

Canada's approach to biosimilars questioned

Health Canada's regulatory approach to a new category of cost-saving drugs known as biosimilars has been halting and overly restrictive, according to generic drug-industry insiders at the recent International Generic and Biosimilar Medicines Association conference.

So far, Health Canada — which in 2012 became one of seven World Health Organization (WHO) collaborating centres for biosimilar regulation — has approved four biosimilar drugs; 19 are approved and widely used in Europe. (Health Canada refers to biosimilars as subsequent entry biologics.)

Biosimilars are near-exact copies of biologic drugs, but are produced through slightly different manufacturing processes that allow companies to bypass patent protections. Biologic drugs, which are derived from biological processes, are expensive to develop; treatment for a single patient ranges from \$25 000 to \$100 000 annually. But biosimilars sold in Europe are 10%–35% less expensive.

Those cost savings could be crucial as sales of biologic drugs in Europe are expected to swell from US\$13 billion in 2014 to US\$23 billion by 2019. In the United States, biologic drugs already account for about US\$82 billion, or 22% of annual drug spending, according to IMS Health. The Canadian Generic Pharmaceutical Association (CGPA) estimated that in 2013 the provinces spent more than \$3 billion on biologic drugs, about 14% of all drug spending. Four of Canada's five top-selling pharmaceutical products are biologic products, with total annual sales of more than \$2 billion in 2014, the CGPA says.

Biosimilars are making headway in some countries. They account for half the biologics market share in the United Kingdom and Germany. In New Zealand, patients are being switched to biosimilars, and in Finland, approved biosimilars can be used interchangeably with biologics. Interchangeability is considered crucial in encouraging clinicians and patients to use biosimilars instead of biologics.

Though Europe is using biosimilars to cut the cost of biologics, both the US Food and Drug Administration (FDA)



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Inflectra, a biosimilar that costs 25% less than the biologic drug, is widely used in Europe for inflammatory bowel disease. Health Canada prohibits this use.

and Health Canada are still developing policies in the face of resistance and lawsuits from brand-name drug makers, said Jeff Watson, president of global generics at Toronto-based Apotex, which has invested in developing biosimilars.

The FDA is considering 57 biosimilars. The first one it approved was blocked by an October 2014 injunction from the manufacturer of the biologic drug it copied. A July 2015 US federal court decision overturning this injunction is now under appeal.

Although Health Canada “will not rule on interchangeability,” Watson noted, the department has warned against it. Health Canada spokesman Sean Upton confirms that in July 2010 the department advised provincial and territorial drug plan administrators that biosimilars “are not ‘generic’ biologics” and it does not support their “substitution” with biologics.

Biosimilars “are new drugs that are not declared to be pharmaceutically or therapeutically equivalent with their reference products, and this should inform decisions regarding interchangeability and substitutability,” says the guidance statement. “The authority to declare two products automatically substitutable by a pharmacist does not rest with the federal government.”

Watson is not the only executive to raise questions about Health Canada's approach.

Michel Robidoux, president and

general manager of Sandoz Canada and inaugural chair of CGPA's biosimilars board, said Health Canada's approach to the biosimilar drug Inflectra diverged markedly from Europe's. Inflectra costs 25% less than its reference product, Remicade, a biologic drug with \$800 million in Canadian sales in 2014.

Robidoux noted that Health Canada approved Inflectra for rheumatoid arthritis but not for inflammatory bowel disease, saying that the data are not convincing. According to the European Medicines Agency (EMA), the majority of prescriptions for Inflectra in 26 European countries are for inflammatory bowel disease.

European regulators examined the same data as Health Canada, said Dr. Elena Wolff-Holz, a member of the Biosimilar Medicinal Products Working Party at the EMA. It concluded that the data Health Canada cites in rejecting Inflectra for use in inflammatory bowel disease were “not clinically relevant.”

“Health Canada makes autonomous decisions,” countered Upton.

Rx&D, which represents Canada's brand-name drug makers, also says that biosimilars “cannot be interchangeable” with biologics. Its stance is “influenced by Health Canada's own position on the same topic,” said spokesperson Sarah Douglas. — Paul Christopher Webster, Toronto, Ont.

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