PAAB GUIDANCE ON WHEN THE ATTENTION ICON IS REQUIRED AND ITS PRESENTATION

A path towards globally first-in-class health product advertising directed to health professionals

January 2024

CAVEAT

Effective February 1, 2024.

BACKGROUND

In a perfect world, all clinical decisions would be supported by the highest possible quality of evidence. However, in the real world, health professionals don't typically have the luxury of deferring therapeutic decisions until availability of the highest possible quality of evidence. In fact, in some domains of decision-making, the highest possible quality of evidence may never become available. Health professionals must make decisions based on the best evidence available at the time. With the approach outlined below, we aim to facilitate the delivery of recent research findings to inform healthcare decision-making. This guidance document pertains to Advertising/Promotion Systems (APS) that are directed to health professionals.

Canada has a unique preclearance mechanism for HCP advertising: an impartial review conducted by a specialized body that is completely independent from the manufacturer. This puts Canada's health product industry in a unique position to leverage potential health benefits from advertising content that informs health professionals of recent findings from a broad spectrum of research types while maintaining a long-standing tradition of truthful and trustworthy advertising.

The guidance provided herein could further promote informed clinician decision-making by ensuring that all research findings are presented responsibly and that the limitations of the evidence are prominently disclosed.

SCOPE

This guidance document applies to health product advertising directed to health professionals. It is important to note; however, that it does not apply to:

- **Class B opioids:** In adherence with Health Canada's Terms and Conditions on advertising for opioids, the advertising for such products is restricted to verbatim extractions from the Terms of Market Authorization (TMA).
- **NOC/c products:** For products or for specific indications authorized under Notice of Compliance with Conditions (NOC/c), advertising presentations relating to efficacy/effectiveness/safety must be sourced from the TMA. CLICK HERE for additional applicable guidance. The evidentiary and disclosure requirements for NOC/c products differ from those for Notice of Compliance (NOC) products.

APPROACH FOR PRESENTATIONS REQUIRING THE ATTENTION ICON

The PAAB's evidentiary standards for marketing benefit claims are unchanged by this guidance document.

For a list of some of the key relevant resources & guidances CLICK HERE. From this point forward, this guidance document uses the phrase "evidence which meets (or does not meet) the PAAB's standards for marketing benefit claims" to refer to standards discussed throughout the linked list of Code sections and guidance documents.

PRESENTATIONS TYPES REQUIRING THE ATTENTION ICON

The following breakdown allows the user to find the criteria that apply specifically to the evidence type they are trying to present. While aspects of the sections are repeated, the sequential presentations as separate sections allows for the clear and concise description of feature requirements which are specific to the data type being presented.

1. HOW TO FORMAT UNBLINDED DATA PRESENTATIONS FOR SUBJECTIVE ENDPOINTS IN APS

The presentation is informational and claim neutral. The data is not used as the basis for **EITHER** overt claims of benefit **OR** creative imagery.

Three key elements required in a data presentation based on evidence that does not meet the PAAB's standards for marketing benefit claims:

- The presentation is boxed (i.e., grey shading or, for faxes, a black outline)
- The presentation begins with an icon and an explanatory statement on the data source
- The presentation discloses key study limitations (when applicable)

Repetition of the data requires repetition of the icon, explanatory statement and disclosure of key study limitations. This sort of data presentation does not lend itself well to a summary page since it cannot be reduced into a concise/summary format.

These presentation standards are not required for data presentations that are exclusively based on content from the TMA. This applies EVEN if they conflict with other study findings, and/or they don't pertain to the specific product promoted in the APS.

1.1 The icon

The icon should be presented prominently at the top of the presentation. CLICK HERE for Attention Icon Guidelines.

The alt tag for the icon is "Attention"

1.2 The explanatory statement on the data source

The statement should be presented prominently at the top of the presentation.

An example of an explanatory statement is "The data in this grey box is from an unblinded randomized control trial. Data relating to subjective endpoints should be interpreted cautiously due to the risk of bias."

1.3 Disclosure of key study limitations

The statement appears as body copy (i.e., at least 75% of font size of main body copy and is easily legible).

1.4 Considerations for audio/video presentations

Video:

– The explanatory statement on the data source may be included on a title/divider screen prior to the presentation of results instead of on every screen where the data is presented

– A closing statement similar to "The presentation of unblinded data is now concluded" should be included to indicate the end of the presentation

Audio:

– The icon and explanatory statement should be included in the audio. The icon can be read as "Attention". A single tone may be included prior to the reading of the explanatory statement to provide a break from the regular background noise or pace of audio, thus alerting the listener to pay attention to the audio that immediately follows the tone. (The intention of this tone is to help break up the audio, in a similar way that a visual break would be created in a layout).

2. HOW TO FORMAT DATA BASED ON DIFFERENT FORMULATIONS IN PRESENTATIONS IN APS

The presentation is informational and claim neutral. The data is not used as the basis for **EITHER** overt claims of benefit **OR** creative imagery

Three key elements required in a data presentation based on evidence that does not meet the PAAB's standards for marketing benefit claims:

- The presentation is boxed (i.e., grey shading or, for faxes, a black outline)
- The presentation begins with an icon and an explanatory statement on the data source
- The presentation discloses key study limitations (see section 2.3)

Repetition of the data requires repetition of the icon, explanatory statement and disclosure of key study limitations. This sort of data presentation does not lend itself well to a summary page since it cannot be reduced into a concise/summary format.

These presentation standards are not required for data presentations that are exclusively based on content from the TMA. This applies EVEN if they conflict with other study findings, and/or they don't pertain to the specific product promoted in the APS.

2.1 The icon

The icon should be presented prominently at the top of the presentation. CLICK HERE for Attention Icon Guidelines.

The alt tag for the icon is "Attention"

2.2 The explanatory statement on the data source

The statement should be presented prominently at the top of the presentation and identify all brands where formulations are inconsistent with the Canadian formulation.

An example of an explanatory statement is "The data in this grey box is from a study evaluating the Norwegian formulation of PsoriaMax. The data should be interpreted cautiously as the inactive ingredients are not identical to the Canadian formulation."

2.3 Disclosure of key study limitations

The statement appears as body copy (i.e., at least 75% of font size of main body copy and is easily legible) and states what the inactive ingredients that differ are in each brand.

2.4 Considerations for audio/video presentations

Video:

– The explanatory statement on the data source may be included on a title/divider screen prior to the presentation of results instead of on every screen where the data is presented

– A closing statement similar to "The presentation of data based on a different formulation is now concluded" should be included to indicate the end of the presentation

Audio:

– The icon and explanatory statement should be included in the audio. The icon can be read as "Attention". A single tone may be included prior to the reading of the explanatory statement to provide a break from the regular background noise or pace of audio, thus alerting the listener to pay attention to the audio that immediately follows the tone. (The intention of this tone is to help break up the audio, in a similar way that a visual break would be created in a layout).

The design

The use of the exclamation mark is intended to capture the user's attention.

The shape of the octagon is to draw a parallel to the universal stop symbol. It indicates that the reader must stop and interpret the content with caution and care.

Recommended icon use

Minimum size

The icon should be scaled to a minimum of 225% of the body copy cap-height in the corresponding box. PAAB will base the calculation on the larger of the text in the copy or the text in images (e.g., graphics). For an explanation of cap-height, see Guidance on Indication and Fair Balance Font Size.

NOTE: This is a minimum, not a standard size. The icon must be large enough to always stand out in the presentation.

Clear space

The clear space surrounding the icon is equivalent to the height of the exclamation point, without its point.

Incorrect icon use

DO NOT
use a knockout

When using the icon, always use a black exclamation mark in a white octagon with a black stroke.

DO NOT
add colours

Only a black and white icon will be considered to avoid any misleading implications associated to a product's brand book.

DO NOT
rotate or scale

The octagon is as wide as it is large. It should keep its proportions at all time.

In use

The disclaimer copy next to the attention icon uses the same font size as the copy, and is bolded black.

The data in this box is from a study evaluating the Norwegian formulation of PsoriaMax. The data should be interpreted cautiously as the inactive ingredients are not identical to the Canadian formulation.

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The grey box colour composition is C0 M0 Y0 K8.

Except for the attention icon and disclaimer text, the font colours within the grey box can adhere to the product's brand book.

To allow maximum legibility when designing a fax, the content is placed in a white box with a black stroke and the text is C0 M0 Y0 K100.

The headline has the same prominence as the main headline

The font size is the same size as regular copy.

The key limitation text needs to be at least 75% of the body copy and easily legible.

The data in this grey box is from an unblinded randomized control trial. Data relating to subjective endpoints should be interpreted cautiously due to the risk of bias.

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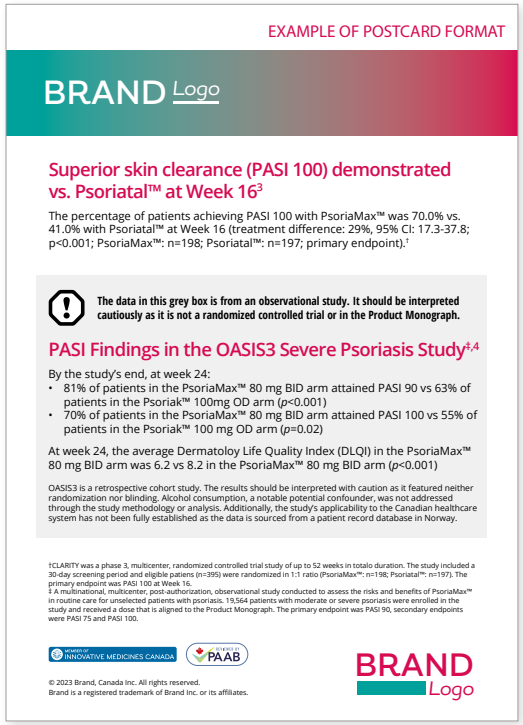
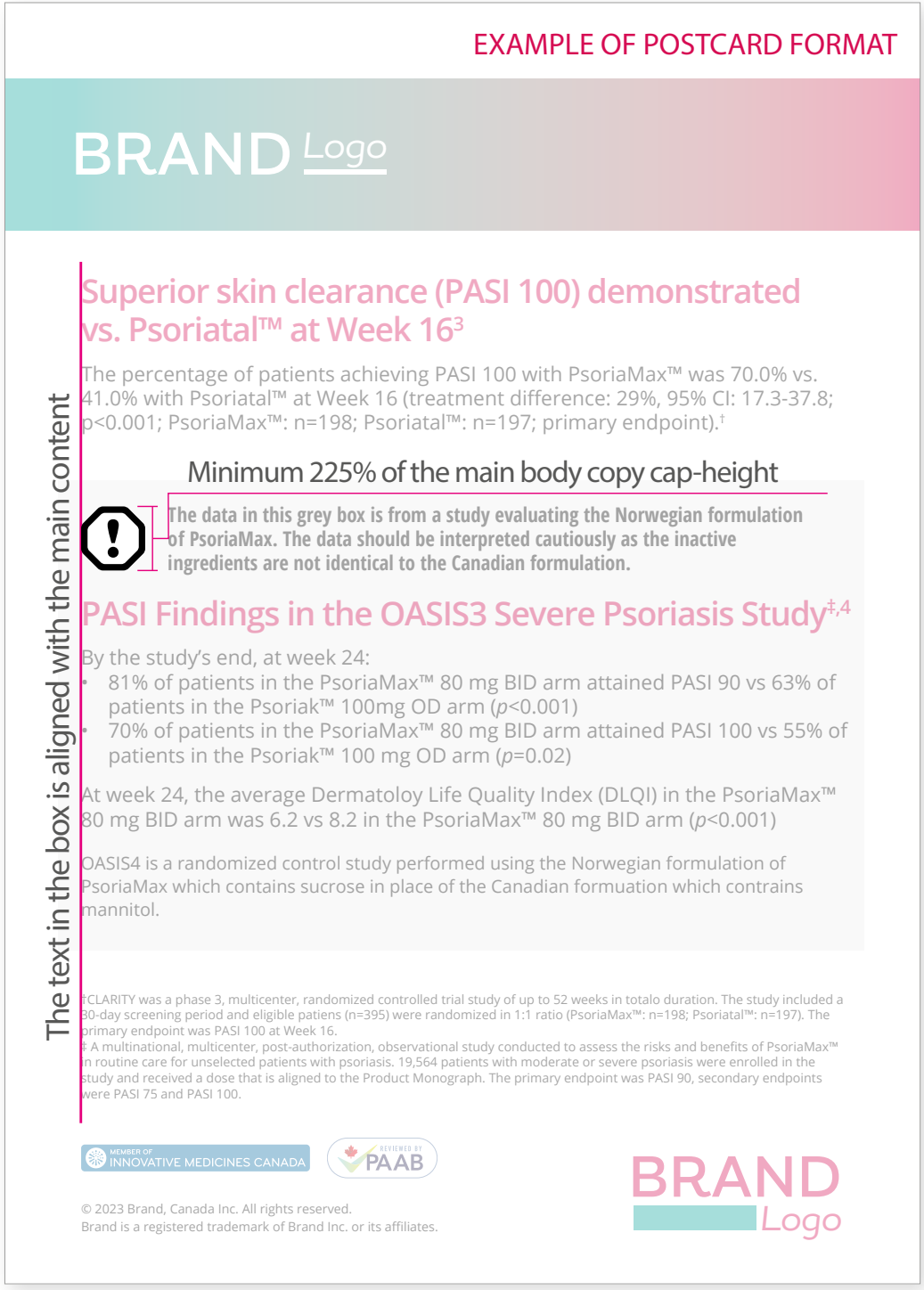
The text is adjusted to reflect the fax layout.

Postcard example

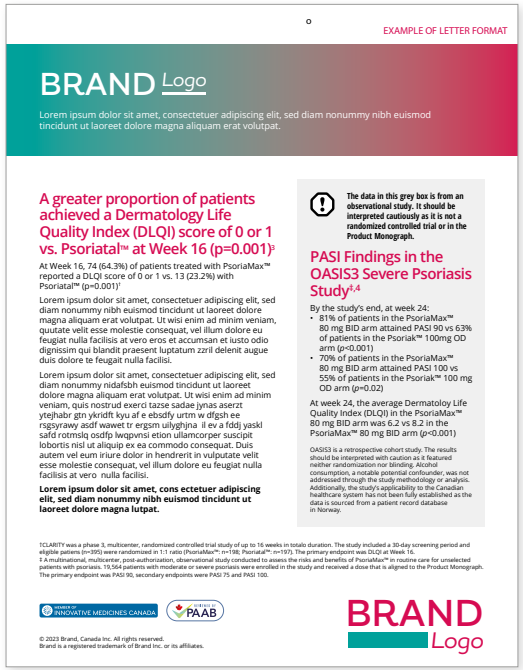
(Formulations Example)





Letter example

(Non-blinded Subjective Endpoints Example)



EXAMPLE OF LETTER FORMAT

BRAND Logo

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A greater proportion of patients achieved a Dermatology Life Quality Index (DLQI) score of 0 or 1 vs. Psoriatal™ at Week 16 (p=0.001)[3]

At Week 16, 74 (64.3%) of patients treated with PsoriaMax™ reported a DLQI score of 0 or 1 vs. 13 (23.2%) with Psoriatal™ (p=0.001)[†]

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The data in this grey box is from an observational study. It should be interpreted cautiously as it is not a randomized controlled trial or in the Product Monograph.

PASI Findings in the OASIS3 Severe Psoriasis Study[‡,4]

By the study's end, at week 24:

- 81% of patients in the PsoriaMax™ 80 mg BID arm attained PASI 90 vs 63% of patients in the Psoriak™ 100mg OD arm (p<0.001)
- 70% of patients in the PsoriaMax™ 80 mg BID arm attained PASI 100 vs 55% of patients in the Psoriak™ 100 mg OD arm (p=0.02)

At week 24, the average Dermatoloy Life Quality Index (DLQI) in the PsoriaMax™ 80 mg BID arm was 6.2 vs 8.2 in the PsoriaMax™ 80 mg BID arm (p<0.001)

OASIS3 is a retrospective cohort study. The results should be interpreted with caution as it featured neither randomization nor blinding. Alcohol consumption, a notable potential confounder, was not addressed through the study methodology or analysis. Additionally, the study's applicability to the Canadian healthcare system has not been fully established as the data is sourced from a patient record database in Norway.

†CLARITY was a phase 3, multicenter, randomized controlled trial study of up to 16 weeks in totalo duration. The study included a 30-day screening period and eligible patiens (n=395) were randomized in 1:1 ratio (PsoriaMax™: n=198; Psoriatal™: n=197). The primary endpoint was DLQI at Week 16.
‡ A multinational, multicenter, post-authorization, observational study conducted to assess the risks and benefits of PsoriaMax™ in routine care for unselected patients with psoriasis. 19,564 patients with moderate or severe psoriasis were enrolled in the study and received a dose that is aligned to the Product Monograph. The primary endpoint was PASI 90, secondary endpoints were PASI 75 and PASI 100.

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BRAND Logo

EXAMPLE OF LETTER FORMAT

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The text in the box is aligned with the main content

Superior skin clearance (PASI 100) demonstrated vs. Psoriatal™ at Week 16[3]

The percentage of patients achieving PASI 100 with PsoriaMax™ was 70.0% vs. 41.0% with Psoriatal™ at Week 16 (treatment difference: 29%, 95% CI: 17.3-37.8; p<0.001; PsoriaMax™: n=198; Psoriatal™: n=197; primary endpoint).[†]

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The data in this grey box is from an unblinded randomized control trial. Data relating to subjective endpoints should be interpreted cautiously due to the risk of bias.

PASI Findings in the OASIS3 Severe Psoriasis Study[‡,4]

By the study's end, at week 24:

- 81% of patients in the PsoriaMax™ 80 mg BID arm attained PASI 90 vs 63% of patients in the Psoriak™ 100mg OD arm (*p*<0.001)
- 70% of patients in the PsoriaMax™ 80 mg BID arm attained PASI 100 vs 55% of patients in the Psoriak™ 100 mg OD arm (*p*=0.02)

At week 24, the average Dermatoloy Life Quality Index (DLQI) in the PsoriaMax™ 80 mg BID arm was 6.2 vs 8.2 in the PsoriaMax™ 80 mg BID arm (*p*<0.001)

†CLARITY was a phase 3, multicenter, randomized controlled trial study of up to 52 weeks in totalo duration. The study included a 30-day screening period and eligible patiens (n=395) were randomized in 1:1 ratio (PsoriaMax™: n=198; Psoriatal™: n=197). The primary endpoint was PASI 100 at Week 16.
‡ A multinational, multicenter, open-label randomized control study conducted to assess the risks and benefits of PsoriaMax™ in routine care for unselected patients with psoriasis. 19,564 patients with moderate or severe psoriasis were enrolled in the study and received a dose that is aligned to the Product Monograph. The primary endpoint was PASI 90, secondary endpoints were PASI 75 and PASI 100.

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BRAND Logo

Fax and Black and White layout Examples

(Formulations Example)

BRAND *Logo*

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The data in this box is from a study evaluating the Norwegian formulation of PsoriaMax. The data should be interpreted cautiously as the inactive ingredients are not identical to the Canadian formulation.

PASI Findings in the OASIS3 Severe Psoriasis Study‡,4

By the study's end, at week 24:

- 81% of patients in the PsoriaMax™ 80 mg BID arm attained PASI 90 vs 63% of patients in the Psoriak™ 100mg OD arm (*p*<0.001)
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At week 24, the average Dermatoloy Life Quality Index (DLQI) in the PsoriaMax™ 80 mg BID arm was 6.2 vs 8.2 in the PsoriaMax™ 80 mg BID arm (*p*<0.001)

OASIS4 is a randomized control study performed using the Norwegian formulation of PsoriaMax which contains sucrose in place of the Canadian formuation which contrains mannitol.

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‡ A multinational, multicenter, post-authorization, observational study conducted to assess the risks and benefits of PsoriaMax™ in routine care for unselected patients with psoriasis. 19,564 patients with moderate or severe psoriasis were enrolled in the study and received a dose that is aligned to the Product Monograph. The primary endpoint was PASI 90, secondary endpoints were PASI 75 and PASI 100.

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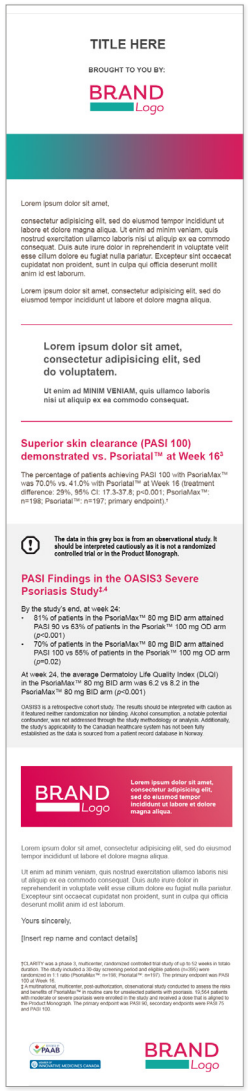
BRAND *Logo*

Alternative to Boxed Data*†

(Non-blinded Subjective Endpoints Example)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BROUGHT TO YOU BY:

BRAND Logo

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Yours sincerely,

[Insert rep name and contact details]

BRAND Logo

In an email and mobile layout, the grey area can cover the whole width or remain boxed.

*Grey boxes bleed all the way to the edges on email and mobile templates only.
†Study parameters can appear anywhere on the spread or through a digital link. The footnote would elaborate on the study description. The sponsor may include additional features of the study (i.e., not limited to limitations); these should be presented in a neutral/non-promotional tone. Examples should not be considered to be the entirety of the piece. All examples would require fair balance.

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Superior skin clearance (PASI 100) demonstrated vs. Psoriatal™ at Week 16[3]

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Lemieux Bédard supported in the design of this document.

GLOSSARY

APS

Advertising/Promotional Systems

Health product

A substance or mixture of substances manufactured, sold or represented by a specific manufacturer for in vivo use in the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or the symptoms thereof; or in restoring, correcting or modifying function(s) in humans. This includes: drugs listed on all schedules of the Food & Drugs Act and Regulations that have a Drug Identification Number (DIN) assigned by Health Canada; and Natural Health Products that includes traditional herbal medicines; traditional Chinese, Ayurvedic (East Indian) and Native North American medicine; homeopathic preparations; and vitamin and mineral supplements that have a Health Canada assigned NPN or DIN-HM and "pharmaceutical products".

This excludes medical devices and cosmetics (except for therapeutic cosmetics) as defined in the Food and Drugs Act and Regulations; products used for in vitro diagnosis of conditions, both normal (pregnancy test kits) or in connection with disordered states of health (blood glucose monitoring devices for diabetes, contact lens solutions, etc.); and food and vitamins being promoted purely for the maintenance of normal health.

Marketing benefit claims

A statement that is designed to promote the sale of a health product. It often highlights a specific product attribute i.e., "longer lasting" or "tastes great".

A promotional statement 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 (i.e., text) or implicit (i.e., 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.