Canadian Provincial Governments Actively Redirecting Patients to Biosimilar Drugs to Save Money

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Biologics are drugs which contain an active medicinal ingredient that is derived from living cells. They are generally proteins, which are larger and more complex than the chemically synthesized small molecule pharmaceuticals (acetaminophen etc.) that have for decades made up the bulk of drugs on the market. Biosimilars are competitor versions that attempt to "copy" the originally approved biologic drug. Biosimilars are approved for marketing by the short-cut of showing to regulators they are sufficiently *similar* to a biologic reference drug that is already approved for sale. This biosimilarity standard is less strict than the *bioequivalence* standard which applies to conventional generic pharmaceutical drugs. Showing biosimilarity allows biosimilar manufacturers to rely largely on the innovator drug's clinical data, thereby dramatically reducing the time and expense otherwise required to obtain market authorization.

We have previously reported on biosimilar drug approvals increasing in Canada. Despite the lower cost of biosimilars, patient uptake has not been as significant as some provincial governments would like. For conventional, small molecule pharmaceutical drugs, provincial governments have typically required substitution of the more expensive brand name drug with a less expensive (bioequivalent) generic drug. This practice of mandatory substitution was not initially extended to biosimilars. Biosimilars were relatively new, so there were lingering safety and efficacy concerns, particularly with respect to switching patients already accustomed to the brand name biologic drug. Since the biosimilar is similar, not bioequivalent, the government formularies took a wait and see approach. In the meantime, provincial drug expenditures increased annually, for a variety of reasons, which created a cost pressure on the government.

Health care providers and patients tend to be cautious, and are not highly motivated to switch from the brand biologic drug to the biosimilar on their own. Most patients would prefer, and in some cases need, to have their choice of drug, the cost of which may be largely paid for by the government or private insurance. For certain drugs, governments have tried to require new patients to *start* on the biosimilar for at least certain indications, to avoid the switching issue. The rheumatoid-arthritis drug, Remicade (common name: infliximab), is one example where most provinces stopped paying for the drug for new patients for certain indications. The new patients had to accept the biosimilar version of infliximab from the start, or pay out-of-pocket for the brand name drug (very few patients on a government insurance plan are likely to self-fund medications). In 2017, the Quebec provincial government also stopped funding the brand name Remicade for new patients for certain indications. Patients already using Remicade could continue on. Earlier this year, the Quebec Court of Appeal struck down this arrangement, on the basis that the government decision lacked procedural fairness. The government may still eventually move to stop paying, but it is required to first give the drugmaker, Janssen, notice and an opportunity to respond. The Quebec government has, at least temporarily, reinstated coverage for Remicade.

The British Columbia provincial government is now effectively requiring dispensing of certain biosimilar drugs to both new and existing patients, for certain indications. The government will no longer pay for the brand name drug for those indications after November 2019. These drugs include entanercept, infliximab and glargine, for certain indications. Patients that do not switch will have to pay for the drug entirely out-of-pocket, or apply for a discretionary exemption for medical reasons. This change applies to patients with government drug coverage, not other patients that get coverage from private insurance plans.

Using Remicade/infliximab as an example, there have been recent, promising clinical studies where patients switch to biosimilars. However, it is also not difficult to find literature that recommends caution and patient-specific

consideration. Brand name companies and biosimilar companies are both spreading their own messages. The brands focus on safety of established treatment and risks of switching. The biosimilar manufacturers emphasize safety of their products, and are pushing for interchangeability.

The British Columbia government is arguably conducting a bit of a science experiment by requiring all patients to switch to biosimilar drugs this year. The government emphasized the cost savings it plans to achieve through requiring the use of biosimilars. To the extent there are patient risks, the government message is essentially requiring patients to plead their case one-by-one or else accept the risks. The success or failure of this approach will have significant implications for other biosimilar drugs.