INNOVATIVE MEDICINES CANADA | MÉDICAMENTS NOVATEURS CANADA

President's Office | Bureau du Président

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Advisory Council on the Implementation of National Pharmacare Secretariat
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Dear Dr. Hoskins and Members of the Advisory Council,

Thank you for the opportunity to provide comments to Advisory Council on the Implementation of National Pharmacare ("the Council").

Innovative Medicines Canada (IMC) is the national voice of Canada's innovative pharmaceutical industry. We advocate for policies that enable the discovery, development and commercialization of innovative medicines and vaccines that improve the lives of all Canadians. We support our members' commitment to being valued partners in the Canadian health care and regulatory systems and greatly appreciated the open and productive dialogue established at our meeting with the Council September 6th, 2018.

National pharmacare options should enhance equitable access for all Canadians. Addressing current gaps while building on and maintaining the current mixed framework of public and private insurance is the most practical and fiscally responsible approach to national pharmacare (i.e., pharmacare should not shift costs currently assumed by private payers to public payers). Following implementation of any pharmacare options, no patient should have a lower level of access or reduced timeliness of access to innovative medicines than they currently have today. However, it is important to be aware that there are a number of significant regulatory and policy initiatives presently underway that may affect access to medicines and the quality of robust national pharmacare options, such as proposed changes to the regulations affecting the role of the Patented Medicine Prices Review Board (PMPRB).

IMC supports comprehensive access to pharmaceuticals for all Canadians and is supportive of consultations on different potential pharmacare models that build on and improve the current system. Our perspectives on pharmacare and answers to specific questions posed by the Council below are informed by the following key principles:

1. **Patient-centric** – Pharmacare provides an opportunity to enhance the breadth and quality of pharmaceutical coverage in Canada. All Canadians should have timely access to the choice of medicines they need to maintain and improve their health, regardless of income, age, or postal code. No patient should go without needed medicines due to a lack of coverage or inability to pay. Pharmacare options must address the current gaps in coverage by providing insurance options for the uninsured and addressing under-insurance gaps that may cause financial hardship or barriers to access.

2. **Value and Sustainability** – IMC stands with governments in the need to create a sustainable and efficient health system that supports the long-term needs of Canadians. Pharmacare options must

be fiscally responsible and practical to implement in the context of Canada's mixed public and private insurance framework. Pharmaceutical decision-making should reflect the value that a medicine brings to individual patients and the societal value it represents within the broader health system over time. For example, policy options should recognize that innovative medicines provide critical savings for health care systems by reducing the need for more costly services. In addition, innovative medicines play an important role in keeping Canadian workers healthy and productive at work helping to drive Canada's economy.

3. **System Responsiveness** – Pharmacare options should be future-focused in that they reflect diverse and evolving patient needs and are responsive to technological change through the timely adoption of innovation.

We look forward to the opportunity to build on our September 6th dialogue to further explore these principles and related policy approaches. In addition to future face-to-face opportunities, we would appreciate an opportunity to comment on the Council's interim report once a draft has been compiled. Input at this stage would help sensitize stakeholders to the scope and direction of the Council's work and allow the Council to troubleshoot potential challenges in advance of the report's broader release.

Thank you again for the opportunity to comment on the questions below and we look forward working with you in the coming weeks and months.

Kind regards,

Pamela C. Fralick
President

1. WHO SHOULD BE COVERED UNDER NATIONAL PHARMACARE?

All Canadians should have timely access to the choice of medicines they need to maintain and improve their health, regardless of income, age, or postal code. No patient should go without needed medicines due to a lack of coverage or ability to pay.

Innovative Medicines Canada supports comprehensive access to pharmaceuticals for all Canadians and notes that there are many ways for this to be achieved. Pharmacare implementation options should address existing gaps in coverage for the uninsured and address under-insurance gaps that may cause financial hardship or barriers to access because of current plan design practices in both public and private insurance markets. Any implementation plan should involve significant consultation with both private insurers and federal/provincial/territorial health system managers to improve coverage opportunities for low-wage workers often termed the 'working poor' and provide options for those times in a person's life when they are not covered through their employer sponsored drug plan (e.g. the gap between retirement and public plan eligibility).

The development and use of the best evidence available will be critical to target pharmacare implementation options and scarce resources to those Canadians most in need of assistance. The Conference Board of Canada has developed and published an analysis of current insurance gaps across Canada. We would welcome an opportunity to work with the Council, insurers, insurance brokers, and the Government of Canada to consider and build on this analysis to better understand the gaps in the current system. For example, it may not be fully understood that approximately 4.1 million Canadians who do not have private insurance and are eligible for public coverage do not enroll in a public plan.[1]

One important consideration is the issue of eligibility. As with all publicly-funded health services, eligibility for these services starts with having a valid health care card issued from the province or territory where the resident normally resides. Given that the health care system in each Canadian jurisdiction is distinct to that jurisdiction, the provision of care has evolved to reflect how that system works. Pharmacare should consider potential options for harmonization of eligibility with each Canadian jurisdiction.

Another important consideration is the issue of voluntary versus compulsory enrollment. For example:

- Quebec has legislated that all residents either participate in the publicly-funded drug plan or are enrolled in a private plan that at a minimum covers the same medicines with the same rules of access as the public plan. This helps to ensure that people are covered throughout their life times, in periods of good health and when unexpected health challenges arise.

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[1] *This figure may be somewhat lower following the implementation of OHIP+ in Ontario. The Conference Board of Canada, Understanding the GAP, December 2017* http://innovativemedicines.ca/wp-content/uploads/2017/12/20170712-understanding-the-gap.pdf

- British Columbia, which has a universal drug plan, has legislation that deems it as the first payer for all residents. B.C. has several different criteria for receiving a benefit, such as co-payments, income-based deductibles, etc., however everyone with a valid card is enrolled.
- In provinces such as Alberta, the public plans are for those on social assistance or for those aged 65 and over. There is also a premium-based plan that any resident with a health card may join, but it is optional.
- Access to cancer drugs is an important example of a unique access challenge. In the four Western provinces, access to medications used to treat cancer are paid for by the provincial cancer agencies in those provinces. However, in Eastern Canada it is more fragmented. In Ontario, as an example, if the cancer drug is an intravenously-delivered medicine, then all Ontario residents have access to these medicines. However, if the drug is taken as an oral medication, then coverage would depend on whether the patient is on the Ontario Drug Benefit Plan (ODBP) or has access to a private plan. Otherwise, the individual may have to pay out-of-pocket.

These examples demonstrate the high complexity across provincial health systems and need for any pharmacare options to account for a range of provincial program designs. Any pharmacare options should be flexible enough to accommodate and compensate for these differences so that the resulting access and financial provisions (cost-sharing) are equitable among provinces and patients.

2. HOW SHOULD NATIONAL PHARMACARE BE DELIVERED?

To provide the greatest value, pharmacare options must be fiscally responsible, sustainable and practical to implement in the context of Canada's mixed public and private insurance framework.

Given the provincial responsibility for health care delivery and administration, pharmaceutical decision-making will continue to reside largely at the provincial level and thus there may be no *single* path for pharmacare delivery. Indeed, based on the July 2018 meeting of the Premiers where pharmacare was a topic of discussion, provincial governments have strong views about what is appropriate for their individual jurisdictions and expect to retain responsibility for designing and delivering public drug coverage. However, it may be that the federal government can play a critical coordinating and financing role to help provinces and private insurers elevate standards and breadth of coverage across the country. From a practical perspective, we encourage federal policy makers to focus discussions with provinces on the broader fiscal framework required to fill current gaps in coverage.

Pharmaceutical coverage systems are diverse and complex reflecting the evolution and characteristics of Canada's various health systems. Therefore, as part of any implementation plan, care and attention as to specific recommendations is required to ensure effective integration with each health system. These include macro-fiscal issues such as the framework for federal-provincial transfers, to more on-the-ground delivery considerations.

In determining the appropriate *scope* of its recommendations, it will be prudent for the Council to recognise the complexity and heterogeneity of existing public and private plans with respect to:

eligibility, enrollment, coverage, level of user-pay (co-pays and deductibles), mechanism of coverage for pharmaceutical-related devices and diagnostics, current pricing, contracting, and supply considerations; criteria or restrictions for individual drugs that range considerably on existing provincial formularies, and differences in delivery (e.g. different cancer care models, infusion centre infrastructure, etc.). Given this complexity is a function of provincial jurisdiction and different decisions made at the provincial level, the Council may wish to focus its recommendations on what implementation options may be possible from a macro-fiscal perspective.

Any pharmacare options being considered should not create incentives for private plans to deny coverage for Canadians or delay listing new medicines or make them reliant on public administrative review processes. For this and other reasons, IMC is not supportive of private insurer participation in current pan-Canadian Pharmaceutical Alliance (pCPA) negotiations, which has been purpose-built for public plans which largely provide coverage assistance to residents aged 65 and over or who are on some form of income or disability assistance. The perspective, decision making, and budget management decisions are not generally mindful of a broader population which might receive benefits. This could lead to significant delays to new drugs entering the private market given the long wait times for reimbursement and negotiations now experienced under public plans. As well, it is important to note that there are no significant barriers to large insurers achieving value through direct negotiations with manufacturers and some insurers already do so.

3. WHICH DRUGS SHOULD BE COVERED AS PART OF A NATIONAL PHARMACARE PLAN?

Pharmacare recommendations should recognize that innovative medicines provide important health-system savings by reducing the need for more costly services.

In implementing national pharmacare options, no patient should have a lower level of access or reduced timeliness of access to innovative medicines than they currently have today.

The Council will want to consider the feasibility of a national voluntary formulary and its potential role vis-à-vis existing provincial formularies. There has been considerable *notional* discussion on this topic but no precise definition of a model that would also be politically feasible from a provincial government, private payer, clinician, and patient perspective. There has been little work to-date on how to manage such a formulary over time. Any potential models would necessarily have to consider issues regarding provincial jurisdiction for health care and the maintenance of current coverage benefits.

Pharmaceutical decision-making should reflect the clinical and qualitative value that a medicine brings to individual patients as well as the economic and societal value it represents within the broader health system over time. Federal and provincial governments currently assess pharmaceutical value-for-money from a narrow perspective and the analytical tools used do not always capture a full societal and health

system perspective regarding value-for-money. As a result, many plans are cost-focused rather than investment focused, and therefore the patient and system benefit is often understated and therefore undervalued. Value-for-money assessments must be improved to better reflect value for patients, employers, the health system and government - i.e. a societal definition of value.

System responsiveness is a key consideration both for pharmacare and for pricing discussions elsewhere in the Canadian system (PMPRB; pCPA). It should be recognized that any pharmacare options will have significant impact on Canada's rapidly-emerging innovation economy and the business-models for adopting new technologies. Pharmacare implementation options should reflect diverse and evolving patient needs and be responsive to technological changes. As discussed at our September 6th meeting, preserving Canada's "Tier 1" status for the launch of new medicines should be a high priority for Canada. How the federal government addresses patented pricing reform (PMPRB changes) and pharmacare will impact how soon new drugs are available to Canadians. An objective and comprehensive understanding of the value that innovation brings to Canadians is critical to strike the right balance on pricing and access to innovation. Further analysis on "Tier 1" and its drivers is needed, and we hope to work with the Council to assess and enhance mutual understanding on this issue.

IMC members are also keenly interested in discussing new options for the coverage of drugs for rare diseases, which is an opportunity for immediate federal-provincial-territorial cooperation and engagement with the industry. These medicines quire better planning and system integration. Real-world-evidence (RWE) and coverage-with-evidence-development can play an important role in future cooperative models. The role and potential impact of Health Canada's Regulatory Review of Drugs & Devices (R2D2) work on RWE should also be considered in this context.

4. HOW MUCH VARIABILITY ACROSS DIFFERENT DRUG PLANS OR JURISDICTIONS SHOULD THERE BE IN THE LIST OF DRUGS COVERED BY NATIONAL PHARMACARE?

Individual provinces have jurisdiction over the list of drugs their plans cover and the criteria associated with coverage. While efforts to enhance alignment are welcome, some variation and flexibility across drug plans may be inevitable. Any efforts to establish a voluntary set of coverage standards or list of drugs should aim to elevate the breadth of coverage across the country according to the best current plans available and should respect the different social objectives of public and private plans.

It will be important for the Council to study the differences between current public and private plans in terms of the range of treatments available to patients. There is a wide diversity of patient needs and characteristics of their illness, even within a single disease state. For many complex conditions patients require access to many different therapeutic options (e.g. patients respond differently to different mental health treatment options; multiple treatment options are needed to address "biologic fatigue" over time, etc.). It is important that Canadians, their employers and labour organizations can compare current product coverage and how that coverage would change under any potential future frameworks.

Jurisdictional and employer flexibility to address local health needs and different social objectives of public and private plans is a strength of the current system. Regardless of model, there are many complex legal and implementation issues that will need to be addressed at the provincial level. The Council should conduct a detailed assessment of the various provincial statutes, regulations, drug plan policies and delivery practices, that could impact pharmacare implementation (for example, British Columbia *Pharmaceutical Services Act*, Québec *Loi Sur L'Assurance Medicament* etc.). Current differences in provincial oncology administration and coverage (infusion and oral medication) and catastrophic drug program policies should also be assessed as part of this detailed review.

5. SHOULD PATIENTS PAY A PORTION OF THE COST OF PRESCRIPTION DRUGS AT THE PHARMACY (E.G., CO-PAYMENTS OR DEDUCTIBLES)?

In the interests of fiscal sustainability and providing the required breadth of products covered to address the health needs of Canadians, most payers will need to retain some level of shared payment, regardless if it is in the form of co-payments or deductibles. Plan design and user-pay decisions are likely to continue to be made at the local level according to provincial and plan needs and fiscal capacity.

Most Canadian jurisdictions currently have some form of co-payment or deductible for pharmaceutical coverage but do not have co-pays for provincial health insurance (primary care). Many international jurisdictions use cost-sharing as part of health insurance and have some level of out-of-pocket spending on pharmaceutical coverage.[2] The challenge with user-pay systems is to find the balance between shared responsibility for a person's care, while at the same time ensuring that cost is never a barrier to taking the medicine. Ideally, any user-pay components should be calibrated based on income and ability to contribute. Co-pay or deductible exemptions for vulnerable and low-income Canadians should also be considered.

Ultimately, these are provincial decisions that must be calibrated based on local population needs and there may be ongoing variability among provinces and plans. However, there may be opportunities for consensus and a role for the federal government to play in tracking differences in user-pay and coverage across the country and providing guidance on best practices over time. In its future fiscal discussions with the provinces, the federal government may want to explore the potential for general income-based recommendations for user-pay contributions. In any event, there is a very real expectation that the provinces and territories will expect financial transfers to contribute to any budgetary adjustments they

[2] *Mossialos E, Wenzl M., Osborn R. and, Sarnak D. ed. 2015 International Profiles of Health Care Systems. The Commonwealth Fund: Washington. 2016. International Profiles of Health Care Systems* https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_fund_report_2016_jan_1857_mossialos_intl_profiles_2015_v7.pdf

may need to make to implement pharmacare. Care should be taken to ensure that any funding mechanism allows for a mixed payer system.

6. SHOULD EMPLOYERS, WHICH CURRENTLY PLAY A SIGNIFICANT ROLE IN FUNDING DRUG COVERAGE FOR THEIR EMPLOYEES, CONTINUE TO DO SO (EITHER THROUGH CONTRIBUTIONS TO A PRIVATE PLAN OR THROUGH A PUBLIC PLAN)?

Employers and the private insurance sector have an important ongoing role to play in providing drug coverage for over 22.5 Million Canadians and their families. Employees with good private plans should always be able to keep those plans and current level of coverage.

Existing private plans typically feature more comprehensive coverage and faster time-to-access than public plans. As discussed above, any pharmacare options being considered should not create incentives for private plans to delay listing new medicines or make them reliant on public administrative review processes. Rather, public listing decision processes should be streamlined to reduce the time to listing for new medicines, the principle being that any new system should be the same or better than any system it is affecting.

Private plans are affordable for all sizes of businesses, whether small, medium, or large, because of industry pooling systems which share the costs of insurance across a larger pool of potential beneficiaries. Employer sponsored plans must remain agile and adaptive to specific patient and workforce needs. These private plans are designed to respond to the needs of employees and their employers (e.g. active workers, mostly younger people, families with young children, etc.), whereas public plans address different social objectives due to different patient populations (e.g. elderly adults and those on social assistance). The private and public markets should continue to operate separately and be free to tailor their services to the needs of their respective populations (healthy work force vs social safety net).

Employers should not be compelled to contribute to a single public plan. However, there are existing Canadian models to encourage greater alignment between private and public plans that could be explored, such as the current framework in Québec.

We recognize that Council members have raised philosophical questions about the current role of employers and labour organizations in the provision of pharmaceutical coverage. More study of the current private insurance system is needed with an emphasis on the different dynamics among large employers and small and medium sized enterprises (SMEs). If insurance gaps or challenges do exist for SMEs, for example in the orphan drug and rare disease space, there may be opportunities to address them through improved risk-pooling mechanisms.

There is no consensus on potential inefficiencies in the private market. Before any policy is implemented that would drastically alter the current insurance market, we collectively need a better understanding of employer financial contributions, levels of coverage, and the financial characteristics of the supply chain that takes a medicine from the manufacturer to the patient (insurer premium income, wholesaler income, pharmacist/retail income). Only through such an analysis can employers and their employees assess trade-offs between their current premium costs and the tax burden they would face under potential alternative models. For example, there are tax deductions available for private and/or group insurance plans. Therefore, to do a comprehensive financial analysis of the funding options it is important to account for the full cost of the current system and then compare with projected costs associated with any new potential models.

The current private insurance market is complex but, in general, functions well and is sustainable. We would question the feasibility and desirability of a fundamental reorganization of the employer-based insurance market at this time. To replace existing private benefit plans with a public plan would almost certainly be a step backward in coverage for most Canadians who currently enjoy these benefits while simultaneously adding to the fiscal challenges already facing a strained public health care system.