Guidance on Indication Placement in Advertising

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Table of Contents

1. Introduction:

An advertisement is misleading if it suggests that a drug is useful in a broader range of conditions or patients than that which has been approved by Health Canada. The segment of patients for whom the product is authorized must set the context for the corresponding benefits (PAAB code section 2.10). Presentation of this content in later sections of a multipage piece does not adequately offset the broad claims of efficacy/safety.

1.1 Glossary:

For the purpose of this document, the following terms can be interpreted per the accompanying descriptions:

Advertising message portion of Advertising Promotion Systems (APS): The main body copy of the advertising containing promotional claims. Also called the "main advertising message portion".

Indications and Conditions of use: Indications for use are the therapeutic/diagnostic/prophylactic uses defined in the Terms of Market Authorization (TMA). Indications may include limitations to the drug product's use (e.g. a specific population). These uses are deemed by Health Canada to be based on substantial evidence of the product's efficacy and safety. These are generally identified by the wording "…is indicated for…" Conditions of use include the circumstances under which the product is used for the authorized indications (e.g. with adjunctive therapies, in-patient vs out-patient, daytime vs nighttime use).

Marketing benefit claim: A statement that is designed to promote the sale of a health product. It often highlights a specific product attribute e.g. "longer lasting", "tastes great", or "proven safety profile".
A promotional statement is designed to inform about the product's availability and benefits so as to form/alter the audience's opinion of the medication. It can be explicit (e.g. text) or implicit (e.g. images), comparative or non-comparative. It can relate to pharmacological or non-pharmacological properties of the product.

> *Not all statements about a product are "marketing claims of benefit". Common examples of product messaging which are not considered marketing benefit claims include product reconstitution instructions, monitoring instructions, dosing modifications for special populations and storage instructions when these are presented as instructions/burdens rather than features/benefits (i.e. presented to instruct rather than alter/form the audience's opinion of the medication in a positive way). How a statement is framed can sometimes affect whether it is a marketing benefit claim. For example, the copy "Arbace: Convenience of a single daily dose" is a marketing benefit claim while "Patients should be instructed to take a single dose daily at the same time each day" is not.*

2. Which "INDICATION and CLINICAL USE" Content is Required to be Presented "Early"?

The "Indication and Clinical Use" section of the product monograph (or equivalent section of other TMA types) is sometimes lengthy. There is often no need to include the entire section early in the APS. Content from this TMA section falls into one of the following three categories:
a) Content required to appear early within the main advertising message of the APS

b) Content simply required to appear somewhere within the main advertising message of the APS (i.e. not necessarily early)
c) Content which may be excluded from the APS

These categories are discussed in detail below:

a) Content Required to Appear Early Within APS Main Advertising Message

The TMA content "is indicated for…" (or equivalent) must be presented prominently along with any other messages from the INDICATION AND CLINICAL USE section that set the boundaries for patient selection for that use. Boundaries for patient selection are often created through specification of patient or disease characteristics upon which use of the product is contingent.

> Tip #1: The manufacturer can limit the content to that relating to the promoted use(s). *Presentation of the other indications is not required as the intent is simply to offset claim copy relating to the promoted uses.*
>
> Tip #2: There is no need to be repetitive.
>
> *The TMA for product XYZ has the following Indication & Clinical Use statement: "Indicated for management of pain in adults who are 50 years old or less. Not indicated in patient above the age of 50". The statement presented early in the APS may read simply "Product XYZ is for management of pain, in adults who are 50 years old or less". Note that this sentence could be reworded but it should appear verbatim at least once in the piece.*

The presentation may be summarized provided the full essence is captured; however, take note of section "6. Presenting INDICATION Content Verbatim Somewhere within APS" below.

b) Content Required to Appear Somewhere Within APS Main Advertising Message

This content describes:

> i) considerations/ conditions/ limitations relating to use of the product in the subset of patients selected for therapy with the product.
>
> *E.g. need for monitoring and dosage adjustments in geriatric patients, need for concomitant drug therapy or lifestyle modification.*
>
> AND
>
> ii) limitations relating to availability of data
>
> E.g. the indication is based on trials which were short term (8-12 weeks)
> E.g. there is limited data on use in geriatric patients

This content must be presented prominently but it may be summarized and re-organized provided the full essence is captured.

> Case: The clinical use content for fictitious drug XYZ includes the following:
>
> "Use of XYZ should be limited to 9 weeks of continuous treatment."

Geriatrics:
"For the population subsets evaluated in the pivotal studies, age did not appear to affect efficacy or safety in a meaningful way. However, safety and efficacy has not been established in patients above the age of 75."

Pediatrics:
"For the population subsets evaluated in the pivotal studies, age did not appear to affect efficacy or safety in a meaningful way. However, safety and efficacy has not been established in patients below the age of 8."

In this example, the copy "Use of XYZ should be limited to 9 weeks of continuous treatment. Efficacy and safety are not established in patients below the age of 8 and above the age 75" would be acceptable. This would not need to appear "early" but it would be required to appear somewhere within the main advertising message portion of the APS.

c) Content Which May be Excluded From the APS

The following content from the INDICATIONS AND CLINICAL USE section may generally be excluded from the APS at the manufacturer's discretion:

- Clinical use content which duplicates the same message conveyed in indication copy or other elements of the fair balance
  E.g. In the above example, if the indication happened to be "Indicated for the treatment of condition ABC for up to 9 weeks", the clinical use element "Use of XYZ should be limited to 9 weeks of continuous treatment" could have been omitted.
- Clinical use content relating only to uses which are not promoted within the APS
- Clinical use content which is reflective of standard practices for any drug from any therapeutic category
  E.g. "Product XYZ should only be prescribed by those knowledgeable about the product and therapeutic area".
- Positive features or positive outcomes observed in patients from pivotal trials can generally be omitted at the manufacturer's discretion
  E.g. "Product XYZ demonstrated complete skin clearance in 90% of patients."
  E.g. "Product XYZ demonstrated no age-related differences in efficacy or safety."
  BUT negative features/ findings cannot be omitted. For example, the statement "This indication is based on progression free survival. No effect was observed on overall survival" would appear somewhere within the main advertising message (e.g. under the "clinical use" heading in the fair balance).

3. What is "Early"?

In the present context, "early" is taken to mean within the main advertising message portion of the spread/ surface/ screen containing the first explicit marketing benefit claim[1]. The PAAB

[1] Other than those listed in section 6.6(d) of the PAAB code

code section 2.10 requirement can also be satisfied with prominent placement on a prior spread/ surface/ screen within the main advertising message.

Consider the following common scenarios:

- In pieces where multiple product uses are mentioned on the first page containing product-related content, the requirements discussed above must be met for all stated uses
- In pieces where multiple uses are promoted sequentially over multiple spreads/ surfaces/ screens, content describing the boundaries for patient selection for each of those uses must be presented on (or before) the first surface containing claims relating to each of those uses
- Occasionally, the first APS spreads/ surfaces/ screens for a product having multiple indications are comprised of claims which are not tied to a particular indication (e.g. this would be the case for most non-therapeutic claims). In such cases, the manufacturer may select the indication for which the boundary content will appear "early". A later page containing claims relating specifically to a different indication would then be required to include the boundary content for that corresponding indication.

4. What is an Explicit Marketing Benefit Claim?

Explicit marketing benefit claims drive the positioning requirements of content describing the boundaries of patient selection. It is therefore important to distinguish between explicit and implicit claim.

For example, the following messages are not likely to be considered explicit marketing claims of benefit:

- Identification of the authorized uses in the context of an overview of the APS content
- An epidemiological statement
- A question about the HCP's practice which does not involve the product

Rulings in specific situations will depend on context, but consider the following hypothetical detail aid cover titles as rough examples (i.e. assume this is the only content on the cover):

This brochure describes the use of Arbace in:

- patients with hypertension
- diabetic patients with proteinurea and hypertension

OR

This brochure describes the efficacy and safety profiles of Arbace in:

- patients with hypertension
- diabetic patients with proteinurea and hypertension

OR

Do you encounter many patients in your practice who are:

- hypertensive?
- diabetic with proteinurea and hypertension?

The indications are not required to appear on any of these covers as they do not contain explicit marketing claims for the product (e.g. they simply introduce the topic to be discussed without further embellishment). On the other hand, a marketing claim of benefit about these uses would require presentation of the indications on the front cover. For example:

Prescribe Arbace for:

- patients with hypertension
- diabetic patients with proteinurea and hypertension

OR

Arbace demonstrated efficacy in:

- patients with hypertension
- diabetic patients with proteinurea and hypertension

OR

Think of Arbace when you see:

- patients with hypertension
- diabetic patients with proteinurea and hypertension

It is important to note that there are occasions where even implicit claims require accompaniment of the indication. Common examples include (but are not limited to) visuals which would otherwise suggest a broader indication and text regarding disease information which could otherwise suggest a broader indication. It is therefore possible that the indication, the clinical use, and/or elements of the fixed fair balance be required to appear prior to the first explicit marketing claims. This is simply not a general requirement.

5. Contrast & Font Size

When compared to the main body copy used throughout the piece, the copy describing the boundaries for patient selection shall be of visually comparable type size, duration, pace, and shade where applicable. Additionally, this copy shall always be displayed in sufficient contrast with the background. The proportion of 75% vs main body copy is a rough guideline often used by review staff to help advertisers meet the requirement of “visually comparable type size”. However, other variables such as positioning, spacing, contrast, selection of font type, and readability can also be important factors in evaluating acceptability of prominence.

6. Presenting INDICATION Content Verbatim Somewhere Within the APS

As stated in PAAB code section 2.10, the content "is indicated for…" (or equivalent) must appear verbatim at least once in the main advertising message portion of the piece. This requirement can be satisfied through inclusion of the verbatim copy early in the piece OR through inclusion of the verbatim copy elsewhere (e.g. within Fair Balance).

Note that any message containing the term “indicated” should contain the verbatim indication (even if the indication had been presented earlier in the APS). The manufacturer may consider alternate terminology similar to “can be used for” so as not to trigger this requirement.