14.3 CANADIAN BIOSIMILAR APPROVAL PROCESS

Biosimilars are regulated in Canada under Health Canada's preexisting powers granted by the Food and Drugs Act and Regulations (Food and Drugs Act, 1985; Food and Drug Regulations, 2016). Biosimilars are reviewed and approved via the same pathway that has been used for many years for assessing new small-molecule pharmaceutical drugs. This pathway involves a new drug submission (NDS) showing the drug's safety, effectiveness, and quality. Health Canada approves drugs for marketing by issuing a marketing authorization, called a Notice of Compliance (NOC). The NOC is issued only after a drug manufacturer's NDS is approved. Biosimilars do *not* proceed via an abbreviated new drug submission, which is the pathway used for conventional generic pharmaceutical drugs. Biosimilars are not bioequivalent to the reference product and have other characteristics considered different enough that Health Canada will usually not approve them via an abbreviated new drug submission (ANDS). The biosimilar manufacturer may nonetheless benefit from a reduced regulatory burden by relying on the previously approved drug's clinical and safety data.

A high-level overview of the regulatory approval requirements for biosimilar drugs is provided in the Health Canada guidance document for sponsors: *Information and Submission Requirements for Subsequent Entry Biologics (SEBs)* (Health Canada, 2010). Health Canada also recommends that biosimilar manufacturers review Europe's extensive published guidance since it is often consistent with the Canadian approach. To date, at least a somatropin, filgrastim, and monoclonal antibody (infliximab) have been approved in Canada. Omnitrope (somatropin; human growth hormone) is the earliest example of a biosimilar that has been approved in Canada (Health Canada, 2009) by relying on clinical data for Pfizer's innovator somatropin product.

14.3.1 Linkage of Canadian Patents to Biosimilar Approval Process

Biosimilar approval can be linked to patent issues in Canada. There is a specialized litigation option available to protect certain patented biosimilar drugs on the market. The process may block a second-entry biological drug that is referencing a patent owner's clinical trial data. This unique Canadian system is informally called the NOC Regulations [*Patented Medicines (Notice of Compliance) Regulations*], and it is well established from its use in relation to conventional pharmaceutical drugs.

14.3.2 The Health Canada Patent Register

In connection with the NOC Regulations, Health Canada maintains its own Patent Register, independent from the Canadian Intellectual Property Office, relating to medicines and their use. However, Health Canada does not have any involvement in examining or issuing patents—it keeps a list of relevant already-issued patents. The Patent Register is somewhat analogous to the US "Orange Book" for conventional pharmaceutical litigation.