

Topics and Trends in Canadian Pharmaceutical Marketing: Volume 2, 2008



Joe Knott,
CEO, Pangaea Group of Companies

FEDERAL BUDGET UPDATE

There is absolutely nothing of significance for healthcare in the budget. We are obviously not going to the polls anytime soon!

HPFB COST RECOVERY FRAMEWORK

The new target date for the dramatic increase in Health Products and Food Branch (HPFB) review fees is January 2009 vs. the previous date of April 2008.

These fees (still incredibly high) will not be indexed but will be reviewed every three years. There are performance standards and if they are not met within 10% for an individual submission, then the sponsor will get a reduction of the same percentage on submissions in the next fiscal year (try and budget for this!).

The current fee proposal has to go to parliament and they may refer it to a Standing Committee, as well as the likelihood of Canada Gazette I and II. Hopefully, this will cause future delays past January 2009.

DRAFT GUIDELINES FOR SUBSEQUENT ENTRY BIOLOGICS (SEBs)

Federal guidelines covering definitions and the regulatory framework have been published for SEBs. Industry feedback was required by March 15, 2008.

The bad news is that we are moving closer to the approval of biosimilars or SEBs; however, we still can have influence on the scope of products to be included, as well as the marketing of these products. The good news is that they will not be interchangeable, meaning a whole new marketing approach by the generic industry. Sandoz and Apotex appear to be the lead players in this activity. Innovators will need to evaluate this activity and take full advantage of notice of compliance (NOC) regulations, as well as data protection.

QUEBEC LEADS REFORM ONCE AGAIN

The Castonguay's prescription calls for user fees and privatization that will resonate outside the province's borders.

Mr. Claude Castonguay, former Health Minister and father of the current healthcare system in the province of Quebec, has submitted a series of recommendations to the current Health Minister, Mr. Philippe Couillard.

The healthcare costs represent 44% of the total spending in Quebec and are growing at 6% per year, well above the 4% economic growth. The Castonguay committee recommended 31 measures aiming at reducing the spending growth to 3.9% per year. Here are a few recommendations worth of interest:

- Increase the productivity (less bureaucracy, decentralized authority and responsibility)
- Increase revenues by increasing the provincial sales tax by 1%, imposing a yearly franchise

to families and a yearly fee for accessing an FP

- Increasing the role of the private sector by seeking a change to the Canadian healthcare law that would allow physicians to offer both public and private services and allow more surgeries to be covered by private plans
- Better usage and control of drugs
- Tighten the rules for the usage of drugs included in the exception list
- Creation of a center of excellence that will take over the functions of the Conseil du médicament, l'agence d'évaluation des technologies en santé (Healthcare technologies evaluation agency) et Commissaire à la santé et au bien-être (Health and wellness deputy)
- Increase the financial contribution of the public program participants who are not aged > 65 years or on social welfare since their contribution is far less than the real cost
- Public nursing homes management should be offered to private organizations under a franchisee-type of arrangement

It is also suggested to consider to regroup the 11 hospital buying groups (also known under approuvements) into one buying group for all institutions across the province.

The Health Minister has already dismissed any tax increase or additional burden on the Quebec tax payers, but has agreed to measures that increase productivity. This report is forcing the government to make difficult political choices. Given the fact that the Liberals are forming a minority government, the task becomes even more delicate as some of these measures are not winners, electorally speaking.

LONG-TERM CARE UPDATE

Quebec continues to review the delivery of long-term care. One recommendation of the Castonguay's report is to offer the management of the public Centre d'hébergement de soins de longue durée (CHSLD) to the private for profit, co-op or municipal, something like a franchisee-type of arrangement. Most of the public CHSLDs are getting old and will require significant investment in the near future in order to be functional.

DOCTORS ONLINE IN QUEBEC

A Quebec City-based company (Myca) is developing a "doctor web" that will enable patients to access physicians by video conference. The plan is for a monthly fee of \$10 and \$50 for each online consultation and the launch is scheduled for June. Stay tuned as this may spread with the current generation wanting immediate answers.

ALBERTA HEALTH AND WELLNESS ANNOUNCEMENT

In early January 2008, Annette Trimbee, Assistant Deputy Minister of Strategic Directions, Alberta Health and Wellness, announced that Mr. Steve Long joined Alberta Health and Wellness as the new Executive Director of Pharmaceutical and Life Sciences effective February 4, 2008.

Mr. Long has extensive experience in the pharmaceutical sector, most recently as the Director, Pharmacy Integration and Strategic Programs in the Calgary Health Region. He has demonstrated his leadership and senior management capacity through his work in a number of complex care settings and successes in fostering innovation and collaborative relationships in Alberta's health system.

FDA DRAFT GUIDELINES FOR OFF-LABEL DRUG USE

The FDA issued draft guidance detailing recommendations for ways in which the pharmaceutical industry can distribute medical and scientific journal articles that involve off-label uses for approved products. As part of its guidance, the FDA recommended that journal articles distributed by drug makers, which involve unapproved uses of products, should be peer-reviewed and published by an organization that has an editorial board.

PHARMA TO CONTINUE LOOKING AT NEW BUSINESS MODELS

The upcoming patent loss of major molecules combined with a slower market uptake of newly-launched molecules is forcing innovative pharmaceutical companies to rethink their traditional marketing methodology. The continued issues with respect to market access, as well as the sophistication of public and private payers, is another contributing factor. The Canadian environment changes of privatization, along with regionalization and dramatic changes in the influencers on prescribers and patients, are making this even more applicable here.

The majority of companies are hopefully going to fine-tune their resource deployment in the targeted segments they play in.

STANDING COMMITTEE ON HEALTH BEGINS DELIBERATIONS ON POST-MARKETING SURVEILLANCE

The House of Commons Standing Committee on Health is doing a study of the post-market surveillance of pharmaceutical products: prescription and non-prescription. The focus of the study will be on the Federal government's role with respect to:

- regulatory authority,
- capacity for monitoring, surveillance and research,

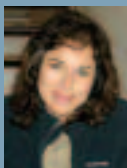
- consumer safety,
- compliance and inspection,
- public access to information and
- adverse reaction reporting.

Initial witnesses provided an overview of how the Branch addressed post-marketing surveillance and the legislative authorities that are needed to implement the proposed product life cycle approach. The committee members asked questions (*i.e.*, why reporting of adverse events by healthcare professionals was not mandatory) and sought assurance that safety would not be compromised during pre-market reviews.

PMPRB AT IT AGAIN

The Patented Medicine Prices Review Board (PMPRB) Discussion paper came out January 31, 2008 with a quick response deadline of March 3 (do you think they really wanted comments?). I highly recommend that any and all stakeholders understand the implications as the final changes will expand their area of influences, as well as make it even more difficult to concretely put prices forward in Canada. **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



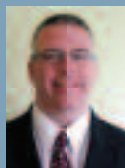
Susan Schrier
Quebec
Pharma Accounts
(514) 466-2733



Lou Grimes
Ontario
Pharma Accounts
(519) 240-3634



Miriam Foell
Ontario
Pharma Accounts
(905) 703-5738



Greg Hay
Ontario
Clinical Trial Accounts
(647) 338-3859



Celia Graham
Ontario
Advertising Agency Accounts
(519) 400-6279

FOR MORE INFORMATION EMAIL SALES@SAMPLINGTECHNOLOGIES.COM

 **BEGINS NEW YEAR WITH THE ADDITION OF NEW SMARTTECHNOLOGY ACCOUNT MANAGERS AND A RENEWED COMMITMENT TO CUSTOMER SERVICE!**

STI and SmartSample® are growing rapidly and we would like to thank all of our customers for our success to date.

Several new Account Managers based in both Toronto and Montreal have been segmented and specialized in your unique areas of business departments such as Sales, Marketing, Market Access, Market Research, Clinical Trials and even with your Agency of Record. We believe this is a significant positive move forward by being able to support you nearby as we strive to provide the best customer service possible.



Real-Time  Data



* SRx is a sample prescription or new patient initiation captured at pharmacy.