Provincial Industry-Payer Agreements in an Era of National Pricing Strategies

National Roundtable

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Executive Summary

In May 2013, the Institute of Health Economics held a National roundtable on product listing agreements (PLAs) in light of Canada's provincial payers moving to a Pan-Canadian Pricing Alliance (PCPA) for pharmaceutical reimbursement. The roundtable brought together industry leaders, senior decision makers and academic experts to promote a common understanding of the current landscape, allow frank discussion and sharing of perspectives and identification of key issues to support future areas of focus and policy development. In particular, the roundtable was an opportunity to have stakeholders discuss the current and future state of industry-payer agreements and price negotiation in Canada, and to discuss opportunities and challenges facing policy development in this area. The meeting covered issues such as: pricing and determining value in agreements; Canadian and international PLA experiences; provincial versus pan-Canadian approaches; and how to instill principles and pragmatism to move forward in Canada on effective and efficient pricing approaches.

Key messages arising from the roundtable were:

- PLAs are providing access to new drugs for patients, despite implementation challenges around determining value-based pricing.

- "Value" needs to be defined in a consultative way that takes into account multiple concepts of value, and allows the final definition to be acted upon to provide evidence-based pricing decisions that reflect opportunity costs.

- Applying PLAs both across provinces and drug classes could add significant value to pricing decisions for patients and the public (increasing access and efficacy).

- Ability to pay will be a key issue in the new PCPA agreements, with different provinces experiencing different abilities to pay for desirable drugs. It is important that this issue is addressed to help to avoid "postcode prescribing".

- Accountability, transparency and confidentiality need to be carefully considered in agreements through the PCPA. Agreement details can remain confidential, but agreement processes and measurable outcomes should be transparent and accountable.

Based on the above key messages, the roundtable suggested the following next steps for PLAs and pricing approaches in Canada:

- There should be continued engagement between industry and payers to ensure that the principles and rules underlying the use of PLAs and agreements through the PCPA take into account key viewpoints.

- As part of this, industry and payers should work to develop an agreed notion of value for new drugs in Canada.

- Canada can lead the world in developing a definition of value that can be used to underpin agreement decisions, as well as developing frameworks and tools to determine the most appropriate pricing approaches to address different types of uncertainty for new drugs.

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Introduction

In 2011, the Institute of Health Economics (IHE) held a National roundtable discussion on innovative approaches to industry-payer agreements. Since then, Canada has undergone a transformation in its industry-payer landscape with the introduction of the pan-Canadian Pricing Alliance (PCPA). To address this and other changes and how they affect stakeholders in drug reimbursement, the IHE convened a new National roundtable to again bring together industry leaders, senior decision makers and academic experts. The aim of the roundtable was to promote a common understanding of the current landscape, allow frank discussion and sharing of perspectives and identification of key issues to support future areas of focus and policy development. In particular, the roundtable was an opportunity to have stakeholders discuss the current and future state of industry-payer agreements and price negotiation in Canada, and to discuss opportunities and challenges facing policy development in this area.

Building on the 2011 meeting, this roundtable looked to expand the shared understanding of what industry-payer agreements are, how they are negotiated and the challenges felt on either side of agreements. The 2011 meeting discussed the typology of "innovative" industry-payer agreements, with a particular focus on health outcomes-based approaches around the world and within Canada. This discussion led to an identification of the main barriers and facilitators seen by stakeholders related to moving forward with "innovative" agreements.

The 2013 roundtable built on the shared understanding of agreements from 2011, and particularly on the shared definitions around the challenges and opportunities for innovative agreements - now called "product listing agreements" (PLAs). The meeting developed from initial presentations from speakers covering concepts such as: defining value delivered by drugs; changes in pricing and PLAs since 2011; international PLA experiences; and, the PCPA. Participants were then engaged in discussion around three key issues at the heart of PLAs in the PCPA era in Canada:

1. Pricing and determining value;
2. Provincial versus Pan-Canadian Approaches; and,
3. Principles and Pragmatism – Moving Forward in Canada.

Each of these three issues was developed through initial comments from payers, academia or HTA experts and industry followed by general discussion to ascertain and explore stakeholder viewpoints and common ground.

This report outlines the main lessons and issues raised at the meeting.

HTA and Value

Opening the roundtable was Alberta's Minister of Health, the Honorable Fred Horne. He set the scene for the meeting by outlining the synergy felt by industry and policy makers in wanting improved access to new drugs for patients through pooling resources and creating a more nuanced understanding of what value means in pricing agreements. He also noted

> *"Ministers seem truly interested and committed in discussions that revolve around pooling our population health risk and pooling our resources on a pan-Canadian basis in order to deliver better access to pharmaceutical products for Canadians."*

that policymakers are interested in becoming "price makers, not price takers" – playing a more pivotal role in defining value for new drugs and how pricing should reflect that value.

This theme of value was expanded on by the first speaker and moderator, Dr. Chris Henshall, Chair of the HTAi Policy Forum.[1] Dr. Henshall presented thinking from the most recent HTAi Policy Forum meeting that discussed HTA and value, beginning with the concept of value and who should define it. He outlined that definitions of value vary between stakeholders (such as patients, the public, decision makers and industry), but the common core element of value in drug pricing decisions was health benefits for patients (with more debatable concepts of value extending to wider benefits for patients, society, caregivers, public health, innovation, the economy and the health system).

"As the old saying goes, value is in the eye of the beholder."

Measuring the value of new drugs is problematic, even with a standard definition of value. Value has predominantly been measured as improvements in overall health, such as through quality-adjusted life-years (QALYs), but there are wider elements of value that could be applied. Even with agreed measures, the value of differences in these measures needs to assigned and recognized. Techniques typically used for this include utility measures in QALYs, or clinically relevant differences in health outcome measures.

When an approach has been agreed to defining and measuring value of a drug, there is a need for an approach to factor it into decision making on pricing. Decision makers are increasingly interested in value for money and the relation of measures of benefit to costs. While value for money is a key consideration in decision making, there are a wide variety of other factors decision makers need to take into account around pricing and reimbursement decisions (such as political expediency, patient need, population dynamics etc). When considering value, decision makers use a combination of formal and informal processes. While different countries have different approaches to measuring value (either with a main focus on measurement of cost-effectiveness assessed using utility-based measures such as QALYs, or assessment of clinical added value), they all focus on value as patient health plus additional wider value elements as considered appropriate for the drug and the illness or patients group(s) involved. They all also use a combination of formal measures of value and judgement of value by decision makers.

One key aspect of value that needs further discussion is the value of innovation. Currently, assessment of health technologies seeks to measure the benefits of an innovation, but may not fully capture at launch all value that a technology may offer – for example benefits only delivered or understood when use of the technology has developed, or benefits arising from further development of the innovation platform on which the technology is based. One approach to managing this uncertainty of ultimate benefit might be to move towards "pro-imbursement" - purchasers and industry working together on the joint development, adoption and funding of new technologies to support agreed unmet needs, building on the foundations of current approaches to "managed entry" It should be noted, however, that significant public support is already provided through public funding for R&D, tax-breaks for innovation, so incorporating the value of innovation into pricing needs to take these existing value structures into account.

[1] The HTAi (Health Technology Assessment International) policy forum is brings together senior people from public and private sector organizations with strategic interests in HTA, members of the HTAi Board, and invited international experts, for strategic discussions about the present state of HTA, its development and implications for health care systems, industry, patients and other stakeholders. The Forum provides an environment where senior people can engage in strategic discussions informed by the perspectives of their different organizations without the constraints associated with discussions of specific products or organizational policies. (http://www.htai.org/index.php?id=643)

Dr. Henshall concluded that health system decision makers, and those who do HTA to support them, need to provide clear signals about how they will define and pay for value. Without such signals, industry and capital markets may be reluctant to make the major long-term investments that are needed to bring new drugs and other technologies to market. To make a system of value-based technology development and adoption work, there is a need to:

- Develop a framework for the definition and assessment of value (one that is clear but not over-restrictive for either side);
- Develop detailed guidance on measurement of value for specific disease areas;
- Further develop joint scientific advice for industry from regulators and HTA / coverage bodies for specific products;
- Explore a framework for progressive licensing and utilization for reimbursement that can help us to incorporate our evolving understanding of value of an innovation; and,
- Improve the adaptation of HTA and coverage/procurement to also cover medical devices.

International Perspectives

International approaches to pricing and reimbursement provide a number of examples from which Canada can learn. Professor Mike Drummond from York University in the UK identified some of the main issues from other countries that are particularly relevant to the Canadian discussion of value and PLAs.

Dr. Drummond began by providing an overview of different examples of PLAs, including price-volume, pay for performance and value-based pricing (VBP) approaches. Price-volume are the simplest forms of PLAs, with calculations of price related to appropriate use of the drug. Price-volume approaches have been shown to be useful where drugs have value that varies across interventions. Pay for performance approaches are used where there is an element of uncertainty around a drug – since the performance of the drug in patients forms part of the evaluation of price. Pay for performance approaches face significant challenges in designing studies to monitor performance, paying the cost of monitoring, and enforcing pricing policies based on monitoring findings.

VBP approaches are used differently in different countries. For example value assessment approaches, transparency of agreement processes and confidentiality of prices differ. In the UK, a proposed framework for VBP negotiations is based on an open cost-per-QALY value, burden of illness and unmet need, the extent of therapeutic innovation and some concept of wider societal benefits (such as impacts on caregivers). Several issues still exist around value in the UK system however. For example, how should value be calculated (what balance of factors); how does local decision making on what constitutes value (such as whether a cost per QALY value is sufficient for local decision making) factor into decisions; how can VBP deal with multiple indications for a therapeutic product; and what level of transparency should be in place for decision-making processes (should there be publication of assessments or prices)?

Internationally, VBP is typically implemented through two main approaches – assessments based on overall economic impact (such as the UK) and the use of clinical benefit or disease-specific value scales (such as in Germany and France). A study from the University of York compared 41 cancer drugs assessed by the UK and French systems and identified correlations between QALY values and clinical benefit scores – so the same drugs tended to be considered high value under each approach. This suggests that the systems are measuring the same sorts of value. While QALY approaches tend to be more transparent that clinical grading approaches,

there does seem to be international convergence to systems that take into account both quantitative measures and expert judgement. For example, the French system is moving into an incremental cost per QALY process to support decisions on drugs that score highly on the clinical judgement scale. All jurisdictions bring multiple factors into price negotiation, it is just that some are explicit and others are not.

Confidentiality of agreements varies between countries. For example, France, Sweden and Australia have confidential agreements, while Germany and the UK have more transparent agreements. In the UK, patient access schemes create this transparency and provide details on decision making and agreements. The patient access schemes in the UK have tended to focus on price-discounts (with over half the cancer drugs purchased through schemes having price-discount agreements), although these price-discounts are only shared within the UK (not internationally).

It is clear from international experience that VBP is an excellent starting point for PLAs. Different jurisdictions use specific approaches to value where they are most appropriate, and vary in their use of transparency. Confidentiality of prices does seem to still secure the most favourable deals for jurisdictions – where access can be improved to improve public health – meaning that transparency remains a desirable but likely unobtainable goal. In addition, reference pricing across international jurisdictions makes transparent pricing undesirable for industry and difficult to implement. Another presenter identified the mechanisms that would be needed to establish VBP (Figure 1).

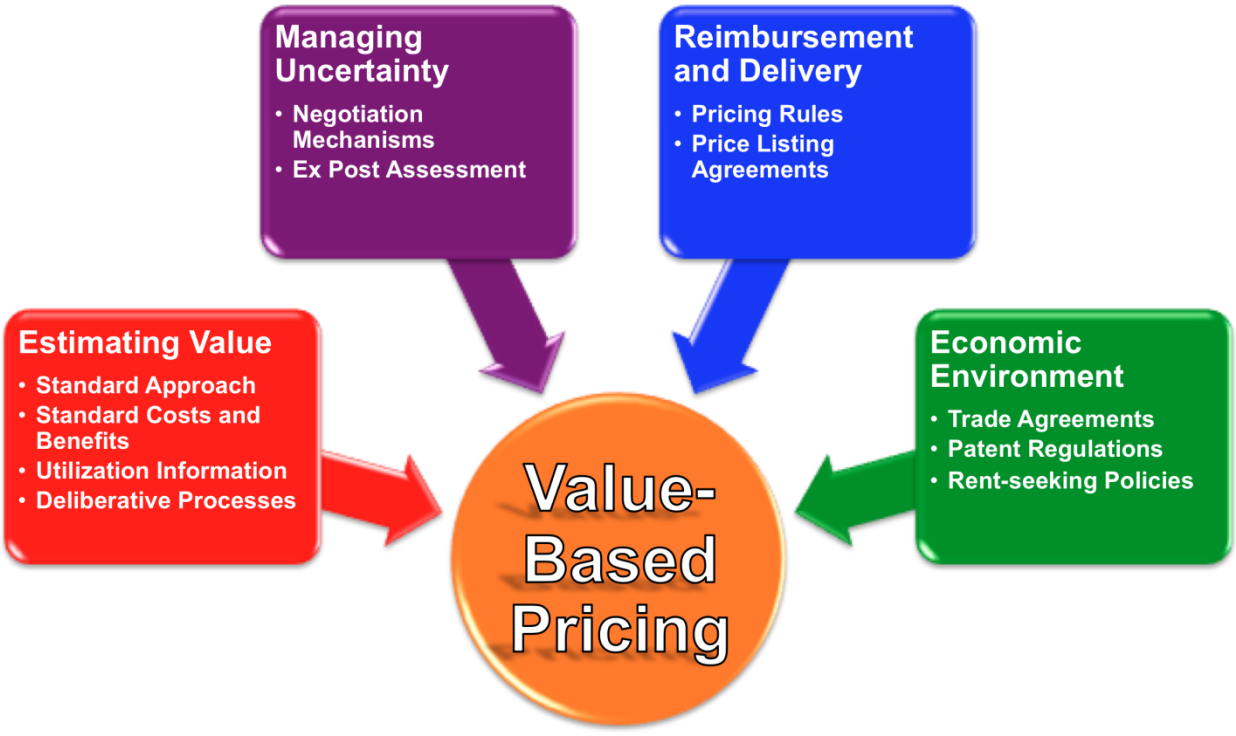


Figure 1. Mechanisms needed for VBP.

The Canadian Situation

Eddy Nason from the Institute on Governance presented background on the current situation in Canada, including how things have changed since 2011's first IHE roundtable on industry-payer agreements. Canada's role in global conversations about PLAs is an interesting one, bearing in mind the changes to the Canadian situation over the last 2-3 years.

In 2011 Canada was in the position of developing and implementing a number of approaches to PLAs – ranging from price-volume arrangements to coverage with evidence development approaches. In addition, it was clear that provinces were developing strength in creating PLAs. The previous roundtable surmised that these PLAs would become more prominent in Canada and would need a combination of a more nuanced understanding of outcomes, value, bringing value to patients, evidence development, and, when and where to use different types of PLAs to reduce uncertainty and add value. However, there were still issues around agreements, for example the contradiction of federal decision making on safety and efficacy through the common drug review, but provincial decision-making on value and listing.

Pricing for drugs from the point of view of payers is generally seen as a response to a number of factors. Simplistically, this can be considered the intersection of containing costs, rewarding innovation and promoting access to health (Figure 2).

Figure 2. Price as a response to three factors

Not long after the 2011 meeting, there was a clear move in Canada to the provinces working together to leverage their purchasing power and knowledge through the development of the pan-Canadian Pricing Alliance.

Pan-Canadian Pricing Alliance

Diane McArthur, ADM at Ontario Ministry of Health and Long Term Care, provided an overview of the PCPA from the perspective of one province that has been engaged in the ongoing development of the alliance. The PCPA initiative is being driven by Council of the Federation discussions, where all provinces (except Quebec) are working to demonstrate Pan-Canadian approaches to support the Canadian health system in the withdrawal of federal leadership in health. PCPA has provinces using collective pricing power to drive down the price of drugs for provincial health systems, address issues of comparative benefit (such as drug cost-benefit versus population health intervention cost-benefits), and avoiding the issue of "whipsawing" (using one province's decision to pay for a drug to put political pressure on other provinces to purchase the drug). The sustainability of public funding in the context of overall health care spending is a concern for all public payers, and this has driven the development of the PCPA with five objectives:

> *"All of us in the public sector are concerned about the escalating costs in the health care system."*

- Increase access;
- Improve consistency of drug listing decisions;
- Capitalize on combined buyer power;
- Ensure consistency of access across provinces and lower costs; and,
- Reduce duplication in negotiations.

At the time of the roundtable the PCPA had negotiated the price of 10 drugs, with 17 ongoing. Every drug that comes through the common drug review is seen as a potential PCPA agreement – with that decision being made by the provinces together. While all provinces together make the decision on whether to collectively price negotiate, individual provinces lead on each negotiation.

Some of the challenges identified in the PCPA approach so far include differences in public plan structures across provinces (including drug program recipients, legislation, regulations and policies, and approaches to formularies), engaging multiple firms in PCPA discussions, and identifying ways to make the PCPA sustainable and appropriate to deliver value for multiple stakeholder groups.

PLAs still form a large part of the PCPA approach. It was stated that PLAs have been valuable for provinces prior to the PCPA – allowing earlier access to drugs and engaging a level of discussion with industry that had not existed in standard pricing agreements. They had also allowed better predictability and management of provincial purchasing budgets, improved value for money in pricing decisions and developed trust and confidentiality between industry and decision makers. It was made clear that PLAs are here to stay in the PCPA environment, since PLAs have been successful, will increase the number of therapies available to patients and the approaches themselves will evolve over time to become more effective, efficient and appropriate. A number of challenges to PLAs in the PCPA were identified however, including: equitable risk sharing approaches, improving outcome measures, assessing drug categories rather than individual drugs, wait times for Canadian company affiliates when dealing with international head offices, balancing innovation with cost for industry, and addressing confidentiality and transparency. One key issue for PLAs in the PCPA is the concept of common contract for all provinces (bearing in mind ability to pay issues).

Discussions amongst stakeholders

With a shared understanding of the context of PLAs in the current Canadian and international context, roundtable participants engaged in discussions over three main issues:

- Pricing and Determining Value;
- Provincial versus Pan-Canadian Approaches; and,
- Principles and Pragmatism – Moving Forward in Canada.

Within each of these issues, discussions were initiated by thoughts from respondents representing industry, academia / HTA, and public payers.

Pricing and Determining Value

The discussion around pricing and determining value centered around 2 main issues: the factors involved in pricing decisions; and payers' ability to pay and need to set priorities for the use of resources.

Factors in pricing decisions

The group considered a number of factors that should be considered in pricing decisions – from both sides of the agreement.

- **Clinical value and comparative value**
  Clinical value is seen as the most important factor by the public and as such is a key part of the thinking of decision makers. Comparative value with other drugs on the market is central to determining clinical value, with price being considered after clinical and comparative value. However, health system decision makers felt that there is often insufficient information on comparative value, particularly around high price products (where comparative information would be most useful).

- **Opportunity costs**
  One key aspect about value that was discussed by the group was the issue of opportunity costs – in health systems with limited budgets, do the benefits of purchasing a new drug exceed the health and other benefits lost as a result of its additional costs? It was stated that there needs to be an approach to assessing what payers (and, indeed, the public) are willing to give up elsewhere in the system to get the benefits of a new drug.

- **Drug classes**
  Payers noted that in terms of adding value to the health system, it would be important to be able to consider the value of whole classes of drugs (often across different pharmaceutical companies). This is clearly a complex issue when it comes to PLAs: while payers may review a class of drugs to guide their decisions on particular drugs within it, individual companies will only wish to discuss PLAs around their own drugs. However, from a payer and health system perspective, being able to link price to the value for a class of drugs rather than individual drugs would allow for more appropriate access and coverage for patients.

- **Value of innovation**
  Payers have a relatively strong approach to identifying the value of an innovation; in their view, the public wants improved health and that is therefore the appropriate measure for

determining the value of a new drug. However, while this approach can identify the clinical value of the new drug, it cannot strongly identify whether investment in that drug provides better value for payers compared to investments in other health and wellness approaches.

Industry argued that taking a narrow view of value as simply improved health in the population would not allow for a realistic return on their large R&D investment. This issue is particularly important in areas of significant unmet clinical needs where existing treatments are relatively cheap and where new treatments may offer clinically worthwhile benefit but are unlikely to deliver sufficient health gain to justify a price to provide a worthwhile return for investors. The strict determination of price by incremental health gain may therefore potentially deter innovation in clinically important areas.

- **Horizon scanning**
  One major issue with drug pricing is around the timelines to develop drugs – both first in class and follow on drugs in the same class. There is a perception amongst payers that follow-on drugs often hit the market around the time that the first in class is coming off patent. Such drugs have often been paid for in the past, but it is unlikely that they will be seen to offer value for money in the current financial climate unless they offer substantial improvements over cheaper generic versions of the first in class. This suggests that there could be a role for improved horizon scanning and planning by both payers and industry that would allow the development and uptake of products that can add value and represent value for money at the time at which they are released, rather than at the time of conceptualization.

  Related to this, industry identified that in the past payers had requested drugs for particular health issues and when the drugs finally arrived, payers were unable or unwilling to pay the full cost of the drug despite requesting the drug in the first place. Horizon scanning would also allow industry to manage the entry of products into the market so high cost products don't all hit the market at once (creating problems for payers prioritization). In addition, horizon scanning for payers can allow the management of other capital costs (e.g. high technology platforms, diagnostics etc) with knowledge of likely drug costs.

Ability to pay and prioritization

From the payer's point of view, the ability to pay and the prioritization of which drugs to purchase are key aspects in the future development of any payment approach (be it individual PLAs or agreements through the PCPA).

- **Ability to pay**
  In the Canadian provincial system, it was noted that in order to get equity of access to drugs, there will need to be inequity of prices across provinces – since difference provinces have different abilities to pay. One suggestion to address this was to have the PCPA organize PLAs with rebates differing between provinces. In Germany "sick-funds"[2] have a risk-structure adjustment to adjust for ability to pay across the country, so richer funds pay into poorer funds where needed. The point was made that willingness to pay is not the same as ability to pay and both are involved in arriving at product listing decisions.

- **Industry tasks and costs**

[2] Sick-funds are statutory health insurance schemes in Germany for all earning over a certain threshold (c.f. http://www.civitas.org.uk/pubs/bb3Germany.php)

From the industry point of view, following the success of many "blockbuster" drugs, R&D investments are increasingly being made in niche areas with higher risk of failure, so that R&D investments are likely to be less efficient than in the past. For "*me-too"* products it is more clear what kind of pricing will make it an interesting option for payers to take on (where the driver for payers is something cheaper than the current option). For new types of drug, there is a need for a clear definition of what value means for the payer, early in the drug development process. Hopefully, R&D investments can then be aligned with payer's views of the priorities amongst unmet health needs of the population and the value of health gain in different areas. A current example of the challenges in this are drugs for rare disorders that may be given high do-not-list recommendations on account of their very high price, but often get listed anyway because they address a clear need in the population that the public and politicians find it difficult to ignore. In addition, understanding what value will mean for the drug, also allows investments made now to develop value even with the time-lag between identifying need and providing the drug (i.e. industry recouping the investment).

- **Payer prioritization**

  Payers explicitly need to identify their prioritization approach for selecting those technologies and services they will purchase with the funds available to them. There are a number of factors that need to be taken account of when prioritizing. First, there is the health gain and opportunity cost already mentioned (and, as noted above, the ability and willingness of payers to pay for health gain may vary, even within the PCPA).

  Second, there is the prioritization of either addressing unmet need, or incrementally improving on the treatment offered by existing medicines (currently the former has been prioritized). For this second issue, there was debate over whether the current cost-per-QALY approach to analyzing health value was the most appropriate to determine priorities for new drugs. A prime example of this issue is the approach to rare-diseases (noted above), where payers may need to prioritize health gains for a small group or even an individual over potentially larger population health gains. One suggestion to address this specific issue was a national program on rare and orphan diseases (although this would still require some payer prioritization of investment into the national program over investment elsewhere). The rare disease issue also highlights the opportunity cost problem, since those with rare diseases are easily identified and their health gains easily quantified – however, much larger populations could see the same total health gain with much smaller health improvements that may be difficult to identify.

  Third, there is a need for industry and payers to understand that everyone is taking a risk in developing and purchasing a new drug. Payers and industry will need to understand what agreements will manage utilization, education, and promotion of products; as well as understanding what to do about lesser effectiveness of products in the real world (both responsibility for change and actions to make changes).

  In reality, both payers and industry agreed that there are efficiency issues in the current health system, and that improving the efficiency of health care would allow greater investment in other areas of the health system (such as drugs for rare and other diseases). Efficiencies are particularly hard to come by where the health system makes investments in rare or orphan diseases that have little existing infrastructure support – since investments in these conditions cannot leverage existing health infrastructure.

Provincial versus Pan-Canadian Approaches

The second discussion amongst participants was around how provincial approaches to pricing fit with pan-Canadian approaches. This is particularly important in the current climate where the PCPA is becoming more prominent in negotiations while existing provincial deals are maintained and run down.

- **Defining when payers or industry are in or out of PCPA negotiations**
  Knowing when either side of an agreement can partake in or remain outside a PCPA negotiation is a key factor in understanding how individual provincial agreements align with those of the PCPA. Currently, provinces can maintain separate PLAs as well as being part of the PCPA, but that could lead to duplication of efforts (particular in negotiations). One approach suggested would be to mix individual PLAs with PCPA negotiations around a bundle of products to allow for provinces to use particular products that meet their needs. The main issues with having both PLAs and PCPA agreements are around getting a better price by going alone, or around ability to pay (jurisdictions involved in the PCPA having to pay prices for drugs that will discourage their use). It was agreed that whatever system is in place, there needs to be a mechanism in place to avoid "postal code prescribing".

- **Understanding ability to pay**
  Different payers have different abilities and willingness to pay for new drugs. This is pertinent for the introduction of the PCPA, where each province's drug plan's difficult decisions about what to fund and what not to fund become complicated by the need to purchase within the collective. For example, some provinces identified that they can only support drugs for small parts of the population. This means that decisions about what to fund (and what to stop funding) need to be taken with great care and consideration in each province. In addition, the ability/willingness of provincial payers to pay for new drugs depends on their view of the significance of the opportunity costs and their ability to manage the consequence of reduced spending elsewhere.

- **Coverage of drugs**
  The prime interest of payers is to improve the coverage of drugs in their province so that there is the most appropriate possible access for patients. In this regard, provinces are open to new processes or options to improve access. However, there was a feeling among payers that increased access needs to be balanced with appropriate prices for a whole range of drugs from industry (not just providing good prices on drugs about to go off-patent). In relation to the PCPA, payers identified that it was possible for individual provinces not be involved in the negotiation on a drug if they remove themselves from the process prior to the PCPA negotiating a price).

- **Assessing pricing approach based on need**
  The priorities in pricing decisions for payers are seen as broadly similar across provinces, with views on the need for a new drug likely to be similar across multiple jurisdictions. This means that the 'need' for a new drug can be considered in a pan-Canadian way, not just a provincial way. But provinces seek to target access on patient groups for which the need for, and the ability to gain value from, the drug is clear. Identifying these groups of patients can take time (depending on the information companies can provide from research at the point of market launch), but payers need to understand that patients are looking for rapid access to effective drugs and industry is looking to maximize their product life-span prior to going off-patent to ensure an adequate return on investment. This means industry and patients do not want to see long drawn out assessments of need across Canada that can delay access.

One point made about the assessment of need is that there may be ways to reduce the time-frame for understanding need (for example, by representative sampling of Canadian patients rather than comprehensive sampling across each province).

- **Using comparators from outside pharmaceutical pricing**
  Both industry and payers were keen to stress that the PCPA approach is not a completely new concept for stakeholders, with other parts of the health system also involved in approaches to pooling resources for purchasing purposes. The example given was that of hospitals using shared service organizations to purchase medical devices. One example given of this approach was to suggest that rare disease drugs could be part of collective purchasing approach that would enable multiple provinces to benefit despite each only having small populations with the condition (and associated small disease-driven budgets for these diseases).

Principles and Pragmatism – Moving Forward in Canada

In order to take forward discussions and approaches to pricing drugs in Canada, there is a need for some shared principles and understanding to define a pragmatic approach.

Payer principles

Initial thoughts on principles came from payers, and covered some of their key concerns for making payment approaches work in Canada.

- **Having measurable outcomes**
  For payers, there is a clear need to be accountable for the funding decisions that they make around new drugs. They therefore need solid evidence to show the value of their investments. In addition to using appropriate information (where available) from pre-marketing studies, this may mean agreeing measurable outcomes for drugs in PLAs, so that the value of the drug to patients can be shown. Agreed and measurable outcomes also help to inform what study design may needed to address uncertainty around new products, as well as the likely timeframe for evidence development around the new product.

- **Accountability and transparency**
  As mentioned above, accountability is an important issue for payers. Ideally, payers would like a payment system that is as transparent as possible for the public to be able to understand payment approaches for drugs. Payers understand the difficulty in disclosing agreements from an industry point of view, but would at least like to see transparent processes for developing agreements (i.e. the fact that there is an agreement and the process through which it was developed are transparent, even if the actual agreement is confidential). One suggestion made was that an independent group could scrutinize agreements for value. The measurable outcomes discussed above should also be transparent. One challenge that payers face around accountability is in how to remove from formularies drugs that should no longer be paid for. There is a clear accountability need for the public to know that drugs can be removed when not needed, but trying to move drugs off formularies is very difficult.

- **A common definition of value**
  While there is a need to build on the existing principles of agreements identified above (accountability and measurement), there is also a need to build a common definition of value between industry and payers. This definition needs suitable for use in developing agreements and adopted in that process. It isn't clear what approach should be used to

define value and the way that patients and the public can best be involved, but the approach taken needs to help identify where efforts should be made in developing agreements (i.e. around improving patient access, how to address competition between similar products etc.).

- **Partnership**
  Payers were keen to stress that there is an imperative for agreements and principles to be developed in partnership between payers and industry if PLAs and agreements through the PCPA are to be successful and beneficial for both partners. There was agreement that there is more partnership and interaction now than ever before between payers and industry which is a positive sign for future value-based PLAs.

Industry principles

While a number of principles are the same between industry and payers, there are some aspects that were identified by industry as of specific importance to them.

- **Knowing payer definition of value**
  Industry were keen to stress that in order to deliver value for payers - something that would be beneficial to all parties - industry needs an explicit and early understanding of what concept of value is driving payers in negotiations.

- **When and where to use PLAs**
  Industry understands that there are opportunity costs in setting up PLAs (for both sides). Industry therefore stressed the need for clarity over when and where it is appropriate to put in place PLAs as opposed to other types of pricing agreements. It was suggested that drugs are an "*experience good*" (a product where value is not known until after the product has been consumed), and as such the conditions for the use of PLAs have to be correct to maximize value in the future.

- **Flexibility and engagement**
  Industry has outlined some principles that they would like to see in place for PCPA agreements (Box 1) and key to supporting those principles is the relationship between industry and payers. It was identified that there is a need for flexibility in relationships. This should be supported by ongoing engagement between industry and payers.

- Agreements should value innovation, patient access and patient outcomes
- Agreements should not focus solely on price and cost
- Agreements should be built transparently in consultation with all stakeholders
- Agreement terms should be confidential, but performance public
- Healthcare professionals should determine appropriate treatments
- Provincial payers should commit up-front to participate
- Agreements should be automatically implemented in participating jurisdictions
- Provinces and industry should be able to act outside the framework
- Agreements should be subject to a clear set of expectations and obligations

Box 1. Proposed set of principles from a member of the pharmaceutical industry

- **Infrastructure needs**
  Effective PLAs require an appropriate infrastructure for collecting evidence on value, as well as an infrastructure for developing and managing agreements, and sharing evidence across provinces. The example of The Netherlands' approach to cancer drug evidence development was identified as a key lesson on how to use infrastructure appropriately to simplify listing decisions – making them both more efficient and more accountable.

Conclusions

Five key conclusions can be drawn from the roundtable discussion:

1. PLAs have been a valuable part of the landscape in providing access to new drugs for patients, despite the need for agreed-upon notions of value to inform pricing.

2. Decisions on how to define the value of drugs in PLAs needs to involve stakeholders from across health – including both industry and payers, as well as health economists, health professionals and patients. The definition of value needs to be operational rather than aspirational – meaning it needs to be measurable and be able to be acted upon in agreements. Ideally, the concept of value for new drugs will take into account opportunity costs of purchasing the drug (i.e. the benefits that would be obtained if the money spent on the new drug were used instead to provide other desirable health outcomes).

3. From the point of view of payers, there would be significant benefits to being able to apply PLAs both across provinces (as part of the PCPA) and across drug classes (to ensure that the right combination of therapies is available at appropriate prices for patients).

4. There is a need for both industry and payers to understand ability and willingness to pay in the new PCPA. If the most appropriate products are to be made accessible for patients across the country and postal code prescribing is to avoided, then the ability and willingness of different provinces to pay for products needs to be considered when developing the agreement.

5. Accountability, transparency and confidentiality need to be carefully considered in agreements through the PCPA. While it is acknowledged by all that confidentiality of agreement details is essential, there is a desire for transparency of processes and outcomes of agreements (including measurement of outcomes in PLAs) to allow for payers to be accountable to the public.

Based on these main themes from the meeting, there was discussion of what the next steps should be for Canada in moving forward on both PLAs and the PCPA. Key amongst those next steps was the need for continued engagement between industry and payers to ensure that the principles and rules underlying the use of PLAs and agreements through the PCPA are developed taking into account multiple viewpoints. Within this engagement, the most important issue identified to move forward on was to develop a consistent notion of value for new drugs.

Since this is a complex problem that has not yet been clearly resolved anywhere in the world, there was a feeling that through further engagement and discussion, a consistent notion of value (and how to measure it) would be an area where Canada could lead the world in maximizing the value of new drugs for patients. It was felt that Canada could also lead the world in developing a framework that would identify how to use different pricing approaches to address different types of uncertainty or risk around new drugs.

In summary, there is an opportunity for industry and payers to work together in Canada through the PCPA and drawing on the existing wide experience of PLAs, to develop definitions and tools that will enable improved value and access for patients both in Canada and beyond.

Appendix A: Meeting Participants

Andrea	Nagle	A/Director, Professional and Industry Relations	Alberta Health
Andrew	Merrick	Director, Patient Access	Eli Lilly Canada Inc.
Andy	Chuck	Director of Economic Evaluation and Analytics	IHE
Barbara	Walman	Assistant Deputy Minister	BC Ministry of Health
Bernadette	Preun	Assistant Deputy Minister	Manitoba Health
Beth	Kidd	Senior Manager, External Relations, AB/SK	AstraZeneca Canada
Brent	Fraser	Director, Drug Program Services	Ontario Ministry of Health & Long-Term Care
Brian	O'Rourke	President and CEO	CADTH - Canadian Agency for Drugs and Technologies in Health
Chris	Henshall	Chair	HTAi Policy Forum
Chris	Sargent	Managing Director	HTAi
Christopher	Groguen	Director of Private Markets and External Affairs	GlaxoSmithKline
Diane	McArthur	Assistant Deputy Minister and Executive Officer	Ministry of Health and Long-Term Care
Don	Husereau	Senior Associate	Institute of Health Economics
Eddy	Nason	Senior Researcher	Institute for Governance
Farzad	Ali	Director, Health Economics & Outcomes Research	Pfizer Canada
Fred	Horne	Minister of Health	Government of Alberta
Frederic	Lavoie	Director of Patient Access	Pfizer
Jean-eric	Tarride	Director, Heath Economics and Reimbursement	AstraZeneca Canada

Jennifer	Chan	Vice-President, Policy and Communications	Merck Canada Inc.
Jens	Grueger	Vice President Global Pricing and Market Access	Roche Pharmaceuticals
John	Sproule	Executive Director Policy and Stakeholder Relations	Office of the Minister of Health
Judy	McPhee	Executive Director, Pharmaceutical Services	Nova Scotia Government, Dept of Health & Wellness
Julia	Brown	VP, Government Affairs & Market Access	Janssen Inc.
Karl	Claxton	Professor	University of York
Kevin	Wilson	Executive Director Drug Plan & Extended Benefits	Saskatchewan Health
Lorraine	McKay	Acting Assistant Deputy Minister	Alberta Health
Mark	Findlay	Vice President, Access and External Relations	AstraZeneca Canada
Matthew	Brougham	Vice-President	CADTH
Michael	Drummond	Professor	York University
Rebecca	Yu	Director, Strategic HTA	Janssen Canada
Susan	Williams	Chief Strategy Officer	Alberta Health
Tama	Donoahue-Walker	Vice President, Patient Access	Merck Canada Inc.

Appendix B: Background Document

In 2011, the Institute of Health Economics (IHE), in conjunction with the annual meeting of the Canadian Agency for Drugs and Technologies in Health (CADTH), held a multi-stakeholder roundtable meeting around "innovative" Industry/Payer Agreements in the pharmaceutical world.[3] Driven in part by an understanding that the cost of pharmaceuticals is a large part of health care spending (OECD 2010; CIHI 2006) and in part by the prevailing approach to improving pharmaceutical value to health care systems through closer collaboration (EU 2008), the roundtable engaged all stakeholders in a debate about the use and utility of "innovative" agreements. The potential for "innovative" approaches in drug pricing had been made clear by the international interest in this issue; with conferences and roundtables addressing the subject in many countries (with conferences in Germany, Singapore, the UK and the USA).

As part of the IHE roundtable, the Institute on Governance (IOG) produced an overview report, providing a typology of approaches and some of the main barriers and facilitators that exist to implementing "innovative" agreements more widely. The background document, based on a combination of published literature and interviews with key stakeholders, identified some general messages:

- These agreements they are likely to become more prominent in the future.
- These "innovative" agreements are diverse and poorly understood, particularly in terms of commonly accepted outcomes (cost management, addressing uncertainty or promoting research investments).
- There is need for early dialogue between industry and payers to create a shared understanding of the new therapeutic and a shared vision of how to bring it to the patients that need it;
- There is a definite need to develop good approaches for ongoing evidence development for therapeutics in the real world;
- Formal product specific agreements are not necessarily appropriate for all new therapeutics. There is a need for better understanding of when and where particular categories of formal "innovative" product agreements can add value to the health system(s) in Canada and reduce uncertainty for payers and industry.

Now, in 2013, it is clear that there has been a shift in the way that these "innovative" agreements relate to pharmaceutical pricing[4] – particularly in Canada with the advent of the Pan-Canadian Purchasing Strategy (CPJ Editor, 2010). At the 2013 CADTH conference the IHE and IOG are updating the background document from the previous roundtable to support a renewed discussion and identify issues to work through moving forward. Key questions include:

- Should a pan-Canadian pricing strategy for drugs apply to only specific products or be more broadly applied?
- How do current provincial product listing approaches fit into a larger pan-Canadian strategy?
- When we talk about focusing on 'value' and not just volume price discounts – what do we mean?

[3] This IHE project was supported by internal funding from the Institute of Health Economics and through project funding received from AstraZeneca. Funding was dedicated by AstraZeneca (global) to support different jurisdictions in conducting policy research and knowledge transfer activities regarding reimbursement approaches.

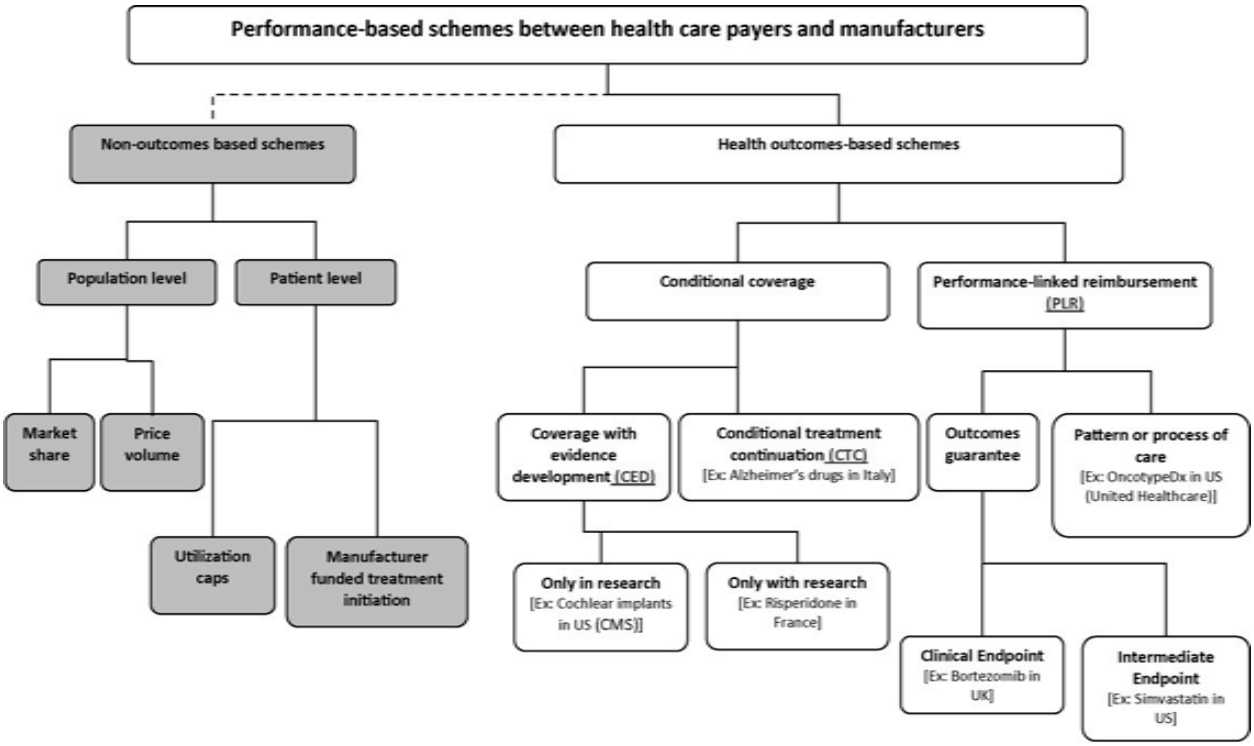
[4] "Pricing" is used through this report where we refer to what has traditionally been called "purchasing". This is due to the changing nomenclature in use by the Pan-Canadian Purchasing Alliance in Canada, done to reflect government setting prices for drugs, rather than purchasing them outright.

- What principles might be applied to the process for negotiation and discussion of changes amongst partners?

Understanding the past

In the 2011 report (Appendix A), "innovative" was used as a cover-all term for a variety of different approaches to industry-payer agreements that had some basis in understanding value and sharing risk. "Innovative" approaches work on a drug-by-drug basis, where the individual qualities of the therapy relate to the formal payment agreement, and payers and industry work together to provide access to new medicines that provide value to patients. "Innovative" agreements included product listing agreements (PLAs), managed entry agreements (Weetman 2008; HGS Consultancy, nd), risk sharing agreements, price-volume agreements, product or outcome guarantees, coverage with evidence development (CED), access with evidence development (AED) (McCabe *et al.* 2010) and payment for outcomes or performance based reimbursement schemes (Carlson *et al.* 2010). These approaches were placed in a typology (Figure 1) based on the relation of value in the agreement to either health or non-health outcomes (Carlson *et al.* 2010), each with their own risks and benefits (see Hutton *et al.* 2007).

Figure 3. Taxonomy of industry-payer agreement approaches (Carlson *et al.* 2010)



Innovative approaches have sprung up in different ways in different jurisdictions around the world, and the previous report identified examples from Europe, Asia and Australasia, North America, and specifically from Canada. Some of the key examples identified were the Pharmaceutical Pricing Regulation Scheme (PPRS) developed to support value-based pricing in the UK (OECD 2010); CED approaches from Sweden (Carlson *et al.* 2010) and Australia (Hutton *et al.* 2007; Klemp *et al.* 2011); price-volume agreements in NZ (Pharmac 2010; Willison *et al.* 2001) and Australia (Towse and Garrison 2010); conditional treatment and performance-linked schemes in the US (Carlson *et al.* 2010; Carlson *et al.* 2009); and a number of CED and conditional treatment approaches in Canada (Klemp *et al.* 2011; Carlson *et al.* 2010; Adamski *et al.* 2010; Sheppard 2010). In addition to existing agreements, a number of provinces and

companies in Canada are looking at portfolio agreements which would include compiling a number of products from one company into an offering for a public plan or even across companies in the class of products.

In support of the literature, interviews with key stakeholders identified six recurring themes:
- Putting innovative agreements in place is a costly business.
- Collaboration is necessary but development of trusted processes and engagement are important.
- Innovative agreements are ones that speak to some concept of "value" which may have differing interpretations.
- Innovative agreements are sometimes seen as a "flavour of the week" rather than part of a sustained approach to addressing uncertainty or mitigating risk.
- Benefits of moving to innovative approaches can accrue to many stakeholders.
- Risks are as numerous and diffuse as benefits.

Based on the documentation, interviews and a broad survey of stakeholders, the report also identified a number of barriers and facilitators to implementing agreements (Table 1).

Table 1. Barriers and facilitators to implementing innovative agreements

Barriers	Facilitators
- Resource intensive agreements. - Lack of trust restricting collaboration and a shared perception of a true sharing of risk across agreements. - Ability to monitor approaches and collect data.	- Willingness of stakeholders to participate where agreements add value. - Ongoing development of frameworks to assess when to use "innovative" approaches. - The comparative-effectiveness research (CER) movement in the US and health technology assessment in other countries.

Finally, the previous report identified three issues to consider in taking forward "innovative" approaches to agreements. 1) Consider what type of drugs to use agreements for; 2) Identify where the uncertainty lies around the new drug prior to setting up the agreement; and 3) Collaborate early in developing approaches. In Canada specifically, there were a number of steps to move forward with agreements appropriately. These included understanding where to use different types of agreement to add value to the health system, clarifying the components of agreements (collaboratively and early), and developing approaches for adjustment of reimbursement criteria where evidence warrants it. These steps looked to the future from our understanding in early 2011, and now it is time to consider where we have moved to in 2013.

New information on agreements addressing uncertainty

In the two to three years since the previous paper, a number of things have changed. Most notable is the shift in Canadian payer priorities towards more collaborative pricing approaches among provinces, but equally important has been new understanding of the way agreements to address uncertainty in pharmaceutical pricing can work. While there may not have been entirely new agreement approaches developed (i.e. those outside of the typology shown above), there has been some progression: predominantly in understanding the roles played by different stakeholders in agreements, but also in the testing of approaches to assigning value.[5]

Stakeholder roles

[5] While not a major influence on value-based pricing approaches, there is evidence from Malaysia on the use of new statistical models for determining value of a new drug using "decision analysis" approaches (Drantisaris *et al.* 2011). It remains to be seen if this approach will inform any existing value based agreement approaches.

For Product Listing Agreements (PLAs) to be successful, each stakeholder in the process must understand what their role is and have the capacity and skills to take that role on. As noted in the 2011 paper, there are major issues around the capacity to deliver PLAs on both sides of the agreement. Public payers have only small human resources to engage in PLAs, which are easily stretched considering the number of new drugs that can come to market each year. Industry face problems around the capacity to engage in evidence development. While pharmaceutical firms may have the manpower to go into complex negotiations, the ability to access evidence on the uptake, effectiveness and efficacy of new drugs in the market is an area where industry interviewees felt there was little infrastructure held by industry. Indeed, this was considered an area where industry interviewees felt that developing infrastructure would portray evidence developed through industry tracking as biased in industry's favour.

Key issue
Stakeholders often lack the infrastructure and capacity to deliver PLAs cost-effectively.

In jurisdictions where there are private payers, such as insurance companies in the US, there has also been recent change in the understanding of stakeholder roles in PLAs. A prime example of this is the US approach to pooling risk for private payers, such as cross-state pooling of risk through health plans (Blumberg and Pollitz 2010). This changes the role that insurers play in purchasing of drugs from industry, since it passes the cost associated with risk in PLAs onto multiple states with different drug pricing laws, spreading costs more evenly across states (Blumberg and Pollitz 2010).

Perceptions of value

Value is a key issue in assessing the role of PLAs in relation to other pricing approaches. As identified clearly in the 2011 report, value can mean different things to different people – something that can lead to confusion in the development of value-based approaches to PLAs. Issues arise here since payers equate value with the delivery of affordable and effective health care, without appropriate ways to consider, and disagreements about whether to take into account, the cost of development of new drugs and the impact of procurement on ongoing innovation.

Key issue
Differing concepts of value can lead to complex negotiations over PLAs.

For payers, value of a new therapeutic is generally tied to the "net health benefit" – the additional health gained through the implementation of a therapeutic versus the cost of introducing that therapeutic (Claxton *et al.* 2008). Net health benefit links closely to the concept of access to therapeutics for the population, since it takes into account the likely coverage of a new drug. This is the place where Health Technology Assessment can play a role (Husereau and Cameron 2011) – in identifying just what the net benefit is to health, and thus provide a value for payers to critically assess new therapeutics against.

Value for payers can also include a political dimension, where it is politically expedient to have a particular drug with 'promise' available to the health system. This political value can be manifested where vocal patient groups can exert political pressure on payers. This was the case with the introduction of government funded "Soliris", a highly expensive rare-disease drug for the blood disease PNH (Blackwell, 2012). Alternatively, political value can be manifested through the identification of coverage for a particular drug in adjacent jurisdictions – for example coverage in the next

Key issue
Payer concepts of value are affected by a combination of health benefits and political constraints that are difficult to standardize and monetize.

province. This is a particularly pertinent aspect of political value in Canada, where each province has its own approach to pricing. From an industry point of view, these political pressures can actually be seen to obscure the concept of value for a new drug, leading to a view that payers actually base value decisions on the best "deal" (i.e. discount) rather than the relation of the price to the actual value of the therapeutic (*interviewee comment*).

An additional interesting quandary for payers around value is that the value of cost-savings achieved through new therapeutics and drugs are often not linked back to the budgets of those payers pricing the drugs or there are issues in 'harvesting' savings. For example, savings on reduced hospitalizations through the effective use of new drugs are not considered part of the budget impact of new drugs for the pricing part of the health system. This is an issue for payers who wish to see improvements in health and the health system, but whose actions are assessed only against the cost of the drug and not its full range of budget impacts.

Key issue
The cost-benefits of improved drug pricing are not always felt in the drug budget, but in other parts of the health system.

Defining value for those in industry is more complex than for payers, since value needs to take into account the value of innovation itself, which underlies the therapeutic value of the new drug or technology (Claxton *et al.* 2008). From the payer perspective, this definition of value can be seen to be paying twice for innovation, since the assumption for payers is that the therapeutic benefits of new technologies capture their value as an innovative product (i.e. are better than existing products), and paying explicitly for R&D costs is simply a way for industry to prospectively pay for further innovation that may or may not be fruitful (Claxton *et al.* 2008). This is a challenge in value perception, since it is generally acknowledged that to develop a successful new drug, a number of failures in research will occur (something explicitly acknowledged in public sector research funding). However, despite this acknowledgement, there is disagreement over whether those R&D costs should be recouped as part of the value of a new drug.

Key issue
Industry considers value-based pricing to include the concept of valuing innovation itself, not just the impact of that innovation.

One impact of this disagreement over the innovation value of new therapeutics has been to create discussion about the impact of value-based pricing approaches on innovation levels within industry (Kanavos *et al.* 2010). What is clear is that defining value in a way that does not take into account R&D costs does not reflect the true cost of an innovative therapeutic, but there are examples of pricing approaches that can help to address the innovation value of new drugs. For example, Coverage with Evidence (CED) approaches inherently include some payment related to ongoing R&D through the evidence development component; while stratified pricing arrangements (such as those in France) inherently link the effectiveness in different populations to the value of a therapeutic and thus to the innovative value for different population groups (Kanavos *et al.* 2010).

The third stakeholder group in the discussion on therapeutics pricing is health care providers themselves. While they are not explicitly involved in the deliberations over the identification of which drugs should be purchased and how, it is important to understand that they will make decisions on how those drugs selected will be used in practice – a key role in PLAs that relate to the use of a new drug (CPL 2012). As such, it is important to consider their concept of value when developing agreements that will affect whether a particular drug will be available for prescription

Key issue
Health care practitioners are not strongly involved in discussions around how to value new drugs.

on a formulary. In general, the role that health care providers should play in this issue has not been discussed at any length. This may be based on the assumption that health care providers will align their concept of value for a drug with that of their patients.

Key issue
Health systems are to become more patient-focused, but patients do not generally take into account public costs of new drugs when considering value.

Patients and the public have perhaps the clearest classification of value for a new drug, in that they identify whether a drug will improve their health as the key factor. In systems with public payers (such as the Canadian system), this is the key driver for patients. However, in systems with either co-payments or personal payment approaches, there is increasing evidence that the value of a new drug is linked to the ability to pay for the treatment in relation to the severity of the condition being treated. For example, in the US, in response to the economic downturn, there is evidence that patients are choosing not to undergo expensive treatments (Carlson 2012). This is an important consideration when considering how Canadian approaches to pricing will evolve to benefit patients (a key promise of governments across Canada in relation to building sustainable health systems).

Driving forces behind value-based approaches

In addition to the expanding concepts of value, what does seem to be new in 2013 around PLAs is a changing driver in the move towards value-based approaches to PLAs. Whereas in 2011, it seemed as though there was a desire from government payers to be able to better manage utilization or link their payment for therapeutics to evidence of their effectiveness in the real world for patients and to open up access to new drugs (Fraser 2009), in 2013 there is evidence that value-based approaches are being driven by industry (*interviewee comment*). What this means is that through confidential PLA approaches, industry can provide different discounts to different payers based on their assessment of how important a client the payer is. This provides the potential for industry to have variant pricing instead of an across the board "best price". An illustration of the power of this is in the discrepancy between prices for Veterans Affairs in the US and Canadian provinces – where some generics are ten times more expensive in Canada than for the US (Law and Katzer, 2012). Indeed, the difference in price between Veterans Affairs and Canada on Soliris was a key factor in recent developments in Canadian pricing approaches.

The Canadian situation

In 2011, it seemed as though there would be ongoing developments within provinces and regions (particularly the Atlantic region) to develop more and more value-related pricing agreements for drugs. This was based on developing approaches in Alberta, Manitoba and the Atlantic provinces to provide guidance on the use of value-related approaches; as well as the increasing numbers of agreements being put in place in Ontario and BC. In addition, the ten-year plan from the 2004 Health Accord identified specifically the desire to "pursue purchasing strategies to obtain best prices for Canadians" and "achieve international parity on prices of non-patented drugs" (Health Council of Canada 2011, p9). What was not expected was the change that occurred in Canada in 2012.

Key issue
Federal role in drug regulation and provincial role in drug pricing.

The development of the Pan Canadian Pricing Alliance (PCPA) in 2012, based on discussions that started in 2010-11 (Blackwell, 2012), placed a question mark over the role that value-related agreements could play in the Canadian context. The PCPA has brought together all the provinces and territories apart from

Quebec, and is using their joint pricing power to drive down the bulk pricing of drugs for provincial health systems. Provinces wish to be 'price makers not price takers'. PCPA addresses a long-standing issue with the Canadian health system: that of the contrast between federal regulation of drugs and the provincial requirement for pricing deals for drugs (Anis, 2000).

This initiative is being driven by Council of the Federation discussions, where provinces are working to demonstrate Pan-Canadian approaches to support the Canadian health system in the withdrawal of federal leadership in the health area. Key leaders in these discussions were three of the largest provinces (Ontario, BC and Alberta). This discussion was initially convened over the pricing of "Soliris", a highly expensive rare-disease drug for the blood disease PNH (Blackwell, 2012). Provincial Health Ministers had heard of the price being given to US purchasers for Soliris, and instructed their provincial systems to come together to strike a similar deal. With Soliris just the start, the PCPA have already negotiated seven other deals, and are working together on 17 agreements for other products. In the PCPA now, no province is controlling the deals, with different provinces taking the lead on different products. This includes moves to use the PCPA to drive down the price of generic drugs,[6] which prior to the PCPA were the highest in the world (up to 90% more expensive than in the US) (Law and Morgan, 2011; Lynas, 2012).

Key issue
Quebec's pricing approach versus that of the PCPA.

Quebec poses an interesting challenge to the PCPA, since they sit outside the bulk pricing approach, allowing them to negotiate rebates and discounts that the provinces of the PCPA are not party to (or indeed, can have knowledge of) – in fact, Quebec have a mandated "best price policy", guaranteeing them the lowest prices in Canada for drugs. While it may cause political issues in Quebec, where there will be pressure to provide the same drugs within the formulary that are available across Canada, it will also lead to the possibility that Quebec can negotiate a deal that is more suited to their population and evidence-capability than the PCPA agreement.

One of the main benefits of the PCPA approach is to prevent "whip-sawing" – using one province's decision to pay for a drug to put political pressure on other provinces (Blackwell, 2012). This benefit is two-fold: first, that it is more likely that there will be coverage across Canada for a drug (reducing health inequities); second, that the provinces will not be forced to pay "over the odds" for a product that is cheaper elsewhere in Canada.

Key issue
Industry has a business model in Canada that is set up to provide confidential deals to provinces.

Industry have begun to articulate the approach that they think the PCPA should be taking, even though the Alliance is very much the product of public payers. A small number of companies have begun to articulate some starting principles for consideration in discussions related to evolution of the PCPA process – these are amalgamated in Box 1.[7]

Box 1. Industry principles for the PCPA (for discussion purposes)

- **Innovation** and **patient outcomes** must be the key underlying principles of PCPA
- Decision making regarding formularies should **financially account for the process of innovation** that underlies drug discovery.

[6] So far, six generics have already had their price set at 18% of brand price through the PCPA (*interview comment*).
[7] These principles are an amalgamation of the thoughts of a small number of firms, but do not necessarily represent industry policy as a whole.

- PCPA should be about making **patient access** to innovative medicines consistent and timely. It shouldn't lead to price competition across therapeutics that are not clinically shown to be interchangeable.
- Each PCPA negotiation should achieve value by meeting the needs of individual health systems and patients – it **should not focus solely on price and cost**.
- A successful PCPA framework **should be built transparently in consultation with all relevant stakeholders** (patients and caregivers, industry, cancer agencies and healthcare professionals).
- **Agreement terms should remain confidential** (no observers should be allowed at the negotiating table), **but performance should be public** (e.g. *time to listing* and *% provincial implementation*).
- Drug plan design and reimbursement models should ensure that **prescribing healthcare professionals continue to be at the centre in determining appropriate treatments for patients** based on clinical practice and judgement.
- **Provincial payers should commit up-front to participate in a PCPA** and should be legally bound to follow through with timely listings (faster than currently, and within 6 months of HTA recommendation).
- The agreement negotiated by the PCPA **should be automatically implemented in the participating jurisdictions**.
- **Provinces should maintain the option the act outside the framework** when required to support provincial priorities and demographics.
- It should be a process that is **voluntary** with drug developers are not obligated to participate.
- It should be **subject to a clear set of expectations and obligations** for both sides of agreements.

As noted, in 2011, there was a prevailing feeling that value-related agreements would become more prevalent in Canada. The advent of the PCPA is seen by some to pose a challenge to that view. While not inconceivable that the PCPA could develop agreements that take into account some concept of value, creating agreements is a complex process when even a single provincial funder is engaged in trying to negotiate a product listing agreement. With multiple funders engaged in a single pricing agreement, PLAs may more often be restricted to simple price-volume approaches that can benefit bulk pricing but do not require complex agreements over evidence levels, stratification of results amongst populations and responsibilities around agreement management that could prove problematic across multiple provinces (Morgan *et al.* 2013).

Key issue
Provinces working together on complex evidence-informed agreements is a challenge.

A number of provinces already have existing PLAs that will run alongside the new PCPA. There is some uncertainty from industry and provincial payers exactly how this might work moving forward. There are advantages that come to individual provinces from keeping flexibility to 'opt out' or 'opt in' depending on the particular circumstances. As identified in 2011, Ontario has developed some PLAs, while the Atlantic provinces were coming together in 2011 to attempt to build agreements as a block. Manitoba has developed a number of agreements focused on partnerships to address appropriate utilization. In addition, Alberta had developed its framework for pricing, which includes a variety of objectives including research and innovation development for inclusion in PLAs. This approach has been praised by industry as providing great potential for innovative industry partnerships beyond price-volume agreements (*Interview comments*). Since 2011, Saskatchewan has also developed a PLA policy.

With the advent of the PCPA, it is the perception that provincial listing approaches have either regressed or been put on hold (*interview comments*). For Ontario, the existing PLAs have to remain in place as they are contracts to work from, but the anticipation is that at the end of the PLA contract, Ontario will attempt to move increasingly to the PCPA approach. For the Atlantic provinces, there seems little value in working together as a block when they can now form part of an even larger bulk

Key issue
PLAs for generics versus PLAs for brand drugs.

pricing approach with greater negotiating power. In Saskatchewan, the PLA policy has been in place in alignment with the PCPA, suggesting that the province sees no issue negotiating PLAs for products that are not covered through the PCPA negotiations. In Alberta, despite the presence of framework, the exact future of PLAs seem to be on hold while the province works with others in determining the scope of the PCPA. These facts are not to say that the PCPA cannot develop more complex value-based PLAs in the future, or that provinces may not continue to have their own agreements.

It is noteworthy that the press release from the Council of the Federation in 2010 identified how the prospective PCPA concept should work. "By capitalizing on their combined buying power, provinces and territories will achieve economies of scale where cost savings can be realized and redirected to the delivery of care to patients." (Council of the Federation, 2010) This statement doesn't preclude PLAs, but it does seem to suggest bulk pricing as the main tool of the PCPA. PLAs within this new context are not likely to disappear completely in Canada, after all, there are considerable numbers in place in Ontario and Manitoba already, and policy makers understand the importance of PLAs in the global pharmaceuticals market (Morgan *et al.* 2013). There is a role for diverse pricing approaches across Canada, even with the PCPA acting on some drugs (Lynas 2012). In particular, there seems to be scope for PLAs to play more of a role on brand drugs that are entering the market where evidence-development may speed access, rather than on generics where bulk pricing may provide simple value to provinces (Lynas 2012).

The global situation

Where Canada has shifted towards a unified approach to bulk pricing, there is no clear pattern across other countries as to what approach to drug pricing is the most appropriate. Approaches range from national approaches to value-based pricing (in the UK), national approaches to bulk pricing (New Zealand) and combinations of product listing agreements and bulk pricing to share risk (the USA).

United Kingdom

The UK is set to proceed with the introduction of value-based pricing for branded medicines, linking price to therapeutic benefit, once the Pharmaceutical Price Regulation Scheme (PPRS) expires at the end of 2013 (CMAJ, 2011). This move, tied to the NHS White Paper "Equity and Excellence" provides benefits to patients by tying NHS drug costs to health benefits for patients. It also provides benefits to pharmaceutical firms, since they can align their development of drugs to clearly stated priority health areas in the NHS (CMAJ, 2011). Going back as far as 2007, the UK has been pushing to develop a value-based approach to pricing, one that was initially slated to save the NHS around £500m GBP (CMAJ 2010).

Value-based pricing in the UK is now becoming a reality, meaning it is having to grapple with two major challenges. First, that the definition of value is likely to differ between UK government payers and the pharmaceutical industry. Second, that the identification, collection and interpretation of appropriate evidence poses severe challenges to both infrastructure and relationships between stakeholders (CMAJ 2010, Towse 2010). To address both of these issues, the National Institute for Health and Care Excellence (NICE) in the UK has been given a central role in both providing a definition of value that is based on evidence, and a method and infrastructure for collecting evidence to support value-based pricing.[8] How NICE will go about developing concepts of value and the evidence to support decisions will be key to the

[8] See http://www.nice.org.uk/newsroom/news/NICECentralToValueBasedPricingOfMedicines.jsp

international understanding of value-based pricing approaches (Sussex, Towse and Devlin 2011).

However, despite assurances that the move to value-based pricing would occur at the conclusion of the current UK PPRS scheme in 2013, there is doubt over how and whether this will occur (Hawkes 2013; Fernando and Moss 2013). Primary amongst the doubts about the value-based pricing approach are concerns about details of the pricing approach to identifying value – a concern highlighted by parliament and by NICE itself (Hawkes 2013; Fernando and Moss 2013). The change over from the PPRS to the value-based pricing approach led by NICE will be a development watched by industry and payers around the world, since it will provide a testing ground for a fully value-driven approach to drug pricing.

New Zealand

In contrast to the UK, the approach in New Zealand has been to develop a national strategy for drug pricing that has led to only modest increases in drug spending over a long period (CPJ 2010). The bulk pricing approach and tendering approaches underpinning this national strategy in New Zealand has led to competitive pricing for both brand name drugs and generics, in a way that Canadian provinces have not been able to replicate with their pricing strategies (CPJ 2010; Lynas 2012). In an evaluation of the New Zealand approach, savings of between NZ$8 million to NZ$13 million were achieved annually through the national pricing approach (Husereau and Cameron 2011). In an analysis of the way New Zealand pays for some common drugs, Morgan *et al.* (2007) suggested that having a national bulk pricing approach in Canada would save up to 79% on drug prices.

New Zealand's approach does receive some criticism in terms of limitations on therapeutic choice and impact on research and development investments. In addition, while drug spending per capita has been reduced in the country, it is noted by some commentators that other health care costs have increased (CPJ 2010) (although the equivalent additional health care cost increases for sectors in countries such as Canada where bulk pricing has not been the norm are not compared in the analysis).

United States

In the US, the situation is quite different, with such a large market allowing for a combination of pricing approaches in different locations and for different products. As noted in the 2011 paper, the majority of known product listing agreements are taken from the US (Carlson *et al.* 2009), but the US also has a set of bulk pricing approaches through a number of payers (Cauchi 2013).

It is the bulk pricing approaches that have been the latest development in the US, with the advent of the health system reforms in the US leading to opportunities for purchasers to work together across State lines in new ways (Blumberg and Pollitz 2010). As of 2012, there were five large multi-state pricing groups coming together to activate bulk discounts that they would be unable to access alone (Cauchi 2013). Interestingly, these multi-State public payer alliances do not tie a State exclusively to pricing negotiated through the group. For example, New York State purchases around ¾ of their prescription drugs through the group, but has individual rebate agreements with manufacturers for the remaining drugs (Cauchi 2013).

Key issue
With the US the largest market for pharmaceutical firms, when payment innovations occur there, they are likely to be transferred to Canada in time.

Clearly the US as a market is at an interesting crossroads, with the convergence of the Affordable Care Act (2010) and the National Institutes of Health comparative effectiveness

drive for listing new drugs. The Affordable Care Act has opened up bulk pricing opportunities for both public and private payers, while the comparative effectiveness approach has created an evidence-driven system around new drugs that can foster evidence-development approaches to PLAs in the US (Deloitte 2012). As the US is the largest single market for pharmaceutical firms, developments in the US will likely have significant impacts on the approaches taken in Canada.

Local versus global

Key issue
Evidence development for Canadian PLAs can affect pricing in larger US markets – creating a disincentive for PLAs in Canada.

As identified above, the pharmaceuticals market is not simply one with multiple local markets spread across provinces and countries – it is a complex interacting international market where standard international prices do not reflect the reality of drug costs. Internationally there are a wide variety of approaches to pricing pharmaceuticals, each of which brings benefits and challenges to the national market in which they operate. However, these approaches work with international pharmaceutical companies, who operate in different ways in different countries for the same products. This can be a challenge to industry, where large markets such as the US will define the success or otherwise of a company's new drug, despite pricing approaches from smaller markets. This leads to two main challenges for industry. First, that smaller markets are seen as less important and that they are therefore not entitled to discounts that larger markets enjoy. Second, and more interestingly for PLAs, that assessing value in a smaller market can have knock-on effects for pricing in larger markets if evidence shows that the value is lower than originally anticipated. This second issue is particularly pertinent for the Canadian market, where developing evidence through PLAs in smaller provinces can affect the price in larger provinces; or indeed collecting evidence in Canada can affect the price of the drug in the USA. To some extent this quandary for industry supports the idea of provinces coming together to access the best prices available within the global market, regardless of the value-linked to that price.

The near future

What is clear from the last two to three years is that pharmaceutical pricing approaches are in constant evolution. This means that any predictions of what the future may hold are subject to significant caveats. However, there do seem to be some aspects of the situation around PLAs and in Canada that can be speculated.

The PCPA currently acts as an alliance of most provinces in Canada to support the purchasing of a discrete number of drugs through national negotiations on price. However, it would seem to only be a short step from the PCPA approach to developing some form of national pricing approach for Canada that could apply to a majority of drugs (Law and Morgan 2011; Lynas 2012; Lockwood 2012; Daw and Morgan 2012). This would have a precedent in the national approach to HTA that exists across Canada, where drug effectiveness is considered nationally, even though drug value is not (Morgan *et al.* 2013; Husereau and Cameron 2011).

However, for a national system to be put in place, a number of barriers would need to be overcome. These range from the differences in policy institutions and structures for drug programs in provinces, through to the resources and infrastructure needed to have PLAs run nationally (Morgan *et al.* 2013). In addition, political factors will also likely influence decisions made nationally on drugs (and the example of Quebec's absence from the PCPA highlights this issue). There is also the issue of federal jurisdiction around assessing drug safety and effectiveness versus provincial jurisdictions over pricing – a complicating factor in CED approaches (Anis 2000).

While Canada is just in the early stages to pursue PLAs to incorporate more complex assessments of value, there are countries and jurisdictions where it seems likely they will be taken further. The development of the value-based pricing approach in the UK is the prime example of this, although other European countries (such as France with its stratified pricing) and parts of the US private payer system (health insurers) seem likely to work on developing value-based and evidence-driven approaches to pricing drugs.

The future of PLAs themselves seems likely to take into account at least three distinct areas: linking PLAs to drug classes (*interview comments*); linking PLAs to personalized medicine approaches (Carlson 2012); and linking PLAs to diagnostics as well as therapeutics (Garau *et al.* 2013). Wherever the future lies for PLAs, it is clear that they are going to form a significant part of the international pharmaceutical market, and Canada will need to understand and be able to implement them in the future – even if it is nationally.

Questions to address at the roundtable

Pricing and Determining Value

- What factors should go into price determination? Should a *me-too* always get the same price?
- How do we account for across-province differences in ability to pay or industry investment/policy?

Provincial versus Pan-Canadian Approaches

- Can you maintain separate provincial product listings while simultaneously pursuing national pricing strategies?

Principles and Pragmatism - Moving forward

- What principles should be identified in developing in further evolving the pan Canadian strategy?
- Are there ways to make confidential negotiation processes publicly accountable?
- Should we develop a more consistent notion of value to support negotiation?
- Are all products amenable to price negotiation? What products should be excluded?
- How can we make outcome-based negotiation feasible?

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