Topics and Trends in Canadian Pharmaceutical Marketing: Volume 1, 2008

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PHARMACY CHAIN PURCHASES GENERIC COMPANY

On December 20, 2007, the Jean Coutu Group announced that it had acquired Pro-Doc, a Quebec based generic drug manufacturer with headquarters in Laval, Quebec. This is an interesting twist given the recent legislation in Ontario and Quebec. Perhaps they intend on bolstering their profit line by competing in the generic arena. This should be interesting to watch.

THERAPEUTIC PRODUCTS DIRECTORATE (TPD) FEE CHANGE

The official notice of fee proposal for Human Drugs and Medical Devices should have been called "The Great Money Grid." The number of days to review is still high. Table 1 provides examples of fee changes.

TPD APPROVAL UPDATE

Overall, the review timeframes have dramatically reduced which is a good thing. There has been positive improvement in the efficiency of various aspects of the review process, but there is also an increase in Notices of Deficiencies (NODs) or Non Compliances (NONs) at both chemistry and manufacturing as well as clinical levels.

ONTARIO ACKNOWLEDGES INDICATION PATENTS

The following was recently sent by the Ministry: On March 9, 2007, generic pramipexole was made interchangeable with Mirapex® under the Ontario Drug Benefit (ODB) **only** for the treatment of Parkinson's Disease and **not** for moderate to severe idiopathic restless legs syndrome (RLS) where you would still use Mirapex® brand name under the manufacturer's Drug Identification Number.

Table 1
Therapeutic products directorate fee change examples

	Current	Proposed	Days
Drug establishment license: Importation/distribution	$1,500	$3,870	-
Switch from prescription to OTC	$17,200	$41,280	180
New active substance			
• Pharmaceuticals	$143,800	$303,480	300
• Biologicals	$143,800	$391,770	300

If a prescription is written for Mirapex®, the brand name Mirapex® should always be dispensed for the treatment of RLS due to the "Indication Patent" as recognized by existing Canadian patent laws. The ODB act has recognized this existing "Indication Patent;" therefore, it is expected that pharmacists should verify the indication with the patient and/or the doctor when a Mirapex® prescription presents.

Mirapex® (pramipexole dihydrochloride monohydrate) is indicated for:

- Treatment of the signs and symptoms of idiopathic Parkinson's disease
- Symptomatic treatment of moderate to severe idiopathic RLS

Mirapex® is a registered trademark of Boehringer Ingelheim (Canada) Ltd.

LONG TERM CARE

The Ontario government is, once again, looking into the movement and payment for Pharmaceuticals into long-term care facilities.

The results should be interesting and definitely affect the revenue of the major pharmacy providers. As we all know, Ontario will definitely not be paying more!

FDA UPDATES

The FDA continues to surprise everyone and their updates and regulations affect the overall industry. The following updates were sent out during the last quarter.

Behind-the-counter drug prescribing

The FDA held public meetings to look at the potential of creating a "behind-the-counter" category of drugs. An agency spokeswoman stated that "the pharmaceutical industry, consumer groups and some of the drug companies have been pushing the FDA to make certain prescription drugs available for dispensing behind-the-counter."

Speeding up approval process for generic drugs

The FDA announced a new program to speed up and modernize the approval process for generic drugs. Under the Generic Initiative for Value and Efficiency, the agency expects to give priority to applications for generic products that are the first of their type and are not subject to blocking patents or exclusivity protections.

Proposed guidelines for off-label drug marketing

The FDA is considering creating guidelines that would allow drug makers to provide physicians with certain medical journal studies of unapproved uses for drugs. While critics contend that the move would undermine current restrictions on off-label drug marketing, Ken Johnson, of Pharmaceutical Research and Manufacturers of America (PhRMA), noted that providing this information to doctors could help them make better prescribing decisions.

There is good work underway and positive improvement to the efficiency in various aspects of the review process, but we observe:

- An increase in NODs or NONs that is of concern
- Backlog sit

QUEBEC UPDATE REGARDING PROFESSIONAL ALLOWANCES

The Quebec health minister, Philippe Couillard, has presented a new ruling regarding the professional allocation allowed to pharmacists by pharmaceutical companies. This could be approved and implemented this fall. The following is how it will work for a generic or brand pharmaceutical company.

For a generic company:

The professional allocation can be paid directly or indirectly by rebate, pay-back, bonus, a good or service or any other benefit.

The pharmacist must utilize these allocations under the following guidelines:

- To fund continuing health education for pharmacists and lab technicians, which must be performed in Quebec
- To fund promotional activities directed to patients as long as they are performed in pharmacies and are science-based
- To fund the acquisition of software for patient education (*e.g.*, for follow-up on chronic diseases or to teach usage of diagnostic devices)
- Funding cannot be used for purchasing hardware, such as computers

- Funding can be used to buy equipment that will improve quality and safety of drug distribution. These costs can be spread over a number of years. This explains why Pharmascience purchased PacMed machines
- The limit of these allocations is equal to 20% of all purchases made for drugs that are listed on the Régie de l'assurance maladie du Québec (RAMQ) drug list

For a brand pharmaceutical company:

- There will be allocations allowed with no limitation but restricted to points 1, 2 and 3 as above
- The pharmacist has the obligation to keep a record of all professional allocations given as they may be monitored by the RAMQ, Health Ministry, Quebec Finance ministry and the Ordre des Pharmaciens du Québec (OPQ)
- Brand or generic companies cannot deal with these allocations at the wholesalers or chain/banner level. It has to be done store by store
- If a company provides illegal funding, the company will have to reimburse the equivalent to RAMQ plus 20%. The manufacturer can also be suspended from the RAMQ for a period of time

PATENTED MEDICINE PRICES REVIEW BOARD UPDATE

Zemplar IV hearing resolved with a voluntary compliance undertaking (VCU)

The hearing on the drug product, Zemplar™ IV (parenteral paricalcitol), sold by Abbott Laboratories Ltd., has been resolved with a VCU. The maximum non-excessive price was set based on the therapeutic class comparison test against Calcijex® IV (parenteral calcitriol). The average transaction price was 66.57% excessive and as of June 30, 2007, the product accumulated about $58K in cumulative excess revenues. The terms of the VCU state the reduction in price of Zemplar™ and a repayment of excess until June 30, 2007, by cash. As well, for the period of July to December 2007, repayment should be made in the form of a payment to each hospital in Canada that paid the alleged excessive price.

It is interesting that payment is going directly to the institutions.

PROVINCE OF ALBERTA

On October 12, 2007, Alberta Health and Wellness notified Alberta pharmacists and Alberta Blue Cross that GlaxoSmithKline (GSK) would reduce the price on Zantac® (ranitidine) from $1.1447 per 150 mg tablet and $2.2894 per 300 mg tablet to $0.18 and $0.36, respectively. This price change went into effect on December 12, 2007. This strategic pricing change from GSK undercuts current generic pricing of $0.4042 (150 mg) and $0.7787 (300 mg) considerably and represents a "shot across the bow" for generic companies in that it tests their resolve to price compete. The implications of this price change are far reaching, as not only Alberta pricing will be affected. Law 130 in Quebec will force the price reduction to be passed on there as well. Overall, Alberta and ultimately Quebec payers will see a reduction of approximately 46% of their ranitidine costs (possibly more, due to generic pricing rules in Quebec).

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