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PRIVATE PAYER PRODUCT LISTING AGREEMENTS IN CANADA

Second Joint Industry/Payer Survey

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Background

Private payers – the community of insurers, pharmacy benefit managers (PBMs) and employers in Canada – have begun building internal competencies aimed at negotiating product listing agreements (PLAs) with pharmaceutical manufacturers. Private payers have expressed interest in participating in the pan-Canadian Pharmaceutical Alliance (pCPA) which now includes all major public plans in Canada. The pricing and reimbursement landscape is evolving rapidly on many fronts, including in the private payer sector. It is important for all stakeholders to understand the activities surrounding private payer PLAs, including when and how they will occur.

In September 2015 PDCI Market Access (PDCI) and H3 Consulting (H3) first surveyed Canadian pharmaceutical manufacturers and private payers regarding their interest, expectations, and experiences with private payer PLAs. Owing to new developments and growing stakeholder interest, PDCI and H3 have now completed a second private payer PLA survey. With more respondents this year from manufacturers and representation from private payers, this edition provides a robust assessment of the private payer PLA activities underway in Canada. This report includes a close examination of the negotiation process and the mechanics and logistics of agreements, an analysis of congruency between manufacturers' and private payers' perspectives, and an exploration of how the landscape has and will continue to evolve.

The objective of this report is to stimulate thought on the scope, issues, and degree of leverage available to private payers and manufacturers through the negotiation of PLAs. While private payer experience, resources and systems capacity to negotiate PLAs is not yet equal to that of the public drug plans, similar forces are at work in both markets. All payers appear to be pursuing strategies to maintain the sustainability of their drug plans while ensuring access to effective new therapies for their plan members. Manufacturers seem to be implementing strategies that will optimize access in an evolving private payer landscape, but the parties necessarily approach PLAs from sometimes different perspectives.

Methodology

PDCI and H3 designed an online survey seeking stakeholder insights on private payer PLAs from pharmaceutical manufacturers and private payers.

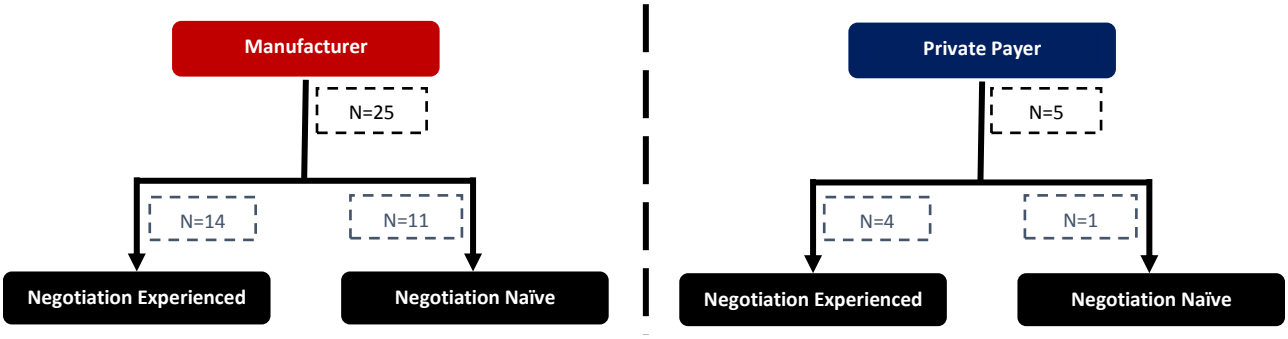
In total, 30 complete responses were received from 25 individual pharmaceutical companies and five different private payer representatives.[1] Replies and comments are believed to be reliable indicators of opinion within both sectors, although the manufacturer sample is certainly more robust given its much larger participation. Pharmaceutical participants included senior market access managers with private payer accountability. Responding private payers were senior product and claim managers working in group benefits

[1] One incomplete response was entered in each stakeholder category. These respondents did not complete the survey and thus are not counted in the recorded sample sizes.

at insurance companies and PBMs. Participants received the anonymized survey data for their sector. Participants were surveyed from June 18 through July 18, 2016, and were assured of complete confidentiality.

Respondents were sorted into one of four question streams based on their stakeholder category (manufacturer or private payer representative) and whether they had experience negotiating private payer PLAs. Figure 1 provides a breakdown of respondents by sector and PLA experience.

Figure 1 - Allocation of Respondents to Four Question Streams



Limitations

Results of this survey may be influenced by:

- Voluntary participation where the only incentives to participate were general interest in the topic and the opportunity to receive detailed responses from their industry sector.
- The low number of private payer responses means few definitive conclusions can be drawn about this group.

Results

Results are analyzed and reported under the following sections:

- **PLAs to Date** identifies the proportion of stakeholders who have engaged in private PLAs, the types of products to which they pertain, and the duration and types of agreements negotiated.
- **Stakeholder Alignment** examines the extent to which manufacturer and private payer representative perspectives align on the main PLA themes (e.g. Negotiation Process, Motivation and Leverage).

PLAs to Date

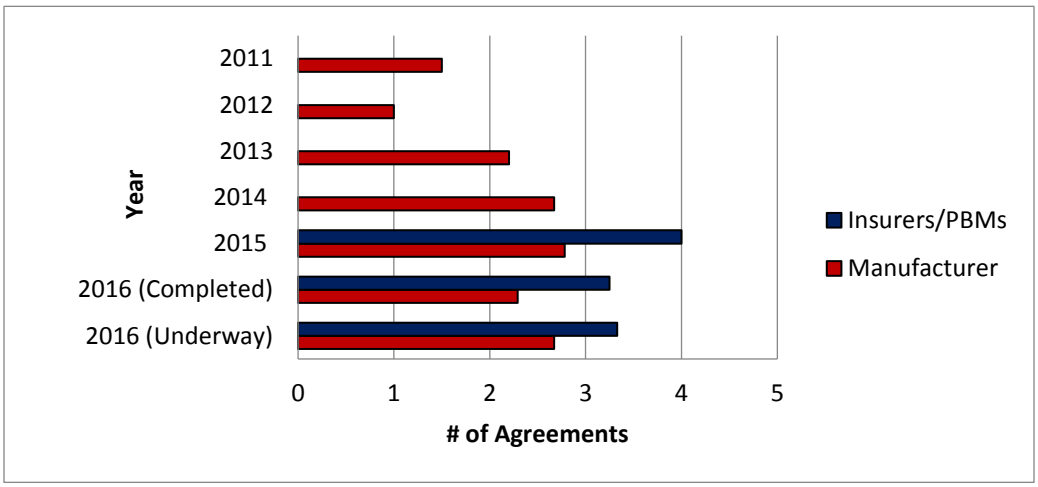
Of 25 responding manufacturers, 14 (56%) reported having participated in a successful private payer PLA negotiation, while four of five (80%) of responding private payers indicated the same.

A Typical Agreement

Drug Type: Speciality Medicine
Agreement Type: Price Rebate
Duration: 3 years
Audit Mechanism: Yes
Time to Completion: up to 1 year

The number of PLAs has been increasing year over year (Figure 2). Manufacturers noted that their earliest agreements were completed in 2011. In contrast, private payers said their earliest deals were only finalized in 2015, suggesting the surveyed payers were newer to PLAs than the manufacturer respondents. Both groups reported an increase - almost double – in the number of private PLAs completed or underway in 2016 compared with the number completed in 2015, which emphasizes the growing importance of this mechanism.

Figure 2 - Average Number of Agreements Reported for Insurers and Manufacturers



For those manufacturers and private payers that have experience in negotiating PLAs, most PLAs have targeted specialty drugs, with fewer agreements in place or underway for traditional drugs. One private payer reported negotiating an agreement for an oncology drug.

However, for those with no PLA negotiation experience to date, manufacturers are primarily interested in PLAs for oncology or specialty drugs, while private payers are interested in PLAs for traditional pharmaceuticals and biosimilars going forward.

Private payer PLAs are mainly structured as price rebates, although caps tied to cost per patient or total cost also occur. No manufacturers reported having negotiated a pay-for-performance or outcome-based agreement to date while payers noted one pay-for-performance and one outcome-based agreement had

been negotiated. However, what constitutes these types of agreements is not well defined and could explain the difference in reporting. Manufacturers and the private payer without PLA experience both reported interest in outcome-based PLAs.

Of the respondents with PLA experience in each group, half (7 of 14 manufacturers and 2 of 4 private payers) reported the active duration of the agreements to be three years. The other half of manufacturers indicated contracts of 1 or 2 years. One payer reported one agreement with a term of less than one year and another payer reported one agreement with a term of 2 years. Audit mechanisms are often included in PLA agreements; however, few respondents on either side have indicated ever initiating an audit (1 of 4 payers and 4 of 12 manufacturers).

All payers reported evaluating previous PLAs to determine if they have been successful in meeting their own objectives, while fewer than half of manufacturers say the same.

Manufacturer Perspective
"We look at the PLA from time of implementation to present, to determine if market share changed significantly from what would have been expected with no PLA in place."

Stakeholder Alignment

The survey sought perspectives and experience surrounding negotiations, motivations, negotiation leverage, and future outlook which are outlined in Table 1:

Table 1 – Comparison of Stakeholder Perspectives and Experiences

	Factor	Manufacturers Reported…	Payers Reported…
Negotiation Process	Initiation	40% of manufacturers reported their preference for negotiations to be **initiated <u>after</u> NOC.**	The same proportion (40%) of payers indicated their preference for discussions to **begin <u>pre-NOC.</u>**
		Both parties, however, indicated this preference may change depending on the drug and a decision about when to engage may be made on a case-by-case basis.	
	Initiating party	Approximately 70% of manufacturers reported having been approached by a payer.	All payers said they had been contacted by a manufacturer.
	Preferred Counterparts	Manufacturers most commonly identified Sun Life, Great-West Life, and Manulife as the payers with whom they would be interested in negotiating, and also reported the **number of patient lives** covered as their primary motivation for negotiating.	Payers did not disclose any preference between manufacturers.

	Factor	Manufacturers Reported…	Payers Reported…
	Improving the Process	Manufacturers indicated that the establishment of **formal timelines** and **payer PLA expertise** could equally improve the process. **Early engagement** and a **formalized process** were also considered to be potential improvements.	All payers identified **early engagement, clear communication/ proposals**, a **negotiation plan** and **expediting manufacturers' internal approval processes** would improve the PLA process.
		Half of both groups agreed that the **duration of the negotiation process needs improvement.**	
Motivations	Benefits of PLAs	Manufacturers reported the main advantage from negotiating a PLA was the **achievement of listing** (8 of 14 reported this as a benefit). Four of 14 respondents said **timely listing** and **protection from genericization** as benefits of negotiating a PLA.	All payer respondents recognized **lower prices for plan sponsors** as a benefit of the PLA process. Three reported the PLA provided the payer with **a general competitive advantage** in the market. Two reported savings passed on to plan members as a benefit.
	Reasons to Negotiate	The primary reason for the 14 manufacturers with PLAs was the **request from the payer**, followed by the **number of patient lives** the payer covered. Four manufacturer respondents (29%) noted that a PLA was required to achieve listing.	All four payers said they engaged in a PLA because of a **request from the manufacturer**, the **high profile** nature of the drug, and the suitability of its therapeutic class for PLAs). A positive relationship with the manufacturer was noted by three payers.
	Perception of Counterpart's Motivations	Manufacturers believe payers are negotiating to **achieve a general competitive advantage** in the market and to assist plan sponsors with lower drug prices.	Payers believe manufacturers pursue negotiations to **achieve successful or preferential listing.**
	Reasons to NOT negotiate	The 11 companies who reported having not negotiated identified either the **lack of opportunity or need** as the primary cause.	The one payer that reported having not negotiated a PLA said a **lack of systems to implement PLAs** was the key reason.
Negotiation Leverage	Payer Leverage	Manufacturers stated that they believed the payers' leverage is associated with the **size of the payer's book of business** and **the threat of refusal to list.**	Payers noted that the **size of their book of business** and their **ability not to list or restrict listing** of the product absent a PLA as key sources of leverage.
	Manufacturer Leverage	Seven said their leverage in negotiations comes from their **previous negotiating experience**. Five reported their **drug's ability to fulfill unmet market needs** and their ability to offer a **competitive price** were also sources of negotiation leverage.	Payers believed manufacturers' advantage comes mainly from **the drug's ability to fulfill an unmet need** and the manufacturer's ability to provide supporting services (three respondents noted each of these as a source of leverage). Two payers recognized manufacturers could offer a more **competitive price** and had more experience negotiating PLAs.

	Factor	Manufacturers Reported…	Payers Reported…
PLA Content	Types of Agreements	Manufacturers who have not negotiated agreements are open to **all kinds of arrangements**, but primarily price rebates followed by caps on expenditure (cost per patient).	Payers reported being open to **price rebates and expenditure caps** (either per patient or total).

Conclusions and Outlook

The level of activity in private payer PLAs is substantial and growing. This activity is apparent not only by the fact that more than half of the 25 manufacturers who responded to the survey noted that they had successfully negotiated a private payer PLA agreement, but also because the number of deals negotiated over the past six years has steadily increased.

Manufacturer Perspective

"At this time, payers have a greater interest in initiating discussions than manufacturers. Moving forward, private payers will individually leverage 1) the PMPRB guidelines modernization which has the goal of making drugs affordable and 2) HTA performed by both CADTH and INESSS in order to drive more pressure on the manufacturer to negotiation a product listing agreement."

There are elements of convergence in perspectives (case-by-case consideration; desire for improved logistics; understanding of the other party's strengths and vulnerabilities), but there are also some areas where stakeholder views diverge, e.g., Post- vs. Pre-NOC timing preference. Both groups have demonstrated a propensity to initiate a PLA negotiation. Specialty drugs and biosimilars appear to be the focus of future negotiations given their relative cost and impact to private drug plan spending. Some insurers already require a listing agreement for particular types of products to be reimbursed. Both manufacturers and payers appear to favour price rebate solutions likely due to the relative ease with which these can be settled, administered and evaluated compared to more complex arrangements.

The survey indicates uncertainties surrounding timing, both from a contract length and negotiation duration perspective. Unlike public PLAs which typically span three years, many private payer PLAs appear to have shorter terms. Negotiations frequently take six months or longer to conclude. Shorter terms may reflect caution on the part of private insurers and PBMs given their minimal prior experience in a market that is rapidly evolving. As familiarity improves, we expect future private payer PLAs will typically run three years. Better processes, systems and resources will improve efficiency for both sides. An important goal for payers and manufacturers is that patients have appropriate and timely access at reasonable cost.

Expectations about the future are similar on both sides of the negotiating table: all agree that the importance and prevalence of PLAs will increase. Manufacturers may anticipate that PLAs will become a condition to achieve private listing at least for certain high-profile and potentially costly new products. More structured,

sophisticated and standardized processes are likely as private payers acquire negotiation experience and greater resource capacity is likely to emerge. Better systems will be necessary to administer the agreements in the future. Both sides reported their expectations that clinical and economic recommendations from the Canadian Agency for Drugs and Technology in Health (CADTH) would play an increasingly important role in private payer PLAs.

Payer Perspective

"There is already more and more buzz around them in the market and I expect more manufacturers to proactively engage in conversation understanding that we need to partner in order to balance access vs sustainability. In order to prepare, we will need to streamline processes as well as increase resources to identify PLA opportunities and run analytics."

Private sector PLA agreements are in their infancy, similar to the public plans dating back 5-8 years. As of September 30, 2016, the pCPA had completed 118 negotiations since its inception. The scale of activity between the two payer groups is still very different, no doubt reflecting more intense policy goals, and much greater experience in the pCPA. However, there will continue to be an increasing number of private payer PLAs initiated by both payers and manufacturers, in anticipation of increasing sophistication and standardization in the negotiation process and system adjudication.

To adequately prepare for this future, manufacturers need to determine their strategy, capabilities, preferences and resource capacity to negotiate, measure and determine product value under evolving market conditions. They need to build internal resources to develop and strengthen their relationships with the private payer community, both nationally and regionally. Companies also need to engage with their finance teams to ensure that there are some clear accounting rules established for such activities.

Private payers have their own important issues to resolve. PLA confidentiality requires significant faith on the part of plan sponsors that their insurer or PBM has negotiated hard for meaningful savings. Current PLAs do not allow any payer to say their price or cost is the lowest, or will remain the lowest, or is at or near the price or cost paid by provincial plans for the same product. Plan members are almost certainly unaware that PLAs exist and ought to be providing them with savings. Smaller insurers do not have the resources to negotiate their own PLAs, and so would have to rely on a PBM to negotiate on their behalf. Relying on CADTH for economic reviews is also problematic for private payers and plan members.

For the past six years, Canadian public payers have developed a coordinated approach to negotiating PLAs with manufacturers and substantially reduced their drug expenditures in the process. As private payers accelerate their PLA activities and resources, the future of private reimbursement is expected to be markedly different. Both manufacturers and private payers need to prepare for the significant changes already arriving in their environment.

About the Authors

Arvind Mani is the Director of Strategy, Policy and Business Development at PDCI Market Access Inc. where he leads and provides strategic advice in the development of reimbursement submission dossiers that help clients demonstrate clinical- and cost-effectiveness to payers and health technology assessment agencies. Arvind has established expertise on emerging market access topics related to product listing agreements (PLAs), biosimilars, and drugs for rare diseases. He has published on a wide array of subjects ranging from companion diagnostics to healthcare reform. Arvind's payer research project work has helped establish a solid relationship with both public and private payer stakeholders in Canada and allows him to offer clients strategic advice to help negotiate PLAs.

Before joining PDCI in 2008, he spent several years as the Director of Corporate Affairs at the National Association of Pharmacy Regulatory Authorities (NAPRA) in Ottawa. Prior to NAPRA, Arvind worked for 8 years at Canada's Research-Based Pharmaceutical Companies (Rx&D), an association that represents the interests of innovative pharmaceutical companies in Canada.

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Chris has been a volunteer director on the Boards of three health service organizations, and has been a member of the Advisory Board for the Sanofi Canada Healthcare Survey since 2003. He holds a Master's degree in Health Science from the University of Toronto, and is a part-time PhD Candidate in the School of Public Health and Health Systems at the University of Waterloo. His dissertation examines how to achieve universal drug insurance.

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