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Office of Pharmaceuticals Management Strategies
Strategic Policy Branch
Health Canada
Brooke Claxton Building
70 Colombine Driveway
Ottawa, ON K1A 0K9
hc.opms-bsgpp.sc@canada.ca

Subject: National Strategy for High-Cost Drugs for Rare Diseases Online Engagement

The Canadian Institute of Actuaries (CIA) welcomes this opportunity to offer its inputs on the National Strategy for High-Cost Drugs for Rare Diseases.

The CIA recently released a public statement on the issue of national pharmacare. Although the statement has a wider focus than this consultation, there are elements of our proposal that address the need for access to high-cost drugs and how this should be managed as part of a strategy for drug insurance coverage for all Canadians.

Our attached submission is composed of two parts: answers to the consultation questions and a summary of our statement on pharmacare with a focus on how it addresses high-cost drugs.

The CIA appreciates the opportunity to provide these comments, and we would welcome further discussions with your team. If you have any questions, please contact Chris Fievoli, CIA Staff Actuary, Communications and Public Affairs, at 613-656-1927 or chris.fievoli@cia-ica.ca.

Sincerely,

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Michel St-Germain, FCIA
President, Canadian Institute of Actuaries

The Canadian Institute of Actuaries (CIA) is the national, bilingual organization and voice of the actuarial profession in Canada. Our members are dedicated to providing actuarial services and advice of the highest quality. The Institute holds the duty of the profession to the public above the needs of the profession and its members.

Part 1 - *Building a National Strategy for High-Cost Drugs for Rare Diseases: A Discussion Paper for Engaging Canadians* - CIA Responses

1a. How can access to high-cost drugs for rare diseases be made consistent in order to improve patient access to these treatments?

The CIA urges the creation of a Canada-wide cooperative overseeing body in charge of, among other things, a national formulary based on the efficacy of the drugs listed. The formulary would include high-cost drugs in addition to standard medicines. The methodology of drug selection should be established following best practices in Health Technology Assessments. Any drug listed in the formulary will be covered by all public and private plans. If a drug is not listed, it does not have to be covered, but primary plans could choose to do so as a benefit to its members.

1b. Which of the proposed options, or combination of options, would be the most effective for improving access and improving consistency? (Select all that apply)

- *A single framework for decision making on high-cost drugs*
- ✓ ***A transparent co-ordinating body***
- *Patient and clinician engagement*
- *Co-ordinated support for research on rare diseases in Canada*

1c. Please explain the option(s) that you selected above.

The CIA believes the most effective option is a transparent co-ordinating body, which we will refer to as an overseeing body. This independent overseeing body would constitute the single framework for decision-making on all drugs, including high-cost drugs, and would have representatives from federal plans, provincial and territorial plans, and private sector plans. There should also be included a small number of relevant experts, such as those in the medical, drug, and insurance fields.

The overseeing body would determine a national formulary that guarantees uniform access among Canadians to a common list of medications that are recognized for their efficacy. This approach, combined with limits on cost-sharing borne by the patient, would guarantee the affordability of prescription drugs – including high-cost drugs – to all those who need them.

Most prescription drugs are already covered by all insurance plans in Canada. This is not true of certain medications that may be covered under some plans and excluded under other plans. The overseeing body that we recommend would make the decision as what must be covered by all plans. Being transparent, this body would be able to explain why a particular drug is on the list while another drug is not. The decision to include a medication on the national formulary would be based on a consensus rather than being based on independent judgment by an insurer, an employer, or a provincial organization.

We support a prescription drug framework built upon what already exists. That means it would allow the continued existence of federal, provincial/territorial and private sector plans. However, we wish to see all Canadians covered. This would be achieved by the federal government backing the costs of any plan. Once the costs for a particular individual in a plan hit a predetermined dollar limit, the federal government would pay all remaining costs for that year. This would lead to lower and far more predictable costs for provincial/territorial and private sector plans.

2a. How can decisions on covering high-cost drugs for rare diseases be made when the evidence is limited?

We would strongly counsel that Canada reviews the actions of the current Health Technology Assessments in the UK and the US. For example, this has been explored by a US actuarial organization in a recent article.

2b. Which of the proposed options, or combination of options, would be most effective for strengthening the evidence base? (Select all that apply)

- *Innovative approval and coverage models*
- ✓ ***A national expert panel***
- *A national data system*
- ✓ ***Independent national and international networks***

2c. Please explain the option(s) that you selected above.

We recommend an overseeing body of experts independent from the provincial and federal plans. It would have two major activities:

- It would create a national formulary. Drugs listed on the formulary would have to be covered by all plans. Drugs not listed could be covered by any primary plan which choses to do so. These decisions would be based on the broadest data sources possible.
- It would negotiate drug prices with the pharmaceutical industry. It would be a single voice for all of Canada.

We also see that Canadian participation in independent national and international networks could be useful to gather information on the efficacy of new and existing drugs and the emergence of new drugs.

3a. Which of the proposed options, or combination of options, would be most effective for getting rare-disease treatments to patients? (Select all that apply)

- ✓ ***Sharing of costs and pooling of risks***
- *Investments up front to reduce the risk in early development*
- *Pay for performance*
- *Supports for "made-in-Canada" innovation*
- *International collaboration*

3b. Please explain the option(s) that you selected above.

We want priority placed on achieving the greatest impact to the overall population. We also want to spread the costs efficiently, including spreading the most volatile of these costs over the maximum number of shoulders (i.e., the entire Canadian population). This can be done most efficiently by pooling risks within an insurer's portfolio, among various insurers (as with the current industry Extended Health Policy Protection Plan pooling and the Quebec Drug Insurance Pooling Corporation), among a public plan's members or, in the case of high-cost patients, with the federal government. Our recommendation is that once the costs for a particular individual in a plan hit a predetermined dollar limit, the federal government would pay all remaining costs for that year.

4. Do you have other ideas that might help improve access and lower costs for drugs for rare diseases?

To repeat our top message: we should spread these costs over the entire Canadian population, by guaranteeing that all Canadians have drug insurance coverage and that the federal government pays all costs that exceed a predetermined dollar limit for any individual. The federal government would become a reinsurer for the provincial/territorial and private sector plans, and thus spread the cost of drugs for rare diseases across the whole country where the risk is better absorbed.

Part 2 – Summary of the CIA's Statement, *Pharmacare: Is There a Pill for That?*

The Canadian Institute of Actuaries believes all Canadians should have access to affordable prescription drugs. We believe the best way to achieve increased health outcomes across the country is through a Canada-wide framework with elements managed by the federal government, provincial/territorial governments, and private insurance. It would enable:

- pooling of costs at the highest level where risk can be better absorbed;
- negotiating prices using the greater weight of the whole country; and
- making sure that all Canadians can access the same medicines, fairly and equitably.

We believe the introduction of a prescription drug framework does not need to mean wholly replacing what we have now with something new. The current private and public programs are working well in many ways; a new framework should focus on helping them work better together and on filling the gaps. The framework would have the following elements:

Provincial flexibility

- **Provinces and territories should be afforded the flexibility to design their own public prescription drug plan and create a structure for the coordination of their public plan with the existing private drug insurance marketplace.**

We believe this framework should allow provinces/territories and private plan sponsors enough flexibility to continue to offer programs beyond the core formulary that reflect the realities of their own populations. Different provinces have different challenges with respect to available budgets, population demographics, existing prescription drug programs, and pharmacy regulations.

Oversight

- **An overseeing body comprised of decision-makers from federal, provincial/territorial, and private plans and other relevant experts should be established to negotiate drug prices on behalf of all public and private plans across Canada. This body should also explore how to implement optimal evidence-based prescribing and public health alternatives to pharmaceuticals.**

We recommend establishing an overseeing body tasked with, among other roles, negotiating wholesale drug prices and rebates with manufacturers. Much of this work is already being accomplished under the pan-Canadian Pharmaceutical Alliance (pCPA) – through which the provinces are working together to negotiate drug prices. Rather than start from scratch, we recommend building on this existing

groundwork. **The overseeing body would be cooperative, including representatives from the federal, provincial, and territorial governments, the insurance industry, and other experts.**

This price negotiation would also include high-cost drugs and rare disease treatments, such as those for orphan diseases – diseases that are so rare that medication to treat them can cost more than $1 million per patient annually. According to Telus Health, in 2018, specialty drugs, including those for chronic and rare diseases, were claimed by just 1.1% of claimants, but accounted for 29% of total drug costs. This has increased significantly over the past ten years; in 2009, specialty drugs accounted for 0.5% of claimants and 12% of costs. This trend is expected to continue as even more expensive therapies come to market, including drugs for rare and targeted cancers and gene therapy.

We call for more research in other areas to reduce overall cost increase. Increasingly, patients expect that medication of one form or another is the solution to their ailment. In many cases, that may be true because the condition has advanced to that state. However, along with prescription drugs, other areas of medical care, public health, and health promotion need increased investment, such as lifestyle changes and therapy that can lead to improved physical and mental health. The overseeing body would research improved protocols for more effective use of pharmaceuticals and to reduce the mix of prescriptions to the elderly – who are among those most prescribed. This will help limit cost increases and may also improve health outcomes.

Coverage

- **A national formulary should be established by the overseeing body, to define the core and specialty medicines that will be covered.**
- **Both public and private plans should cover, at a minimum, all drugs included in the national formulary, to guarantee consistency across the country. Any plan could be allowed to cover drugs beyond those listed in the formulary if they wish.**
- **The cost borne by the patient as deductible, coinsurance, or copayments would be limited to an affordable amount.**

The formulary must be consistent across all provinces and territories, as portability – one of the fundamental principles of the Canada Health Act – cannot be achieved if there are differences in the formulary between jurisdictions. **Therefore it will be very important to have representation from all jurisdictions and private payers in the selection of the national formulary and to ensure transparency and avoid unintended consequences.**

Formulary inclusions

We foresee a challenge with respect to prescription drugs Canadians are currently taking that may not be listed on the national formulary. Differences between the national formulary and existing public formularies should be reviewed for gaps. We recommend starting with a core formulary that would be built up over time based on evidence of efficacy.

Another important element to consider is the introduction of new, very expensive drugs, such as biologic drugs and similar therapies. To the extent that these drugs will be deemed useful and that their coverage under the framework will be considered necessary, we should expect these drugs to have a significant impact on the annual increase of drug cost per capita in Canada. Based on recent data, the

Drug Spending Model (DSM) assumes that new drugs add 4.5% per year to overall projected prescription drug spending.

According to the Canadian Institute for Health Information, greater demand and the rapidly rising number of high-cost drugs on the market have combined to take our spending on prescription drugs from its 1985 level of $2.6 billion or 0.5% of Gross Domestic Product (GDP) to $34 billion or 1.6% of GDP in 2018.

We agree with the principle of biosimilar substitution, to support the use of biosimilars and encourage patients and prescribers to choose the most cost-effective therapies to ensure the sustainability of the framework. Biosimilars made up less than 7% of Canada's biologic market in 2017, while the OECD average was more than 30%.

Insurance and reinsurance

- **Private plans should continue to cover costs up to a certain limit based on each plan's risk appetite, using a mix of self-insurance, insurance, and reinsurance. Industry organizations could continue to share costs across insurers.**
- **Provincial and territorial plans should cover up to a certain limit of an individual's aggregate costs.**
- **The federal government should pay for costs beyond the defined limit.**
- **High-cost drugs on the national formulary, including those for orphan diseases, should be reinsured by the federal government on an individual basis for both public and private plans. Such drugs would first have to be listed in the formulary based on evidence of efficacy and negotiated price.**
- **There would be no premiums for this federal reinsurance.**

Private plans and provinces/territories should act as primary insurers and cover the first tier of costs, with the federal government "reinsuring" the costs beyond a defined limit. In this way, the annual cost to be paid by the patient could be quite low or be a function of taxable income in the previous year. Provinces and territories could choose that people receiving social assistance, government disability benefits, or the federal Guaranteed Income Supplement benefit could be made exempt from copayments and/or deductibles. This is especially important for vulnerable or at-risk populations, including seniors. Over time, these mechanisms could be adjusted subject to evidence-based decision-making.

Risk pooling

A key principle underlying insurance is the law of large numbers; as the size of a group grows, the more certainty there is around a particular outcome. Due to the infrequent nature and size of specialty drug claims, many plan sponsors and provinces have experienced significant volatility in the costs of their drug plans. This has led to the introduction of drug caps or maximums, delays in listing certain drugs, or even ceasing drug coverage altogether.

The costs for these large and infrequent drug claims are most appropriately pooled at the largest group level available in the Canadian market – the federal government. Further, costs for more frequent, predictable, and lower-cost drugs can continue to be, and are appropriate to be, insured at the provincial/territorial or private plan sponsor level aligned within the national framework.

The federal government will have an important role to play in building a risk-based framework to hold together the various public and private plans. **The federal government should act as a reinsurer to all drug insurance plans in Canada, public and private**, as follows:

- Specialty or high-cost drugs, including drugs for orphan diseases, should be reinsured on an individual basis by the federal government for all drug plans in Canada, public and private. This would use a formulary-based approach, in which costs for drugs on the formulary over a specified dollar threshold would be paid for by the federal government. This would remove significant cost volatility from provincial/territorial and private plans.

This type of risk-sharing framework already exists within Canada, created by governments looking to more appropriately share costs across a broader base:

- The Quebec Drug Insurance Pooling Corporation (QDIPC) was established in 1997 following the adoption of the Prescription Drug Insurance Act, which sought to provide all Quebec citizens with coverage for the cost of pharmaceutical services and medications. All insurers and administrators of employee benefits plans share the risk of high-cost medications. QDIPC administers this pooling system, and is the only body recognized for this purpose by the Quebec government.

This framework would offer two clear advantages to the provinces/territories and employers: their total costs would be capped by the basic coverage limit (after which the federal reinsurance kicks in), and the volatility of the costs would be much lower, that is, year-to-year costs would be more predictable. For the federal government, this framework gives them a level of participation and a say in how it is run. For individuals, their costs would simply be covered, and they would not need to be involved in any level of reinsurance.

Planning for the future

We urge convening a task force of medical professionals, pharmaceutical experts, insurance leaders, private plan sponsors, government representatives, and actuaries to identify more accurate, consistent data on the costs and potential savings of the framework, and to perform a financial analysis over a long-term horizon.

Canada's prescription drug framework should feature comprehensive objectives to get better value for cost, including assisting both the public and the medical community to improve health outcomes. Importantly, the framework should undertake periodic reporting on achievement of its objectives with benchmarking against the best performers globally. And specifically, it should have transparent reporting to Canadians on overall health costs versus life expectancy. All of this should be supported through the development of a cost-effective information system to feed into the reporting on objectives, efficacy of the framework, and development of information.

Given the importance of the sustainability of such a program, consideration should be given to the mechanisms used to ensure sustainability in other long-term plans – such as the CPP and the Employment Insurance program. Periodic actuarial valuations similar to a pension valuation should be done and a report prepared for the public.

Conclusion

This framework would offer two clear advantages to the provinces/territories and employers: their total costs would be capped by the basic coverage limit (after which the federal reinsurance kicks in), and the volatility of the costs would be much lower, that is, year-to-year costs would be more predictable. For the federal government, this framework gives them a level of participation and a say in how it is run. For individuals, their costs would simply be covered, and they would not need to be involved in any level of reinsurance.

We believe a well-managed prescription drug framework can result in lower overall costs and better health outcomes and contribute to the long-term economic recovery from COVID-19. The pandemic has shone a bright light on problems in our health care system. Investments today in the system – including prescription drug coverage – would benefit both today's Canadians and the generations to come.