It will also be important to consider how these new policy objectives work with other federal pharmaceutical policy initiatives (e.g., the National Strategy for Drugs for Rare Diseases, Agile Licencing regulations, and the

Biomanufacturing and Life Sciences Strategy, all discussed further below).

2. **Consult on the potential role and scope of pharmacare legislation:** While the concept of pharmacare has been discussed, there has been no public discussion on the specific role and implications of *legislation* in this area. The Federal Government should launch a public stakeholder consultation on the issues of role and scope noted above, including draft legislative text elements.
3. **Publish PEI learnings:** Publish and disseminate learnings on the Federal-PEI Pharmacare model and its successes to date to facilitate discussions with other provinces. These findings could also be presented for discussion to the Conference of Provincial and Territorial Health Ministers and the pCPA Governing Council to solicit their views.
4. **Report findings of the new Drug Shortages Committee:** Complete and report on the work of Health Canada's Committee on Drug Shortages for potential pharmacare implications. If this work is part of pharmacare umbrella issue, that body should advance its important work prior to the government introducing pharmacare legislation.
5. **Sustainable funding support based on rigorous and credible analysis:** To be successful, pharmacare requires long term financial support, the scope of which will vary depending upon the policy objectives (e.g., What financial commitment would be needed to help fill coverage gaps, and/or what commitment would be needed to expand of the PEI model to other provinces?). Provincial and territorial governments may be reluctant to participate in initiatives where they could be left "footing the bill" due to future policy changes or fiscal constraints.
    - A condition precedent should be a long-term financial analysis validated by a credible arm's length organization. The recent example from the expansion of dental care, which was projected in Budget 2023 to cost more than double the original government estimate, must be taken to heart[5].

Strategic and Integrated Approach Incorporating Related Policies

The Federal Government has advanced a number of pharmacare-related files in recent years. A siloed approach to pharmacare will have negative impacts on other Federal Government health and economic policies related to pharmaceuticals and the life sciences. A holistic,

[5] https://www.budget.canada.ca/2023/pdf/budget-gdql-egdqv-2023-en.pdf *estimates the annual cost of dental care coverage expansion to be $4.4 billion per year, up from the earlier estimate of $1.7 billion per year.*

strategic, and integrated approach – involving Health Canada, ISED, Finance Canada, and other agencies – is essential for new initiatives to be launched and for current initiatives to meet their existing objectives:

- **Pan-Canadian voluntary formulary or essential medicines list:** In 2022, and at the Federal Government's request, CADTH conducted a consultation and finalized a document on a Pan-Canadian "Formulary" For more information, please see IMC's submission to the consultation.
    - CADTH published a sample list 277 drugs and 10 associated products three high-volume therapeutic areas: Cardiovascular disease, diabetes, and psychiatric illnesses.
    - The Federal Government should formally respond to this work and articulate the potential role for its formulary development work. It should also be noted that linkage between a Pan-Canadian formulary and legislation may not be necessary or advisable.

- **Canadian Drug Agency (CDA):** In 2020, the Federal Government established the Canadian Drug Agency Transition Office (CDATO) which has been engaged in bilateral stakeholder discussions but has not formally consulted or released policy details.
    - There may be a productive role for a future CDA in the areas of data, infrastructure and appropriate prescribing. There should, however, be formal public consultations on potential role and responsibility of the CDA in the near future and in advance of pharmacare legislation. Similar to the formulary, it is unclear if a CDA would need to be enshrined in legislation, given its purpose and role could also change over time.

- **"Bulk Buying" and the pCPA:** Provinces and Territories are responsible for provincial drug insurance. "Bulk Buying" is often used colloquially in reference to joint price negotiations conducted through the pan-Canadian pharmaceutical Alliance (pCPA). Federal drug plans have participated in the pCPA since 2016, which has realised $2.67 billion in annual savings for Canadians on innovative name drugs alone.
    - The Federal Government should clarify its intent not to duplicate this work, but rather to augment pCPA resources to accelerate its work and improve its capacity and expertise to meet the needs of an evolving pharmaceutical research pipeline.

- **Drugs For Rare Diseases (DRD)** – In March 2023, the Federal Government announced its National Strategy for Drugs for Rare Diseases which includes $1.5 billion in funding over three years, $1.4 billion of which is earmarked to enhance patient access to drugs, diagnostics and screening. There remain a number of key details and negotiations to successfully deliver on these aspirations.

- In collaboration with the provinces and territories and following consultation with stakeholders, Health Canada should see this important work through to a successful implementation as soon as possible. Given that expanding access to DRDs will have a positive impact on patient health outcomes, progress on this initiative must not be delayed or complicated by negotiations related to pharmacare.

- **Agile Licensing Regulations**: In April 2023, Health Canada completed regulatory consultations on amendments to the *Food and Drug Regulations,* known as Agile Licensing. While not yet implemented, the changes are intended to apply aspects of the faster and more streamlined systems used during the COVID-19 pandemic on an indefinite basis.
    - While the drug approval process is a vital part of the public access pathway, it is only the first step in a complex process that encompasses HTA recommendations, the pCPA, and provincial drug plan listings. Access strategies are set an international level with reference to market conditions, which would include a potential pan-Canadian formulary. While any linkage between Agile Licensing and pharmacare is unclear, consideration must be given to the impact of such a formulary on the willingness of manufacturers to submit drugs for approval and the timing for submissions in Canada.

- **Biomanufacturing and Life Sciences Strategy:** In July 2021, Health Canada and ISED announced the Biomanufacturing and Life Sciences Strategy (BLSS), an initiative to improve Canada's domestic capacity to produce vaccines, therapeutics and other life-saving medicines. In conjunction with provincial life sciences strategies, BLSS is a crucial step towards ensuring that Canada will be considered an important hub for life sciences in a competitive global environment.
    - One pillar of the BLSS is for Canada to leverage its regulatory system to support increased innovation, and world-class expertise and infrastructure for clinical trials. As with Agile Licensing, any linkage between pharmacare and BLSS is unclear, but it will be important to ensure that the new policy does not undermine efforts to make Canada a more attractive investment destination for biomanufacturing and life sciences ecosystem companies.

Conclusion

Innovative Medicines Canada supports comprehensive access to pharmaceuticals for all Canadians. Specifically, our industry believes that a pan-Canadian pharmacare option which addresses the unmet needs of uninsured or underinsured Canadians and reflects the value of the current mixed public-private model, is realistic, feasible and would result in timely and tangible patient health benefits.

The Federal Government has laid a productive path to support improvements in the delivery of pharmaceutical care. These include investments in the National Strategy for Drugs for Rare Diseases and pilot pharmacare investments to fill pharmacare gaps such as the ongoing initiative with PEI.

As a first pharmacare priority, the Federal Government should accelerate progress on parallel measures to fill insurance and access gaps in other provinces. If a rationale for pharmacare legislation can be substantiated, it should be well designed to reflect public-private market dynamics, respect provincial jurisdiction, and be carefully calibrated to elevate standards of access.

IMC would welcome further dialogue and collaboration on this important policy issue.