September 14, 2015

Notice to stakeholders

Subsequent Entry Biologics Scientific Advice Meeting Pilot

Health Canada's experience with the regulatory review of subsequent entry biologics has triggered the need to implement a step-wise review approach for these products. The development process for a subsequent entry biologic differs from that of a traditional new drug. Early in the drug development process, the sponsor selects a reference biologic drug and performs an extensive side-by-side comparability characterization of the subsequent entry biologic. The intent of the comparability exercise is to demonstrate the degree of similarity between the subsequent entry biologic and the reference biologic drug.

Heath Canada is implementing a three year pilot beginning September 14, 2015 to explore a step-wise review approach to complement the subsequent entry biologic development process. During the pilot, a subsequent entry biologic sponsor may request a scientific advice meeting in order to receive advice from Health Canada on their comparability package early in the subsequent entry biologic development process. The onus is on the subsequent entry biologic sponsor to ensure they meet the eligibility criteria for a subsequent entry biologic as outlined in the *Guidance Document: Information and Submission Requirements for Subsequent Entry Biologics (SEBs)* (http://www.hc-sc.gc.ca/dhp-mps/brgtherap/applic-demande/guides/seb-pbu/notice-avis_seb-pbu_2010-eng.php). The pilot is open to any subsequent entry biologic sponsor that wishes to participate.

How does a sponsor request a Subsequent Entry Biologics Scientific Advice Meeting?

A sponsor requests a subsequent entry biologic scientific advice meeting by contacting the Office of Regulatory Affairs (http://www.hc-sc.gc.ca/contact/dhp-mps/hpfb-dgpsa/bgtd-pbtg-ora-bar-eng.php) in the Biologics and Genetic Therapies Directorate. The request should be made at least 6 months in advance. Three meeting dates are to be provided.

Following confirmation of the Subsequent Entry Biologic Scientific Advice Meeting date from the Office of Regulatory Affairs, the sponsor submits the Subsequent Entry Biologic comparability package to the Office of Submissions and Intellectual Property (http://www.hc-sc.gc.ca/contact/dhp-mps/hpfb-dgpsa/osip-bppi-eng.php) at the following address:

Office of Submissions and Intellectual Property (OSIP)
Therapeutic Products Directorate
Finance Building # 2
Tunney's Pasture, A.L. #0201A1
Ottawa, ON K1A 0K9
Fax: (613) 941-0825

The comparability package should be organized in the International Conference on Harmonisation (ICH) Common Technical Document (CTD) format as a distinct collection of data in module 3 with an associated section in the Quality Overall Summary containing appropriate cross-references. Sponsors are encouraged to refer to the *Guidance Document: Information and Submission Requirements for Subsequent Entry Biologics (SEBs)* (http://www.hc-sc.gc.ca/dhp-mps/brgtherap/applic-demande/guides/seb-pbu/notice-avis_seb-pbu_2010-eng.php) for additional guidance on the preparation of the comparability package.

Ten days following submission to the Office of Submissions and Intellectual Property, the Subsequent Entry Biologic comparability package is forwarded to the Office of Regulatory Affairs. The Office of Regulatory Affairs processes the submitted Subsequent Entry Biologic comparability package and sends it to Biologics and Genetic Therapies Directorate evaluators for review. The comparability package is reviewed within ninety days.

The sponsor and the Biologics and Genetic Therapies Directorate discuss the comparability package at the time of the scheduled Subsequent Entry Biologic Scientific Advice Meeting. Within fourteen days of the Subsequent Entry Biologic Scientific Advice Meeting, the sponsor provides a written record of the meeting to the Biologics and Genetic Therapies Directorate.

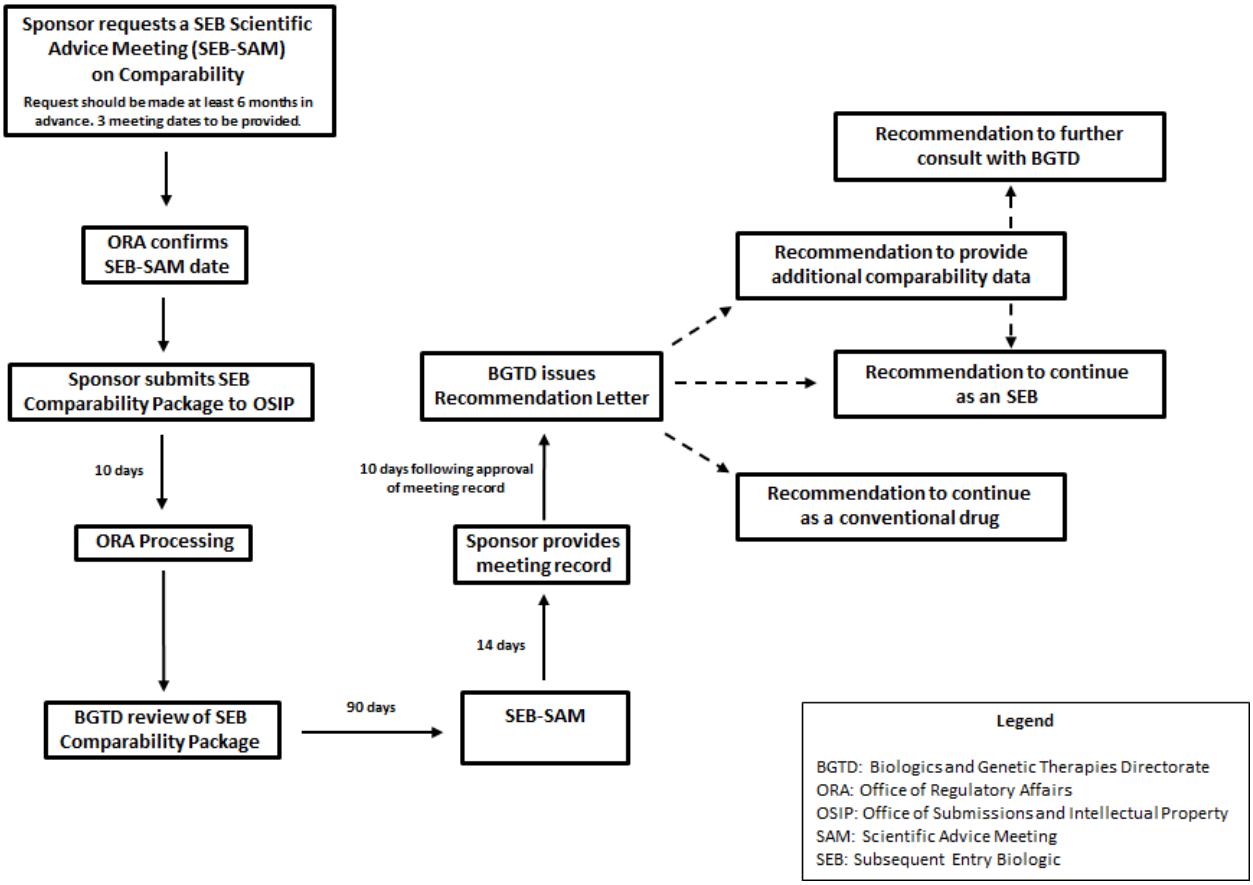
Ten days following approval of the record of the meeting, the Biologics and Genetic Therapies Directorate issues a recommendation letter to the sponsor including one of the three following recommendations:

- A recommendation to continue as a Subsequent Entry Biologic;
- A recommendation to continue as a conventional drug; or
- A recommendation to provide additional comparability data.

If the Biologics and Genetic Therapies Directorate recommendation is for the sponsor to provide additional comparability data, then one of two of the following recommendations is provided once the sponsor provides the additional comparability data:

- A recommendation to continue as a Subsequent Entry Biologic; or
- A recommendation to further consult with the Biologics and Genetic Therapies Directorate.

SEB Scientific Advice Meeting



Contact Information

For further information on the Subsequent Entry Biologic Scientific Advice Meeting, please contact the Office of Regulatory Affairs (http://www.hc-sc.gc.ca/contact/dhp-mps/hpfb-dgpsa/bgtd-pbtg-ora-bar-eng.php within the Biologics and Genetic Therapies Directorate.

Additional Information

Additional information on subsequent entry biologics can be found below:

Fact Sheet: Subsequent Entry Biologics in Canada:

http://www.hc-sc.gc.ca/dhp-mps/brgtherap/activit/fs-fi/fs-fi_seb-pbu_07-2006-eng.php

Guidance Document: Information and Submission Requirements for Subsequent Entry Biologics (SEBs):

http://www.hc-sc.gc.ca/dhp-mps/brgtherap/applic-demande/guides/seb-pbu/notice-avis_seb-pbu_2010-eng.php