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Canada to Develop Regulatory Pathway for Biosimilars

By Adrienne M. Blanchard and Dr. Alan West

On January 30, 2008, Health Canada released its consultation document entitled Draft Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs). The document released by Health Canada can be found at:

http://www.hc-sc.gc.ca/dhp-mps/brgtherap/activit/consultation/seb-pbu/2008-notice-avis_e.html.

Health Canada is seeking input on the appropriate regulatory pathway for these products (known as biosimilars in the EU and as follow-on biologics in the U.S.). Written comments on the Draft Guidance were due by April 16, 2008, and further consultations are scheduled to take place.

Current Regulatory Pathway for Follow-On Biologics in Canada

While the Draft Guidance recognizes that regulations should be developed and implemented, it is aimed at outlining the rules that are to apply to these products before regulations can be finalized.

Canada differs from the U.S. in that there is some regulatory authority for Health Canada to approve products through a hybrid-type approval. Provided

that some clinical data and other acceptable data, such as published studies on the comparable innovative product and/or comparative studies to that product are submitted and found sufficient for the Minister to make a finding of safety and effectiveness, the Minister may be able to approve the SEB.

Protection of Intellectual Property Rights

The Draft Guidance deals with a number of issues of health and safety regulation for SEBs. Notable by its absence is any specific provision for the protection of intellectual property rights. Rather, the document merely states that intellectual property protections will be applied.

Scientific and Submission Requirements for Follow-on Products

The Draft Guidance sets out, in general, the scientific issues that must be addressed by an SEB submission sponsor who seeks approval. It does not prescribe with clarity the kind of information that will be required for such submissions. However, the Draft Guidance states that Health Canada intends to issue product-specific guidances, as has been done in the EU, which would outline the information and data requirements for specific classes of SEBs.

For certain scientific issues, the Draft Guidance leaves unanswered or unaddressed a number of questions. For example, in cases where the reference biologic product has more than one indication. In one instance, the Draft Guidance states that SEBs sponsors should be eligible to apply for indications that fall within those granted to the reference biologic product and that any claims made by the SEB must be supported by suitable scientific data. Yet, later in the document, the Draft Guidance states that, "Where the mechanism of action strongly supports an indication, a SEB sponsor would be granted additional indications for which data has not been provided." The standards that are to be applied to SEB products for which approval is sought for different indications of the reference product are therefore not clear and will presumably be clarified in the final Guidance.

Interchangeability with the Reference Product

The issue of interchangeability is also referenced in the Draft Guidance. According to the Draft Guidance, approval of an SEB does not necessarily mean it is "substitutable" for the innovative product. The Draft Guidance describes "substitutability" as follows: two products are substitutable with each other if they can both be used in lieu of the other during the same treatment period. The Draft Guidance sets out that "cross-over" studies would be required to demonstrate substitutability. It therefore suggests that Health Canada intends to pronounce on the degree to which an SEB may be substitutable with the innovative product. It is thus likely that any conclusions by Health Canada as to the similarity between an SEB and its reference product will inform the provinces as to whether an SEB is interchangeable with the innovative product for reimbursement purposes.

Use of a Foreign Reference Product Unapproved in Canada

The Draft Guidance also states that a foreign product that has not been approved in Canada might be used as a reference product by an SEB sponsor. Specifically, the Draft Guidance states that such a reference product may be considered on request to the Minister or on recommendation by the Minister. Moreover, the document states that foreign biologic products that have been approved by regulatory agencies who are parties to a Memorandum of Understanding or information-sharing agreements with Health Canada have a better chance of being approved as suitable reference biologic products. This proposal raises questions as to how a safety assessment by Health Canada can be made for the SEB in these circumstances, given that Health Canada will not have the original data from the innovator on which to make its own assessment of similarity to the SEB.

Next Steps

The next steps for Health Canada will be to finalize the Draft Guidance as a document to govern its internal processes that will be followed when it reviews an SEB application, before to the adoption of a specific regulation related to the pathway for SEBs.

It is uncertain when regulations will be proposed. Health Canada is now undertaking, in parallel track, consultations on its proposal for a "Progressive Licensing Framework," a process that is expected to involve significant amendments to the Food and Drugs Act and the Regulations. This initiative is intended to give Health Canada new powers of regulatory oversight over the entire life of a product, extending its powers to require product recalls and to require sponsors to provide post-marketing information throughout a product's life cycle. It is quite possible that the regulations necessary to set standards for approval of SEBs will be brought into this process in the future. However, given the Draft Guidance lacks specific protections for intellectual property, a faster timeline may be urged to set the pathway in regulation.