

## The Rules are Changing...

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On June 15, 2009, Green Shield Canada, one of Canada's benefit management companies sent out a letter to members of the pharmaceutical industry and healthcare industry members announcing a change to the established rules.

Their announcement stated that effective July 2, 2009, for a defined list of pharmaceutical prescription products dispensed to members of the drug benefit group plans for General Motors Canada Limited and Chrysler Canada Inc., only the brand name products would in fact be covered as a healthcare benefit. Additionally, for one other brand product the effective date of this policy is September 1, 2009 (about 7 months before the patent for the brand is thought to expire).

The change in policy specifically states, "If a pharmacy submits a claim for a generic of one of the above brand products, the claim will be rejected" and the response "ineligible due to preferred benefit agreement by plan sponsor; alternate brand is eligible" will be given.

Most of the products covered on the agreement have expired patents and have or will shortly have multiple generic equivalents available on the market, offered at typical generic product price levels.

This change of the rules could have some important implications to the drug industry, the provincial formulary listing processes and the current legislation affecting generic substitution.

The questions that came to mind are:

1. What is the part of the arrangement that we do not see published?
2. How does this arrangement impact provincial drug formulary listings in Ontario, in Quebec or in any other province?
3. What will be the response of the generic companies?
4. How will this affect you, the pharmaceutical executive, and the marketing decisions you are currently making with respect to your product line?

5. How does this change the definition of Best Available Price or Acquisition Price for some jurisdictions?
6. What happens if this becomes pervasive across more private payer plans?

Let's speculate about the potential answers to these questions.

***What is the part of the arrangement that we do not see published?***

To consider the answer to this question we must first understand where the participants are coming from.

1. Green Shield Canada is thought to be a passive participant. This means they get paid a percentage, or a handling fee for each claim processed. If they manage the claims for General Motors and Chrysler anyways, their fees should not change significantly. Even if the face value of the claims are higher than they would be had the prescription been filled by a generic product it would be expected that there is a negotiated rebate back to the employer – sponsors of a part of the fee.
2. For the brand drug companies involved, there is a major benefit in that when the brand goes generic, typically most of the sales are recorded by the generic equivalents being dispensed, due to the mandatory substitution rules in effect in most provinces of Canada and the attractive savings to consumers and payers. Generally these rules extend to even the patients whose prescriptions are not covered by a formulary and where coverage is offered by a private insurance coverage plan like Green Shields or other similar organizations.

Therefore the positive for the drug company is increased sales dollars and units.

As we know that “deals” have been cut by pharmaceutical companies in achieving listing at the formulary (in some provinces), It is likely that a rebate of some form is in place between the drug company and the employer - sponsor. As the generic price of drugs is typically 50-70% of the brand price, a rebate of 30-50% (or quite possibly more) is conceivable. The brand drug company may also believe that some other benefits may accrue to its

product's usage patterns by creating this new segment of consumer, in all provinces in Canada.

3. For the employer-sponsors, GM or Chrysler, the potential of achieving some savings in healthcare costs is the major driver for them to consider entering this type of arrangement. Both of these companies are in financial distress. Increasing costs is not on their agenda. Therefore any cost reduction would be welcomed.

Ultimately, the answer to this question is that there is very likely some form of rebate being paid by the manufacturers involved to the payer and that this rebate is sufficient to at least offset the cost of the generic drug.

***How does this arrangement impact provincial drug formulary listings in Ontario, in Quebec or in any other province?***

This is a very difficult question to speculate upon. Quebec has rules in place which guarantee their listed product prices (on their drug formulary), are the lowest retail prices in Canada. Other provinces offer plans which have a universality built into the plan and

“Acquisition Cost” is the basis for reimbursement. Historically, unpublished rebates have not triggered price reductions in Quebec.

Although the agreement between the drug companies and GM and Chrysler do not directly impact the drug benefit programs in every province, the nuance that the “brand” product has rebates associated with it, for selected patient groups, coupled with the concept that the formulary-listed price for the brand and the derived price for the generic equivalents are all drawn into question because of this deal. It would be interesting to speculate what would happen if the provinces insist on finding out the terms and conditions for this deal and impose them on the formulary listings following the principles of BAP (best available price).

An additional consideration for the companies is related to their future formulary listing for any new products coming to market. No brand company will be willing to embark upon any pathway which could create barriers to formulary acceptance of new and expensive products such as biologicals, as an example.

Will the Ministry of Health in Ontario change all the rules and force companies to end the current rebate systems? It seems that the July 10<sup>th</sup> meeting discussed later has responded to this question.

### ***What will the response be of the generic companies?***

There can be 2 streams of response, one immediate and reactionary. The other strategic and longer to implement:

The immediate response is likely to be:

1. Patient goes to pharmacy to fill an eligible prescription.
2. Pharmacist fills the prescription with a generic product and files claim
3. The claim is rejected as it was filled with the generic brand.
4. The generic company pays for the prescription.

Rumor has it that 3 of the major pharmacy chains have already started using this system.

The strategic responses will likely attempt to change/enforce policy and prevent the migration of these types of programs across to other employers and plans. The generic industry will likely use their association to attack this plan on behalf of their biggest client, the retail pharmacist, who aside from the generic company, faces the largest potential loss in this game. The attack will likely be directed at the formulary level using PR. Their position would likely be that the intent of this agreement compromises existing legislation and rules.

### ***How will this affect you, the pharmaceutical executive, and the marketing decisions you are currently making with respect to your product line?***

It is clear that the rules are changing. It is also clear that brand companies are re-visiting their product strategies, their product life cycle strategies and are considering plans which until recently have been left to the side. The door is open to creative, business retention strategies that can be executed by the brand name companies in protecting their brands sales generation potential. While they likely still recognize that some sales revenue will be lost to generics and that as always,

this is normal - They appear to be moving towards executing plans that preserve some piece of their business.

***How does this change the definition of Best Available Price or Acquisition Price for some jurisdictions?***

This remains to be seen. Rebates on price have been a tool to obtain reimbursement for products on the public formularies and while there have been efforts to curtail them; they are an important cost-savings lever for branded products operating under the auspices of the PMPRB. With less pricing regulation for post-patent products and the decreased need for promotion or product development following the patent-protected period, rebate driven strategies may well thrive and find their way back across to the public plans as a result. There are already instances of brand companies discounting prices in return for significant public business both before and after genericization.

***What happens if this becomes pervasive across more private payer plans?***

If this type of arrangement spreads to other large employers, and expands the product list being covered, this could cause a multi-priced system covering drugs and medical supplies across Canada which would be inflationary for those who pay for the products used via private insurance or on a cash basis.

Given the potential for significant disparity in pricing from one plan, employee, employer or retailer, who knows, we may be on the cusp of the perfect storm that helps drive a National Drug Formulary Or the emergence of regulation over post-patent products.

**Conclusion**

Ultimately and understandably, the drug companies are looking for ways to preserve revenues especially given the imminent threat of significant numbers of substantial patents already or about to expire. Will this single deal achieve any positive results for them? It will be interesting to witness whether this type of arrangement will become pervasive, and especially whether it will transfer over to the public sector as the formularies look for opportunities to cut costs. This becomes the latest in a series of strategies that attempt to retain some level of



brand revenue following patent expiry. We expect significant exploration of post-patent opportunities going forward.

What does this all mean? We see the start of a major re-alignment of the prescription drug business in Ontario, which could lead or influence greatly, the rest of the country. The “brand” drug companies are looking for ways to preserve the revenue generation ability of the brands whose patents have expired or are about to expire. Will the deal described above achieve any positive results for them? How will this deal withstand review by the change process just announced by the Minister and his team? We believe that the pressure from the provincial formulary bureaus will eventually force the cancellation of this deal.

How will the generic companies respond to the latest challenges being poised to their current business model and operations. How will their competitiveness be maintained? How will they differentiate themselves from one another? These are all very important questions to consider?

Another important question is, “how will the business of pharmacy change?” and “how will patient care be impacted by changes to health care delivery with respect to drugs?”

A friend shared an expression which is well known in her company, “we must stop breathing our own air.”