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Industry-Payor Agreements for Pharmaceuticals: Backgrounder

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Industry-Payor Agreements for Pharmaceuticals: A 2013 update

Abstract: This paper provides an update on the situation around product listing agreements (PLAs) in Canada and beyond. It builds on a previous paper developing a typology of agreements and the main barriers and facilitators for them in Canada. The paper identifies a number of key issues that need to be addressed for PLAs to work effectively and efficiently in the current Canadian pricing climate with the new Pan-Canadian Purchasing Alliance.

Introduction

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/Payor Agreements in the pharmaceutical world.[1] 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 purchasing 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 payors 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 payors 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[2] – particularly in Canada with the advent of the

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

[2] "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.

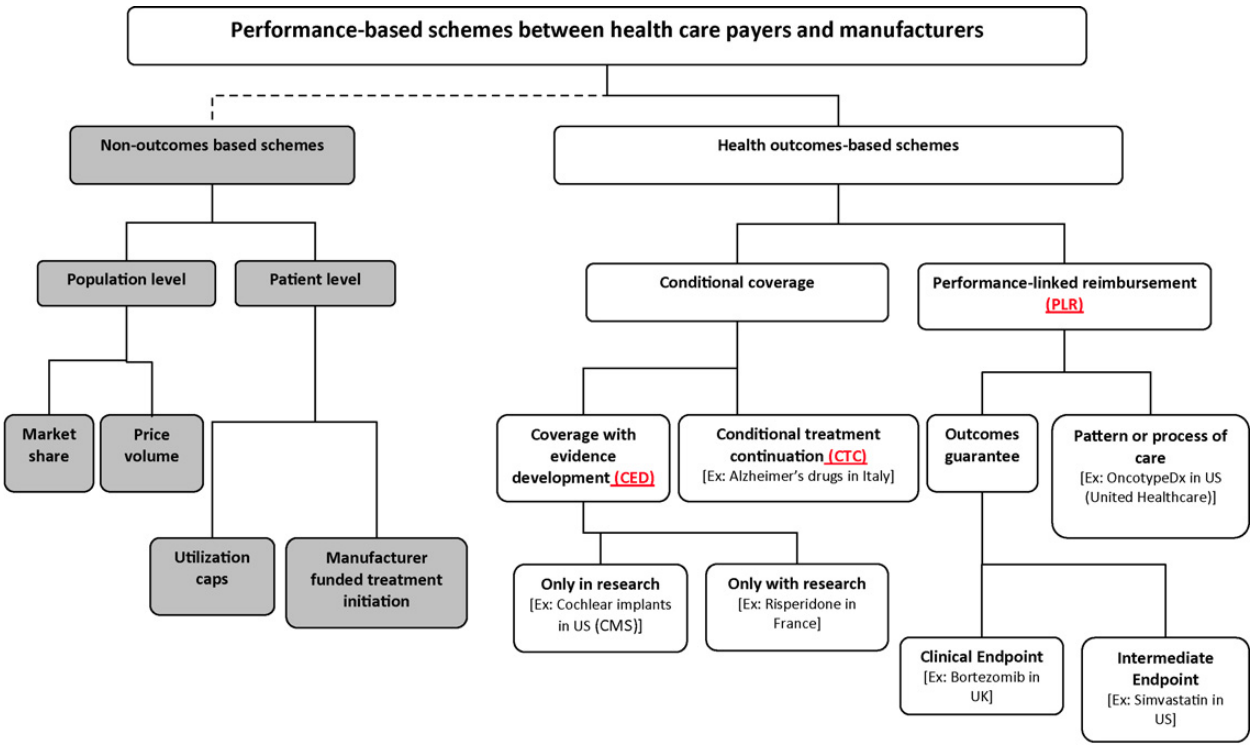
Pan-Canadian Purchasing Strategy (CPJ Editor, 2010). At the 2013 CADTH conference the IHE and IOG are updating the background document from the previous roundtable to support a renewed discussion and identify issues to work through moving forward. Key questions include:

- Should a pan-Canadian purchasing 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?
- 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-payor 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 payors 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 1. Taxonomy of industry-payor 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 bundling 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.[3]

Stakeholder roles

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

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 has no infrastructure (indeed, it is an area where industry feels it cannot have infrastructure for fear of seeming biased in its evidence collection).

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 and the public 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.

[3] 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.

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 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*).

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

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 purchasing 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 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 care practitioners are not strongly involved in discussions around how to value new drugs.

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 Kratzer, 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 purchasing.

The development of the Pan Canadian Purchasing 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,[4] 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 purchasing 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.

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

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.

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 payors. Some companies have begun to

[4] So far, six generics have already had their price set at 18% of brand price through the PCPA (*interview comment*).

articulate some starting principles for consideration in discussions related to evolution of the PCPA process (Box 1).[5]

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.
- 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 seem naturally 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 (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 payors 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

[5] These principles are an amalgamation of the thoughts of a small number of firms, but do not necessarily represent industry policy as a whole.

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*).

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 pricing approach with greater negotiating power. 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.

Key issue
PLAs for generics versus PLAs for brand drugs.

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.[6] How NICE will go about developing concepts of value and the evidence to support decisions will be key to the 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. Also, 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

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

State purchases around ¾ of their prescription drugs through the group, but has individual rebate agreements with manufacturers for the remaining drugs (Cauchi 2013).

Clearly the US as a market is at an interesting cross-roads, 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.

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.

Local versus global

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.

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

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 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 purchasing 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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Appendices

Appendix A: 2011 Report - Industry-Payor Agreements for Pharmaceuticals: Outcomes and risk in reimbursement

Nason and Sproule, March 2011

Abstract: This paper provides a typology of "innovative" industry-payor agreements, and focuses on examples of health outcomes-based approaches that are in place around the world and within Canada to explain the diversity of approaches currently being used. In addition, the paper provides information on the main barriers and facilitators that are identified in moving forward with "innovative" agreements.

Introduction

The Institute of Health Economics (IHE) has been performing a project investigating "innovative" Industry/Payor Agreements in the pharmaceutical world.[7] In support of this work we have been assisted by the Institute of Governance in conducting stakeholder interviews and summarizing current literature. This report provides an overview of such agreement approaches, providing a typology of approaches and some of the main barriers and facilitators that exist to implementing "innovative" agreements more widely. This paper feeds into the roundtable being held by the IHE on April 3rd, 2011 in conjunction with the annual meeting of the Canadian Agency for Drugs and Technologies in Health. The roundtable will help to identifying building blocks for success, knowledge gaps and areas for research and policy tool development. This initial report will be built upon, from points raised in discussions and presentations from experts and stakeholders, to form a final report that will hopefully support policy development in this area. Through the interviews and survey information some general messages emerged:

- There is need for early dialogue between industry and payors 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;
- 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 payors and industry.

Formal product specific agreements are not necessarily appropriate for all new therapeutics. It is clear that such arrangements make sense for certain products and to address certain issues of uncertainty and require some very specific skills and capacity in developing and monitoring. They can be expensive in terms of time and effort so need to be tailored to particular circumstances. They do however provide a potential vehicle to allow quicker and better access for patients to valuable medicines while providing measures to address payor concerns about outcomes, cost and appropriate use.

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

Purchasing pharmaceuticals is an expensive business. In the OECD countries, pharmaceutical spending accounts for 17% of total health spending on average (OECD 2010). In Canada, we fall almost exactly on this average, with 17.5% spend in 2005 (CIHI 2006). Finding ways to provide value for money in this spending will have significant impacts on health care budgets.

One way to improve value is to create closer collaboration between industry and government payors, something that the EU's High Level Pharmaceutical Forum has formally endorsed (EU 2008). They have promoted the principle of active collaboration between member states and stakeholders, including industry, to provide: improved evidence generation; partnerships for patient education and involvement; ongoing engagement to match health system and innovation priorities; and development of pricing structures that appropriately recognize value.

As noted in a recent OECD Report on *Value for Money in Health Spending*:

> *"Product-specific agreements could well prove to be a useful new instrument in promoting patient access to innovative treatments while linking public funding to therapeutic value. However, as yet, there is insufficient evidence to be confident in their utility. As these agreements are developing quickly in OECD countries, their results in terms of benefits and costs need to be assessed. The assessment should focus on their design (are all agreements workable?) as well as their final outcomes."* (OECD 2010, 172)

This quote serves to highlight two key factors around "innovative" agreements. First, that they are likely to become more prominent. Second, that they are currently poorly understood, particularly in terms of concrete outcomes. While the first of these points speaks to the need for this IHE and IOG work, the second point guides our thinking on what the work should entail. As such, the following issues paper in support of the IHE roundtable discusses the breadth of "innovative" agreements around the world, and then focuses in on what the challenges are in developing these approaches in the Canadian context.

The burning platform for understanding "innovative" approaches has 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). For example, in February 2010, the Health Technology Assessment International (HTAi) Policy Forum, a venue for discussion between high-level global industry leaders, payors and assessment agencies, held a focused dialogue on managed market entry of new technologies.[8] The scope of discussion at the 2010 meeting addressed "*managed entry agreements"* and included strategies for adding value across the lifecycle of a technology, from early engagement with payors and regulators for evidence generation to optimizing technology performance in clinical settings.

What's in a name? Terms and nomenclature

So far we have referred to these agreements as "innovative". This is for two very good reasons. First, the concept of innovative is a relative term when considering a global market place for pharmaceuticals, and what is considered innovative in one jurisdiction may not be in another. Second, that "innovative" is really a cover-all term for a variety of different approaches to industry-payor agreements.

[8] The Institute of Health Economics operates as the secretariat for HTAi and supports the HTAi Policy Forum and Board activities.

It is important before we move into assessing what exists internationally, that we provide some definitions of "innovative" agreements. In general, "innovative" agreements are those that move away from traditional pharmaceutical purchasing approaches of "pass or fail" admission to payor formularies. "Innovative" approaches therefore work on a drug-by-drug basis, where the individual qualities of the therapy relate to the formal payment agreement and payors and industry work together to what is a common goal of providing access to new medicines which provide value to patients.

Product listing agreements (PLAs) – This is the term most commonly used to describe "innovative" approaches (as broadly defined above). PLAs are formal agreements by product or defined group of products, between individual companies and payors to address uncertainty or risk around appropriate use, budget impact, or outcomes associated with the reimbursement and associated use of pharmaceutical products.

Managed entry – Another common term often referred to in discussions around "innovative" agreements, *managed entry* refers to the process of payors working with industry to manage the way that new therapeutics are brought into the market (Weetman 2008). By working together to manage the entry of the therapeutic, industry has a greater likelihood of succeeding in the market, while payors have greater knowledge of the therapeutic that is entering the market (HGS Consultancy, nd).

There are different names for these formal agreements focused on different objectives and parts of the product life cycle etc. (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). There are also innovative partnership arrangements being considered between payors and industry that support appropriate utilization, disease management initiatives or linking reimbursement with other local research investments. Approaches are either attempting to address some uncertainty or to achieve some specified outcome.

Different approaches

As identified above, within PLAs and managed entry, there are a number of different approaches that can be taken to relate the pricing of the therapeutic to its performance. Recent work has developed a typology of these approaches, splitting them into approaches that are health outcomes-based, and those that are non-health outcomes-based (Carlson *et al.* 2010).

Health outcomes-based schemes are those that relate the price of the drug/therapeutic to the health outcomes of individuals or populations that are using the therapy. As such, they relate the value of the drug to the health impact it can achieve. Within health outcomes-based approaches, there are a two main types of approach identified, each with a subset of approaches within them:

(1) Conditional coverage: schemes where coverage is granted conditional on the initiation of a program of data collection.

a. **Coverage with evidence development (CED):** binary coverage decision is conditioned upon the collection of additional population level evidence, from a pre specified scientific study, to support continued, expanded, or withdrawal of coverage.

CED has been suggested to have numerous benefits and risks for different stakeholders in the drug purchasing process. These are nicely summarized by Hutton *et al.* (2007) and are presented in the table below.

Stakeholder	Benefits	Risks
Decision makers	• Allows patient demand to be met through managed entry of promising technologies with significant uncertainties. • Influence over evidence generation to ensure it meets decision-makers' needs.	• Potential for investing in technologies that prove not to be cost-effective. • Extra burden of monitoring and review in the light of further evidence (and possible costs of data collection if not fully borne by manufacturer). • Difficulty in withdrawing technologies that prove not to be cost-effective.
Healthcare providers	• Access to promising technologies earlier in their life cycle. • Increases treatment options available to patients.	• Risks involved in using technologies that are not fully evaluated or recommended by guidance. • May increase exposure to litigation.
Industry	• Adoption (initially limited, but with potential to expand) of technologies with equivocal evidence that otherwise might be rejected.	• Delays to market access for effective technologies. • Additional burden of data collection/analysis. • Restrictions on pricing decisions.
Patients	• Access to promising technologies that may otherwise not be available	• Access to technologies that may prove to be ineffective or for which dis-benefits may outweigh benefits.

i. **Only <u>in</u> research:** coverage (CED) conditional on individual participation in research (i.e. only patients participating in the scientific study are covered).

ii. **Only <u>with</u> research:** coverage (CED) conditional on a scheme to conduct a study that informs the use of the medical product in the full patient population.

b. **Conditional treatment continuation (CTC):** continuation of coverage for individual patients is conditioned upon meeting short-term treatment goals (e.g. tumor response or lower cholesterol).

(2) Performance-linked reimbursement (PLR): schemes where the reimbursement level for covered products is tied to the measure of clinical outcomes in the "real world".

a. **Outcomes guarantees:** schemes where the manufacturer provides rebates, refunds, or price adjustments if their product fails to meet the agreed upon outcome targets.

b. **Pattern or process of care:** schemes where the reimbursement level is tied to the impact on clinical decision making or practice patterns (e.g. whether or not patients adhere to the treatment course suggested by a risk predicting genomic test).

Non health outcomes-based schemes

1) **Market share** – also called "penetration pricing" – the use of low pricing at the entry point into the market in order to increase market share in the drug category. This becomes problematic for companies if pricing is benchmarked internationally.

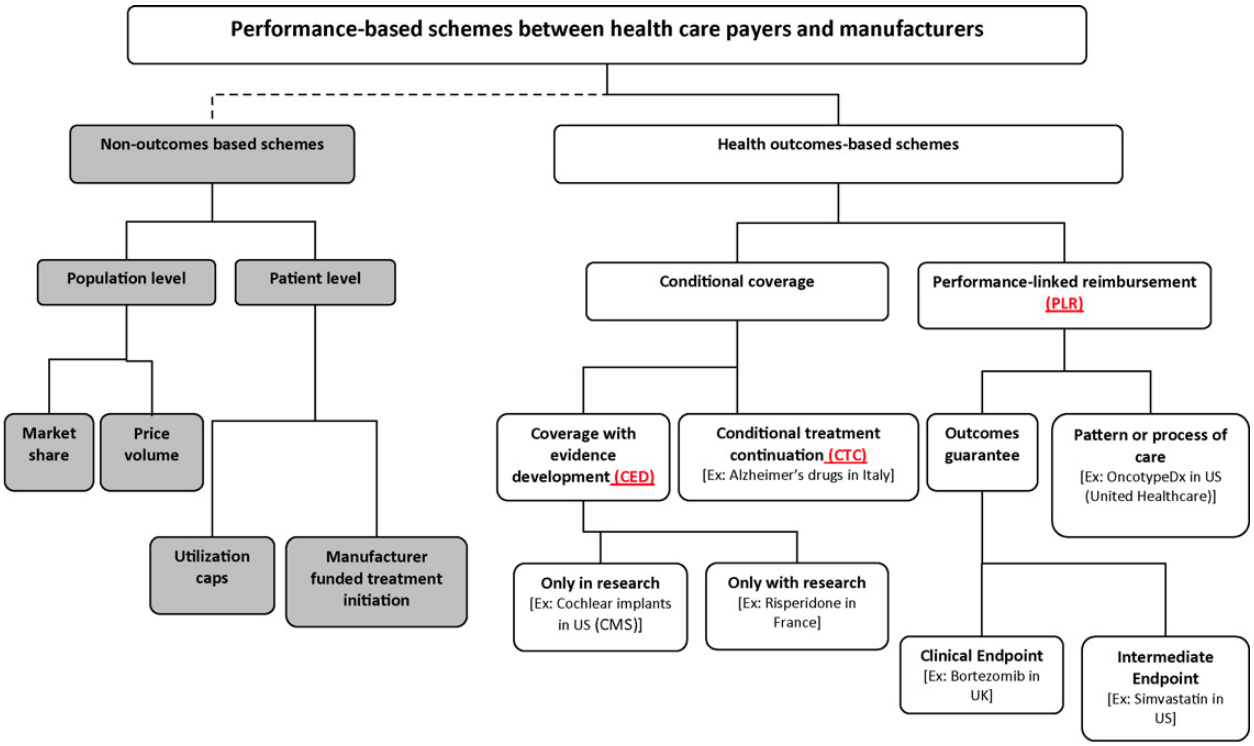
2) **Price-volume** – can be modified to incorporate different populations at different price/volume levels. Provide reduced prices as volumes of pharmaceuticals used increases. For target populations this is more innovative. There is some evidence around the effectiveness in budget management from the EU, with France reporting estimated savings of 400 million EUR for 2005; Italy saving 800 million EUR in 2006; Portugal saving 10 million EUR in 2006; and the UK saving around £15million per year between 1992-1999 (Espin and Rovira 2007)

3) **Utilization caps** – risk sharing approach, similar to price-volume approaches but are at an individual not population level; measures utilization by patients, not health outcomes.

4) **Manufacturer funded treatment initiation** – true risk sharing, since the full costs of initial treatment are paid for by industry until enough evidence is provided to convince payors (NO coverage with evidence development).

While it is important to be able to classify the approaches into this typology, it is worth noting that there are numerous examples of hybrid approaches, which will build on more than one aspect of the typology above. Figure 1 below provides a visualization of this typology.

Figure 2. Taxonomy of industry-payor agreement approaches (Carlson *et al.* 2010)



Using the wide lens – The international picture

The sale of pharmaceuticals is a global business, and the presence of international reference pricing has been one of the drivers behind creating innovative approaches to purchasing agreements – as it allows industry to maintain an international reference price while entering a market they would not be able to at that reference price (Touhmi 2010). Innovative approaches have sprung up in different ways in different jurisdictions around the world, and below we identify some of the most relevant from Europe, Asia and Australasia, and North America.

Europe

Europe has been very active in testing new approaches to industry-payor agreements, with different countries taking different approaches. The UK and Sweden have been particularly active in developing a variety of "innovative" approaches, but these vary in their scope and structure.

NICE (UK) and flexible pricing

In the UK, the PPRS has established that certain drugs can enter the market at lower cost, with the knowledge that if they are shown to be more effective in consequent NICE assessments, then their price will be increased. Roche has agreed to discount by 14.5% the price of its treatment for non-small cell lung cancer (erlotinib) in order to equalize its price to a cheaper competitor until definitive results of head-to-head clinical trials are available and a new NICE appraisal (OECD 2010).

In the UK, the new Pharmaceutical Pricing Regulation Scheme (PPRS) signed in December 2008 for five years aims to introduce value-based pricing for drugs purchased by the NHS. The government and the industry have agreed to "flexible pricing": companies can increase the price of their products after market entry provided new evidence has been produced about the benefits of their drug – as assessed by the National Institute for Clinical Excellence (NICE); *see box to the right* (OECD 2010). In addition, the UK have been involved in other approaches, such as manufacturer funded treatment initiation, where UCB agreed to provide the first 12 weeks of its treatment for moderate to severe rheumatoid arthritis (certolizumab pegol) at no cost to the NHS, with the NHS continuing to fund the treatment if the clinical response is positive for individuals (OECD 2010). The NHS is also involved in utilization capping, with a deal with Novartis on treatment for acute wet-macular degeneration with the drug ranibizumab. The NHS pays for the first 14 cycles of treatment, but any additional treatments are paid for by Novartis (OECD 2010). The UK has also been involved in outcome guarantees, with Velcade for the treatment of multiple myeloma being paid for through a risk sharing agreement based on the proportion of patients achieving partial or full response as measured through 50% reduction in serum M-protein. Should patients fail to reach this level, then Johnson and Johnson (the manufacturer of Velcade) will refund the cost of those patients (Trueman nd).

In Sweden, there have been numerous examples of coverage with evidence development. These include pharmaceutical companies providing additional data:

- To support the economic value of inhalable insulin in a Swedish clinical day-to-day setting.
- On the long-term effects of rimonabant and its economic value in a Swedish clinical day-to-day setting.
- On the cost-effectiveness of rasagiline versus entakapon and selegilin.
- On the long-term effects of lyophilisate (a drug for grass pollen allergy) and a new health-economic evaluation based on costs and medical effects of the drug in clinical practice.
- On the long-term effects of Champix, a smoking cessation drug.

- On ongoing and planned studies in order to determine the cost-effectiveness from a long-term perspective for the HPV drug Quadrivalent. Data to be provided every 6 months starting from 01/10/2007.
- On the effect of Neupro (for Parkinson's disease) in the Swedish clinical day-to-day setting. (All from Carlson *et al.* 2010)

Italy has also taken on a number of "innovative" approaches, with conditional treatment continuation, outcome guarantees and manufacturer funded initiation all used. For example, Alzheimer's disease drugs are provided free by manufacturer and assessed for short-term effectiveness during the patient's first 3 months on the drug. If treatment goals are met after 3 months, then treatment is continued for a maximum of 2 years with the drug costs reimbursed by the National Health Service. In addition, Novartis has agreed to refund the cost of treatment with nilotinib for CML for every patient who does not reach an agreed hematological response after 1 month (Carlson *et al.* 2010).

Belgium and the Netherlands both have forms of conditional coverage schemes that take into account multiple factors relating to the value of the new therapeutic.[9] These factors can include: effectiveness in clinical practice; pharmaco-economics in clinical practice; size of the target group; sales volumes; and, reimbursement status in other EU Member States (EU 2008). In Germany, a health insurance fund signed an agreement with Novartis to obtain a refund of a patient's treatment for osteoporosis if an osteoporosis-related fracture occurs (OECD 2010).

Greece is revising its reimbursement and pricing policy to a modified *price-volume* approach that will use the three lowest prices in the European Union as benchmark for price at market entry. This will then be combined with "dynamic pricing" after market entry such that an annual increase in sales exceeding 5% will lead to a 2.5% price reduction for Greek government payors (OECD 2010).

Asia and Australasia

Australia have been one of the major countries who have taken on "innovative" approaches, with numerous non-health outcomes-based approaches and a small number of health outcomes-based ones. New Zealand have yet to move towards "innovative" approaches, but their spend on pharmaceuticals is also lower than other reference countries, so they have not yet felt the need to move to value-based pricing (Sundakov and Sundakov, 2005). There are some instances when price-volume agreements can be used in NZ however (Pharmac 2010; Willison *et al.* 2001). In Asia, Singapore has not yet moved to "innovative" pricing approaches, but they do seem ready to in the near future, with a roundtable in Singapore on the subject of innovative pharmaceutical pricing models concluding:

> *It was timely for all stakeholders to give thought on how innovation in formulary decisions could be introduced into the system and what drugs could be included under such schemes. Moving forward, if there was interest by healthcare institutions or pharmaceuticals to moot innovative pricing proposals, it would be fitting to engage in discussions with the Healthcare Finance Division at the Ministry of Health*. (SingHealth Centre for Health Services Research 2009)

[9] In the Netherlands the focus has been on expensive cancer drugs

In Australia, the Medical Services Advisory Committee (MSAC), which determines the coverage of medical devices, can allow interim funding for data collection that will help to show the effectiveness of a new therapeutic. However, this CED approach is one that must take place within an agreed research framework, and as such the data collection approaches are developed in partnership between government payors and industry (Hutton *et al.* 2007; Klemp *et al.* 2011). The box to the right provides an example of where CED is in use in Australia.

Australia and Coverage with Evidence Development

In Australia, Actelion pharmaceuticals have agreed to link the price of Bosentan, a drug for pulmonary arterial hypertension, to the survival of patients followed in an observational study. This is a prime example of CED using an only in research approach (Carlson *et al.* 2010).

As an example of outcomes guarantees and conditional treatment continuation, Medicare Australia will provide conditional reimbursement to Novartis for imatinib mesylate on an assessment of short-term effectiveness evaluated at 18 months. Reimbursement will continue for patients in whom it is effective and cease for those it isn't effective. A similar approach is taken for etanercept, a drug for rheumatoid arthritis (Carlson *et al.* 2010). Also, while we are not covering price-volume agreements in detail here, they are common in Australia, where they are used to manage utilization uncertainty in a country with multiple populations (Towse and Garrison 2010).

North America

In the U.S., the focus on "innovative" agreements has generally been around the medical device industry, rather than pharmaceuticals (Carlson *et al.* 2010). This is likely due to differences in the level of evidence required to reach the market in the U.S. for devices and drugs. For those drugs that have been purchased through "innovative" agreements, the U.S. has a combination of coverage with evidence development, conditional treatment and performance-linked reimbursement schemes.

For U.S. CED schemes, all are funded by the health insurer CMS and cover activities undertaken as part of approved clinical trials. They include: coverage of Percutaneous Transluminal Angioplasty and Stenting of intracranial arteries for the treatment of cerebral artery stenosis ≥50% in patients with intracranial atherosclerotic disease; use of PET scans for dementia patients in trials; and, cochlear implants for those in trials (Carlson *et al.* 2010). Drug agreements in the U.S. tend to be in conditional treatment and performance-linked schemes. For conditional treatment, CMS will reimburse erythropoiesis-stimulating agents until the patient achieves a hemoglobin level of 10 g per dl (Carlson *et al.* 2010). For performance-linked approaches, there have been four interesting agreements identified in the U.S. These are shown in the table below:

Disease area	Product	Manufacturer	Payor	Description
High cholesterol	simvastatin	Merck	Patients and insurers	Merck promised to refund patients and insurers up to 6 months of their prescription costs if simvastatin plus diet did not help them lower LDL cholesterol to target concentrations identified by their doctors.
Breast cancer	Onco*type* Dx	Genomic Health	United-Healthcare	UnitedHealthcare agreed to reimburse the Onco*type* Dx test for 18 months while it and Genomic Health monitor the results. If the number of women receiving chemotherapy exceeds an agreed upon threshold, even if the test suggests they do not need it, the insurer will negotiate a lower price.
Type 2	sitagliptin;	Merck	CIGNA	Merck has agreed to peg what the insurer CIGNA

diabetes	sitagliptin + metformin			pays for the diabetes drugs sitagliptin and sitagliptin + metformin to how well type 2 diabetes patients are able to control their blood sugar.
Osteoporosis	risedronate	Proctor & Gamble, sanofi-aventis	Health Alliance	Two companies that jointly sell the osteoporosis drug risedronate agreed to reimburse the insurer Health Alliance for the costs of treating non-spinal fractures suffered by patients taking that medicine.

* Table taken from Carlson *et al.* 2009.

The final approach identified in the table, that for risedronate, is particularly interesting as it is the first identified example of a pharmaceutical company paying for disease-related outcomes that were not prevented by the drug in question (Carlson *et al.* 2009). This is a major step for "innovative" agreements, as it is a significant departure from simply reimbursing the cost of the drug or discounting the costs of further treatment. This approach is worth watching further to see how it develops as it may change the approaches taken more widely than just the U.S.

In sharp focus – Canada and the provinces

In Canada, pharmaceutical purchasing is determined by the provinces, although with significant input from the common drug review at the national level. Each province has the ability to determine which drugs it wants to fund on its formulary, and this can include drugs that were not recommended for listing by the common drug review, if the province deems it appropriate to fund based on some negotiated arrangement. The participating provinces in the Common Drug review utilize and do not repeat a centralized cost-effectiveness assessment but are independent in terms of their policy response. There is clearly pressure for some harmonization in listing decisions and this is profiled with increased communication between provinces amongst particular patient access advocacy organizations.
For "innovative" agreements, in Canada, this means looking at primarily provincial decision-making as private payors generally provide open formularies passing on costs to plans. The federal government does run a number of major drug programs and as well is responsible for regulatory approval. As part of that regulatory or market authorization process Health Canada will occasionally identify promising drugs that are yet to provide enough evidence to warrant full notice of compliance (NOC) status, and will label these drugs as "compliant with conditions". This means that Health Canada will expect further trials and significant monitoring of the drug in circulation (Health Canada). A phased conditional regulatory approval combined with perhaps a phased conditional reimbursement approach signals a new world of evidence gathering which could occur along the entire life cycle of a product.

For the drug companies, identifying specifics around a particular agreement with a province may understandably not be transparent. There is significant secrecy around where innovative agreements have been put into practice in Canada and the terms and conditions. This has made it difficult to identify exactly who is involved in "innovative" agreements, and to what extent.

One example available is and old one from Saskatchewan, where the drug finasteride (Proscar) for benign prostatic hypertrophy, has been provided by Merck with an agreement to refund the cost of the drug in situations where a patient receiving the drug subsequently proceeded to surgery (Klemp *et al.* 2011). Interestingly, with this example of performance-related reimbursement, the outcome was that the utilization of the agreement was lower than expected due to strict conditions on which patients were deemed eligible for the refund (Klemp *et al.* 2011).

Ontario has been using conditional treatment approaches, with an agreement between an Ontario health authority and Pfizer, Novartis and Johnson & Johnson over Alzheimer's drugs providing for patients using donepezil, rivastigmine, or galantamine. The patients will be reimbursed for a period of up to 3 months for patients on those drugs, after which further reimbursement will be made available to those patients whose disease has not progressed/deteriorated while on this drug (Carlson *et al.* 2010).

In Alberta, it was identified by one interviewee that there was a move towards reinvesting money saved through pharmaceutical purchasing agreements into an "innovation fund" for new drugs. This is difficult to corroborate however. Alberta has had some experience with appropriate utilization agreements and has proposed a policy suite of a number of approaches in its new pharmaceutical strategy. These include price-volume agreements, CED (which experienced difficulties around data collection) and "listings with research capacity" (where the drug company provided the funding to research the effectiveness of the new drug, rather than performing the study themselves).

Sandoz Canada promised to reimburse individuals, hospitals and government drug plans where patients with treatment-resistant schizophrenia discontinued clozapine within six months. This was initiated to address acquisition cost concerns versus typical anti-psychotics among the Provinces (Adamski *et al.* 2010). Sanofi-Aventis agreed to reimburse the cost of docetaxel to provincial payors if an agreed responder level was not reached in patients with cancer due to concerns about its efficacy and costs (Adamski *et al.* 2010).

Manitoba was also cited as a location with potential for interesting "innovative" agreements, since the presence of a "utilization management agreement" between government payors and industry requires industry to provide comparative effectiveness data. However, this agreement approach currently only requires industry to show that their new therapeutic is more effective than existing approaches, and does not link payments to health outcomes. The Atlantic Provinces have yet to move to "innovative" approaches beyond some price-volume agreements. For QC it is currently unknown to what extent they are taking forward "innovative" approaches.

The Atlantic Provinces, BC and Alberta are all working on developing systematic approaches to "innovative" agreements, according to interviewees. However, since these are work in progress, and agreements are likely to be kept secret when the systems are in place, it is difficult to provide details on the systems being developed. Alberta have some information on their developing system, in that the framework being developed has four arms:

- price volume approaches;
- utilization management approaches;
- listing with evidence development approaches;
- listing with research capacity approaches (a new category in AB that speaks to agreements in which the drug company will provide value back to the province in terms of research capacity building in the area their product is focused. This is technically a sub-category of CED approaches).

One major problem with the lack of information on innovative approaches in Canada is that there is very little information on whether they work on not in the Canadian context. While not available in the literature, there is evidence from one interviewee, that one CED approach used in Ontario for Plavix, was not hugely successful, since the length of time it took to get data on outcomes was so long compared to the need for reimbursement.

Even with a little data, we have attempted to develop a matrix of Canadian provinces and their current involvement in "innovative" purchasing agreements (table below). This will be adjusted with feedback from roundtable participants and further discussions with jurisdictions.

Provinces and existing (available) innovative arrangements[10] - *DRAFT* *(based on initial information gathering will be supplemented for final report)*

INNOVATIVE APPROACH CATEGORY	Province										
	BC	AB	MB	SK	ON	QC	NB	NS	PEI	NFL	Territories
Conditional coverage					✓						
Coverage with evidence development (CED)		✓									
Only in research		✓									
Only with research		✓									
Conditional treatment continuation (CTC)					✓						
Performance-linked reimbursement (PLR)	✓	✓		✓	✓						
Outcomes guarantees	✓	✓		✓	✓						
Pattern or process of care											
Market share											
Price-volume	✓	✓		✓	✓		✓	✓			
Utilization caps											
Manufacturer funded treatment initiation											

* Shading relating to the Atlantic Provinces represents their united approach to innovative agreements, where they are developing systems across the Atlantic Provinces, rather than in specific provinces.

The views of key stakeholders

In addition to the existing literature and documentation on this subject, the project team interviewed 25 key stakeholders in industry, government, HTA, academia, insurance and other stakeholder groups from Canada and internationally.[11] We supplemented this interview information with survey data from a short six-question web survey for stakeholders we could not access for interviews.

Interview main themes

From the interviews, there were a number of recurrent themes, regardless of the stakeholder group that people came from.

Theme one – Innovative agreements are ones that speak to some concept of "value": Nearly all the interviewees identified that for an agreement to be innovative, there needed to be some link to the value of a new drug to the health system. This value can be realized through evidence of real-world effectiveness, or through a way to link price to health outcomes.

[10] It should be noted that these approaches are generally kept secret in order to protect the international list price of any drug being purchased through an innovative agreement approach.
[11] See Appendix A for the list of organizations interviewed as part of this project

Theme two – Innovative agreements are sometimes seen as a "flavour of the week": In reality, innovative approaches should be considered only in specific circumstances, such as for expensive but potentially effective drugs, or for therapeutics that work well in specific populations. However, interviewees felt these approaches are often pushed where they may not be appropriate. There are other approaches to managing the use of pharmaceuticals which do not involve formal agreements (restricted listings, specialist prescribing, guideline development and dissemination to prescribers/patients).

Theme three – The benefits of moving to innovative approaches can accrue to many stakeholders: While the main benefit mentioned across interviews was improving patient access to drugs, there were also benefits identified for payors (shared liabilities; access to drugs that might not be recommended for listing by the common drug review; ability to manage drug access for specific sub-populations), industry (earlier entry to the market; increased sale of drugs that might not make it into payor systems through traditional means; chance to be reimbursed based on good performance, as well as penalized for bad), and the health system (doctors are able to provide more choice and focus drugs to populations better; chance to make sure the health system is not paying for drugs that aren't effective in sub-populations).

Theme four – Risks are as numerous and diffuse as benefits: Industry bears a risk in any agreement that speaks to outcomes or evidence, since revenues may no longer be dependent on just a reference price and product volumes. However, the risks to other stakeholders can be equally as large. For payors, adding new drugs to the formulary can be very risky without clear understanding of expected outcomes. Should a new drug not be shown to be as effective as hoped, then it becomes very difficult to remove it from the formulary, even with innovative agreements that speak to exactly that issue. For patients, having a drug removed from the formulary can create major stress and worry; this can also lead to patients suddenly being asked to pay for expensive drugs that had previously been covered.

Theme five – Putting innovative agreements in place is a costly business: On all sides, it was acknowledged that any agreement that deviates from the current approaches to purchasing drugs is going to require significant administrative and legal human resources to implement. In addition to the human resources cost of setting up agreements, there are also significant costs associated with the data on effectiveness and outcomes that underpin many innovative approaches. In general the cost of collecting and analyzing such data would be prohibitive to putting in place agreements in the current financial climate.

Theme six – Everyone needs collaboration, but not everyone wants it: One issue that came through clearly in all the interviews is that for any innovative purchasing agreement that looks at value, outcomes and evidence, the agreement would work more effectively if industry and payors work together to develop, implement and evaluate the agreement. However, perceptions from the different groups about 'motives' of the other are a significant barrier. Building trust is a major issue that will need to be effectively addressed if innovative agreements are to succeed.

Survey findings

The survey of interested stakeholders conducted to support the roundtable resulted in 38 respondents from industry, government, academia and HTA.[12] It identified that the majority of people in industry and all the people in government are already involved in some sort of

[12] Full results from the survey are shown in Appendix B.

innovative agreement. The majority of respondents considered that innovative approaches would become more important in the future, with only a single dissenting voice in the academic community feeling that these approaches will become less important.

When considering the most important values brought by innovative approaches, respondents identified "patient access" as the most important value. However, there is no clear single value brought by innovative agreements. In addition to patient access, managing real world patterns of use of drugs, and addressing effectiveness and cost-effectiveness were seen as areas where innovative agreements can add value. Issues relating to cost and budget management were less important.

The survey asked about barriers and facilitators to putting innovative agreements in place. The major barriers seen are: Capacity or expertise in government; Process of monitoring the performance of agreements (organizational capacity and structure to monitor); and, Ability to gather information on performance to assess objectives of the agreement. Interestingly, the main facilitator for innovative approaches is "Willingness in industry". Considering Industry form the largest single responding group in this survey, this would not seem surprising, however investigation of the responses by sector shows that the majority of people who considered this a facilitator were in fact from government, academia and HTA (ten responses to Industry's seven). Issues around the level of certainty of the benefits for industry, payors and patients were considered to be more neutral in terms of implementing new agreements.

When, where and why? Barriers and facilitators to implementing approaches

Since the aim of this roundtable is to better understand the need for, and appropriate implementation of, innovative industry-payor agreements, the table below summarizes the major barriers and facilitators for innovative approaches that we have identified through all the lines of enquiry in this work. We have also identified which types of innovative agreement these barriers and facilitators relate to.

Table 2. Barriers and facilitators to implementing innovative agreements

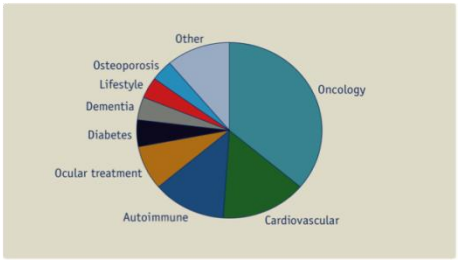
Barriers	Facilitators
Resources – For both industry and payors, innovative agreements can be resource intensive (admin, data collection, legal needs, etc.). *This barrier is applicable to all approaches, but particularly pertinent for conditional coverage and performance-linked approaches.* Trust – Since agreements have always been about negotiation, there is a lack of trust between the two sides of agreements that restricts collaboration and true sharing of risk across agreements. *This barrier is applicable to all agreements, but is particularly true for coverage with evidence development approaches, where there is a lack of comfort over who should develop the evidence on effectiveness.* Ability to monitor approaches and collect data – there is a strong level of uncertainty across	Willingness of stakeholders – In general, industry and payors are interested in moving forward with innovative agreements where they add value. Clearly there are discussions over where that is, but there is a willingness on both sides to move forward with these approaches. *Willingness is stronger for agreements that show value and relate it to reimbursement, as well as for agreements that have lower development costs.* Ongoing development of frameworks to assess when to use "innovative" approaches – The development of these frameworks in multiple provinces suggests that there will soon be guidelines that provinces and industry can learn from and work within. *This is useful for all approaches.*

stakeholders that there is the capacity to monitor effectiveness in the real world, and to collect and analyze data effectively. *This is a barrier mainly for coverage with evidence development approaches, but can apply to all approaches that require some form of post-market surveillance.*	<u>The comparative-effectiveness research (CER) movement in the U.S. is leading us to a value-based approach to drug pricing</u> – Since there is now such a focus on CER in the U.S., there will likely be a move towards more evidence-based drug purchasing decisions. *This should affect all approaches, but with an emphasis on CEDs*

Taking it forward – things to consider when developing approaches

There are a number of factors to consider when taking forward value-based approaches to purchasing agreements. However, based on the literature, interviews and survey, the following are the three main factors we consider need careful consideration.

1. **What types of drugs?** It is important to note that the literature strongly points to "innovative" agreements being most useful for drugs that relate to high cost or high importance (however it is defined) diseases and conditions. The chart to the right shows the conditions that innovative agreements are currently used for, indicating the relative importance of the two major causes of death in Canada (cardiovascular diseases and cancer). When entering into any new agreement, it is clear that the benefit for patients must outweigh the costs of implementing the agreement and the risks associated with developing evidence in clinical practice.



Taken from: Sheppard A 2010

2. **Where is the uncertainty?** "Innovative" approaches all relate to uncertainty around new drugs. It is important to understand where the uncertainty for the new drug lies before creating some form of conditional listing agreement. Uncertainty may be in the effectiveness of the drug, it may be in the epidemiology of the condition for which the drug works, it may be in the value of the health gain from the drug. Where the uncertainty lies will be key to developing the correct approach to funding the drug. For uncertainty over effectiveness, CED approaches may be effective. For uncertainty in epidemiology, outcome guarantees may be more appropriate.
3. **Collaborate early in developing approaches.** The key message from interviews and in the literature has been that for "innovative' approaches to be truly successful, they require strong levels of communication and trust between both sides of the agreement. By beginning the conversations about the need for "innovative" agreements early on in the development of the drug, industry and payors can benefit from a shared understanding of the need for the drug and where likely uncertainty will be in the system.

Where to now? How should we take on this information

In conclusion, there is a significant level of information now on "innovative" approaches, albeit with little of it in Canada. The need for these approaches has been stated in every continent, and there is now a definite movement towards linking health outcomes to the cost of drugs purchased.

For Canada to move forward in this brave new world, there are a number of steps to take:

- A definite need to develop good approaches to evidence development for therapeutics in the real world;
- A need for better understanding of when and where particular categories of “innovative” agreements can add value to the health system(s) in Canada;
- A set of defined characteristics for “innovative” agreement components in provinces or even nationally;
- A need for early dialogue between industry and payors to create a shared understanding of the new therapeutic and a shared vision of how to bring it to the patients that need it;
- An acceptable way for payors to adjust reimbursement criteria if evidence shows a new product isn’t cost-effective in the particular population.

The first step on this journey is to bring all of the stakeholders together and to then decide on: a) the needs for these approaches; b) the people to involve in developing strategies to address those needs; and c) the road map for bringing these approaches to life where appropriate. The aim of the IHE roundtable is to do just that through stimulating thinking on the issue and providing a forum for open and frank discussion across stakeholder groups.