Topics and Trends in Canadian Pharmaceutical Marketing: Volume 2, 2007

Joe Knott,
CEO, Pangaea Group of Companies

JOINT ONCOLOGY DRUG REVIEW, FEBRUARY 2007 MEETING

In February 2007, a meeting was held in Toronto updating the progress of the Joint Oncology Drug Review—for an article published by the *Globe and Mail*, go to: http://www.theglobeandmail.com/servlet/story/RTGAM.20070222.wcanccolab0222/

Basically, premiers from all provinces have signed on to the review, except for Quebec.

It will function similar to the Common Drug Review (CDR) process; representatives from all provinces will collaborate to create a consensus recommendation, but the decision to actually list the product will be up to the individual provinces.

They are using the current Ontario process for reviewing new cancer products (with a few tweaks) and therefore, Cancer Care Ontario (CCO) and the Commitee to Evaluate Drugs (CED) will be involved in decision making with the provinces. The other premiers have agreed to use the Ontario process as the framework for a national review.

Starting March 1, 2007 all new cancer products will go through this new review process (in all provinces except Quebec).

They still admit that there are some unanswered questions about certain aspects of the review process and although they will actually make recommendations in the first year, it has been defined as an "interim process" and they will make changes along the way.

Hopefully this will not be another CDR where "No" means "no" and "Yes" means "maybe."

QUEBEC NEW DRUG POLICY

Health Minister Philippe Couillard has released the new drug policy in Quebec. This is available at: http://msssa4.msss.gouv.qc.ca/fr/document/dossierpresse.nsf/9990d07f20130db985256dce00553853/cbed762fc9f1fb1d85257272004f904e?OpenDocument

Overall principles

The new policy is based on four basic principles:

a) Accessibility to drug therapies
b) Providing drugs at a reasonable price
c) Optimal usage of drugs
d) A healthy biopharmaceutical industry in Quebec

Details at a macro level

There are 29 different orientations or actions that will take place during the next three years.

Specific details are not described in great length in the document but some concrete announcements were made today. (Remind you of legislation without regulations? Here we go again!)

- The drug program remains, but a new list will be created (more details to come later regarding this new list)
- Therapeutic value becomes an essential part in the decision making
- A more transparent review system for new drug application
- The exception and management of the drug list will be easier to manage
- Theapies for rare disorders will be easier to access

Pricing

Authorized price increases will take effect as of April 18, 2007 and the maximum for 2007 will be a 2.03% increase.

The best price available remains. Well, maybe manufacturers that seek a price increase will have to contribute to a fund to overcome the effect of the price increase on the healthcare budget (this should

be interesting to watch). It is rumoured that the government is asking for up to a 70% increase!

There will be risk-sharing discussions with Brand Pharmaceuticals. Not too many details about this rule.

There will be a new mechanism called the "maximum payable price" (*prix maximal payable* or PMP). This measure will be in place only when a drug company is asking for a higher increase than the one authorized. Then, the patients will have to absorb the price difference (note this is a first and a huge move in public policy).

The ministry may accept higher increases but it seems that this will occur only in the odd case.

Generics

For generics, the price will go from 70% to 63% down to 60% and 54% starting in June 2007. If it is a single-source generic, the first entry will be submitted at 60% but the following entries are to be submitted at 54%. What about the single source that remains at 70% in Ontario and the rest of the country?

Marketing allocation to pharmacists from generic companies will be limited to 20%. A monitoring system will be in place. BAP 15 remains. No reference-based pricing policy to come.

Distribution

The distributor up-charge is reduced from 9% down to 7%. Marketing practices of pharmaceuticals and wholesalers and distributors will be monitored.

There were other announcements made regarding the flow of information towards patients to enhance optimal use of drugs; however, few details were discussed.

PRIVITIZATION CONTINUES

The following are Toronto's private health clinics:

- Cleveland Clinic Canada
- Copeman Healthcare Centre
- Medisys Executive Health Sciences
- Medcan Clinic
- Scienta Health Centre
- Wellpoint

CORPORATE REALIGNMENTS (if this is the politically acceptable word now)

Significant changes have recently taken place in the Montreal market, namely with Pfizer and sanofi aventis. Head office cutbacks took place and entire sales forces were removed.

It will be interesting to watch the other companies' response, particularly in the area of Primary Care Salesforce deployment.

AQPP

The Association Québécoise des Pharmaciens Propriétaires (AQPP) has reached a three-year agreement with the Health and Social Services Ministry regarding their fees structures. These are the highlights:

- The dispensing fee will be increased annually by a mere 2%. For large volume dispensing pharmacies, the dispensing fee is now at $7.58
- The fee for *l'opinion pharmaceutique* (OP) has also increased. The OP is an act by which the pharmacist is proactively taking charge by modifying a patient prescription. Also, the ministry will have added several additional indications for OP related to poor compliance. These are:
  - Asthma
  - TB
  - Dyslipidemia
  - Cardiac conditions
  - Type 2 diabetes
  - Epilepsy
  - Psychiatric disorders
  - HIV

  Until recently, only OP related to hypertension was reimbursed.
- Pharmacist's will receive a proportional dispensing fee for a one-year prescription that can be given for a period starting at seven days ($1.89) and not exceeding 90 days ($24.30). There is no mention of a potential authorized fee for dispensing a seven-day trial medication

PHARMACY ALLIANCES

Pharmacies continue to create strategic alliances at least at the Banner level.

The most recent is in the Quebec market. Proxim has acquired 50% of Pharma plus, a pharmaceutical distributor based in Quebec City. With this acquisition, Proxim is also increasing its number of pharmacies by 14 (for a total of 287) reaching sales of $866 million. Proxim has signed an agreement with AmerisourceBergen so they can export the Proxim concept elsewhere in Canada. On the same token, AmerisourceBergen becomes the priority distributor of the banner Proximed (around 20 pharmacies) which are clinic-style pharmacies and part of the global Proxim.

CDR

The latest statistic on the Common Drug Review (CDR) is that 47% of all submissions have been given a positive recommendation after Health Canada's approval. Biological submissions have received a 28% positive recommendation. Therefore, 53% of all submissions and 72% of all biologic submissions have received a negative recommendation from CDR.

Only 10% of the positive recommendations from CDR have received full listing approval of the provincial drug plans, which equals < 5% of total submissions.

NATIONAL PHARMACEUTICAL STRATEGY

The National Pharmaceutical Strategy is getting closer to establishing a Canada-wide research network for Real World Drug Safety and Effectiveness. Health Canada and the Food and Drug Administration (FDA) have been criticized for the lack of post-marketing surveillance of new drugs.

It is too bad that they have not as of yet developed and delivered the catastrophic drug strategy.

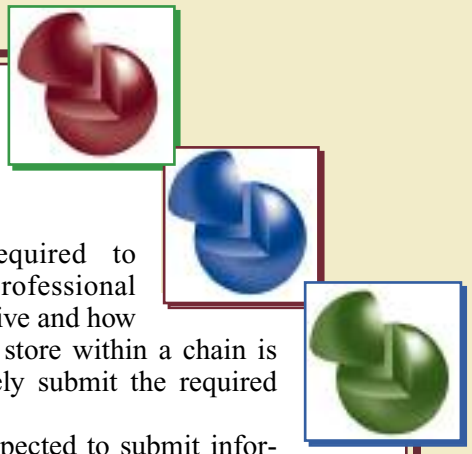
BILL 102

Reporting Framework for Professional Allowances

On February 21, 2007, the Executive Officer provided an update on the development of a reporting framework for professional allowances. Manufacturers and pharmacies are required to report on specific information relating to the payment, receipt and use of professional allowances. Each manufacturer and pharmacy is required to report the information to the ministry on a biannual basis.

Information to be submitted by manufacturers

Drug manufacturers are required to submit information detailing every professional allowance to each pharmacy and are required to retain any related financial and accounting documentation that may be needed as part of the Ministry's audit process. Two senior officers of the company or the manufacturer's auditors are required to certify that the information reported to the Ministry is complete and accurate.



Information to be submitted by pharmacies

Pharmacies are required to report on the professional allowances they receive and how they are used. Each store within a chain is expected to separately submit the required information.

Pharmacies are expected to submit information that would outline:

1. Total generic drug sales for drug products reimbursed under the Ontario Public Drug Programs and those sold in the private market (Wooa…. I thought that they were only interested in the public domain!)
2. Amount of professional allowances received based on generic drug products reimbursed under the Ontario Drug Programs and those sold in the private market
3. Type of activity as described in the definition of professional allowance in both the Ontario Drug Benefit Act (ODBA) and Drug Interchangeability and Dispensing Fee Act (DIDFA) regulations (*i.e.,* number of clinic days or education days held at the pharmacy, education event attended by the pharmacist, or the number of prescription dispensed as compliance packaging)

Pharmacies are required to report the actual costs for some activities and for other activities; the framework will assign a "standard" cost. All related documentation needed for the ministry's audit process is to be retained at the pharmacy and certified by two senior officers.

PRICING AND FORMULARY UPDATES

The majority of pricing negotiations were completed late February 2007 and an update was published on March 5, 2007. For further pricing and formulary updates go to: http://www.health.gov.on.ca/english/providers/program/drugs/edition_39.html **CPM**

For more information, contact Joe Knott, CEO, Pangaea Group of Companies at: (416) 516-3524, E-mail: jknott@pangaea-consultants.com www.pangaea-consultants.com