



Drug Pricing & Reimbursement



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LET GOWLINGS PROVIDE YOU WITH A ROADMAP TO NEGOTIATING THE HAIRPIN CURVES OF THE CANADIAN PRICING AND REIMBURSEMENT LANDSCAPE

- Inventing, and securing marketing approval of, an innovative pharmaceutical/biopharmaceutical is only part of the business process that must be undertaken in relation to a new drug.
- That business process is neither complete nor successful until the medicine in question is assured of a market presence at a price that is acceptable compensation for the innovation and the cost of bringing the particular medicine to market.
- Key questions regarding pricing, formulary listings and reimbursement must be addressed long before a product receives regulatory approval. In fact, the main questions regarding these issues must be asked and answered at the early stages of the development of the drug.
- In Canada, as elsewhere, there are huge pressures on drug payers to limit the costs of medicines. This has translated into drug pricing and reimbursement systems that are increasingly complex and restrictive.
- The rapid pace of change in regulatory systems requires ongoing monitoring and response. At the provincial level, Ontario and Québec are implementing major changes to their drug systems; at the intergovernmental level, the National Pharmaceuticals Strategy has called for expansion of the Common Drug Review and other new policies; federally, the Patented Medicine Prices Review Board is conducting a review of its price guidelines.
- The results of reviews by pricing and reimbursement authorities in Canada may impact markets in other countries as a result of increased transparency and collaboration among international authorities.

NEW STRATEGIES AND APPROACHES ARE NEEDED TO ENSURE THE APPROPRIATE AND TIMELY POSITIONING OF A NEW MEDICINE IN THE PRICING AND REIMBURSEMENT REGIMES. THEY NEED TO ADDRESS:

AN INTEGRATED PROCESS

- What are the interrelationships among the various decision-making bodies? How will reviews by one body impact the others?
- What are the relevant timelines?
- How will decisions by public authorities impact the private market?

PATENTED MEDICINE PRICES REVIEW BOARD (PMPRB)

- How is the PMPRB likely to categorize the medicine?
- Which pricing test is likely to apply?
- What will be the impact of the maximum non-excessive price calculated by the PMPRB?
- What will be the impact of the PMPRB's limits on price changes in the long run?

CANADIAN AGENCY FOR DRUGS AND TECHNOLOGIES IN HEALTH (CADTH) – COMMON DRUG REVIEW

- How is the Canadian Expert Drug Advisory Committee (CEDAC) likely to assess the medicine in terms of clinical and cost-effectiveness?
- What is CEDAC likely to recommend to public plans for listing purposes?

PUBLIC DRUG PLANS

- How is the plan likely to use the CEDAC recommendation? What further submissions may be necessary to the drug plan to obtain a favourable listing decision?
- How will the Conseil du médicament in Québec review the drug?
- In the case of Ontario, what further negotiations or agreements may be necessary in light of Bill 102?
- In the case of cancer drugs, what alternative or additional steps may be required to obtain a favourable decision under special funding and approval systems?
- How will the application of specific requirements in one jurisdiction (e.g. Ontario's Bill 102, Québec's lowest price rule) impact pricing and reimbursement discussions in other jurisdictions?
- On an ongoing basis, what opportunities may exist to remove or amend restrictions on use?

CADTH – CANADIAN OPTIMAL MEDICATION PRESCRIBING AND UTILIZATION SERVICE (COMPUS)

- For drug classes under review (currently proton pump inhibitors and diabetes drugs) what is the likely impact of recommendations for best practices in prescribing and use?

GOWLINGS' DRUG PRICING & REIMBURSEMENT TEAM CAN PROVIDE STRATEGIC ADVICE ON:

- Approaches to policy formulation in Ontario and other provinces;
- Dealings with intergovernmental bodies such as CADTH and federal bodies such as Health Canada and the PMPRB;
- Specific regulatory proposals such as the regulations governing the Ontario Drug Benefit plan and the pricing guidelines of the PMPRB;
- Product launches, including pricing and reimbursement strategies to obtain positive listing recommendations;
- Submissions to the Canadian Expert Drug Advisory Committee for purposes of the Common Drug Review;
- Submissions to provincial health ministries and their expert panels, such as the Committee to Evaluate Drugs in Ontario;
- Submissions to the PMPRB;
- Reformulating existing strategies as may be required by government policy reviews and changing market conditions; and
- Submissions for applications to provincial and federal regulatory bodies for reviews of price changes, as required.



INVITE GOWLINGS' DRUG PRICING & REIMBURSEMENT TEAM TO CONDUCT A BEST PRACTICES AUDIT FOR YOU

- What are you doing now?
- What, if anything, is missing?
- What processes can be put in place to ensure that your new medicines get on the market at acceptable prices and are approved for reimbursement in Canada's key markets?
- What processes should be implemented to avoid running afoul of key legislative/administrative requirements, such as the Patented Medicines (Notice of Compliance) Regulations, PMPRB requirements/deadlines and a myriad of provincial requirements?

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For further information, please contact:

Martin Mason
Leader, Drug Pricing & Reimbursement Team
160 Elgin Street, Suite 2600
Ottawa, Ontario
Canada K1P 1C3
Tel: (613) 786-0159
Fax: (613) 788-3451
martin.mason@gowlings.com

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