Yearly Biologic Product Reports: Questions and Answers

1. What is the Yearly Biologic Product Report (YBPR)?

The Yearly Biologic Product Report (YBPR) is a report that must be submitted annually by manufacturers of all Schedule D (Biologic) drugs in accordance with *Guidance for Sponsors: Lot Release Program for Schedule D (Biologics) Drugs* (http://www.hc-sc.gc.ca/dhp-mps/brgtherap/applic-demande/guides/lot/gui_sponsors-dir_promoteurs_lot_program_e.html). The report contains production information on both drug substance and drug product lots, including test methods and results, reasons for any recalls and corrective action taken, as well as other pertinent post-market information.

Health Canada has the authority to request a YBPR based on section C.01.014.5, C08.007 and/or C.08.008 of the *Food and Drug Regulations*, which requires manufacturers of Schedule D (biologic) drugs to provide information annually to Health Canada. Section C.04.015 of the *Food and Drug Regulations* requires manufacturers to provide information supporting Lot Release.

2. What is the purpose of the YBPR and how is the information in the YBPR useful to Health Canada?

As part of Health Canada's life-cycle approach to the regulation of biologics, the Biologics and Genetic Therapies Directorate (BGTD) uses information from the YBPR to assess the on-going safety and quality of the products, to verify the consistency of manufacturing processes, and to highlight any trends. In addition, the YBPR is useful for providing regulatory context when only a few lots produced in a facility are released in Canada, or when post-NOC changes are filed infrequently. The information may also be used to support assignment of a product into a different Lot Release Evaluation Group, or justify continuation of the current level of oversight.

3. What information should be included in the YBPR?

Specific details on required content are provided in Section 5.1.1 of the *Guidance for Sponsors: Lot Release Program for Schedule D (Biologics) Drugs (http://www.hc-sc.gc.ca/dhp-mps/brgtherap/applic-demande/guides/lot/gui_sponsors-dir_promoteurs_lot_program_e.html#5_0).* The following types of the information should be included in the YPBR:

- Production information on both drug substance and drug product lots,
- Information on drug substance and drug product test methods and results, including trend analysis for stability-indicating methods,
- Facility information, including foreign regulatory decisions that affect Good Manufacturing Practices (GMP) status,
- Analysis of Adverse Drug Reaction Reports (Canadian and International) **attributable to product quality** (post market technical complaints),

- All product recalls, including the reason of the recall and a summary of any corrective actions taken, and
- If changes affecting the Certified Product Information Document (CPID) have been made, an updated CPID is to be provided

4. What are the format requirements for the YBPR?

In order to decrease the regulatory burden for sponsors, no Canadian-specific format is required. Sponsors may file a report prepared for another competent regulatory authority, such as the FDA or EMEA, as long as it contains the Canadian specific information outlined in the Guidance Document.

5. When should the YBPR be submitted to Health Canada?

Reports are requested no later than October of each year as an Addendum to the Annual Drug Notification Report. However, this submission date is flexible and sponsors are free to negotiate an alternate yearly filing date, for example one which coincides with filing to another regulatory body, by contacting the Regulatory Affairs Division (see Question 11 for contact information).

6. How do I submit the YBPR?

An electronic PDF version and paper copy or duplicate paper copies of the YBPR can be submitted as an addendum to the Annual Drug Notification Report. The YBPR report may also be submitted directly to the Regulatory Affairs Division at the contact address below.

7. What is Health Canada's feedback to sponsors with respect to YBPRs?

The Regulatory Affairs Division will issue:

1. an acknowledgement letter upon receipt of the YBPR;
2. an information request (with a 30 day target), if clarification or additional information is required;
3. a final letter to indicate that the review is complete and to provide feedback to sponsors, if necessary.

8. Is the YBPR required for each DIN or can similar products (e.g. different strengths) be grouped together?

Scientifically justified groupings may be submitted as one YBPR. Questions regarding groupings should be forwarded to the Regulatory Affairs Division in BGTD at the contact address below.

9. Is the YBPR required if I have a DIN, but my product is not being manufactured or sold?

A YBPR is required for all Schedule D (Biologic) Drugs regulated by BGTD whether or not your product is being manufactured or sold. If no lots are manufactured or sold within the reporting year, the sponsor should submit the YBPR indicating this.

10. Where can I find more information?

Detailed information is available in the *GUIDANCE FOR SPONSORS: Lot Release Program for Schedule D (Biologic) Drugs* found on the following website: http://www.hc-sc.gc.ca/dhp-mps/brgtherap/applic-demande/guides/lot/gui_sponsors-dir_promoteurs_lot_program_e.html.

11. Who can I contact if I have more questions?

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