

DRUG NEWS

A recap of drug activity in 2009, along with new trends and developments in the pharmaceutical industry that plan sponsors need to know. **BY SCOTT WARNER**

In terms of private payers, the past year was a transitional year and gives a glimpse into the issues that private plan sponsors will face over the next five years. At a high level, the increase in overall dollars spent was relatively low at 6%, according to Canadian pharmacy benefit managers. Generics accounted for just over half of all claims by number of prescriptions. However, looking at the big picture, the real story continues to be the onslaught of biologic drugs and the cost issues associated with these products.

Looking at the top 10 drugs claimed by unique drug identification number (Figure 1), three of them are biologics. In terms of overall dollars, Lipitor remains in the lead—on this list, three variants of Lipitor combine to total about 4.4% of total spend. Next is Remicade, a biologic with an average value of about \$3,500 per claim (bearing in mind that average claims values are dependent on any number of variables including co-pay, plan designs, co-ordination of coverages with the Ontario Drug Benefit (ODB) and so on). Of the other two biologic drugs on this list, Enbrel has an average cost of around \$1,645 per claim, and Humira averages \$1,660 per claim. Examining the claim amounts per item instead of grouping similar products allows us to see, in greater detail, the impact that biologics are having on drug claims costs.

The Generic Cliff

The year in review for prescription drug plans in 2009 brings a new term to the lexicon of pharmacy plan management. The “generic cliff” comes ever closer as we witness patent expiration on some of the biggest names in prescription drugs. Most notable is Lipitor, expected to expire in 2010, but the list of expirations from now to 2014 (Figure 2) is an impressive who’s who of top drugs.

We might expect this to be good news—after all, conventional practice has been that once a drug goes off patent, a lower-cost generic enters the market to provide price relief to plan sponsors. However, this model is rather “last decade.” Since traditional single-molecule drug pipelines are not as robust as in years past, pharmaceutical firms are proving to be very dynamic in their ability to guard their traditional turf using new pricing policies. Today, it is not uncommon to

FIGURE 1: THE TOP 10 DRUGS CLAIMED IN 2009

Rank	Drug Name	Average Cost/Claim
1	Remicade (100mg injection)	\$3,515.66
2	Nexium (40mg tablet)	\$122.77
3	Lipitor (20mg tablet)	\$77.20*
4	Crestor (10mg tablet)	\$61.43*
5	Lipitor (10mg tablet)	\$63.12*
6	Enbrel (50mg/ml pre-filled syringe)	\$1,644.90
7	Plavix (75mg tablet)	\$81.95*
8	Humira (40mg/ml injection)	\$1,659.78
9	Lipitor (40mg tablet)	\$74.68*
10	Prevacid (30mg capsule)	\$73.01*

* Includes co-ordination of coverage with ODB

Source: Green Shield Canada

FIGURE 2: PRESCRIPTION DRUGS COMING OFF PATENT BY 2014

• Lipitor	• Arimidex
• Diovan	• Atacand
• Femara	• Crestor
• Arthrotec	• Oxycontin
• Cozaar	• Plavix
• Hyzaar	• Prograf
• Micardis	• Celebrex
• Singulair	• Gleevec

Source: Ontario Ministry of Health and Long-Term Care

FIGURE 3: BIOLOGICS APPROVED BY HEALTH CANADA IN 2009

Brand/Generic	Company	Description
Abilify (aripiprazole)	BMS	Antipsychotic for schizophrenia and bipolar disorder
Afinitor (everolimus)	Novartis	Kinase inhibitor for advanced kidney cancer
Besivance (besifloxacin)	Bausch & Lomb	Ophthalmic suspension for bacterial conjunctivitis
Cimzia (certolizumab)	UCB	TNF-alpha blocker for moderate to severe rheumatoid arthritis
Inspra (eplerenone)	Pfizer	Aldosterone blocker for left ventricular systolic dysfunction/heart failure post-myocardial infarction
Metvix (methyl aminolevulinate)	Galderma	Topical photodynamic therapy for actinic keratosis and superficial basal cell carcinoma
Multaq (dronedarone)	Sanofi-aventis	Antiarrhythmic for atrial fibrillation
Nplate (romiplostim)	Amgen	Thrombopoiesis stimulator for idiopathic thrombocytopenia purpura
Omnitrope (somatropin)	Sandoz	Growth hormone for growth failure in children and deficiency in adults
Onglyza (saxagliptin)	BMS	DPP-4 inhibitor for control of blood sugar in adults with type 2 diabetes
Pristiq (desvenlafaxine)	Wyeth	Serotonin-norepinephrine reuptake inhibitor (active metabolite of venlafaxine) for treatment of depression
Simponi (golimumab)	Centocor/Schering-Plough	TNF-alpha blocker for rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis
Soliris (eculizumab)	Alexion	Complement inhibitor for paroxysmal nocturnal hemoglobinuria
Tykerb (lapatinib)	GSK	Kinase inhibitor used with capecitabine for advanced breast cancer
Vidaza (azacitidine)	Celgene	Antineoplastic for myelodysplastic syndrome or acute myeloid leukemia
Vyvanse (lisdexamfetamine)	Shire	Prodrug of dextroamphetamine for ADHD
Xeomin (clostridium botulinum neurotoxin type A)	Merz Pharma	Muscle relaxant for treatment of focal spasticity, such as blepharospasm, post-stroke limb spasticity and cervical dystonia

Source: Canadian Pharmacist Letter

have brand name products aggressively priced to counter generics before patent expiry. Going forward, it does not seem as though generics will be able to offer the same savings to plan sponsors that they used to, although they remain the majority of claims by number.

Loss of Traditional Generic Savings

The unintended consequence of Bill 102, the *Transparent Drug System for Patients Act*, is that it puts greater cost pressures on private sector payers. Since most of the private payer drug spend is on generic products, addressing generic pricing gaps would greatly benefit private payers. Yet in Canada, that does not necessarily translate into lower costs, with or without patent protection. There is a relatively new practice of re-pricing the brand to compete with the generic even before the brand comes off patent protection.

For example, take Crestor, a brand name drug used to lower cholesterol levels that will come off patent within the

next four years. Today, it costs \$145.63 for the 10mg variant. Simvastatin, a generic statin (a class of drugs used to lower cholesterol) and a relative equivalent, costs about \$148.20. No savings there—but this is where drug pricing policy in Canada desperately needs attention. In the U.S., that same generic prescription costs \$80.11 (all figures in Canadian dollars).

When plan sponsors think of generics and lower costs, paying \$80 as opposed to \$145 reflects the thinking behind plans that tout generics and generic equivalents. This pricing disparity is indicative of new opportunities for brand to generic competition—opportunities that did not exist even three years ago.

In reaction to this reality, there's an emerging trend of plan sponsors going directly to the manufacturers to negotiate pricing, foregoing the traditional wholesale model that is so well entrenched. Manufacturers and the local pharmacist—who, in the case of direct cost negotiations, are not at the table—will not have their interests represented. It

FIGURE 4: BIOLOGICS IN THE PIPELINE

Drug Name	Manufacturer	Administration	Indication
tocilizumab	Roche	IV	Rheumatoid arthritis
velaglucerase alfa	Shire	IV	Gaucher disease
omacetaxine	ChemGenex	SC	Chronic myeloid leukemia
denosumab	Amgen	SC	Osteoporosis
fampridine SR	Acorda	Oral	Multiple sclerosis
pazopanib	GSK	Oral	Renal cancer
ofatumumab	Genmab/GSK	IV	Chronic lymphocytic leukemia
alglucosidase alpha	Genzyme	IV	Pompe disease

Source: Solutions In Health

is widely expected that in 2010, there will be another attempt to address this complex issue.

The Biologics Story

In 2009, Health Canada approved 19 single-molecule entries into the marketplace. It also approved 10 biologics for use, proving that new higher-cost therapies are coming to market in increasing numbers (see Figure 3).

Looking ahead to 2010 and beyond, the virtual depletion of single-molecule pipelines for new blockbuster drugs is a profound change from what industry pundits have become accustomed to. New biologics are dominating (see Figure 4), and their sales are forecast to grow at twice the rate of traditional products for the next five years, led by new drugs for cancer. There are currently about 1,100 new cancer drugs in the biotech pipeline, an impressive 200 in Phase III clinical trials, around 400 in Phase II, less than 200 in Phase I and less than 300 in the research or pre-clinical stage. Cancer, infectious diseases, neurology and cardiovascular are the top four areas of new biotech products.

The prediction that the top 10 drugs will soon comprise mostly specialty or biologic products is well known: as many as seven of 10 biologic substances could make their way on to this list by 2015. This is good news—these products work and work well—but if this occurs, the underlying financial model of employee group benefits is threatened, which should greatly concern plan sponsors and other industry participants.

Pharmaceutical firms have been in pursuit of biotechnology for many years, and this is not simply a move to generate added revenues. These firms were among the first to recognize that the future of the industry is biotech or biologic products. Anti-cancer antibodies will be among the most prized assets in this class—which, by 2013, will be a market that exceeds \$160 billion and will account for 50% of the top 100 drugs by 2014.

Research shows that biologics are *the* story and will remain so for the next decade or more. Pharmaceutical firms are moving to acquire biotech firms and fund their research. Last year, Roche moved to acquire Genentech outright (they had previously been in a partnership), Abbott acquired BASF and AstraZeneca acquired Cambridge Antibody Technology. These moves are strategic and point to the future, when smaller firms will develop products and will then be targeted by larger firms to bring these products to market. Again, this will be good news down the road for new

treatments and therapies but will put even more pressure on drug plan sponsors to manage the costs.

The Problem with Subsequent Entry Biologics

It might seem logical that there could be generic versions of biologics—and, therefore, price relief—but this is not going to happen, at least not in the traditional manner. Subsequent entry biologics, or “bio-similars,” are better viewed as independent products, not generics of biologics. Simply put, it is not possible to duplicate a biologic substance.

Consider this definition of biologic from the U.S. *Public Health Service Act*: “a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man.” Creating any substance that fits that definition is an amazing feat; duplicating it in a standalone environment is not within the realm of contemporary science. A product such as Lipitor is a single molecule or simple compound, whereas biologics may contain thousands if not millions of molecules. The best we can hope for is a similar product. Compounding this issue is the relatively slow response time from Health Canada in creating the regulatory process for the evaluation and approval of bio-similar products—despite having already approved Omnitrope, the first bio-similar for sale in Canada.

The underlying message in all of this is that drug plan costs are set to increase in a manner that we haven’t seen before. It is debatable whether private payers will be able to manage the looming cost pressures. Market costs for large amount pooling are increasing rapidly, and very few underwriters are willing to entertain new products to manage this risk.

With no national pharmaceutical strategy in place for the country, private payers will be forced to act. Given the budgetary problems that federal and provincial governments are having, it appears as though private payers will have to craft their own solution and then wait for governments and legislation to catch up. Furthermore, 2010 is the year to consider placing a maximum on your drug plan. Even if it is not implemented, there is a pressing need to evaluate your exposure to the significant risk of drug plan cost increases, now and in the years to come. **BC**

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