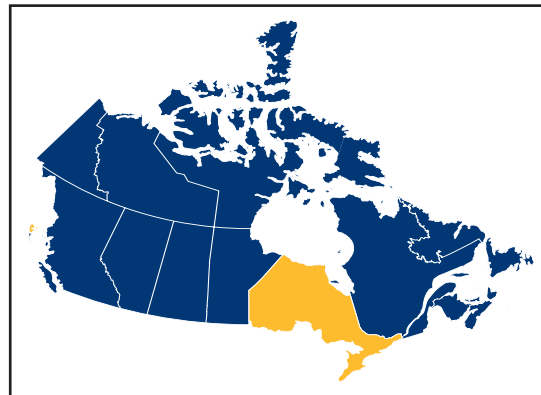




An IMS
Viewpoint

Ontario's Bill 102: The Long and Bumpy Road Ahead

With the passage into law of Bill 102, the Transparent Drug System for Patients Act (TDSPA) is reshaping Ontario's drug system, both publicly and privately. This Act will have a spillover effect into other provinces as well. Both innovative and generic manufacturers in the pharmaceutical industry need to carefully review these legislative reforms and the supporting regulatory amendments and revise their:



- market access,
- reimbursement and
- revenue projections for 2007 and beyond.

Careful navigation of this road ahead will be the key to their success. So, the questions we now ask ourselves are:

- What are the implications for:
 - brand companies,
 - generic companies,
 - pharmacies and
 - physicians?
- How will they affect market access and reimbursement policy in Ontario and in the rest of Canada?
- What will the impact be on prices, agreements and volume discounts?

New rules of the road

The key reforms that have been implemented as of October 1st, 2006 include:

- Requirements that manufacturers enter into pricing and volume discount agreements as a condition for new and existing listings
- Provisions that lay out the criteria for expedited and conditional listings for some drugs, including unlisted ones
- A prohibition on rebates to pharmacists and the codification of professional allowances intended to replace those rebates
- A new 50% generic pricing rule

As long as manufacturers are willing to enter into agreements with the Executive Officer (EO), market access should not be hindered any more than it is now. The legislation also states that, "Nothing in this Act shall be construed as permitting therapeutic substitution." However, the Act will allow for the interchangeability of "similar" products.

The Operational details of the new Committee to Evaluate Drugs are still to be clarified, along with how the new Committee will function in relation to the Common Drug Review and the role of the two citizen representatives. Other unresolved issues include:

- The makeup and terms of reference of the Citizen's Council
- How the proposed Innovation Fund will be funded and operate
- When the Ontario Drug Benefit (ODB) program will convert almost 90,000 federal government retiree beneficiaries to secondary payer status

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Bumps in the road

The legislative and regulatory changes in Ontario will undoubtedly have a spin-off effect on other provincial and territorial drug programs, although market access should not be further hampered in the near term. With the new Ontario regulation that generic prices must be 50% of the brand price, other provinces will expect to pay lower generic prices. Alberta and British Columbia will be important provinces to watch. Quebec is waiting in the wings to pass its own package of drug reforms—the *Politique du médicament* was tabled almost two years ago. Quebec could more or less adopt Ontario's reforms or implement a made-in-Quebec approach.

On October 31, 2006 and November 1, 2006, the EO released two *Notices from the Executive Officer*. The first outlined a range of outstanding implementation issues related to the TDSPA, where work was

Why the New Act?

The Ontario government felt it was essential to introduce the new Act for several reasons. First, the Ontario Drug Benefit (ODB) program felt it was not getting full value for its \$3.5 billion in drug expenditures and needed to better leverage its purchasing power. It also believed that:

- there were opportunities to achieve better results and increase access to drugs,
- public participation in the decision-making process was absent and
- administrative barriers to access needed to be resolved.

The government also saw a need for increased collaboration with the private insurance sector to help employers better manage drug costs.

The new legislation created the position of the Executive Officer (EO) for the Ontario public drug programs. Ron Sapsford, Deputy Minister of Health and Long-Term Care, was appointed as EO in the first week of October, 2006. The new Act bestows considerable authority on the EO, which was previously assigned only to the Health Minister and Cabinet. The government believes that the EO's authority will lead to faster decisions, make the system more responsive, while providing more transparency.

underway to find resolutions and was committed to an immediate response. The next day, the EO added specific resolutions to the report, some of which were of greater importance to pharmacy than to brand and generic manufacturers. However, the EO indicated that limited exceptions to the 50%

price rule would be negotiated for specific single-source generic products and first-to-market generics. A full Formulary is scheduled to be published in January 2007.

Despite the expected contraction of the 2007 ODB program expenditures resulting from the new Act, the IMS forecast for the total Canadian market is still pegged at a buoyant 7.4% sales growth over 2006 levels. The TDSPA is one of many negative events shaping this forecast, along with numerous positive events. Keep in mind that the TDSPA mechanism on agreements is structured so that brand prices will be maintained. Any offsets deemed necessary by the EO and agreed to by manufacturers will be achieved through these agreements. **CPM**

Bill 102 is a significant event that will demand new approaches to market strategy, analysis, planning, and monitoring. To obtain a copy of the IMS Health Canada white paper, The Transparent Drug System for Patients Act, 2006: A Review of Drug Plan Reform in Ontario and Implications for Other Provinces, please contact Raquel Bowes at (905) 816-5094 or rbowes@ca.imshealth.com. To discuss how IMS consulting experts can assist you in responding to changing market conditions, please contact your IMS Health representative.

REACH THE EMERGING PHYSICIAN TARGET GROUPS.

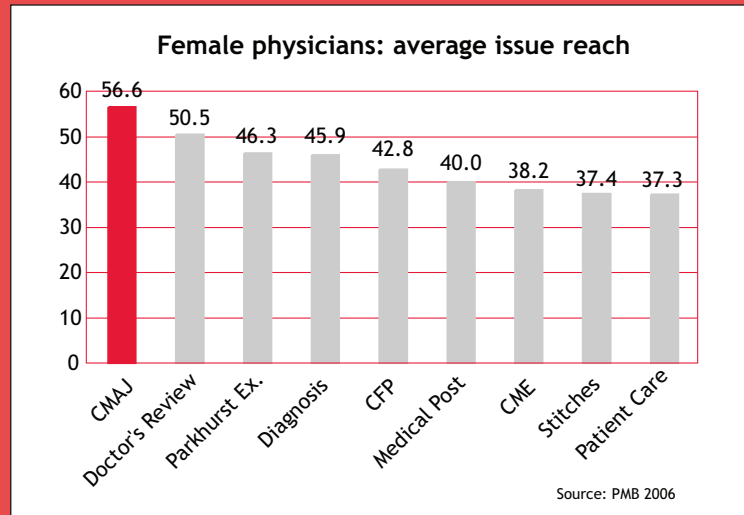
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