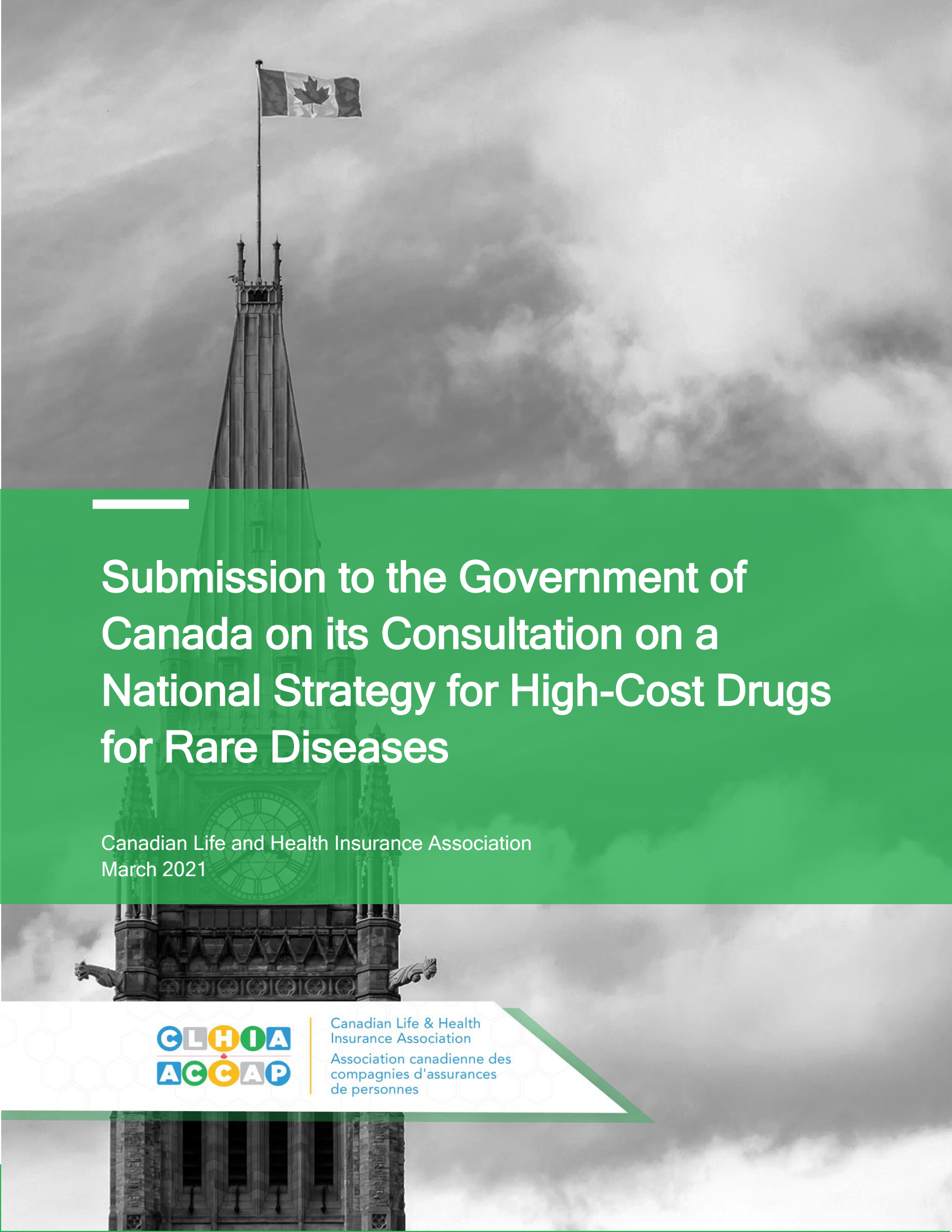

Submission to the Government of Canada on its Consultation on a National Strategy for High-Cost Drugs for Rare Diseases

Canadian Life and Health Insurance Association
March 2021

Canadian Life & Health Insurance Association
Association canadienne des compagnies d'assurances de personnes

OVERVIEW

The CLHIA is a voluntary association with member companies which account for 99 per cent of Canada's life and health insurance business. The life and health insurance industry plays a key role in providing financial security to Canadians, protecting millions of Canadians through a wide variety of life, health, and retirement income products.

Protecting 29 million Canadians

26 million with drug, dental and other health benefits

22 million with life insurance averaging $222,000 per insured

12 million with disability income protection

$103 billion in payments to Canadians

$53 billion in annuities

$38 billion in health and disability claims

$12 billion in life insurance policies

Canada's life and health insurers play a key role in providing a social safety net to Canadians. The industry provides more than 26 million Canadians with access to a wide range of health supports through extended health care plans, including prescription drugs. In 2019, life and health insurers paid over $38 billion in health benefit claims, including $12.5 billion for prescription drugs.

$12.5 billion spent on drugs through benefit plans

CLHIA members paid out over $650 million for Canadians for rare diseases drugs in 2020

The Canadian Life and Health Insurance Association (CLHIA) is pleased to provide the consolidated view on behalf of its member companies to the Government of Canada on its consultation on a national strategy for high-cost drugs for rare diseases ("rare disease strategy").

The life and health insurance industry helps Canadians by providing them with access to drugs for rare diseases through extended health benefit plans. In 2020, CLHIA members paid out more than $650 million for rare disease drugs to over 13,000 insured Canadians. Smart reform in this area will ensure that the costs and risks of providing Canadians with access and financial support for drugs for rare diseases are shared across both public and private payers in Canada as well as pharmaceutical manufacturers. Working together will build on the strong foundation that exists today while improving access for Canadians and the financial sustainability of the system, without impeding innovation and availability of advanced, cutting-edge treatments in Canada.

The government's discussion paper on a national strategy for high-cost drugs for rare diseases ("discussion paper") presents questions on how to address three key issues: improving patient access, evidence-based decision making and sustainability for an effective rare disease strategy. In this submission, we provide comments on how to address those key issues and we present risk and cost sharing approaches that include private payers. These approaches will minimize impacts to patients and ensure the sustainability of the program over time.

We appreciate the federal government's commitment to continue to engage with the industry following this consultation. The CLHIA has a strong desire to work with all levels of government to fully develop the framework and details on the rare disease strategy and we look forward to an ongoing dialogue on these important issues.

PRIVATE SECTOR ROLE IN RARE DISEASE STRATEGY

Canadian life and health insurers provide 26 million Canadians with access to a wide range of prescription drugs, including rare disease drugs, and other health supports through extended health care plans. In total, the industry paid over $38 billion in supplementary health care claims in 2019, including the cost of prescription drugs, dental procedures and other supplementary health expenditures.

Canadians highly value their current coverage. A recent survey shows that more than 80 per cent of Canadians place a great deal of value with their private drug plan.[1] In addition, 84 per cent of those surveyed believe that nothing should be done that puts group benefits such as eye care, dental care, and other services at risk of being cancelled by employers.

Through these plans, insurers offer unique tools and supports for patients struggling with rare diseases, including navigation to patient support programs and case management. In addition, the industry has invested in significant infrastructure and expertise to process prescription drugs claims for Canadians in an efficient and timely manner, making it as seamless as possible for patients at the pharmacy. These extended health care plans have been especially important throughout the COVID-19 pandemic and the private payer system has proved its resilience throughout. Workplace plans have shown remarkable resilience, with industry-wide data collected by the CLHIA showing that 98.5 per cent of the 26 million Canadians who had extended health benefits at the beginning of March 2020 continued to have coverage.

In particular, the industry plays a critical role with respect to drugs for rare diseases. In 2020, insurers paid out more than $650 million for rare disease drugs to over 13,000 insured Canadians.[2] Smart reform will build on this solid base and will not jeopardize the coverage that so many Canadians already enjoy.

DISCUSSION PAPER KEY ISSUES

The discussion paper presents questions on how to address three key issues: improving patient access, evidence-based decision making, and sustainability. The CLHIA believes that a successful rare disease strategy will take a holistic approach and address all three of these key elements.

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[1] Based on a survey of 3,000 individual Canadians conducted by Abacus Data in March 2018.
[2] Based on data collected from CLHIA member companies. The list of drugs used is based on the Patented Medicine Prices Review Board's list of rare disease drugs (2018) plus additional drugs that have launched since 2018.

Issue 1: How to improve patient access to high-costs drugs for rare diseases and ensure that access is consistent across the country

The CLHIA supports the concept of a single framework for decision-making on high-cost drugs for all Canadians regardless of whether they have public or private plans. It is important that private payers remain part of the model for high-cost drugs in order to minimize the impact on patients and ensure the sustainability of the system.

Patients want comprehensive and equitable access no matter what kind of plan they have. As such, we believe it is fundamental that the government develop a national formulary of drugs for rare diseases and consistent coverage criteria. Private payers would work with government to ensure that private plans at least meet any such national formulary to ensure consistent access across the country. Private plans may exceed the national formulary in terms of drug offerings depending on what plan sponsors offer their employees.

It is critical that private payers can inform the design of the formulary and have a seat at the decision-making table. Participation by private payers is essential to ensure that the formulary and criteria that are established meet not only the needs of the public payers, but the distinct considerations of private plan sponsors and plan members.

Development of a definition and inclusion criteria for the rare disease formulary is an essential milestone. Criteria must offer clear guidance on the scope of the rare disease program, which will help determine decisions on which drugs will be listed in the program and why. Drug manufacturers, payers, plan sponsors and patients would all benefit from the stability and predictability that clear inclusion criteria would provide. Factors to consider could include: the prevalence of the disease, the price of the therapy under review (to ensure the highest cost drugs remain accessible), the level of uncertainty in existing clinical evidence, the health impacts of the disease and other potential uses of the drug. Prior authorization is a common tool for specialty drug management across both public and private plans. However, the many programs often differ in what forms are used and what criteria are used to adjudicate claims. There is an opportunity within the rare disease program to align on criteria for prior authorization approval amongst key stakeholders.

The development and management of a rare disease formulary should incorporate additional factors beyond those that have traditionally been used by public payers. For example, a drug might help someone return to work, support productivity, reduce disability rates or improve mental health. Such factors have traditionally not been a determining factor in the public plan health technology assessments. A healthy, productive workforce ultimately benefits our public health system beyond reduction of hospitalizations, and these are valid considerations in any formulary assessment.

The CLHIA also believes that a transparent coordinating body could support improved patient access. We would be pleased to work with a coordinating body to help ensure alignment across the entire system and improve communication and engagement among key players. As part of this, patient and clinician engagement are essential elements of an effective rare disease strategy and a federal program could provide an effective point of contact to coordinate their input as well as disseminate program information. Private payers already have well established relationships with employers and

plan members, which can be leveraged to ensure broad inclusion and understanding of any new programs.

Finally, the CLHIA believes that coordinated support for research on rare diseases in Canada would provide useful information to inform the choices of the program. A research arm of the rare disease strategy could further the practical risk mitigation goals of novel funding arrangements, such as pay-for-performance (e.g. outcomes-based agreements, managed entry agreements). As well, research on rare disease drugs would support a holistic approach to care through ongoing monitoring and effectiveness of the drugs. Infrastructure for research activities, such as the development of shared databases and patient registries to generate real-world evidence, are also important to support clinical outcomes, trials, foster an environment of innovation and development in Canada, and to deepen global understanding of rare diseases.

Issue 2: How to ensure decisions on covering high-cost drugs for rare diseases are informed by the best evidence available

The CLHIA recognizes rare disease treatments present unique challenges and agree that coverage decisions need to incorporate real-world evidence to ensure patients have access to the best available treatments.

As described in the federal government's discussion paper, innovative approval and coverage models could tie approval of funding of rare disease treatments to how well they work. The CLHIA supports this approach. We believe that these models have the potential to support faster, more consistent access to treatments, mitigate clinical and financial risks associated with poorly characterized diseases and generate outcomes that support the long-term viability of the program.

With respect to the establishment of a national expert panel, the CLHIA believes that engaging a panel of experts with broad knowledge and expertise is a good first step in meeting the technical and operational challenges of a rare disease strategy. We understand that the government is envisioning an expert panel that would include specialists with clinical experience in the rare disease space. We believe these experts would provide essential clinical expertise to the program. However, we also believe that consideration should be given to expanding the list of experts represented for the design and maintenance of a robust program. The list of experts could be expanded to include patients, health economists, actuaries and payers (public and private) to improve overall recommendations, build consensus and improve feasibility.

One of the key challenges for decision-makers in the rare disease space is limited data and clinical evidence. The CLHIA supports the concept of a federal national data system to help address this challenge and believes it's important that private payers are included within the system so that it reflects the needs of all Canadians. Private payers play a significant role in the prescription drug system and have access to a significant amount of data on the types of drugs Canadians rely on. Leveraging this data would provide important information to any national data system. We believe that establishing a national data system and/or rare disease registry should be a priority as it will play a critical role in helping to develop an effective pay-for-performance or other innovative coverage arrangements. It will also support necessary rare disease research initiatives in Canada.

Finally, the CLHIA also believes that having independent national and international networks can help address the challenge of having insufficient data and local expertise to support patients.

Issue 3: How to ensure spending on high-cost drugs for rare diseases does not put pressure on the sustainability of the Canadian health care system

According to the Patented Medicines Prices Review Board (PMPRB), expenditure for expensive drugs for rare diseases (EDRDs) are the fastest growing market segment in Canada. From 2012 to 2019, EDRD expenditures grew by 32%, more than six times the growth rate observed for all prescription medicines.[3]

Improving the financial sustainability of the system is vitally important given the growing cost of drugs for rare diseases and the pressure it places on existing drug plans as well as Canadians without drug coverage. As mentioned above, the CLHIA believes that the costs and the risks of the system need to be shared across all stakeholders and that the program should continue to leverage the strengths of the existing system, such as shared accountability between public and private plans, in order to ensure the stability of the program.

There is a common misconception that most private plans in Canada include a lifetime or annual maximum for plan sponsors. In fact, the majority of plans don't include this type of control. Private drug plans instead employ a wide variety of tactics to contain costs, manage risks and support the long-term sustainability of programs, including but not limited to formulary management and prior authorization.

Going forward, it will be important to have tools in place to manage the clinical and financial risks of high-cost drugs for rare diseases. There are many options to consider, including simple product listing agreements and pay-for-performance agreements, as well as real-world evidence management and "sun-setting" options that can help manage the life cycle of these drugs. Appropriate infrastructure, such as registries, would need to be developed to support ongoing rare disease understanding, best practices and health technology management. The assumption is that this will be managed by the coordinating body. These options would take time to establish as each would require investment in data sharing before being implemented. Private payer data and private payer expertise is important to inform this development to ensure all Canadians are fairly represented in the solution.

BUILDING A RARE DISEASE STRATEGY

As a key player in the system, the life and health insurance industry recognizes that the status quo is not sustainable and that it is important to take meaningful steps to make improvements for the benefit of all Canadians. We believe that an effective rare disease strategy will incorporate the key element of all three points discussed above.

The Federal Budget 2019 announced up to $1 billion over two years, starting in 2022-23, with up to $500 million per year ongoing, to help Canadians with rare diseases access the drugs they need.

We believe that it is important that the committed funding is spent efficiently. As noted above, the amount spent on drugs for rare diseases has grown exponentially. The private payers' market itself paid more than $650 million on rare disease drugs in 2020. This already far exceeds the earmarked annual funding of $500 million in 2022-23.

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[3] Patented Medicine Review Board, *Annual Report 2019*. https://www.canada.ca/en/patented-medicine-prices-review/services/annual-reports/annual-report-2019.html

The challenge is to find a rare disease strategy that balances the needs of Canadians faced with chronic, debilitating, or even life-threatening rare diseases against the increasing and unpredictable costs to ensure the system remains sustainable, while encouraging innovation and the availability of treatments in Canada. We believe that a federal first-payer model for drugs for rare diseases would not achieve this balance. Under this option, the assumption is that all costs for rare disease drugs covered by public and private plans would be borne by the federal government, including the more than $650 million currently paid by the private system. This amount is expected to increase even more by 2022-23 when federal funding is expected to flow. This committed federal funding would not be sufficient to cover the costs paid for by public and private plans. In addition, creating a new federal program would create unnecessary disruptions for patients who are receiving this coverage.

There are approaches the federal government could consider to address the key issues noted in the discussion paper (access, evidence-based decision making, sustainability) that work within the existing system. We have identified two approaches below for consideration. It is important to note that each of these approaches would require detailed discussions with provincial governments and private payers. To be successful, the financial model should minimize disruption for Canadians, leverage existing systems wherever possible, be based on a consistent formulary and criteria for coverage, and share risks across stakeholders. The funding model must be designed for sustainability so all stakeholders can benefit from a predictable and consistent environment.

The approaches below could be used alone or integrated together to keep plans affordable and encourage plan sponsors to provide coverage. They could be used to establish a consistent system that would improve access to medicines, where every Canadian would have access to either a public or private plan. These options would allow Canadians to continue receiving coverage from their existing plans and avoid disruption for patients and their families.

The impacts on key stakeholders would vary considerably depending on design details. In particular, impacts would differ based on decisions around formulary, out-of-pocket costs for patients (e.g. co-pays) and funding models. We have outlined some potential impacts below and would be pleased to provide additional analysis following further discussions with government.

Cost Sharing/Re-insurance

Under this approach, the federal government would share the cost of all drugs on the rare disease formulary (as discussed above) beyond a certain threshold. This approach could achieve savings and improve predictability of costs for both provincial and employer plans. It is important that private payers are included in this approach to minimize impacts to patients and plan sponsors and ensure the sustainability of the overall system.

Funding from the federal government could be administered one of two ways. Both of these approaches would require some administrative changes, which will require further discussions with provincial government and private payers:

a) Payers (both public and private) would cover the cost of all drugs on the rare disease drug formulary up to a set threshold. The federal government would pay amounts above the threshold. This could be administered directly at the pharmacy.

b) Payers (both private and public) would continue to include all drugs on the rare disease drug formulary. The federal government would then "reimburse" each payer for the cumulative expenses above the thresholds for all drugs on the formulary that were reimbursed. Funding from the federal government would flow on a predetermined basis to payers. Savings from this approach would reduce overall costs to plan sponsors.

Pooling – with Federal Contributions

Pooling is primarily a risk sharing mechanism that helps ensure that no individual payer has a disproportionate burden of the financial costs on a predetermined set of drugs (in this case this list would be the national formulary discussed above). Effectively, pooling shares the cost across all participants in an equitable manner – often based on the relative size of each participant. In addition to the risk share benefits of pooling, federal funding would offset costs borne by other payers. Pooling is an administrative arrangement but can be complex to implement and require a significant degree of expertise to establish and manage on an ongoing basis. It will require some type of agreement between the payers which will take time to implement.

Any strategy requires funding for the development and ongoing management activities. This should be a consideration for the transition office, coordinating body and decision-making committee. It will be challenging to have a national rare disease funding framework in place by 2022-23 but foundational activities, such as establishing a coordinating office and developing data-sharing infrastructure can start today.

Additional Considerations – Joint Public/Private Price Negotiations

Given the rarity of the conditions likely to be included in the rare disease program, we believe it is important to bring together full buying power of both the public and private sectors in future pricing negotiations and strongly recommend that Canada implement a common negotiation strategy for the price of high-cost drugs for rare disease.

CONCLUSION

The industry greatly appreciates the opportunity to provide its views to the Government of Canada on its consultation on a national strategy for high-cost drugs for rare diseases. We would be pleased to provide further detail or answer any questions on the issues identified within this paper. Should you have any questions, you may contact Karen Voin, Vice President, Group Benefits and Anti-Fraud at kvoin@clhia.ca.

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