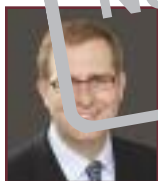




MARKET INSIGHTS

Beyond 2011



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Subsequent Entry Biologics in Canada: Will They Impact Market Dynamics?

Spending on biologics in Canada surpassed \$2 billion in 2010, and, with drug spending expected to continue rising for the foreseeable future, and with specialty biologics making up 50% of late stage drug development pipelines, payers see the advent of Subsequent Entry Biologics (SEBs) as another tool to help control burgeoning health costs.

In their simplest form, SEBs are biologics — drugs created by biological processes — with a demonstrated similarity to a previously approved biologic drug. SEBs are not exact versions of a referenced product and require different development and regulatory processes to receive a Health Canada notice of compliance. In essence, if the process is the product, they will be biobetters.

The regulatory environment for SEBs is different for Canada, the US and Europe

Europe has had guidelines in place for seven years and has issued product specific guidelines for six therapies with several more in development. The European Medicines Agency (EMA) already approved fifteen products across four therapeutic areas.

The US has an abbreviated pathway for “well characterized” and less complex biologics such as low molecular weight heparins (LMWH) and human growth hormones (HGH). For more complex biologics, the FDA has publicly announced that they will release guidance documents before the end of 2011.

In Canada, the regulatory environment for the approval of SEBs continues to evolve. Health Canada issued SEB guidelines in March 2010. Unlike the generic approval process, the guidelines for SEBs are administrative documents that do not have force of law but provide Health Canada with flexibility in its approach to approving SEBs. Thus far, Health Canada approved one SEB in April 2009. Other SEBs are anticipated; and the next products to be approved are expected to be the

same as those already approved in Europe. The current environment in Canada does not provide the same transparency as other jurisdictions, which leaves competitors and approval dates open to speculation.

Are SEBs Interchangeable with the Reference Biologic?

Since 1995, Health Canada has made a Declaration of Equivalence (DOE) for generic drugs. The DOE essentially states that two products are functionally and therapeutically equivalent. Health Canada’s current stance is that SEBs will not be declared equivalent to the reference biologic. Each SEB will have its own distinct name to ensure the development and implementation of risk management and pharmacovigilance plans, adverse event reporting, and Periodic Safety Update Reports (PSURs). When it comes to “switching” products, Health Canada recommends that any change in therapy (brand to SEB, SEB to SEB, or SEB to brand) requires the intervention and agreement of the prescriber.



Despite the Health Canada guidelines, pharmacy is regulated at the provincial level, and the regulations surrounding interchangeability and therapeutic substitution will differ by province. Each province has its own rules and declares the liability borne by the dispensing pharmacist. Thus far, Québec is the only province to pronounce its position surrounding interchangeability and SEBs. In June 2010 Québec declared that SEBs will be considered as distinct biologics. As the interchangeability regulations are currently written, the same policy is expected to be adopted by all other provinces.

The SEB Commercial Model

Globally, the penetration of SEBs has been modest at best. SEBs represent less than 0.25% of the global biologics market, and Europe and specifically Germany has the bulk of these sales. Without a Health Canada declaration of equivalence and the ability for pharmacists to automatically substitute a product

when dispensing, SEB manufacturers are required to generate their own new prescriptions and patients for their products. The competitive dynamics for SEBs will more closely resemble a competitive entry to the originator — a brand versus brand dynamic instead of a brand versus generic dynamic.

In Europe, the discount for SEBs relative to the brand price ranges from 20 to 30%. In Canada, the only approved SEB currently sells at a 40% discount relative to Brand. Despite the lower discount relative to small molecule generics, the higher price of biologics can make the savings for payers substantial. Without automatic substitution at their disposal, third party payers may use other mechanisms to favour dispensing SEBs over reference products, such as fully-managed plans, prior authorizations, and tiered formularies.

The requirement of a novel business model for the commercial success of SEBs may create a new breed of competitors. Generic

players, such as Teva and Hospira, may integrate SEBs within their current innovative divisions, while commercial heavyweights, such as Merck and Pfizer, may integrate SEBs within their therapeutic portfolios.

Impact on the Biologics Market

The question is not if, but when and what kind of SEB competitors will enter the Canadian market. The continuous changes in the healthcare landscape require constant monitoring of the environment for changes that may modify current assumptions. Innovative companies with biologics must institute measures to successfully prepare and compete in this new market paradigm. **GPM**

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