Health Canada Santé Canada

April 4, 2014

Notice

Our file number: 13-117266-125

Final Release: Plain Language Revisions to Part III: Patient Medication Information and Associated Templates of the *Guidance Document - Product Monograph*

Health Canada recently announced a number of measures that will be taken to support the health and safety of Canadian families, one of which is improving drug product labels. As part of the Health Products and Food Branch Strategic Plan, the Plain Language Labelling Initiative proposes changes to both regulations and guidances. The goal is to provide more relevant and easier to understand drug information on labels, in order to help Canadians make better informed decisions about their medications.

As part of this initiative, Health Canada is pleased to release the revised Part III: Patient Medication Information section (formerly titled: Consumer Information) of the *Guidance Document: Product Monograph*, along with five revised associated templates. Comments received during previous consultations were taken into consideration during the development of the finalized guidance document and templates. Feedback related to Part I: Health Professional Information or Part II: Scientific Information will be invited during upcoming consultations on the rest of the guidance.

Changes to Part III have a focus on plain language, including:

- a more descriptive title;
- eliminating columns and streamlining the use of headings;
- providing some information in a Question and Answer format;
- using simpler language and shorter sentences;
- requiring font types and sizes which enhance legibility; and
- using Grades 6-8 level vocabulary where appropriate to enhance comprehension.

In order to provide industry with sufficient time to transition to the 2014 Patient Medication Information format, there will be a phased implementation. Please note that under certain circumstances, the 2014 format could be applied to drugs which may otherwise be outside of the scope described for the phased implementation. In these cases, Health Canada will notify the sponsor.

…./2

Canada

Phase I

Beginning June 1, 2014, the requirement to file under the 2014 Patient Medication Information format will apply to the following submission types only, for biologics and radiopharmaceuticals and for prescription pharmaceutical products:

- New Active Substance (NAS) New Drug Submissions (NDS);
- Abbreviated New Drug Submissions (ANDSs) and Supplements to Abbreviated New Drug Submissions (SANDSs), **where the corresponding innovator PM is in the 2014 Part III format**.

Phase I will last 18 months, ending November 30, 2015, at which time the Department will have performed an assessment of the work to confirm the direction of Phase II.

Phase II

Beginning December 1, 2015, the requirement to file under the 2014 Patient Medication Information format will expand to include all New Drug Submissions (NDS) for biologics and radiopharmaceuticals and for prescription pharmaceutical products.

Abbreviated New Drug Submissions (ANDS) and Supplements to Abbreviated New Drug Submissions (SANDS), where the innovator PM is in the 2014 format will continue to be part of the scope.

Phase II will last 18 months, ending May 31, 2017, at which time the Department will have performed an assessment of the work and future direction.

As part of the assessments, Health Canada will review this implementation plan to consider when the requirements should be expanded to include other submission types.

For those products falling within the scope of Phase I and II, these documents replace the *Guidance Document: Product Monograph*, adopted September 22, 2003; Standard Template (Appendix E), dated February 2010; Notice of Compliance with Conditions Template (Appendix F); Subsequent Entry Products Template (Appendix G); Schedule C Template (Appendix H); and the Schedule D Template (Appendix I), effective June 1, 2014.

…/3

Any questions should be directed to:

Bureau of Policy, Science and International Programs
Therapeutic Products Directorate
Health Products and Food Branch
Health Canada
1600 Scott Street
Holland Cross, Tower B
2nd Floor, Address Locator 3102C5
Ottawa, Ontario
K1Y 4N7

Telephone: 613-948-4623
Facsimile: 613-941-1812
E-mail: Policy_Bureau_Enquiries@hc-sc.gc.ca

We appreciate your time and effort as we work together to improve the health and safety of all Canadians.