Health Intelligence

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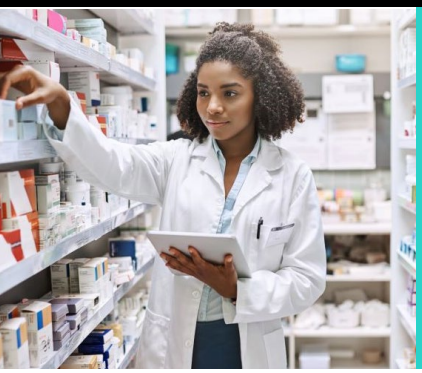

Curating the Cabinet

Understanding the Pharmacy & Therapeutics Committee Approval Process for Hospital Products in Canada

SIGNIFICANCE: A rigorous decision-making process, overseen by Pharmacy and Therapeutics Committees (P&TC), governs the addition of new products to hospital formularies in Canada. This process helps to optimizes the use of finite funds to provide quality patient care. Recognizing the variability in P&TC operations and influence across the country, pharmaceutical companies require an understanding of this process—its players, positioning, and priorities—to achieve their market access objectives and ensure widespread adoption of their products in Canada.

In this article, we share key insights for pharmaceutical companies bringing new products to the Canadian market, highlighting considerations for the current and future hospital formulary decision-making landscape.

KEY FINDINGS:

- **Clinical data is central to P&TC decision-making.** Pharmaceutical companies should continue to prioritize the generation of compelling clinical data, ideally comparing their product against the standard of care and publishing these results in high-quality, peer-reviewed journals. Further, these trials should aim to strengthen the product's value proposition by demonstrating improved patient outcomes and more efficient use of resources, such as clinician time.
- **P&TC decision-making must remain impartial and independent.** Pharmaceutical companies are expected to understand and respect the independence of P&TC members who are expected to be impartial when making decisions to approve and implement products for clinical practice. Pharmaceutical sponsors should be prepared to respond to opportunities, when provided, to maximize their product's potential for success by being responsive to information requests and supportive in product implementation.

FUTURE OUTLOOK: Anticipated changes to the health system may modify preferred evidence required to support P&TC decision-making. As health systems evolve to be more sustainable and integrated with provincial or federal level healthcare entities, there is potential for both additional types of evidence (e.g. pharmacoeconomic, real-world evidence and social impact data) and additional stakeholder perspectives (e.g. patient representatives) to become increasingly influential in P&TC decision-making.

THE BOTTOM LINE: Pharmaceutical companies can benefit from a detailed understanding of the complex landscape of hospital formulary management and decision-making to fully capitalize on the market potential of their products within the Canadian healthcare system.

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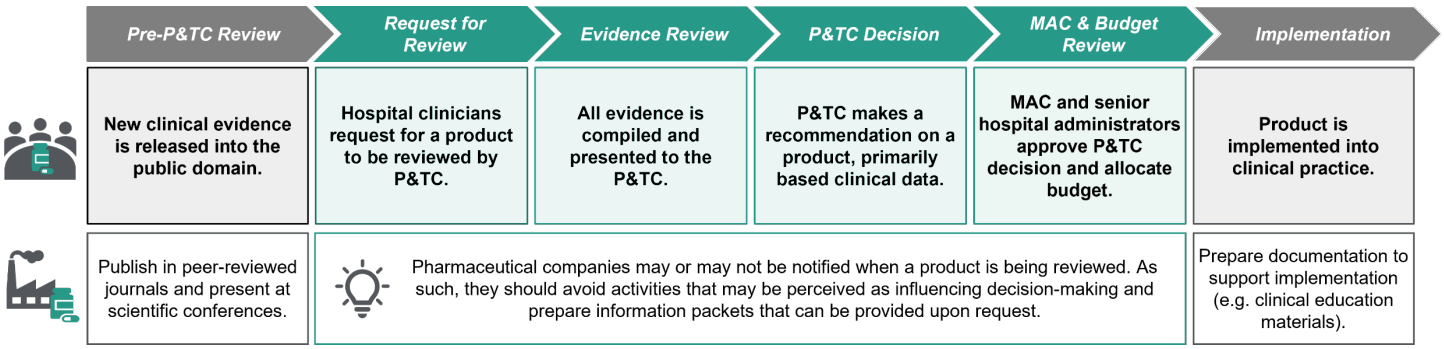

Figure 1: P&TC Review Process.
MAC: Medical Advisory Committee, responsible for ratifying P&TC recommendation and identifying required operational needs for product implementation.

INTRODUCTION TO FORMULARY DECISION-MAKING

P&TCs are the gatekeepers of the hospital's medicine cabinet.

Before a new pharmaceutical product or therapeutic is integrated into clinical practice within the hospital setting, a decision must be made to place it on the hospital's formulary. Hospital formulary decisions are made by a committee of clinicians, pharmacists, and hospital administrators, commonly known as the Pharmacy and Therapeutics Committee (P&TC). An overview of the approval process is outlined in Figure 1. The P&TC's primary mandate is to make formulary recommendations based on empirical evidence to ensure the safe, appropriate, and cost-effective use of drugs and therapeutics to deliver high-quality patient care. Additionally, over the years, the P&TC's purview has expanded to include development of guidelines for medication use, making a positive P&TC recommendation essential to bring pharmaceutical products into hospital standard of care.

P&TC level of operation varies across Canada leading to provincial differences in the path to market.

While all P&TCs share a common mandate, their level of operation and therefore sphere of influence can vary by province across Canada (Figure 2). For instance, in Ontario, P&TCs function at the hospital or hospital network level, achieving faster review timelines but leading to differences in hospital formularies, particularly among hospitals with variations in availability of resources that support product implementation and/or the needs of the patient community served. In contrast, P&TC decision-making occurs at the provincial level in British Columbia, resulting in longer review times, but greater consistency in hospital formularies across the province. In some cases, provincial P&TCs may apply formulary conditions to restrict specific products to select institutions or regions based on the availability of appropriate resources and equipment.

CRITICAL CONSIDERATIONS

Since P&TC approval is key for a product to be added to a hospital's formulary and ultimately integrated into hospital order sets, information systems and clinical practice guidelines, it is important for pharmaceutical companies to understand the underlying process. The following considerations are critical to P&TC decision-making in Canada.

1. Clinical data is central to P&TC decision-making.

To support hospital formulary decision-making, P&TCs examine *all available evidence* for proof that a new product improves upon the current standard of care by addressing an unmet need, enhancing patient or clinician experience, and/or improving cost efficiency; however, not all evidence is given equal weight. For example, data provided directly by a pharmaceutical company is often viewed with skepticism and critically examined for bias. Clinical data remains the primary focus of P&TC, with Phase 3 or even Phase 4 clinical trial data—comparing the new product against the current standard of care—being the most persuasive. In the case of innovative or expensive treatments, Phase 4 data may inform modifications to earlier decisions based on insights from longer-term results and/or

real-world efficacy. Additional types of evidence, such as pharmacoeconomic data, budget considerations and ease of implementation (e.g. cost to operationalize), can also play a significant role in determining the likelihood of P&TC approval, especially in cases where clinical benefit is more modest.

Pharmaceutical companies can position their products for success by proactively considering these factors during product development and clinical trial design. This may involve incorporating secondary clinical outcomes such as hospital length of stay and number of follow-up visits to demonstrate clear financial benefits to hospital systems and stakeholders, thereby strengthening their products' overall value proposition.

Future Outlook:

As health systems prioritize healthcare efficiency and sustainability due to resource constraints, pharmacoeconomic evidence, such as cost savings and cost-utility analyses, may become more important in formulary decision-making (Figure 3). There has also been an increasing focus on leveraging real-world evidence (RWE) to assess the safety and effectiveness of a drug—especially for rare diseases, for which traditional clinical trials are notoriously difficult. For instance, Health Canada is partnering with key organizations including CADTH and INESSS to optimize the use of RWE for drug regulatory decisions across a product's life cycle. Such a transition may lead to P&TCs using RWE more often in hospital formulary decision-making. With the launch of several initiatives aimed at improving access and affordability of drugs for rare diseases, including Canada's inaugural National Strategy for Drugs for Rare Diseases and a substantial investment of up to $1.5 billion over three years, pharmaceutical companies should anticipate changes in the P&TC review process for therapeutics targeting rare indications, including increased influence of RWE.

Furthermore, provinces across Canada are moving toward greater system integration, including in formulary decision-making, to ensure continuity of patient care and consistent adoption of best practices. Provinces, such as British Columbia, Saskatchewan and New Brunswick have transitioned to a standardized provincial hospital formulary and single decision-making process for all health authorities. As such, more P&TCs are making decisions that have an impact on a larger and more diverse provincial population. Consequently, there are new and important opportunities to align P&T decisions with provincial drug plans and government priorities. This shift has the potential to lead to formulary decision-making processes that are longer in duration and encompass considerations beyond hospital-based outcomes, such as the socio-economic impact of new products on the broader healthcare system. As the healthcare landscape evolves, it is crucial for pharmaceutical companies to consider the shifting priorities of formulary decision-making bodies regarding preferred evidence types and how this might impact their approach to market access in Canada.

2. P&TCs are committed to impartiality and independence.

P&TCs are accountable for upholding best practices in patient care and ensuring responsible use of taxpayer dollars. P&TCs deliver on these expectations by basing decisions on high-quality, unbiased evidence. P&TC members take pride in their role as independent decision-makers, and actively avoid any activities that could bias their judgement or be perceived as a conflict of interest. P&TCs' commitment to independence impacts how requests for hospital formulary reviews are initiated, which evidence sources they deem valuable (see above), and how they interact with pharmaceutical companies. Typically, P&TCs only review products upon request from practicing clinicians, who must

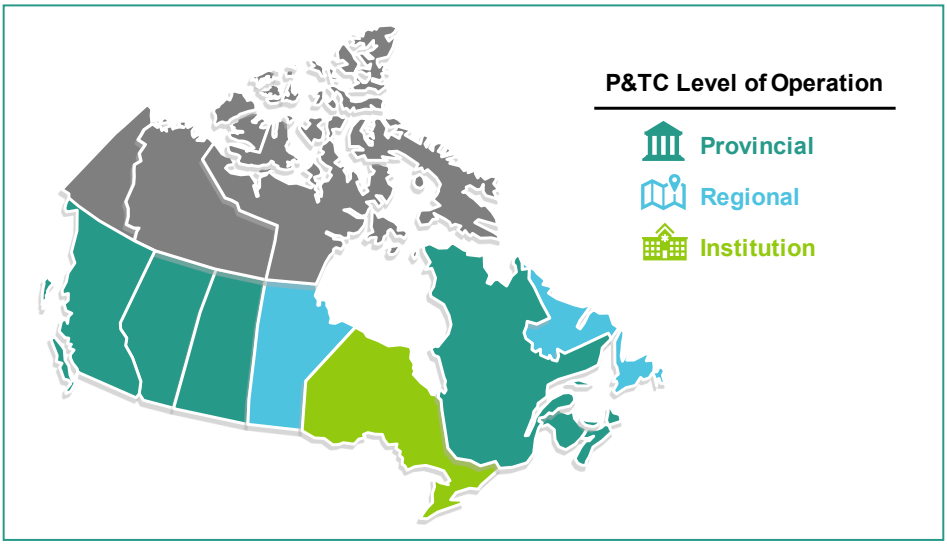

Figure 2: P&TC Level of operation and decision-making influence.

disclose any relationships with pharmaceutical companies. To further avoid potential conflicts of interest, P&TC members are highly unlikely to engage in any product-related discussions directly with pharmaceutical companies.

It is important that pharmaceutical companies understand and respect that the P&TC decision-making process must remain impartial and independent to avoid creating a negative perception of their product during review. Before P&TCs review, pharmaceutical companies can build awareness of their product and clinical data by presenting at scientific conferences and publishing in peer-reviewed journals. Any direct engagement activities that involve clinicians accepting monetary incentives from pharmaceutical companies will need to be disclosed during the P&TC review process and may lower the likelihood of formulary approval. During P&TC review, drug evaluation pharmacists, who are responsible for reviewing drugs and compiling the necessary evidence for P&TC decision-making, may contact pharmaceutical companies for product or manufacturing information. In such instances, pharmaceutical companies should respond as a collaborative partner and share additional evidence to support the review process, while also taking care not to overstep or pressure the P&TC.

After receiving a positive P&TC recommendation, pharmaceutical sponsors may have the opportunity to provide resources that can support implementation and accelerate adoption of their products, including clinical education materials, use and storage specifications, and confirmation of a robust supply chain. Being recognized as a collaborative partner with reliable supply can alleviate logistical concerns related to product implementation and support the adoption of future products in the pipeline.

Future Outlook:

Public drug plans, hospitals and health authorities are collaborating more frequently to enhance continuity of care for patients, both within and across provinces. The increasing collaboration between formulary decision-making bodies may require additional policies and restrictions concerning interactions with pharmaceutical companies to prevent system-level bias in decision-making. For instance, in 2017, a National Hospital Formulary Collaborative, involving representatives from P&TCs from various health authorities across 10 provinces and the Canadian Agency for Drugs and Technologies in Health acting as a liaison between them, was established to explore opportunities for collaboration and knowledge sharing on best practices. Furthermore, a pan-Canadian Advisory Panel has been assembled to establish a framework for a unified formulary within the national pharmacare program and address concerns regarding access,

Clinical Evidence	Clinical evidence is the primary factor that influences P&TC formulary decision-making, with Phase 3 or 4 clinical trials designed to compare against standard of care considered the gold standard.
Pharmaco-economic Evidence	Pharmacoeconomic evidence, such as cost avoidance and cost utility studies, are important, albeit secondary to clinical evidence and considered in the context of value to patients.
Hospital Budget	P&TC recommendation is not contingent on availability of hospital budget; however, the MAC is responsible for making the final formulary approval based on budget and other operational considerations.
Convenience Factors	"Convenience factors," such as ease of use and product format, can significantly impact healthcare resource utilization, efficiency and patient outcomes, and are considered during P&TC decision-making.
Equipment & Resources	P&TCs may take operational needs into consideration, placing formulary restrictions to limit access based on availability of supporting hospital infrastructure, clinical expertise, resources and equipment.

Figure 3: Factors influencing P&TC decision-making.
MAC: Medical Advisory Committee, responsible for ratifying P&TC recommendation and identifying required operational needs for product implementation.

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affordability and appropriate use of prescription drugs in Canada. In step with these efforts to increase coordination and collaboration among P&TCs, pharmaceutical companies should respect the P&TC's decision-making independence and focus on releasing product information in the public domain and collaborating with hospital systems following P&TC recommendation to ensure seamless implementation.

The healthcare industry in Canada and around the world is recognizing the importance of incorporating diverse voices and expertise in healthcare decision-making. As such, patient representatives are being acknowledged as essential contributors to these processes. Although patients will not be directly responsible for making formulary decisions, P&TCs are increasingly considering patient perspectives on the potential positive or negative impact of candidate drugs during the drug prioritization process. Taking this into account, pharmaceutical companies should prioritize patient-centered product development by embedding a deep understanding of the unique needs and experiences of patients into their processes. It is important to note that restrictions and disclosures related to conflict of interest are likely to apply to patient representatives, as they do to other P&TC-associated stakeholders.

CONCLUSIONS

As a pharmaceutical company seeking to establish a foothold in the Canadian market, it is critically important to maintain a comprehensive understanding of the formulary decision-making process, including key differences across health systems, what evidence is considered valuable during P&TC review and what strategic actions can be taken to maximize access while minimizing any perceived influence on the process. We are also in an era of change, with more integration across health entities and select services moving toward privatization. Transformation in how healthcare is regulated and delivered to patients may complicate the path to market for pharmaceutical companies, emphasizing the need for a deep understanding of the market access landscape as it evolves.

HOW WE CAN HELP

Shift Health applies its extensive expertise in **market access** and **policy strategy** to help pharmaceutical partners of all sizes differentiate their products and position them for commercial success.

- We engage directly with payers, providers, and patients to collaboratively develop market access strategies that enable companies to mitigate risk and accelerate time to market.
- We support policy teams in creating evidence-based strategies and communication materials to effectively navigate, inform and influence the complex web of policy and related stakeholders.
- We help industry leaders in maximizing the value of their pharmaceutical portfolio or asset by providing support in **opportunity evaluations** and **product strategy** throughout its entire life cycle.

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