Topics and Trends

in Canadian Pharmaceutical Marketing:

Volume 3, 2010

Joe Knott,
The Pangaea Group

COURT AFFIRMS HEALTH CANADA'S BROAD DISCRETION IN REVIEW OF DRUG SUBMISSIONS

A manufacturer must apply for marketing approval, Notice of Compliance (NOC), before a drug can be sold in Canada. To obtain the NOC, the manufacturer must apply to Health Canada for a new drug submission (NDS). Hospira filed its NDS without any clinical data but relied on the wide-spread use of the drug to establish safety and efficacy. Health Canada rejected the NDS for failure to comply with regulation requirements. Hospira applied to set aside this decision.

The Federal Court in Hospira Healthcare Corporate vs. Canada affirmed that Health Canada has broad discretion in interpreting the Food and Drug Regulations in determining the content of an application for the marketing approval of a drug.

ONTARIO MOVES FORWARD WITH GENERIC PRICING REFORM

Much to the chagrin of Pharmacy and the generic industry, the Ontario government has moved forward on reducing generic pricing from 50% to 25% of Brand for the public market. It also is reducing generic pricing in the private and cash market to 25% over a three-year phased period. The price reductions will likely see over 53% of Canada move to 25% soon.

They also attacked the current levels and use of Professional Allowances reducing them from 20% to 0% on the public side and phasing in controls and reductions on the private side over the next three years.

The reaction by Pharmacy has been volatile and this battle will be ongoing in Ontario right up to next year's election.

ARE PROVINCIAL LISTING AGREEMENTS FINISHED?

Over the past four years, since 2006, some Provincial governments and the industry have been in private negotiations aimed at listing new chemical entities as well as lowering prescription costs. Because the Ontario Drug Benefit is one of the world's largest purchasers of pharmaceuticals, manufacturers were prepared to cut deals they wouldn't elsewhere. As such, the government pays much less than the listed price, because the companies return part of the money through rebates. To avoid other governments and private drug plans demanding the same deal, these rebates are kept confidential.

It now appears to be unravelling. Following a back and forth battle with the Privacy Commissioner, the Executive Officer released 2007 quarterly data for 47 different companies. Many Corporate head offices are now asking local executives how this information, guaranteed to remain private, is now public.

Quebec now is threatening legal actions against any of these companies that have not given the lower price to Quebec as is the current agreement with Industry. It is rumoured that BC is thinking of releasing their deals.

Stay tuned as this will be interesting if the companies remove the current deals, leaving the Provincial governments with a difficult decision to remove the newly listed products from the formulary.

IS GET-UP GONE IN CANADA?

The recent decision of the Federal Court of Canada in Apotex v. Registrar of Trade-marks and Glaxo Group Limited (March 12, 2010) continues a line of cases that restricts the use of "get-up" (which refers to colour, shape of packaging, *etc.*) as a trademark in respect of prescription pharmaceutical products.

Glaxo Group Limited had obtained a trademark registration for the dark and light purple colours as applied to certain portions of the visible surface of an inhaler. Apotex and other generic drug manufacturers instituted proceedings to strike out this trademark registration on the grounds that it was not distinctive.

HEALTH CANADA RELEASES FINAL GUIDANCE ON SUBSEQUENT ENTRY BIOLOGICS

Health Canada has released the final version of its guidance document, Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs) (Final Guidance), which is an update of the draft guidance released by Health Canada on January 30, 2008 and March 27, 2009 and applies to all pending and future drug submissions for SEBs in Canada.

An SEB is defined by Health Canada as "a biologic drug that enters the market subsequent to a version previously authorized in Canada and with demonstrated similarity to a reference biologic drug." SEB manufacturers may make reference to the information contained in an innovator's biologic drug submission—that is, the reference biologic drug submission—in order to reduce the amount of clinical data required to obtain marketing approval for its product.

This is one of the most important issues between the Brand and generic Industry as the majority of current and future growth is in this category of medications.

EMERGING MARKETS WILL ACCOUNT FOR 48% OF MARKET GROWTH IN 2013

An IMS Health study suggests that high-growth pharmaceutical markets, such as China, Brazil, Russia and India, will account for 48% of market growth in 2013, compared to 37% in 2009. The review identified 10 new "pharmerging" countries, up from seven countries labelled in 2006, forecasted to grow significantly during the period.

Canada now ranks ninth and it will continue to be difficult to obtain corporate investment if we continue to slip and market access delays continue.

QUEBEC'S MEDICAL-USER-FEE FINDS A "LOOPHOLE" IN CANADA

Premier Jean Charest insisted he would go ahead with the plan to impose user fees for public healthcare services. The government needs an additional $500 million a year to cover a portion of rising healthcare costs and it plans to collect it through a form of user fees.

The PQ position is that once people realize that those who must visit doctors regularly, such as pregnant women, cancer patients and the chronically ill, all of whom will be asked to pay for the medical visits, the protest will become so widespread, that the government will have no choice but to retreat. This will be an interesting battle and all provinces are watching.

CPM

For more information, please call
Joe Knott at 416-516-3524
e-mail: jknott@pangaea-consultants.com
www.pangaea-consultants.com