



Guidance Document for Promotional Monographs

January 2013

Document title

A promotional monograph is defined as a product monograph (PM) that has been modified by the addition of promotional elements. Promotional monographs should not be labeled as “Product Monograph”; they should be identified as advertising/ promotional systems (APS) with titles similar to “Promotional Monograph”, “Marketing Monograph”, or “Clinical Monograph”.

Common exceptions:

- *A product monograph whose only modification is the insertion of blank note pages does not require PAAB review.*
- *A product monograph whose only modification is the non-selective addition of tabs for each heading throughout the product monograph would not require PAAB review.*
- *A product monograph wrapped in a simple cover (e.g. brand colours) does not require PAAB review. However, review is required if images are added (in which case the above restriction pertaining to document title would apply).*

Note that no documents other than the Health Canada approved product monograph may contain the Health Canada issued control number.

Modifications

Modifications may be based on the PM or other sources. They may be text boxes or images. Modifications should be presented in such a way as to be clearly distinguished from the PM itself. For example, callouts positioned in the margins may be used for text.

Callouts based on the PM: These may be used to emphasize specific content from the PM. Lines or arrows may be used to link the callout to the section of the PM that is its source. If quotation marks are used, the callout should not contain visual treatments that are not in the PM; if quotation marks are not used, visual treatments may be acceptable. Statements requiring a disclaimer should be disclaimed as they would be in any other APS.

With respect to quantification of claims (including but not limited to speed of onset, length of duration), when the claim appears in a callout on the same page as the PM data that quantifies the claim, lines or arrows may be used to link the callout to the quantifying data.

Callouts that are not based on the PM: These should be clearly presented as non-PM material. They should not be linked to sections of the PM by the use of lines or arrows or be presented within quotation marks. They should be clearly referenced to their sources and qualified, quantified and disclaimed as they would be in any other APS.

Qualification/quantification for taglines will be treated as they would be in any other APS.

The product monograph (PM) within the promotional monograph

The PM should be presented verbatim. It should not contain visual treatments that create emphasis not present in the PM (e.g. bolding, underlining, boxing, capitalizing, shading, colour treatments, etc.). For pages containing PM text, elements such as graphs, callouts, images can only appear in the page margins so as not to segment the PM text.

Indication and Fair balance

A promotional monograph is considered to be promotional because it contains embellishments that emphasize benefits and features of the product. Hence, indication and fair balance is required. Refer to the PAAB documents “Guidance document for indication placement in advertising” and “Guidance on base fair balance level selection and placement”. Fair balance may be presented as a block on the front or back covers OR it can appear as callouts throughout the APS.

Emphasis on positive features while ignoring negative features is not acceptable. Balancing copy should appear in close proximity.

As an example, there is a callout, “Drug X is not expected to cause clinically important pharmacokinetic interactions with drugs that are metabolized by cytochrome P-450 isozymes”. However, Drug X does interact with drugs that prolong the QT interval. This latter piece of information should be presented as a callout to balance the former and it should appear in close proximity. This is consistent with how such claims are treated in other types of APS.

Prescribing Information:

Prescribing information is not required to be attached or linked to this document as the product monograph is housed within it.