Topics and Trends

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NEW INITIATIVE BY THE ONTARIO GOVERNMENT

July 2009—Ron Sapsford, Deputy Minister, Ministry of Health and Long-Term Care, presented the progress established in making the Ontario drug system more transparent and accountable, ensuring patients have world-class care and process. He also believes that there is still significant potential to improve the value for money equation. As such and in order to improve the system, he is instituting a series of discussion tables with industry associations, organized as sector-focused themes and cross-cutting issues.

Sector-focused themes include: pharmacy, brand manufacturers, generic manufacturers, distributors/wholesalers and employers/private insurers. Cross-cutting issues include: patient focused outcomes and sustainability of drug plans.

The comments on the Retail Pharmacy Channel as well as the generic industry were pretty blunt and potentially threatening.

Stay tuned.

The discussions are to commence in July with a wrap-up forum during the week of September 21 to discuss feedback, pressure points and timelines for next steps.

ALBERTA BILL 34

This new bill is enabling legislation that will allow dramatic changes as well as payment for services. The section covering the Drug Programs Act is targeted to:

- There will be legislative authority to negotiate and implement listing allowances
- Pricing of medications (one part will be a new "generic" model with lower fees with higher volumes)
- Pharmacy services changing the fee for dispensing to cognitive services

US SENATE PANEL SUPPORTS 12-YEAR EXCLUSIVITY FOR BIOLOGIC DRUGS

The US Senate Health, Education, Labor and Pensions Committee voted 16 to seven in favour of a proposal to protect biologic drugs from generic competition for 12 years. The measure is part of a larger healthcare bill that the committee could vote to approve this week.

Lawmakers, including Senator Orrin Hatch (R-Utah) who co-sponsored the 12-year measure, said a shorter exclusivity period would stifle innovation and put US companies at a disadvantage to international competitors, especially those in the EU. The committee rejected an alternate proposal that would have started with a seven-year exclusivity period, with additional years possible for innovations.

A PMPRB WIN FOR THE INDUSTRY

A decision on the judicial review initiated by Pfizer and Rx&D on the mandatory reporting of third party rebates was published July 10.

The Federal Court concluded that, "The Board acted outside its jurisdiction in requiring the reporting of rebates of payments made by patentees to third parties." As a consequence, the August 2008 PMPRB "Stakeholder Communiqué," that required the mandatory reporting of all benefits, is set aside.

It is assumed that in the absence of further guidance, the current Guidelines regarding the appropriate treatment of programs and free goods will continue to apply in 2009.

According to the analysis in the Decision:

- Judge disagreed with Board interpretation that Leo Pharma (Dovobet case) decision addresses third-party benefits
- Ex factory price appears to be understood in the industry as referring to the transaction between the patentee and the first purchaser of the medicine
- Provinces are not parties to the sale at the ex factory level

ABUSE OF PROCESS—FEDERAL COURT OF APPEAL

In a recent decision, Apotex Inc. v. Janssen-Ortho Inc, the Federal Court of Appeal has limited the scope of the abuse of process doctrine in applications under the Patented Medicines (Notice of Compliance) Regulations. In particular, the Court held that even when an innovator company has been successful in a patent case against one generic manufacturer, it is not an abuse for a second generic to re-litigate the same issues. This is an important clarification in the law and will affect the way in which innovators conduct and argue cases under the Regulations.

BAN ON DRUG PATENT SETTLEMENTS SAVING CONSUMERS $3.5 BILLION ANNUALLY

An analysis by the US Federal Trade Commission indicated that a ban on patent settlements between brand and generic drugmakers would reduce spending on prescription drugs by $3.5 billion each year. The elimination of these deals, in which drug manufacturers pay potential competitors to delay the launch of generic products, would serve "as a way to control prescription drug costs, restore the benefits of generic competition and help pay for healthcare reform," the FTC announced on June 24.

DRUGMAKERS REACH DEAL TO REDUCE US MEDICARE COVERAGE GAP

The pharmaceutical industry agreed to a proposal to provide drug discounts to US Medicare beneficiaries that could be worth up to $80 billion over the next 10 years. The proposal, which is part of a healthcare bill drafted by US lawmakers on June 19, aims to reduce the coverage gap that affects recipients once their drug costs reach a certain level.

As part of the deal that was negotiated between PhRMA and lawmakers, drugmakers would "provide a 50% discount to most beneficiaries on brand name medicines covered by a patient's Part D plan when purchased in the coverage gap," according to industry representatives. In addition, the entire cost of the medicine purchased in the coverage gap will count towards the Medicare recipient's out-of-pocket expenses.

PROPOSED AMENDMENTS TO ADVERSE DRUG REACTION REPORTING

On June 13, 2009, the Canada Gazette published proposed regulations amending the Food and Drug Regulations relating to adverse drug reactions, permitting more rigorous monitoring and reporting of drug safety requirements, in order to enforce Canada's reporting requirements for adverse drug reactions.

Under the current regulations, manufacturers are required to:

- Submit a case report to the Minister within 15 days of becoming aware of any serious adverse drug reaction associated with a drug
- Prepare an annual summary of all adverse events associated with the drug, to be submitted if the drug is not safe

WILL ALBERTA'S CENTRALIST MODEL SUCCEED?

Alberta has, in the past decade or so, created the best, most innovative health system in Canada. Regionalization allowed health authorities to shape services to local needs, created better continuity of care, made the health system more responsive, improved public health and led to strong alliances between university researchers and health regions.

If Stephen Duckette (the new Chief Executive Officer of Alberta Health Services) succeeds, the centralized corporatist model he is trying to introduce in Alberta will likely be copied across Canada—if he fails, it will likely take decades for the province to recover.

VACCINE AID—ADVANCED MARKET COMMITMENT

A group of wealthy nations is launching a first-of-its-kind program designed to encourage pharmaceutical companies to develop vaccines for diseases common to poor countries.

The $1.5 billion (US) program marks a departure from previous charitable efforts to increase poor countries' access to vaccines. Instead of buying existing drugs and giving them away, the donors will guarantee pharmaceutical companies a future mark big enough to justify developing new vaccines needed in nations too impoverished to afford them on their own. The donors are: Italy, Britain, Canada,

Russia, Norway and the Bill and Melinda Gates Foundation.

The first target will be a vaccine to prevent pneumococcal disease, which kills 1.6 million people in the world every year, the majority of them young children in the developing world.

ONTARIO WAITING TIMES FOR CANCER PATIENTS

Cancer patients in urgent need of surgery are still waiting up to twice as long as they should for care, according to the watchdog agency that monitors healthcare in Ontario.

Overall waiting time for cancer surgery have decreased, but more than half of high-urgency cancer patients had to wait longer than the medically recommended 14 days, with some waiting as long as four weeks, the Ontario Health Quality Council reported in its annual survey.

CANADA'S FEDERAL COURT OF APPEAL LIMITS DAMAGES AVAILABLE TO DELAYED GENERICS

On June 4, 2009, in Merck Frosst Canada Inc. v. Apotex Inc., the Federal Court of Appeal released an important decision limiting the range of damages available in actions under section 8 of the Patented Medicines (Notice of Compliance) Regulations. In particular, the Court of Appeal confirmed that section 8 damages do not include either an accounting of the innovator's profits or any damages for loss of market share that extends beyond the period for which the generic company's approval was actually delayed.

The Regulations are intended to provide innovators with protection from early generic entry in light of Canada's scheme to allow early working of patented drugs by generic pharmaceutical companies.

NDMAC OFFICIALLY LAUNCHES ITS NEW NAME

After months of consulting and strong support from the members and stakeholders, the NDMAC announced on May 21 that the association name has changed to Consumer Health Products Canada (CHP Canada). With the inclusion of "consumer health products" in the name, it makes it much easier for people to instantly understand their representation. The association tagline has been slightly changed to "Advancing evidence-based self-care" and a new logo introduced.

ONTARIO MD HIRING FREEZE OVER

On April 17, the Ministry of Health put a halt on all new physician registrations in order to re-calibrate its financial forecast of doctors joining family health teams vs. those involved with the numerous other physician-renumeration models in the province. On May 21, the freeze was lifted with the explanation that the freeze was due to "back-office administration" and had nothing to do with the recessions impact on Ontario.

HEALTH RECORDS

US corporations have been pushing the health sector to embrace information technology in order to bring down healthcare costs. They say electronic medical records would improve outcomes, reduce redundancies and inefficiencies in patient care and yield data to pinpoint cost-effective treatments.

Budget crisis or not, President Obama has named healthcare reform as one of his top domestic priorities and the electorate agrees. Independent groups estimate that Obama's plan, which will incrementally extend the employer-based system, will cost anywhere from $1.2 trillion to $1.6 trillion over 10 years.

ONTARIO JOINS THE FRAY GIVING BROADER POWERS TO HEALTHCARE WORKERS

Premier Dalton McGuinty announced that Ontario will move ahead to allow pharmacists, nurse practitioners and others to provide some services now performed by doctors.

At a minimum, pharmacists will be able to change dosage and duration. There are 11 regulated health professionals that will be affected. The drive is patient care as well as improved access.

COUTU REGROUPS STRATEGICAL DIRECTION

Jean Coutu Group (PJC) Inc. is betting that US healthcare reforms and the efforts of a renewed management team at Rite Aid Corp. will help turn around its investment in the battered US drugstore giant.

In the meantime, the Longueuil, Quebec-based

Coutu chain is ramping up its growth in Quebec as it moves to counter expansion by rivals such as Shoppers Drug Mart.

Coutu acquired a 32% position in Rite Aid two years ago in a cash-and-stock deal involving the sale of Coutu's 1,800 Eckerd and Brooks drugstores in the US to Rite Aid.

HOME CARE OUT OF THE SHADOW WITH PREDICTIONS OF RAPID GROWTH

According to the Canadian Healthcare Association the recipients of home care grew by 51% over the past decade. In Ontario alone, 185,000 Ontarians receive every day services from nurses, therapists and other healthcare providers. It is estimated that non-medical services such as homemaking and personal support presents 67% of care delivery, followed by nursing services at 27% and occupational physiotherapies at 6%.

The Canadian home care market is estimated to be worth $6.6 billion which equates to < 4% of all monies spent by governments on healthcare. The following stats are scary indeed:

1. Statistics Canada reports that about 13% of the population are ≥ 65-years-old and that number is predicted to grow by 25% over the next 20 years
2. Governments have realized that home care offers a number of advantages, including lower cost when compared to hospital care and freeing-up hospital beds
3. Also making an impact is the array of occupations expanding into the private sector of home care (*i.e.*, Registered Nurses (RNs) Licensed Practical Nurses (LPNs), Certified Caregivers, Personal Care Aids and a variety of therapists)

In May 2009, the Ontario government announced that it was investing $272 million to help seniors receive needed health services while improving flow of patients by allowing them to either by-pass the hospital system completely or allowing them to leave the hospital earlier.

When you match the above with the ongoing increase in prescribing responsibilities by nurses and pharmacists, this is a channel that Pharmaceutical companies should be looking into.

TRADE-MARKS OPPOSITION BOARD INSTITUTES NEW PRACTICE

The Trade-marks Opposition Board has revised its practices regarding non-use of trademark. Section 45 of the Trade-marks Acts permits third parties to request that the Registrar institute proceedings to confirm that the owner used the trademark within the three years preceding the date of the request. The owner of the registered mark has three months from the date of receipt of notice from the Registrar to submit evidence of use. Failure to provide this notice will result in the mark being expunged. This will take effect on September 14, 2009. CPM

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