

Topics and Trends in Canadian Pharmaceutical Marketing: Q1 Report, 2007



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BILL 102

The Executive Officer (EO) has issued numerous updates. The EO has clearly stated that Bill 102 and the government interest is the public sector only. The actual text can be found on a link at the following website: http://www.health.gov.on.ca/english/providers/program/drugs/edition_39.html. As we watch this website on a daily basis we learn the price changes, apparent deals as well as announcements.

The Bill itself has wonderful intentions; however, we all know that the road to... is paved with good intentions!

Price modifications, 'deals,' generic and brand pricing are being finalized, hopefully before the end of January. Highlights include:

- Generic prices have officially moved to 50%; however, now single source generics will possibly move back to the original 70%
- Price increase negotiations (I use this term loosely) continue and the results can be found on the above-mentioned website
- Corporate deals are being negotiated
- Pharmacies can use the professional allowances for any of the activities identified in the Code of Conduct
- The professional allowance is still 20% for the public market
- The exception to the 50% generic rule is now official
- Cost to operator mechanism remains until March 1, 2007, stay tuned!

- Pricing deals and listings continue. Please check the above-mentioned website
- Sabre rattling continues over the pricing issue
- Long term care is now being looked at

AMENDMENTS TO CANADA'S INTELLECTUAL PROPERTY PROTECTION REGIME

The Patented Medicines (Notice of Compliance) Regulations to The Patent Act (commonly known as the Linkage Regulations) can be described as follows:

- Health Canada manages the Patent List, which identifies all pharmaceutical patents eligible to be protected by the Linkage Regulations
- A generic drug manufacturer cannot get approval for its drug from Health Canada until it addresses all of the patents on that list and proves it is not infringing the original patent(s) or that the patent(s) is/are not valid
- The Minister of Health is prevented for a maximum of 24 months from issuing approval of the generic product while the courts determine if the generic product infringes the innovator's listed patent(s)

This is the first major legislative change in pharmaceutical intellectual property protection policy since 1993.

The key elements of the amendments, involving data protection (data exclusivity) are as follows:



- Canada will now provide patentees with eight years of data exclusivity for the first product incorporating a new medicinal ingredient. Accordingly, once an innovator receives its first approval to market its product, the regulations will prevent a generic manufacturer from receiving approval for marketing its drug by comparing it to the innovator's product via an Abbreviated New Drug Submission (ANDS) process for a period of eight years
- The new regulations also state that a generic company may not file its ANDS for a period of six years within the eight-year period
- An additional six months of data exclusivity is provided if the innovator completes pediatric research with respect to such product
- As a transitional measure, data exclusivity will apply to all approval submissions for products that had been filed with Health Canada for review, but had not yet been granted approval, as of June 17, 2006

AMERISOURCEBERGEN EXPANDS

On December 1, 2006 AmerisourceBergen Corporation announced that it has acquired all of the outstanding stock of Access M.D., Inc. (AMD) for approximately \$12.9 million US. AMD is a Canadian company providing services to manufacturers of specialty pharmaceuticals, such as injectable and biological therapies, including:

- reimbursement support programs,
- third-party logistics and
- nursing support services.

Based in Montreal, Canada, AMD will become part of the AmerisourceBergen Specialty Group and provide an opportunity for manufacturers to coordinate and leverage patient access programs across the US and Canada.

MEDICAL RECORDS

IBM Canada has won a \$24 million services agreement to build a pan-Canadian communicable disease surveillance system. Once the system is complete, it will enable public health professionals to log on to a secure, easy-to-use portal and quickly enter information about cases, symptoms and outcomes, providing health officials with a timely and comprehensive view of the state of public health. Should a serious communicable disease occur, the system will alert public health officials who will plan and direct actions to protect Canadians.

QUEBEC

The Quebec Supreme Court has granted the syndic from l'Ordre des Pharmaciens du Québec to access documents from Pharmascience (and also from other generic companies) that would provide evidence that pharmacists have received gifts from the generic industry, which is against their code of practice. Penalties directed to pharmacists who are at fault are the most likely outcome of this decision.

On the same topic, the Régie de l'assurance maladie du Québec (RAMQ) has taken legal action against generic manufacturers for \$200 million, Pharmascience being targeted specifically for \$39 million. It is foreseeable that the documents retrieved from the generic companies, who first declined to provide them, will help serve the RAMQ in their court battle with the generic industry.

On another note, Proxim, a newly-created banner in Quebec in 2006 that regrouped smaller pharmacies (4000 square feet or less), is in discussion with a group of pharmacies in the Maritimes regarding a potential partnership between the two chains. It is also aiming at teaming up with a retailer to give access to a broader audience. I guess more to follow in 2007.



SAP (SPECIAL AUTHORIZATION PROGRAM) SUPREME COURT RULING

Therapeutic Products Directorate (TPD) receives requests for 500 different drugs annually that total 30,000 requests. They approve 22,000 of these requests and refuse > 8,000.

In October 2006, the Supreme Court overturned the TPD right to refuse authorization for products: *Justice Francois Lemieux, Humanitarian Reasons vs Science*.

TPD APPROVALS

There have been some pleasant surprises in recent approvals coming earlier than expected.

NOVEMBER SUPREME COURT DECISION

This ruling against AstraZeneca could have significant implications for Brand Pharma. Generics may not have to address every patent on the Patent Register and possibly only those patents that are relevant to the cited product, such as the Canadian reference product. This could bring several new entries of major molecules into the market earlier than expected.

QUEBEC: PHARMACIST TO DOCTOR KICKBACKS

The Quebec government legislation banning kickbacks from pharmacist to doctor has been tabled to forbid doctors from taking gifts, favours and discounts of significant value from pharmacists. Fines are set in the range of \$750 to \$1,000.

ROLE CHANGE FOR ALBERTA PHARMACISTS

On April 1, 2007, legislation is expected to take effect allowing Alberta pharmacists to write prescriptions without consulting a doctor. While they won't be allowed to write prescriptions for narcotics or steroids, Alberta pharmacists will be able to refill existing prescriptions and provide emergency supplies of previously prescribed medication. **CPM**

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