



CLHIA REPORT ON PRESCRIPTION DRUG POLICY

ENSURING THE ACCESSIBILITY, AFFORDABILITY AND SUSTAINABILITY OF PRESCRIPTION DRUGS IN CANADA





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EXECUTIVE SUMMARY

The prescription drug system in Canada must be fundamentally reformed if it is to serve Canadians well in the long-term. The current system is inequitable both in terms of access and price. It is also increasingly being challenged from a financial perspective by the ongoing growth in drug costs which, ultimately, must be paid by plan sponsors, typically employers, or ordinary workers who pay for their prescription drugs through co-payments or directly out-of-pocket.

Rising drug costs, particularly related to the increasing incidence of rare but very high cost drugs, undermines the ability of employers to continue to offer drug coverage benefits to employees. In 2011, life and health insurers made benefit payments for prescription drugs of \$10.1 billion and private payers accounted for roughly 55 per cent of all prescription drug purchases. A pullback on drug coverage by employers would have dramatic implications, not only for individuals, but also for governments who are themselves struggling with rising healthcare costs.

Any long-term solution to these challenges will require both public and private payers to make adjustments to their programs and to work more collaboratively going forward. The Canadian life and health insurance industry has a unique and important perspective on how the current system functions and therefore how to reform pharmacare for the benefit of Canadians. As administrators of the vast majority of drug benefits plans in Canada, we have a responsibility to employers and individual Canadians to constructively seek improvements to the current system. In addition, the industry is unique amongst payers in that we operate on a national basis, which gives us a strong and deep pan-Canadian perspective on the issue of drug coverage reform.

The paper covers the entire life cycle of the drug market in Canada starting from how drugs are approved for sale and priced, through to the purchase and reimbursement of drug costs. At each stage, it makes important, actionable recommendations to address the weaknesses of our current system. The ultimate goal from a policy perspective must be to ensure that Canadians have access to the drugs they need without undue financial hardship as a result of prescription drug costs.

All the recommendations in the paper are important and need to be addressed over the medium term. As a priority, however, the paper argues that fundamental reform is required of the Patented Medicines Prices Review Board's mandate and practices in order to reduce drug prices for all Canadians. It also recommends that, as a priority, discussions start on creating a common, national minimum formulary as a means to reduce complexity in the system and that governments lead a discussion to work towards the creation of a new, collaborative, end-to-end approval and funding regime for orphan drugs. The new orphan drug regime will ensure that Canada has both a robust process to approve orphan drugs from a safety and effectiveness perspective and a plan for how to fund orphan drugs so that Canadians will be able to access them once approved.

While fundamental reform is pursued, the paper suggests that shorter term and more tactical reform also be implemented. As a priority, the paper recommends that provinces start to automatically list generic drugs once they have been approved as bio-equivalent with the brand drug. This will eliminate the current lag in listing new generics and will immediately generate savings for all Canadians. The paper also recommends that, as a priority, governments implement improved processes to reduce the complexity in the system so that individuals can smoothly transition between public and private coverage and that a monitoring framework for off-label prescribing be developed to address concerns over patient safety and cost escalation.

The time for reform is now. The Canadian life and health insurance industry is committed to meaningful reform in this sector and looks forward to engaging with governments and other stakeholders to ensure Canadians continue to benefit from a strong pharmacare system well into the future.

1. INTRODUCTION

Prescription drug coverage in Canada is a mixed public and private accountability and must be fundamentally reformed if it is to serve Canadians well in the long-term. There are a number of concerns that need to be addressed going forward to ensure its sustainability, not the least of which is the continuing growth in the total cost of prescription drugs for all payers. Canada ranks second highest, behind the U.S., in total per capita spending on drugs (both prescribed and non-prescribed) of 25 OECD countries. If Canada were able to implement reform to move us more in line with the median of the OECD in this regard, we would save over \$9.6 billion per year in drug costs. This is money that provinces can use to reduce their deficits, employers can use to grow their businesses and create new jobs and workers can use for other priorities. Moreover, spending on prescription drugs over the past decade has grown faster than any other category of health care expenditures.¹ The loss of patent protection for a number of blockbuster brand drugs, coupled with aggressive generic pricing reform by the provinces for the benefit of all payers, has resulted in a moderation in the growth of drug cost in the last couple of years. However, most experts feel that we are coming to the end of a period of relative calm and that the ongoing financial sustainability of drug plans in Canada is far from assured.

Better managing the overall cost of drugs going forward is critical. Plan sponsors, typically employers, include drug benefits as part of a competitive supplementary health plan in order to attract and retain employees, as well as to ensure a healthy and productive workforce and, ultimately, they must bear the costs of drugs. However, employers have limited resources and do not have to provide supplementary health plans with drug benefits to their employees. The key concern from a sustainability perspective is how to manage the recent and forecasted increase in the number of high cost drugs and drug therapies available and being prescribed to

¹ Canadian Institute for Health Information (CIHI). *Drug Expenditure in Canada, 1985 to 2010*. April 2011.

patients. Currently, specialty drugs represent about 20 per cent of plan costs for employers, but only one per cent of total claims. They are forecast to represent 25 to 35 per cent of cost by 2015.² Such drugs have a significant annual cost (some can be well over \$50,000 per year) and are typically indicated for genetic enzyme disorders, cancer treatments, and auto-immune disorders.

If the growing burden of high cost drugs, in particular, is not addressed there is a real risk that employers will take steps to restrict their drug coverage. In 2011, benefit payments for prescription drugs in Canada by our industry totaled \$10.1 billion and private payers accounted for roughly 55 per cent of total drug purchases. Any significant reduction in coverage by employers would have dramatic implications, not only for individuals, but governments as well. Governments in Canada are increasingly looking to moderate the rate of growth of their health expenditures and, given their respective difficult fiscal situations, would be challenged to take on a significant proportion of the drug spend that is accounted for by private plans currently.

In addition, the current patchwork of drug coverage results in inequities between Canadians. A drug that is covered for an individual in one province may not be covered for an individual in another province. As well, the price that is paid for the same drug will vary greatly across Canada depending on whether an individual is covered by a provincial plan, private insurance or is paying out-of-pocket. The system is also highly complex system and difficult to navigate. Most worryingly, it is clear that in some regions of the country, many Canadians do not have any, or only inadequate, drug coverage. These gaps in coverage can result in significant financial strain for these individuals.

Any long-term solution to these challenges will require both public and private payers to make adjustments to their programs and to work more collaboratively going forward. The Canadian life and health insurance industry has a unique and important perspective on how the current system functions and therefore how to reform pharmacare for the benefit of Canadians. As

² ESI 2011 Drug Trend Report.

administrators of the vast majority of drug benefits plans in Canada, we have a responsibility to employers and individual Canadians to constructively seek improvements to the current system. In addition, the industry is unique amongst payers in that we operate on a national basis, which gives us a strong and deep pan-Canadian perspective on the issue of drug coverage reform. The ultimate goal from a policy perspective must be to ensure that Canadians have access to the drugs they need without undue financial hardship as a result of prescription drug costs.

2. GUIDING PRINCIPLES

This policy paper presents actionable recommendations to help assist in the development of sound prescription drug policy. The recommendations are grounded in fundamental principles, as set out below, which we believe should guide the policy decision-making process.

1. **Accessibility:** All Canadians should have access to proven/effective prescription drugs when they need them.
2. **Affordability:** No Canadian should suffer undue financial hardship because of the cost of the prescription drugs they need.
3. **Sustainability:** The prescription drug system in Canada must be financially sustainable over the long-term.
4. **Patient Safety and Education:** Patient safety is paramount – the drugs Canadians use need to be safe and effective for their condition. Education is critical to enable Canadians to make informed decisions.
5. **Fairness:** All Canadians should have access to prescription drugs at the same cost whether being paid for by public or private plans, or directly out-of-pocket.

3. ANALYSIS AND RECOMMENDATIONS

The CLHIA puts forward a number of recommendations for addressing the challenges of ensuring Canadians have access to the prescription drugs they need at a price they can afford and that the system is sustainable over the long-term. The recommendations are grouped into the following broad areas:

- A.** Ensuring safety and encouraging innovation;
- B.** Ensuring availability of cost effective prescription drugs;
- C.** Improving reimbursement models;
- D.** Improving collaboration with key stakeholders; and
- E.** Ensuring access to orphan drugs.

A. ENSURING SAFETY AND ENCOURAGING INNOVATION

Pharmaceuticals play an important role in the health care system and in the daily lives of Canadians. They save lives, prevent the spread of disease, improve quality of life and can help control pain. It is critical that prescription drugs are safe and effective to ensure these benefits are maximized and to ensure confidence in the prescription drug system in Canada.

At the same time, it is important that Canada foster an innovative environment for the development of new prescription drugs. Innovation in prescription drugs, for instance, can lead to a shift from invasive treatments with potentially serious risks to less-invasive therapies focused on prevention and health maintenance. This can help Canadians to remain healthy and independent as they age and also save costs for the entire health care system.

a.1 Head-to-head Clinical Trials

Clinical trials, which are the final stage of drug development, test the safety and efficacy of new drugs. This phase of development provides not only the data that is needed to assess safety and

efficacy, but it can also facilitate, in some instances, early access to new medicines. A well-functioning clinical trial system in Canada, and globally, is important in order to ensure Canadians have access to safe and effective drugs. Having a transparent, strong and vibrant clinical trial system in Canada also helps to protect and maintain the key medical expertise in the country.

Ensuring a maximum degree of transparency of clinical trials is critical to give physicians and patients the opportunity to properly assess the effectiveness and potential dangers associated with a new drug. In this regard, it's important that clinical information from clinical trials - whether positive or negative - be transparent and available.

Recently, the Canadian clinical trial system has been criticized for its relative lack of transparency. For example, a survey of the international registries "clinicaltrials.gov" and "controlled-trials.com" showed that between May 2011 and May 2012 only about 50 per cent of the patient clinical trials filed with Health Canada were publically registered.³ In response, as of April 2013, Health Canada made their full database public. The Canadian life and health insurance industry supports Health Canada's commitment in this regard.

Ultimately, payers in Canada leverage the data from clinical trials to help in the assessment of the potential benefits of adding a new drug to their list of covered drugs. Generally, clinical trials are conducted by comparing the new drug's effectiveness against a placebo. While it is important to understand if a new treatment provides benefits over no treatment, in the majority of cases what a payer is assessing is the benefit of a new drug versus an existing drug or drug therapy.

THEREFORE, THE CLHIA RECOMMENDS THAT:

- **WHERE APPROPRIATE, CLINICAL TRIALS IN CANADA BE HEAD-TO-HEAD TRIALS BETWEEN THE NEW DRUG AND EXISTING DRUGS OR DRUG THERAPIES.**

³ http://www.hc-sc.gc.ca/dhp-mps/consultation/drug-medic/consult_ct_db_ec_bd-eng.php

a.2 Approval of New Drugs

Health Canada reviews every new drug product before it can be sold in Canada. The process can take between one to two years and includes three main steps as set out below.

1. The drug manufacturer must submit scientific proof to Health Canada that the product:
 - is safe;
 - does what it is supposed to do; and
 - follows all Canadian quality standards.
2. Health Canada reviews and approves the drug if it meets these conditions.
3. Health Canada issues a Notice of Compliance (NOC) and a Drug Identification Number (DIN) for all new approved drug products.

Overall, Health Canada strives to maintain a balance between the potential health benefits and risks posed by prescription drugs, with the highest priority being public safety.

a.2.1 Improving Speed to Market of New Drugs

The approval process for prescription drugs in Canada generally works well. Health Canada currently prioritizes the review of breakthrough drugs through its Priority Review of Drug Submission Policy. However, there may be scope to increase the pace with which new drugs get approved. For example, in 2010, Health Canada took 527 days, on average, to approve new drugs, up from 472 days in 2009. Moreover, between 2006 and 2010, Health Canada took longer to approve new drugs than regulators in Europe and longer than the U.S. FDA in six of the seven years spanning the period between 2004 and 2010.⁴

A thorough approval process is important to ensure that the health outcomes of new prescription drugs are well understood and that patient safety is protected. However, the

⁴ Mark Rovere and Brett J. Skinner. *Access Delayed, Access Denied 2012: Waiting for New Medicines in Canada*. Fraser Institute.

Canadian life and health insurance industry believes that Health Canada could seek further efficiencies and improve the speed to market of prescription drugs by, for example, recognizing approvals in select other jurisdictions.

THEREFORE, THE CLHIA RECOMMENDS THAT:

- **HEALTH CANADA SPEED UP ACCESS TO NEW DRUGS BY ENTERING INTO BILATERAL AGREEMENTS TO RECOGNIZE APPROVALS IN OTHER SELECT JURISDICTIONS, SUCH AS THE U.S. OR EUROPE, THAT HAVE PROCESSES SIMILAR TO CANADA'S WITHOUT IMPACTING PATIENT OUTCOMES.**

a.2.2 Post-Market Review of Prescription Drugs

The post-market review of prescription drugs is important to ensure that the benefits promised during the initial drug review and approval stage have actually been realized. Once a new drug is on the market, actual population exposure to the drug often differs significantly from the clinical trial samples, both in terms of the number and diversity of people receiving treatment. For instance, general population exposure may include people with multiple medical conditions taking a number of other medications and groups that were not tested during clinical trials (e.g., children and pregnant women) and will necessarily span longer timelines than was the case during the clinical trial phase. As a result, different effects may be observed post-launch than were seen during the clinical trial and approval stages.

Currently, there are limited regulatory requirements to ensure that drug companies conduct additional research into product safety and effectiveness once their drug has entered the market. Under the *Food and Drugs Act*, Health Canada has limited authority to deal with post market safety issues. Drug manufacturers are required by law to inform Health Canada of any serious adverse reactions to their products. If a serious health risk is identified, Health Canada can take action ranging from distributing new product safety information to the public and/or the health care community, to removing the product from the market. Health Canada does not itself do any follow-up analysis of effectiveness or adverse reactions; rather the onus is on the

drug manufacturer to raise concerns with Health Canada. Health care professionals and consumers may also report adverse reactions, although on a voluntary basis.

The Canadian life and health insurance industry believes that a robust post-marketing surveillance regime is needed in Canada. While there is no clear consensus on the best approach, globally, countries are moving to establish systems to track the safety and effectiveness of drugs post launch. We believe Canada should also move in this direction and that we can leverage the important work that has been done abroad in this regard.

THEREFORE, THE CLHIA RECOMMENDS THAT:

- **HEALTH CANADA ESTABLISH A NEW, ROBUST POST-MARKET SURVEILLANCE OF PRESCRIPTION DRUGS AND THAT IN DOING SO, HEALTH CANADA LEVERAGE LESSONS LEARNED FROM INTERNATIONAL EXPERIENCE.**

a.2.3 Off-Label Use

Off-label use of a prescription drug refers to a situation where medications are dispensed to treat conditions other than those for which they have received regulatory approval. Off-label use can also include prescribing different dosages or frequencies, lengthening or shortening the duration of treatments, or using different routes of administration than is indicated on the drug label. Health Canada does not regulate off-label use of medications and takes the position that physicians' prescribing practices fall under the jurisdiction of provincial and territorial medical regulatory authorities.

Roughly 11 per cent of medications are being prescribed off-label in Canada.⁵ A recent study led by researchers at McGill University raises some concerns with widespread off-label prescribing in Canada as, according to this study, nearly 80 per cent of off-label use lacked scientific evidence backing.⁶

⁵ Tewodros Eguale; David L. Buckeridge; Nancy E. Winslade; Andrea Benedetti; James A. Hanley; Robyn Tamblyn. *Drug, Patient, and Physician Characteristics Associated with Off-Label Prescribing in Primary Care*. JAMA Internal Medicine. May 28, 2012.

⁶ *ibid.*

In addition, off-label use can drive up costs to the system. This is particularly true with higher cost drugs where their original price was established based on a small estimated potential market but which, through off-label prescribing, ultimately has a much larger volume of sales in the market.

Prescribing off-label can be a valuable tool for physicians and is generally accepted medical practice. However, the life and health insurance industry believes that there should be greater oversight into the practice of off-label prescribing – not only to ensure patient safety but also to help with the financial sustainability of the system.

THEREFORE, THE CLHIA RECOMMENDS THAT:

- **HEALTH CANADA IMPLEMENT A GOVERNANCE AND MONITORING FRAMEWORK FOR OFF-LABEL PRESCRIBING THAT FOCUSES ON THE HEALTH IMPLICATIONS FOR CANADIANS AS WELL AS THE IMPLICATIONS FOR THE FINANCIAL SUSTAINABILITY OF DRUG COVERAGE IN CANADA.**

B. ENSURING AVAILABILITY OF COST EFFECTIVE PRESCRIPTION DRUGS

In order for Canadians to benefit from innovation in drugs, they need to have access, in a cost effective manner, to new drugs. The availability and relative cost of new drugs to Canadians is a function of a number of different factors.

b.1 Role of the Patented Medicine Prices Review Board (PMPRB)

The PMPRB is an independent quasi-judicial body established by Parliament in 1987 under the *Patent Act*. The PMPRB's mandate is primarily one of consumer protection and has two aspects:

1. Regulatory – to ensure that prices charged by patentees for patented medicines sold in Canada are not excessive.

2. Reporting – to report on pharmaceutical trends of all medicines and on R&D spending by pharmaceutical patentees.

With respect to pricing, the PMPRB sets the maximum price (the Therapeutic Class price) for new drugs in Canada using a blend of therapeutic improvement reviews and international referencing. PMPRB prices primarily impact those covered by private insurance and those paying out-of-pocket for their drugs and are of lesser importance for those on public drug plans due to the widespread use of product listing agreements (PLAs) by the provinces.

b.1.1 Fundamental Reform to PMPRB Mandate

The Canadian life and health insurance industry believes that the overall mandate of the PMPRB needs to be fundamentally reformed. Rather than setting therapeutic drug class pricing with the goal of ensuring drug prices “are not excessive” we believe that the mandate should be to strive for prices that are as low as possible based on the prevailing market forces. This would be more in keeping with the overall consumer protection goal of the PMPRB. It would also reduce many of the distortions and inequities currently in the market that result from artificially high PMPRB prices that then incent the proliferation of confidential PLAs by the provinces. Indeed, it is clear that the PMPRB reference price does not represent the true price in the market for the majority of Canadians. Accordingly, we believe that the PMPRB should no longer explicitly target prices against a select group of comparator countries.⁷ Rather as we outline in section b.1.2, the PMPRB should use a market-based approach to strive for the lowest possible price for Canadians. International price referencing should only be one input into what an appropriate price should be.

Fundamental reform often takes time to accomplish. Therefore, while this fundamental reform is being implemented, we believe that short-term action should be taken to help reduce prices

⁷ The PMPRB currently strives to set prices at the median of 7 OECD comparator countries, which include France, Germany, Italy, Sweden, Switzerland, U.K., and the U.S.

for Canadians. In this regard, until the mandate and operations of the PMPRB have been amended, we believe that the PMPRB should expand the list of comparator countries that are used to calculate the Median International Price Comparison with an eye to ensuring that the comparator countries are more representative of the OECD as a whole.

THEREFORE, THE CLHIA RECOMMENDS THAT:

- **THE MANDATE OF THE PMPRB BE CHANGED SUCH THAT ITS GOAL IS TO ACHIEVE THE LOWEST POSSIBLE PRICES FOR CANADIANS, LEVERAGING AN ECONOMIC AND MARKET DRIVEN PROCESS WITH INTERNATIONAL REFERENCING BEING ONLY ONE OF MANY INPUTS TO THIS PROCESS; AND**
- **IN THE SHORT-TERM, WHILE MORE FUNDAMENTAL REFORM IS BEING IMPLEMENTED, THE LIST OF INTERNATIONAL COMPARATOR COUNTRIES BE EXPANDED TO MAKE IT MORE REPRESENTATIVE OF THE ENTIRE OECD.**

b.1.2 More Aggressive Use of Value-based Pricing

One notable trend globally has been a recent move to "value-based pricing" by national regulators. Under value-based pricing agreements, payers and pharmaceutical companies agree to link payment for a medicine to value achieved, rather than volume. Agreements dictate price (and/or coverage) relative to actual, real-world performance.

In 2012, for example, Germany radically changed its reimbursement system to a value-based pricing system. Pharmaceutical companies have one year to prove the value of new pharmaceuticals when compared to existing offerings. Achieving value will result in obtaining a premium price compared to the competition; not achieving value will result in a price based on similarly effective, existing (and potentially generic) pharmaceuticals.

Beginning in January 2014, the U.K. is also moving to more of a value-based method of pricing. In their new model, the existing Pharmaceutical Pricing Regulation Scheme (PPRS) will be replaced with value-based pricing for branded medicines sold to the National Health Service (NHS)⁸.

The PMPRB currently uses a form of value-based pricing in that breakthrough prescription drugs have higher prices accorded to them than "me-too" type drugs. However, we believe that there is scope for Canada to be more aggressive in this regard. Value-based pricing provides an incentive for innovation in the marketplace as medications that offer no, or only limited, benefits would not receive premium pricing. In addition, a more aggressive use of value-based pricing would align with the industry's views and, as stated above, would move the PMPRB to a competitive, market-based approach to setting prices.

THEREFORE, THE CLHIA RECOMMENDS THAT:

- **THE PMPRB EXAMINE WAYS TO BE MORE AGGRESSIVE IN USING VALUE-BASED PRICING APPROACHES TO SETTING PRICES.**

b.1.3 Regular Review and Adjustment of Therapeutic Class Prices

The PMPRB rewards true pharmaceutical innovation with better pricing than "me-too" type drugs.⁹ However, all new drugs, even those that have no incremental therapeutic value, can price up to the top of their respective Therapeutic Class. Of the 109 New Drug Products

⁸ The U.K. will begin with a basic price threshold, expressed as cost per QALY or other outcome metric, and then include three factors: (1) BOI in terms of unmet treatment need or severity of illness; (2) extent of medication innovation involved; and (3) wider societal benefits.

⁹ It does this by applying the following pricing framework which is based on a therapeutic assessment of each new drug as follows:

- 1) Breakthrough – Median of International Price Comparison (MIPC)
- 2) Substantial Improvement – Higher of top of Therapeutic Class Comparison (TCC) and the MIPC
- 3) Moderate Improvement – Higher of mid-point between top of TCC test and the MIP, and top of TCC
- 4) Slight/No Improvement – Top of TCC.

introduced in 2011, only 1 per cent was ranked as breakthrough and only 5 per cent were classed as Substantial Improvement.¹⁰ Subsequently, prices can rise at a rate no faster than moving average of the Canadian consumer price index. There is currently no process for the PMPRB to reset Therapeutic Class prices over time if market conditions change.

Expanding Indications Impacts on Potential Market Demand: Case of Remicade

The experience of the drug Remicade over the last decade illustrates the significant impact expanding indications over time can have on the potential market for a new drug.

Remicade is Canada's second largest drug product, with sales of over \$500 million. It was first approved in 2001 for Crohn's disease and its price was set accordingly. The cost of Remicade can vary by patient based on body weight and indication, but generally has an annual cost of about \$35,000 per patient.

Since 2001, Remicade has been approved for an additional eight indications. While it is important to note that not all individuals with these conditions will be prescribed Remicade, based on the incidence of these additional indications in Canada, it is clear that there has been a material increase in the potential market for Remicade since launch. It should be noted that in addition to these additional indications, Remicade has also been used in off-label prescribing for autoimmune disorders such as Lupus and Graft versus Host disease, further increasing its potential market.

Indication		Number of Canadians Impacted
<i>Original Indication</i>	Crohn's Disease	130,000
<i>Expanded Indications</i>	Ulcerative Colitis	88,500
	Rheumatoid Arthritis	300,000
	Ankylosing Spondylitis	300,000
	Psoriatic Arthritis	250,000
	Plaque Psoriasis	470,000
	Lupus	50,000
	Total	1,588,500

Even though Remicade's potential market had dramatically increased, no follow-up review of its therapeutic class price has been undertaken by the PMPRB and, as a result, Remicade's price has remained constant over this period.

¹⁰ Michelle Boudreau, Executive Director, PMPRB, presentation at Pharma Pricing and Market Access Outlook Europe 2013 conference in London, UK (<http://www.pmprb-cepmb.gc.ca/english/view.asp?x=1511>)

The Canadian life and health insurance industry believes that it is important that a mechanism be developed to review therapeutic price levels on a periodic basis to ensure that the price ceilings reflect the current market reality. There are two situations, in particular, where we believe that it would be appropriate to reduce the therapeutic class price. The first situation is where the indications, or off-label use, for a particular drug have expanded to the point where the market they serve is significantly greater than for what the drug's price was calibrated to originally. The second situation is where there have been many new "me-too" type competitors in a therapeutic class. The industry believes that in these situations, it is reasonable that the therapeutic class price cap be re-evaluated and lowered.

THEREFORE, THE CLHIA RECOMMENDS THAT:

- THERAPEUTIC CLASS PRICE LEVELS BE REVIEWED PERIODICALLY (E.G., EVERY 5 YEARS) OR IF INCREASED INDICATIONS RESULT IN A MATERIAL CHANGE IN VOLUME (E.G., A 100 PER CENT INCREASE) TO ENSURE THEY REFLECT ANY MATERIAL CHANGES IN THE MARKET SINCE THE PRIOR REVIEW.

b.1.4 Introducing a Formal Institutional Role for Private Insurers

The PMPRB Board of Directors currently consists of not more than five members who are appointed by the Governor-in-Council. The current make-up of the PMPRB consists of individuals with backgrounds in medicine, public policy, pharmacy, law and education (e.g., university professors).

As we outlined above, the PMPRB pricing is particularly relevant for private payers in Canada, but not as much for public payers. We believe that there is a clear benefit to ensuring a meaningful private payer representation on the PMPRB Board going forward. This would help ensure that the Board's decisions and the PMPRB's overall strategy are clearly informed by the consumers whose interests they are mandated to protect.

THEREFORE, THE CLHIA RECOMMENDS THAT:

- **THE BOARD OF THE PMPRB BE REQUIRED TO INCLUDE PRIVATE INSURER REPRESENTATION TO ENSURE THAT THEIR PERSPECTIVES ARE CONSIDERED IN THE OVERALL OPERATIONS OF THE PMPRB GOING FORWARD.**

b.2 Provincial Listing Process

Once a drug is approved for sale in Canada by Health Canada and its reference price has been established by the PMPRB, the provinces, collectively, conduct a "value for money" assessment of new drugs as a key step in the decision on whether or not to list the new drug on the provincial formulary. There are essentially three processes as set out below.

1. NON-CANCER DRUGS (COMMON DRUG REVIEW - CDR)

The CDR is jointly funded by all provinces, except for Quebec, and reviews all non-cancer drugs. This review can take between six and eight months. The CDR does a cost-benefit analysis and recommendations for public funding are based on effectiveness and cost considerations. The CDR recommends which new non-cancer drugs should be covered under publicly funded drug benefit plans in Canada.

2. THE PAN-CANADIAN ONCOLOGY DRUG REVIEW (PCODR)

The pCODR is jointly funded by all provinces, except for Quebec, and reviews all cancer drugs. The review takes between five and eight months to complete. The pCODR review does a cost-benefit analysis and recommendations for public funding are based on effectiveness and cost considerations. The pCODR recommends which new cancer drugs should be covered under publicly funded drug benefit plans in Canada.

3. THE INSTITUT NATIONAL D'EXCELLENCE EN SANTÉ ET EN SERVICES SOCIAUX (INESSS)

In Quebec, INESSS conducts the evaluation of new drugs. The review does a cost-benefit analysis and recommendations for public funding are based on effectiveness and cost considerations. INESSS recommends which new drugs should be covered under RAMQ (and by extension private plans) in Quebec.

Once these recommendations are received by the provincial Ministers of Health, the provinces conduct an additional review with their own expert committees. These committees typically consider the drug's clinical value, patient and social impact, public and patient input and CDR/pCODR/INESSS recommendations. Ultimately, any decision to list a drug rests with the Minister in each province. It is at this stage that often the province enters into negotiations with the drug manufacturer on what are referred to as PLAs. As we discuss in section b.2.2 below, these agreements establish a confidential, lower, volume-based price for public plans.

Finally, as we mentioned above, this review process only begins after the Health Canada and PMPRB approval processes are complete. We believe that there is scope for the CDR/pCODR/INESSS to start their cost-benefit analysis earlier, potentially in parallel with Health Canada and PMPRB's reviews, as a means to accelerate the availability of new drugs for Canadians.

THEREFORE, THE CLHIA RECOMMENDS THAT:

- **THE CDR/pCODR/INESSS PURSUE OPPORTUNITIES TO RUN THEIR ASSESSMENTS IN PARALLEL WITH HEALTH CANADA AND PMPRB'S REVIEWS IN ORDER TO ACCELERATE THE AVAILABILITY OF INNOVATIVE DRUGS FOR CANADIANS.**

b.2.1 Product Listing Agreements (PLAs)

In an effort to control health care costs, PLAs are increasingly being used by provincial governments. PLAs are confidential, often volume based, agreements between the province and the drug manufacturer that establish the true effective price for a particular drug for the

province's public drug plan. Ontario has been a leader in this regard. For instance, from 2006-07 through to 2011-12, the province has negotiated roughly 175 PLAs with manufacturers. In addition, as of 2011, through the Council of the Federation's pan-Canadian bulk buying alliance, the provinces have collaborated on negotiating PLAs for 9 new drugs and an additional 18 are currently under negotiation.

PLAs are problematic for a number of reasons. First, they are confidential and end up pitting public plans against each other for better pricing. Second, this process disadvantages private plans and those paying out-of-pocket by ultimately keeping prices high for those purchasing their drug privately. Finally, the effective price for a drug after the PLA is negotiated, can result in the Minister making different cost-benefit listing decisions than what was recommended by the CDR/pCODR/INESSS reviews. This is a particularly challenging issue for private payers in Quebec (and likely New Brunswick going forward) because Quebec mandates a standard drug formulary that all private insurers must offer even though the private payer may not benefit from any reduced pricing. It is important to note that competition law restrictions make it very challenging for private payers to work together to enter into agreements similar to PLAs.

The Canadian life and health insurance industry feels strongly that there should be only one price for a prescription drug for Canadians regardless of whether they have public coverage, private coverage or are paying out-of-pocket. Any divergence from this fundamental principle creates a situation where Canadians are treated differently, and may have different access to drugs, with no basis in sound public policy.

As noted earlier in the paper, we believe fundamental reform to how PMPRB sets prices is required. We would note that a more market-based approach to setting prices will reduce the need for PLAs as the PMPRB price would already reflect market and economic factors. However, to the degree that PLAs continue to be used by the provinces in Canada, we believe that they should equally benefit private payers and Canadians paying out-of-pocket.

THEREFORE, THE CLHIA RECOMMENDS THAT:

- **TO THE EXTENT THAT PLAs CONTINUE TO BE USED BY PROVINCIAL GOVERNMENTS, THESE LOWER PRICES SHOULD BE EXTENDED TO ALL PAYERS.**

b.2.2 Assessing the Value of Genetic Tests

An emerging issue that has been raised by some stakeholders with the CDR/pCODR/INESSS approval process relates to the emergence of personalized medicine whereby tests can be done prior to administering a drug to determine whether an individual will respond to the drug. This is an exciting area of medical advancement and may drive down drug costs as only those likely to respond will be prescribed a particular drug. However, it is currently not clear which oversight body will assess the predictive value of a particular test. In addition, it raises the issue of whether a cost-benefit analysis of a particular drug should include both the costs of the test and drug - as in practice they will both be required for each patient.

At the moment, the respective mandates of the CDR/pCODR/INESSS address only drugs and not the tests and this represents a gap in the regulatory environment in Canada.

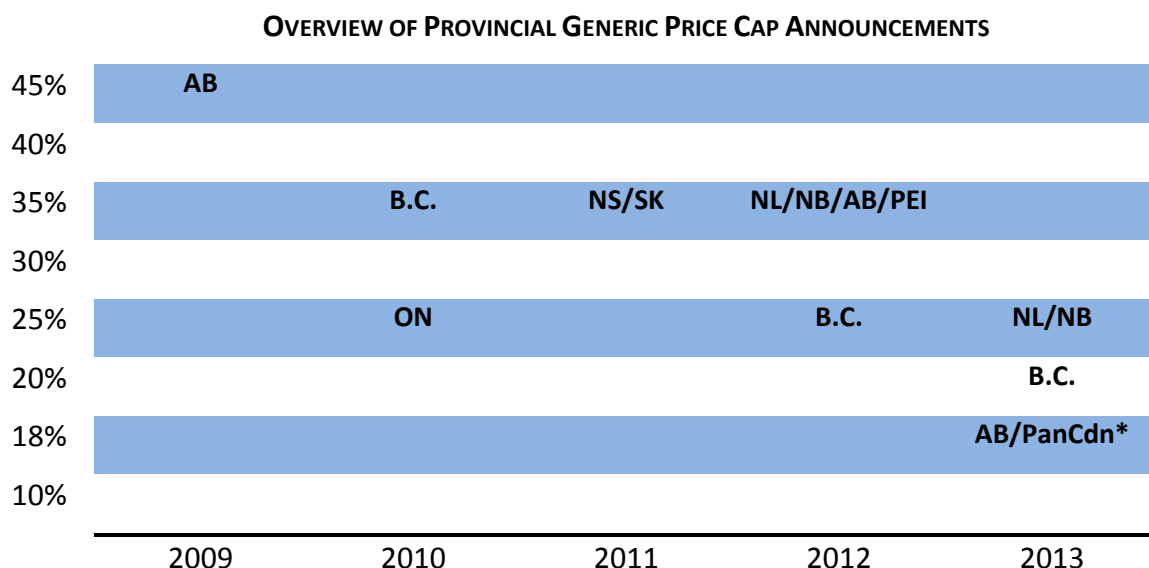
THEREFORE, THE CLHIA RECOMMENDS THAT:

- **THE CDR/pCODR/INESSS MANDATES BE EXPANDED TO INCLUDE GENETIC TESTS THAT ARE TIED TO PARTICULAR DRUGS AND THAT THEIR ASSESSMENT CONSIDER THE PREDICTIVE VALUE OF EACH TEST AS WELL AS THEIR RELATIVE COST-BENEFIT WHEN DONE IN CONJUNCTION WITH A DRUG.**

b.3 Bringing Generic Drugs to Market

Generic drugs are a safe and effective alternative to brand name drugs and their use plays an important part in helping to control prescription drug costs in Canada. As illustrated below, in late 2009, the Province of Alberta set an important precedent by announcing its intention to cap generic drug prices as a percentage of the brand name drug at 45 per cent for both public

and private payers. Since then, all provinces in Canada have aggressively pursued lower generic drug prices not only for their respective public plans, but private payers too.



* Pan Canadian purchase agreement set cap for all provinces, except Quebec, at 18% for 6 top selling generics

We applaud the provinces for the leadership role they have played in this regard. Indeed, this, coupled with the recent expiry of patents on a number of blockbuster drugs, has resulted in important savings for both provincial governments and private payers.

b.3.1 Reducing Need for Costly Litigation

The process for generic drugs to enter the market in Canada is not straightforward, however. The vast majority of generic drugs enter the market as a result of litigation brought by generic drug manufacturers against patents. In fact, 8 of the 10 top-selling generic drugs in Canada came to market through generic drug companies challenging patents, which the Canadian courts have determined are invalid or non-infringed.¹¹

¹¹ Canadian Generic Drug Association.

The current model of using litigation of patents to allow access to generic drugs is a relatively costly approach that would benefit from fundamental reform. We understand that the *Patent Act* will be opened up for review over the medium-term and as part of this review we believe that the approach to issuing patents for brand prescription drugs should be reviewed and updated to reduce the need for generics to litigate in order to gain market access.

In the interim, however, we recognize that the current system has some implicit disincentives for generic manufacturers to challenge patents which may be unnecessarily delaying the entry of new generics to market. For example, when a generic manufacturer is successful in its litigation (under regulations of the *Patent Act*) and is granted market authorization by Health Canada, the brand company can still sue the generic again on the same patent or patents under a separate legal action under the *Patent Act*.

In addition, once a generic manufacturer has succeeded in its patent challenge, several other companies who did not incur any litigation costs are often also ready to enter the market, driving down the available market share for the patent challenger thus reducing their opportunity to recover legal costs and so reducing the incentive to challenge patents. Although the challenger is entitled to damages for being kept off the market during the patent challenge, the damage entitlement has been narrowly construed to prevent recovery of the challenger's actual losses.¹²

In the U.S., this first mover disadvantage is addressed by providing a 180-day exclusivity period for the first generic company to successfully challenge a brand patent. This provides a six month period where the lead generic has exclusivity in the market and can recoup the costs of the legal challenge through market volume. If this were to be introduced in Canada the price of the generic would normally be regulated and therefore not subject to monopolistic pricing.

¹² Tim Gilbert and Nathaniel Lipkus, "The Social Value of the Pharmaceutical Patent Challenge : toward a better Canadian balance between innovation and access" GilbertsLaw.ca (March 2012)

THEREFORE, THE CLHIA RECOMMENDS THAT:

- DURING THE UPCOMING REVIEW OF THE *PATENT ACT* THAT AMENDMENTS BE MADE TO REDUCE THE NEED FOR UNNECESSARY LITIGATION IN ORDER FOR GENERICS TO GAIN ENTRY INTO THE MARKET; AND
- IN THE INTERIM, THAT CANADA INTRODUCE A 180-DAY EXCLUSIVITY PERIOD FOR THE FIRST GENERIC COMPANY TO SUCCESSFULLY FILE A GENERIC APPLICATION WITH A CHALLENGE TO A BRAND PATENT.

b.3.2 Generic Interchangeability

To market a generic drug, the manufacturer must file an Abbreviated New Drug Submission (ANDS) with Health Canada, containing data that demonstrates the drug's bio-equivalence with a reference product. The ANDS must contain sufficient information for Health Canada to assess the bio-equivalence of the generic to the reference product, as well as evidence of tests conducted on potency, purity and stability of the new generic drug.

Costs to Canadians of Delayed Listing of Generics - Example of Rosuvastatin

The current delay in time between when a generic drug is deemed bio-equivalent by Health Canada and when it is listed on a provincial formularies results in millions of dollars of unnecessary costs for Canadians on an annual basis. The recent experience with rosuvastatin - the generic version of the popular anti-cholesterol drug Crestor - is illustrative in this regard. As shown below, the delays in listing rosuvastatin provincially extended from 18 days up to six months in different provinces from the date rosuvastatin received its notice of compliance.

Rosuvastatin notice of compliance Received on March 15, 2012		
Province	Listing Date	Delays from NOC
British Columbia	April 2, 2012	18
Alberta	May 1, 2012	47
Saskatchewan	May 1, 2012	47
Ontario	May 29, 2012	75
Quebec	June 1, 2012	78
Manitoba	September 24, 2012	193
Newfoundland	October 1, 2012	200

Source: CGPA

The cumulative delays in listing of rosuvastatin cost Canadians over \$42 million in additional costs than they would have incurred had the drug been listed automatically.

Currently, the provinces subsequently conduct an additional assessment of the generic drug through their expert committees to establish whether or not to cover the generic drug. It is unclear what the benefit is of the additional review by the provinces in cases where bioequivalence has been established with the Canadian brand reference product. That is, if a brand drug has already been listed on the provincial formulary and a generic has been approved as bio-equivalent with the Canadian reference product by Health Canada, it would seem reasonable that the generic drug should be automatically deemed interchangeable. The additional expert committee review in these cases delays access by Canadians to the generic drug and delays savings to payers (both public and private) without any clear benefit.

THEREFORE, THE CLHIA RECOMMENDS THAT:

- WHERE A BRAND DRUG IS CURRENTLY ON A PROVINCIAL FORMULARY AND A GENERIC HAS BEEN APPROVED AS BIO-EQUIVALENT WITH THE CANADIAN BRAND REFERENCE PRODUCT BY HEALTH CANADA, THAT THE GENERIC BE AUTOMATICALLY INTERCHANGEABLE WITHOUT THE NEED FOR ADDITIONAL REVIEW BY THE PROVINCES AND AUTOMATICALLY LISTED.

b.3.3 Off-Formulary Pricing and Caps

There have been a number of initiatives introduced in the provinces to cap prices of generic drugs as a percentage of their brand equivalent. These initiatives have been effective in containing costs in recent years and we applaud governments on these efforts.

There are concerns, however, that generally the caps on generic prices apply only to those generic drugs that are listed on the public, provincial formulary. This creates an incentive for generic drugs to forgo listing on the provincial formulary in order to charge higher prices to private payers and those paying out-of-pocket in the province. This also deprives the public payers of the ability to benefit from the reduced cost of the generic alternative.

THEREFORE, THE CLHIA RECOMMENDS THAT:

- REGARDLESS OF WHETHER A DRUG IS LISTED ON A PROVINCIAL FORMULARY, GENERIC PRICE CAPS APPLY TO ALL GENERIC DRUGS APPROVED FOR SALE IN THEIR RESPECTIVE PROVINCE.

b.3.4 Clarity on Subsequent Entry Biologics (SEB) Approval Process

The introduction of SEBs is potentially an important market trend going forward from an affordability and sustainability perspective. Biologic drugs often provide significant improvement in health outcomes and can have dramatic and life altering impacts for patients.

At the same time, they can also be very expensive and, as outlined in the introduction of this paper, the growth in biologics is impacting the sustainability of drug plans in Canada.

Health Canada defines a SEB, or biosimilar, as a biologic drug that enters the market subsequent to a version previously authorized in Canada, and with demonstrated similarity to a reference biologic drug.¹³ To date there has only been one SEB approved in Canada. However, according to Health Canada, there are numerous potential SEB sponsors that will file in 2013.

In 2010, Health Canada published its finalized guidance document for the approval of SEBs. However, the SEB approval process is still quite uncertain and open to interpretation and we believe Canadians would benefit from greater clarity on how this process will work.

We also believe that it is important that there be a rigorous process to set SEB pricing in Canada. It is logical that the PMPRB should take this on in addition to its current role of regulating prices for new brand drugs and biologics.

THEREFORE, THE CLHIA RECOMMENDS THAT:

- **HEALTH CANADA CLARIFY ITS APPROACH TO REVIEWING AND APPROVING SEBS THROUGH, FOR EXAMPLE, A SPECIFIC REGULATORY PROCESS FOR THE APPROVAL OF SEBS; AND**
- **THE PMPRB SHOULD REVIEW AND REGULATE THE PRICING FOR SEBS GOING FORWARD.**

¹³ Health Canada Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs), 2010/03/05.

b.3.5 Interchangeability of SEBs and Safe Switching

Health Canada determines bio-equivalency between generic and brand drugs. The provincial government regulations then define rules for a pharmacist's ability to interchange a generic drug for a brand name drug. In the case of SEBs, however, Health Canada has stated that they are not generic biologics and therefore authorization of an SEB is not a declaration of pharmaceutical or therapeutic equivalence to the reference biologic drug. Therefore, SEBs are not interchangeable according to the process used for generic drugs.

While the industry recognizes that this is a challenging area, it is important that a process for establishing the interchangeability of SEBs be pursued. In this regard, Canada should look to work that has been done in other jurisdictions. For instance, according to the U.S. Biologics Price Competition and Innovation Act of 2009, a biologic is considered interchangeable if it "can be expected to produce the same clinical result as the reference product in any given patient." In addition, a standardized clinical guideline for safe switching from a biologic drug to its SEB would be beneficial for public and private payers and patients in Canada. How to safely switch from a biologic to a SEB is a complex issue that would be well suited to a standardized approach that is driven by the best available medical evidence.

THEREFORE, THE CLHIA RECOMMENDS THAT:

- **HEALTH CANADA DEVELOP A POLICY AND PRACTICE WITH RESPECT TO DESIGNATING SEBs AS BIO-EQUIVALENT (AND HENCE INTERCHANGEABLE) AND THAT THIS BE INFORMED BY THE WORK UNDERWAY IN OTHER JURISDICTIONS; AND**
- **THE COUNCIL OF THE FEDERATION'S HEALTH CARE INNOVATION WORKING GROUP DEVELOP NATIONAL CLINICAL GUIDELINES FOR WHAT WILL CONSTITUTE SAFE SWITCHING FROM BIOLOGICS TO SEBs THAT ARE GROUNDED IN THE BEST AVAILABLE MEDICAL EVIDENCE.**

C. IMPROVING REIMBURSEMENT MODELS

It is imperative that Canadians have access to the prescription drugs they need without undue financial hardship. The current system of drug coverage in Canada is a patchwork of public and private coverage. The Canadian pharmacare system is made up of 14 different public plans that are generally run independently of each other. Each has its own design features and characteristics with respect to reimbursement, approach to coordinating with the private sector and setting, among other things, formularies.¹⁴ Working in conjunction with this is the private payer system that in turn is highly complex with the coverage, formularies and terms of each plan determined by the plan sponsor (usually an employer).

Given the patchwork of coverage in Canada, understanding the system and individual coverage can be a significant challenge for physicians, pharmacists and Canadians. As well, the current patchwork of coverage in Canada results in gaps in coverage that can result in significant financial burden for some Canadians, depending, on where they live or who their employer is. Standardization across the system, therefore, is an important policy goal for Canada.

c.1 Standardized Coordination Processes

Transitioning between plans, whether public or private, is a challenge for an individual who has to do so. This can occur when an individual retires or reaches the age of 65, moves provinces, changes employers, is prescribed a new drug that is not on their plan's formulary or perhaps reaches a cap in their private coverage. In such situations, individuals are often faced with the very stressful challenge of navigating the system in order to maintain some form of support. Unfortunately, in extreme cases, individuals can be faced with having to re-qualify in

¹⁴ For example, currently in Quebec, even if a private benefit plan has a mandatory generic substitution policy, the plan must reimburse a minimum of 68 per cent of the full cost of the drug that was purchased by the individual - regardless of whether the drug that was purchased was the higher cost brand drug. The same limitation does not apply to the provincial public plan.

order to continue with drug they are currently taking or even potentially losing coverage they currently have. There is much scope for greater alignment of processes and collaboration across plans in Canada that would benefit physicians, pharmacists and Canadians.

THEREFORE, THE CLHIA RECOMMENDS THAT:

- **PROVINCIAL GOVERNMENTS COMMIT AS A PRIORITY, TO WORK WITH PRIVATE PAYERS TO DEVELOP TRANSPARENT AND EFFICIENT OPERATIONAL PROCESSES TO FACILITATE THE SEAMLESS TRANSITION OF PATIENTS BETWEEN PUBLIC AND PRIVATE COVERAGE.**

c.2 Development of Common National Minimum Formulary

Lack of harmonization on which drugs are covered in different public and private plans is a key frustration with the current system in Canada. Different drugs can be available to patients depending on their province and/or the plan design chosen by their employer. This may be particularly pronounced for new drugs. This complexity is problematic for prescribers and patients and ultimately undermines Canadians' confidence in the system.

The industry believes that Canadians would benefit from the establishment of a common national minimum formulary. A national minimum formulary would ensure a baseline of coverage for all Canadians and would reduce some of the existing complexity in the system. This would offer consistency across jurisdictions and coverage, which would benefit both consumers and prescribers across Canada. Moreover, this could help reduce the costs associated with the complexity of the system. In order for such a minimum standard formulary to be meaningful for Canadians, it would need to be comprehensive enough to address coverage of drugs that treat chronic illness and rare diseases. Such an approach would still allow those provinces, plan sponsors or individuals, who want additional coverage to have it.

THEREFORE, THE CLHIA RECOMMENDS THAT:

- **GOVERNMENTS, IN COLLABORATION WITH THE PRIVATE SECTOR, WORK TOWARDS
THE DEVELOPMENT OF A COMMON, NATIONAL MINIMUM FORMULARY.**

c.3 Development of High Cost Drug Strategy

Over the last few years there has been a significant increase in the number of very high cost prescription drug therapies available and being prescribed to patients and this trend is expected to accelerate. These prescription drugs have a significant annual cost (some can be well over \$50,000 per year) and are typically indicated for genetic enzyme disorders, cancer treatments, and auto-immune disorders. Such disorders are likely to be long-term in nature and to result in very significant ongoing costs.

Currently, specialty drugs represent about 20 per cent of plan costs for employers, but only one per cent of total claims. They are forecast to represent 25 to 35 per cent of cost by 2015.¹⁵ The rapid expansion of the incidence of very high cost and recurring drugs represents not only a significant challenge for employer sponsored plans, but for provincial drug plans as well.

To date, there has been no concerted action by provinces to implement a comprehensive high cost drug strategy. In spite of this, the Canadian life and health insurance industry launched a national drug pooling agreement in January 2013 that collectively protects fully insured private drug plans from the full financial impact of high cost drugs. This will help ensure that Canadians with fully insured employer drug benefit plans can continue to access the drugs they need. This initiative is a significant step forward but more can be done.

¹⁵ ESI 2011 Drug Trend Report.

While the largest provinces and private insurers have significant scale, the smaller provinces and private insurers do not have the same capacity to spread risk. Ultimately, the incidence of high costs drug treatments will strain the ongoing sustainability of the system and impact Canadians differently across the country.

THEREFORE, THE CLHIA RECOMMENDS THAT:

- FROM A SOCIAL POLICY PERSPECTIVE THAT IT WOULD BE IN THE INTEREST OF GOVERNMENTS AND PRIVATE INSURERS TO ENTER INTO A DIALOGUE TO DEVELOP A NATIONAL, COMPREHENSIVE, HIGH COST DRUG STRATEGY IN ORDER TO ENSURE THE SUSTAINABILITY OF DRUG COVERAGE GOING FORWARD.

D. IMPROVING COLLABORATION WITH KEY STAKEHOLDERS

Canada's health care system is currently made up of a number of siloed delivery systems whose actions nevertheless have significant impacts on each other from a cost and patient care perspective. This leads to inefficiencies and waste. Greater collaboration among health care professionals has the potential to deliver significant patient benefits and cost savings.

d.1 Introduction of Prescribing Committees

Prescribers are the start of the reimbursement process. While the vast majority of prescriptions are written by physicians, increasingly, other providers are able to do limited prescribing – including nurse practitioners and pharmacists. Decisions by prescribers have significant cost implications, particularly when they prescribe higher cost drugs where lower cost and equally effective alternatives are available. It would, therefore, be beneficial for Canada to develop processes and standards to help to ensure consistent high quality and cost effective prescribing of prescription drugs across Canada.

In this context, there are examples from other jurisdictions that could be leveraged. In the U.K., for example, prescribing committees have been adopted. These committees work at a regional level throughout the U.K. and are mandated to provide the strategy to ensure consistent high quality and cost effective use of medicines.

THEREFORE, THE CLHIA RECOMMENDS THAT:

- **PROVINCIAL GOVERNMENTS IMPLEMENT PRESCRIBING COMMITTEES, WHOSE MANDATE WILL BE TO SET PRESCRIBING STANDARDS FOR PRESCRIBERS BASED ON A RIGOROUS ASSESSMENT OF THE CLINICAL AND COST EFFECTIVENESS OF DRUGS.**

d.2 Encouraging Active Consumerism

Pharmacists represent the final step in the drug cost system and they play an important role in managing costs. For instance, pharmacists' mark-ups and dispensing fees, along with their ability to influence generic substitution or therapeutic substitution are key drivers of costs. While the manufacturer wholesale price of drugs is fairly consistent for both public and private payers, there can be significant differences in the price for private payers after the pharmacist mark-up and dispensing fees are factored in. This results in different prices for public and private payers, which clearly is not equitable.

The Canadian life and health insurance industry believes that it is important to encourage active consumerism in the market as a way to influence these pricing practices. In order for this to occur, however, consumers need to have visibility into these costs and also need to be better educated about the implications of cost on the sustainability of their drug coverage.

THEREFORE, THE CLHIA RECOMMENDS THAT:

- **ALL PHARMACY RECEIPTS IN CANADA CLEARLY DISCLOSE THE DISPENSING FEE CHARGED, AS WELL AS THE PHARMACY MARK-UP, IN ORDER TO INCENT A GREATER DEGREE OF CONSUMERISM IN THE MARKET.**

d.3 Expanding Pharmacists' Scope of Practice

Pharmacists can also play an important role in helping to better manage costs and improve patient outcomes. The industry supports the continued expansion of the scope of practice of pharmacists in Canada. Better leveraging pharmacists' capabilities will free up physician capacity, improve patient service and also reduce overall costs to the system.

As well, pharmacists can play an important part in improving overall prescription drug adherence by leveraging their detailed knowledge of their patients and their drug refill history. Better adherence to drug therapies will not only improve health outcomes but also reduce waste in the system which ultimately drives up costs.

Therapeutic substitution is important for both the public and private sectors. In this regard, a number of provinces now allow for therapeutic substitution by pharmacists. However, there remains work to be done on this front, as not all provinces in Canada have expanded pharmacists' scope of practice to allow for this. As well, in our industry's experience, there are relatively high administrative costs to pharmacists when doing a therapeutic substitution that act as a disincentive for doing higher volumes of therapeutic substitution. Governments need to address this through designing more streamlined processes if therapeutic substitution is going to meet its potential as a cost saving activity to the system.

THEREFORE, THE CLHIA RECOMMENDS THAT:

- **THERE BE A CONTINUED, THOUGHTFUL, EXPANSION OF THE SCOPE OF PRACTICE FOR PHARMACISTS AND, IN PARTICULAR, THAT ALL PROVINCES ALLOW FOR THERAPEUTIC SUBSTITUTION BY PHARMACISTS WITH THE MINIMUM DEGREE OF ADMINISTRATIVE COMPLEXITY.**

E. ENSURING ACCESS TO ORPHAN DRUGS

The Canadian life and health insurance industry believes that ensuring access to prescription drugs that effectively treat rare diseases is an important policy objective. This is particularly challenging, however, with orphan drugs, that only affect a very small number of patients (typically less than 5 in 10,000 persons).¹⁶

e.1 Collaborative End-to-End Approach to Approval and Funding of Orphan Drugs

Currently, orphan drugs are approved in Canada through the same regulatory process as other drugs. Alternatively, under the present Canadian system, a patient can apply for access to an unapproved drug if his or her physician makes an application under the Special Access Program (SAP). In each SAP application, a Canadian physician makes a request in respect of a single patient for up to a 6 month supply of an unapproved drug for emergency treatment purposes.

In October 2012, Health Canada announced that it is committed to developing a regulatory framework to be used specifically to approve orphan drugs. The new framework will be outlined in new regulations and these regulations will be subject to public consultation. The timeframe for the introduction of the regulations, however, is unknown at this time.

The Canadian life and health insurance industry supports the development of an orphan drug regulatory framework in Canada to approve orphan drugs. However, we believe that developing a new approval process for orphan drugs without due consideration for how the system will fund such new drugs will be problematic going forward and lead to serious disappointment if a patient cannot afford an effective drug. Accordingly, we believe that it is important for Canada to design and implement an end-to-end review and approval process for orphan drugs that will include not only a safety and effectiveness review but also work towards the establishment of an equitable and sustainable funding arrangement for such drugs.

¹⁶ http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/_2012/2012-147a-eng.php

This process should explicitly include public and private payers, pharmaceutical manufacturers, health care professionals (e.g., physicians) and patient groups. All stakeholder groups have a vested interest in working to design a robust approval and funding system that will be sustainable in the long-term and we believe that such a system will only be sustainable if it is designed collaboratively with all stakeholders.

THEREFORE, THE CLHIA RECOMMENDS THAT:

- **GOVERNMENTS LEAD THE WORK TOWARDS CREATING A NEW END-TO-END APPROVAL PROCESS FOR ORPHAN DRUGS THAT WILL INCLUDE NOT ONLY A SAFETY AND EFFECTIVENESS REVIEW BUT ALSO WORK TO ESTABLISH AN EQUITABLE AND SUSTAINABLE FUNDING ARRANGEMENT FOR SUCH DRUGS AND THAT THE REVIEW PROCESS SHOULD INCLUDE PUBLIC AND PRIVATE PAYERS, DRUG MANUFACTURERS, HEALTH CARE PROFESSIONALS, AND PATIENTS GROUPS.**

4. CONCLUSION & PRIORITIES FOR REFORM

The current system of pharmacare must be fundamentally reformed if it is to serve Canadians well in the long-term. This paper presents actionable recommendations to governments on a wide range of reforms that will help address the key gaps and sustainability challenges of the current system.

While all of the recommendations in this paper need to be addressed over the medium term, as a priority, the industry believes that reform should be undertaken as follows:

- Reform the Patented Medicine Prices Review Board's mandate and practices in order to achieve lower prices for all Canadians;

- Start a dialogue on creating a common, national minimum drug formulary to provide greater consistency in the system; and
- Governments work with all stakeholders towards the development of a collaborative, end-to-end approach to the approval and funding of orphan drugs in order to ensure Canadians' access to new orphan drugs going forward.

These reforms may take time to implement and the industry is cognisant of the pressing cost and equity challenges with the current system. While more fundamental reform is being pursued, therefore, the industry believes that a number of high priority, shorter term and tactical reforms should be undertaken to:

- Automatically list generic drugs on provincial formularies once they have been approved as bio-equivalent as a means to quickly realize significant costs savings for all Canadians;
- Implement improved processes for the transition of patients between public and private coverage in order to address the complexity and uncertainty that exists with the current system; and
- Develop a monitoring framework for off-label prescribing in order to address patient safety and cost escalation concerns.

The Canadian life and health insurers believe that the time for reform is now. We are committed to meaningful reform in this sector and look forward to engaging with governments and other stakeholders to ensure Canadians continue to benefit from a strong pharmacare system into the future.

LIST OF CLHIA RECOMMENDATIONS

A. ENSURING SAFETY AND ENCOURAGING INNOVATION

1. The CLHIA recommends that where appropriate, clinical trials in Canada be head-to-head trials between the new drug and existing drugs or drug therapies.
2. The CLHIA recommends that Health Canada speed up access to new drugs by entering into bilateral agreements to recognize approvals in other select jurisdictions, such as the U.S. or Europe, that have processes similar to Canada's without impacting patient outcomes.
3. The CLHIA recommends that Health Canada establish a new, robust post-market surveillance of prescription drugs and that in doing so, Health Canada leverage lessons learned from international experience.
4. The CLHIA recommends that Health Canada implement a governance and monitoring framework for off-label prescribing that focuses on the health implications for Canadians as well as the implications for the financial sustainability of drug coverage in Canada.

B. ENSURING AVAILABILITY OF COST EFFECTIVE PRESCRIPTION DRUGS

5. The CLHIA recommends that:
 - the mandate of the PMPRB be changed such that its goal is to achieve the lowest possible prices for Canadians, leveraging an economic and market driven

process with international referencing being only one of many inputs to this process; and

- in the short-term, while more fundamental reform is being implemented, the list of international comparator countries be expanded to make it more representative of the entire OECD.
6. The CLHIA recommends that the PMPRB examine ways to be more aggressive in using value-based pricing approaches to setting prices.
 7. The CLHIA recommends that therapeutic class price levels be reviewed periodically (e.g., every 5 years) or if increased indications result in a material change in volume (e.g., a 100 per cent increase) to ensure they reflect any material changes in the market since the prior review.
 8. The CLHIA recommends that the Board of the PMPRB be required to include private insurer representation to ensure that their perspectives are considered in the overall operations of the PMPRB going forward.
 9. The CLHIA recommends that the CDR/pCODR/INESS pursue opportunities to run their assessments in parallel with Health Canada and PMPRB's reviews in order to accelerate the availability of innovative drugs for Canadians.
 10. The CLHIA recommends that to the extent that PLAs continue to be used by provincial governments, these lower prices should be extended to all payers.
 11. The CLHIA recommends that the CDR/pCODR/INESS mandates be expanded to include genetic tests that are tied to particular drugs and that their assessment consider the predictive value of each test as well as their relative cost-benefit when done in conjunction with a new drug.

12. The CLHIA recommends that:

- during the upcoming review of the *Patent Act* that amendments be made to reduce the need for unnecessary litigation in order for generics to gain entry into the market; and
- in the interim, that Canada introduce a 180-day exclusivity period for the first generic company to successfully file a generic application with a challenge to a brand patent.

13. The CLHIA recommends that where a brand drug is currently on a provincial formulary and a generic has been approved as bio-equivalent with the Canadian brand reference product by Health Canada, that the generic be automatically interchangeable without the need for additional review by the provinces and automatically listed.

14. The CLHIA recommends that regardless of whether a drug is listed on a provincial formulary, generic price caps apply to all generic drugs approved for sale in their respective province.

15. The CLHIA recommends that:

- Health Canada clarify its approach to reviewing and approving SEBs through, for example, a specific regulatory process for the approval of SEBs; and
- the PMPRB should review and regulate the pricing for SEBs going forward.

16. The CLHIA recommends that:

- Health Canada develop a policy and practice with respect to designating SEBs as bio-equivalent (and hence interchangeable) and that this be informed by the work underway in other jurisdictions; and
- The Council of the Federation's Health Care Innovation Working Group develop national clinical guidelines for what will constitute safe switching from biologics to SEBs that are grounded in the best available medical evidence.

C. IMPROVING REIMBURSEMENT MODELS

17. The CLHIA recommends that provincial governments commit as a priority, to work with private payers to develop transparent and efficient operational processes to facilitate the seamless transition of patients between public and private coverage.
18. The CLHIA recommends that governments, in collaboration with the private sector, work towards the development of a common, national minimum formulary.
19. The CLHIA recommends that from a policy perspective that it would be in the interest of governments and private insurers to enter into a dialogue to develop a national, comprehensive, high cost drug strategy in order to ensure the sustainability of drug coverage going forward.

D. IMPROVING COLLABORATION WITH KEY STAKEHOLDERS

20. The CLHIA recommends that provincial governments implement prescribing committees, whose mandate will be to set prescribing standards for prescribers based on a rigorous assessment of the clinical and cost effectiveness of drugs.

21. The CLHIA recommends that all pharmacy receipts in Canada clearly disclose the dispensing fee charged, as well as the pharmacy mark-up, in order to incent a greater degree of consumerism in the market.
22. The CLHIA recommends that there be a continued, thoughtful, expansion of the scope of practice for pharmacists and, in particular, that all provinces allow for therapeutic substitution by pharmacists with the minimum degree of administrative complexity.

E. ENSURING ACCESS TO ORPHAN DRUGS

23. The CLHIA recommends that Governments lead the work towards creating a new end-to-end approval process for orphan drugs that will include not only a safety and effectiveness review but also establish an equitable and sustainable funding arrangement for such drugs and that the review process should include public and private payers, drug manufacturers, health care professionals, and patients groups.

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