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The Latest on Generic Biologics

Following the first biologic drug approval in 1982, over 250 have been approved in the US. Between 2003 and 2006, they accounted for 24% of all new chemical entities. Several will come off patent in Canada over the next few years; some patents have already expired. The market impact of these changes is not clear.

Health Canada approved the first Subsequent Entry Biologic (SEB) in April 2009. All SEBs are reviewed like completely new entities: they are not deemed bioequivalent and therefore not generically substitutable. The federal government is now constructing a comprehensive regulatory framework.

In the US, no government agency has regulatory authority over these products yet. In a recent report, the Federal Trade Commission (FTC) believes competition between the original and "Follow-on Biologic" (FoBs = SEBs) will reduce prices, lower overall health care costs, and provide more consumer choice. However, it believes the FoB discount is likely to be 10% to 30%, so the original biologic will retain most of its market. In comparison, chemical generics may command 50% - 70% or more of the market. Eventually, original biologic manufacturers will offer their own discounts, and many generic and brand-name companies are actively developing FoBs.

It is likely there will be fewer FoB competitors for a given drug due to high costs for manufacturing and FDA approval. Further, FoB products may need time to establish 'real-world' safety and efficacy.

Biologics are often far more effective than older chemical drugs, but need to be affordable or patients cannot benefit. While SEBs and FoBs will help lower cost, broader access will remain a challenge.

Source: Health Canada; Various news releases - Canadian Generic Pharmaceutical Association, April 23, 2009; (US) Federal Trade Commission, June 10, 2009; (US) Generic Pharmaceutical Association, June 10, 2009.

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Let's Get It Together

What's "it"? The Canadian Council on Integrated Healthcare (CCIH) defines "it" as "equitable and reasonable access [to prescription drugs] without undue financial hardship for all Canadians". Despite our national wealth, there remain significant gaps in drug coverage. All provinces west of New Brunswick have taken pride in their "universal" plans, while Atlantic provinces have been attacked for exposing too many residents to catastrophic personal drug expenses. Do these stereotypes fit reality?

The CCIH reminds us that access to drugs depends on employment status, wealth, health status, and province of residence. Provincial plans have very different levels of coverage and eligibility. About 6.5% of households in 2002 spent more than 3% of their after-tax income on prescriptions. By 2006, that figure had risen to 8%, ranging from 4.6% in Ontario to 16.5% in Saskatchewan. Stereotype aside, there are more people paying over 3% in Manitoba (12.7%) and Saskatchewan, both of which have universal pharmacare programs, than in Newfoundland and Labrador (12.1%), which does not. At 8.6%, Nova Scotia is just above the national average, and not far above BC at 8.3%. A universal program by itself does not protect anyone from high-cost drugs; minimum standards of coverage are also needed.

The group suggests three principles to improve access to prescription drugs:

- A needs-based (not age-based) approach,
- Federally mandated principles and financial incentives, strict accountability, and
- Room for each province to tailor a plan to fit their own priorities.

Among other components, the CCIH also calls for a nationally consistent minimum formulary, integrated partnerships involving governments, employers and patients, and a limit on out-of-pocket expenditure.

After so many years, commissions, reports, and promises, the CCIH has joined in the chorus of calls for action.

Source: Canadian Council on Integrated Healthcare, 2009. "I'll just take my medication every other day..." Available at: www.ccih.ca.

Ontario: Bill 102, Part 2

The Ontario government introduced big changes in its drug procurement systems and cost structure when Bill 102 was proclaimed as the Transparent Drug System for Patients Act in 2006. It has now served warning on all drug manufacturers, pharmacy, drug distributors, and private payers that more changes are needed, and will come very quickly. Fortunately, consultation is occurring. Given the huge \$4 billion scale of the Ontario Drug Benefit (ODB) programs, other provinces will be watching closely. And so should plan sponsors and advisors.

The government claims the first round of changes saved it \$600 million in the first two fiscal years, and it has cut in half the plans' growth rate, to 5%. It has negotiated over 60 listing agreements and over 100 pricing agreements with brand-name drug manufacturers - all secret.

Now, Ontario seems particularly concerned it will pay much more for generic drugs that are priced high relative to many other countries. It also believes there are too many pharmacies, that their profit margins are too high, and that over 40% of pharmacies provide no value-added services to their patients. It is aiming again at the still-generous allowances paid by generic manufacturers to pharmacies. Highly profitable drug manufacturers are also under the gun. In general, these factors imply more room to squeeze and restructure, and consequently greater risk of cost-shifting to private payers.

This time, though rushed, the government appears committed to more open consultation and stakeholder engagement. Many believe the government and private insurers and employers can and should work more closely to manage much more of the market. Four rounds of meetings and discussions are planned before October 1, and businesshealth has been invited to join a very select group of participants. Stay tuned.

Source: Presentation by Ron Sapsford, Deputy Minister, Ontario Ministry of Health and Long-Term Care, July 2009.

Health Impacts Productivity

A new American study concludes that employers must measure and manage absence and presenteeism because they have such a significant effect on total health costs.

Most often in the US, the focus has been on medical (hospital, physician, and surgery) and drug expenditures, or on the costs of specific diseases. Given important differences in the supply and funding of hospital and physician services, the economic findings of many US workplace health studies have consequently had limited value in other countries.

This new study included data from 51,648 survey respondents employed at ten companies. The researchers found that health-related productivity costs, defined as absence and presenteeism, were over twice as high as costs for medical and pharmacy claims. Two important factors would increase this ratio for Canadian organizations. First, they pay essentially none of the medical costs assumed by US employers, and second, short and long term disability costs were excluded from the analysis.

Absence and presenteeism are not well measured by most employers. However, these two productivity impacts considerably change the cost ranking of diseases. The most expensive conditions overall for the employers in this study were depression, obesity, arthritis, back/neck pain, and anxiety. The lowest productivity share of total cost (for back/neck pain) was about 50%; the second lowest, for arthritis, was about 75%. Absence was measured as full- and half-days away over the last four weeks, and presenteeism was the response to the employee's self-reported rating (score 0 - 10) of their overall performance over that same period.

The study concludes that the most important health cost issue for employers is the association of poor health with weak productivity. Emerging from a serious recession, improving worker health will be very important to organizations everywhere..

Source: Loeppke, R, M Taitel, V Haufle, T Parry, RC Kessler, K Jinnett, 2009. Health & Productivity as a Business Strategy: A Multiemployer Study. JOEM 51: 411-428.

Lessons from US Health Reform Efforts

As the United States struggles again with reforming its health system, the non-partisan Commonwealth Fund has suggested a way to pay for change. Administration of American public and private health insurance is the most expensive anywhere - an estimated 7.5% of all health expenditures in 2005, versus 4.2% in Canada, 3.3% in the UK, and just 1.9% in Finland. Most (60%) of the costs arise from private insurance; US public programs cost about half as much to administer as private plans.

With changes, the report estimates the US could save about US\$200 billion over the next decade. That would help provide coverage for nearly 46 million uninsured Americans.

The heart of the change is the creation of a national insurance exchange to replace the expensive individual and small group markets. Features would include (i) mandatory coverage, either as individuals or through an employer (ii) a choice of public or private plans, (iii) a standard benefits package, (iv) no health underwriting, (v) premium subsidies for those with low income, and (vi) portable coverage. The US insurance industry is said to support comprehensive reform.

Canadians have a good health system, though we struggle with care rationing and poor information management. An insurance exchange is a bold idea that could reduce insurance costs and eliminate coverage gaps for many. Employer health plans are rarely portable, and there is no minimum standard plan available to all Canadians. Public plans already have lower costs, but post-Chaouilli, could benefit from some private competition to provide better services on a more timely basis.

All health systems are concerned about costs and sustainability. Canada needs to watch closely as health reform unfolds in the US and elsewhere; some of their ideas could help us too.

Source: Collins SR, R Nuzum, SD Rustgi, S Mika, C Shoen, K Davis, July 2009. The Commonwealth Fund Issue Brief: How health care reform can lower the costs of insurance administration.

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