PAAB GUIDANCE ON REAL-WORLD EVIDENCE/DATA

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

CAVEAT

While this guidance document has been updated to reflect broad industry and HCP consultation, it remains in draft form pending review by Health Canada. Upon completion of the consultation process, the PAAB Code will be revised for alignment with this guidance document.

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.

For the purposes of this guidance document, the PAAB considers the following sources of Real-World Evidence/Data (RWE/RWD) as the basis for APS presentations of health product effectiveness and/or safety:

- pragmatic trials
- cohort studies (prospective and retrospective)
- case control studies
- variants of these three designs

For disease information, the PAAB considers these same sources in addition to cross-sectional studies. Note that neither individual case studies nor case series are acceptable as evidentiary basis for APS messaging.

Data from patient support programs can be considered for the uses outlined in section 1.2 of this document.

RWD from recognized/validated market data providers can be considered for market share and retention/persistence presentations.

APPROACH FOR PRESENTATION OF RWE/RWD IN APS

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.

Study data presentations based on evidence which does not meet the PAAB's standards for marketing benefit claims may appear in APS in the following circumstances:

- The evidentiary support meets the requirements outlined in section 1
- The APS presentation of the results meets the requirements outlined in section 2

How this new approach differs from the prior approach for RWE in APS:

Under this new guidance, observational studies are no longer required to have the same comparator(s), duration, magnitude of effect, and study population as a randomized controlled trial (RCT) that meets the standards for marketing benefit claims. Additionally, observational study presentations in APS are no longer required to be preceded by a presentation from an RCT showcasing the same subpopulation, endpoint, and/or comparator. In fact, such RCT may not exist. A more detailed differentiation between the new and prior approaches is outlined on the PAAB Forum.

As the RWE would now act as the basis of evidence for the presentation, prominent differentiation from other forms of evidence presented in the APS (e.g., RCTs) and a clear disclosure of limitations becomes critical.

1. REQUIREMENTS FOR INCLUSION OF RWE/RWD IN APS

1.1 Consistency with the Terms of Market Authorization (TMA)

As is true of APS presentations based on RCTs, presentations based on RWE/RWD must be consistent with the sponsor product's TMA. Neither presentations based on RCTs nor those based on RWE/RWD may contradict anything in the TMA. Assessment of consistency with the TMA entails consideration of:

1.1.1 Indicated disease/condition:

Information relating to management of a different disease/condition than that for which the product is indicated is not permissible in advertising. Additionally, efficacy or effectiveness presentations in APS must NOT be based on use of the sponsor's product to manage different severity, stages, or manifestations of a disease than those conveyed in the TMA. For example, factors such as medication history and disease characteristics from assessments used in clinical practice should align with the indication.

1.1.2 Patient population:

The APS presentation must be derived from analysis of patients that fall within the indicated population and are aligned with any relevant contraindications from the TMA. In instances where an overall study population exceeds the product's indication, it may be possible to present data from a pre-planned patient subset that reflects the indicated patient population or relevant subset thereof.

1.1.3 Dosing/administration, limitations (e.g., statement of treatment duration limits), and directions for handling/use:

The manner in which the respective health products are utilized to generate evidence/data must not contradict the TMA (e.g., dosage, administration route, titration schedule where protocol driven, duration of use, and so on). In instances where a study evaluates several dosing options, where some are not aligned with the product's recommended dosing per the TMA, it may be possible to present data from the pre-planned subset that reflects the product's recommend dosing.

Where the TMA does not contain statements of treatment duration limits and the study exceeds the duration of the longest relevant study in the TMA, the principles outlined in Sections 1, 3, 4, and 5 of the guidance on study duration apply (section 2 of the guidance document on study duration will be updated to enable inclusion of RWE).

1.1.4 Endpoints/Outcomes:

Endpoints/Outcomes must be "consistent with" (though not necessarily "the same as") those in the TMA. Regardless of whether the evidentiary basis for the presentation is RWE/RWD or an RCT, endpoints are not generally limited to those explicitly included within the TMA. Though the approach for RWE/RWD mirrors that for RCTs in this respect, the following examples are intended to clarify questions received during the consultation process.

Example 1.

A hypothetical health product is indicated for the treatment of adult patients with type 2 diabetes mellitus (T2D) to improve glycemic control. The TMA contains the following efficacy endpoint: HbA1C.

- Can data pertaining to Fasting Blood Glucose in patients with T2D be considered in the APS? **YES.**
- Can data pertaining to reduced risk of cardiovascular complications in patients with T2D be considered in the APS? **NO.**

Example 2.

A hypothetical health product is indicated for the treatment of advanced solid-state tumours. The TMA contains the following efficacy endpoints: Objective Response Rate and Complete Response Rate.

- Can data pertaining to quality of life in patients with advanced solid-state tumours be considered? **YES.**
- Can data pertaining to overall survival in patients with advanced solid-state tumours be considered? **YES.**
- Can data pertaining to rate of development of second primary neoplasms (SPN) in patients with advanced solid-state tumours be considered? **NO.**

1.1.5 Additional guidance pertaining to BOTH patient population and dosing

It is understood that real-word evidence tends to evaluate more heterogenous populations and tends to be less protocol driven than RCTs. It is not unusual for a small proportion of the study population to deviate from the Terms of Market Authorization. With this in mind, no APS presentation may be derived from an evidentiary source where > 20% of patients are not aligned with the relevant indication, contraindications, limitations of use, or dosing/administration recommendations from the TMA. This threshold applies to the patients from the particular analysis from which the APS presentation is derived, not necessarily the overall study population. For example, a study's overall population may exceed the aforementioned threshold as long as the **pre-defined** sub-population upon which an APS presentation is based adheres to the threshold.

1.2 Reference is published and peer-reviewed

All APS presentations based on RWE or RWD must be published and peer-reviewed in reputable scientific journals with the following exceptions:

- Presentations based on non-comparative retention/persistence data or adherence data from the sponsor's Patient Support Program (PSP) or Patient Assistance Program (PAP).
  Note that the retention/persistence rate or adherence should be attributed to the health product's support program (rather than being framed as a direct/sole result of the health product in and of itself). Where this data is not published and peer-reviewed, the submission must include sufficient information for PAAB to validate the methods relating to data measurement, recording, analysis, and reporting. Comparisons across patient programs (i.e., versus PSPs offered by competitors) are not acceptable.
- Comparative or non-comparative data from recognized/validated market data providers (for market share and retention data).
- The study is not presently published but has been peer-reviewed and accepted for publication at a future date. A copy of the Author Accepted Manuscript (AAM) must be submitted to the PAAB as the basis for review. Note that the AMM is also sometimes referred to as the author's manuscript or the accepted manuscript. For the purposes of this document, it is intended to refer to the version of the article that follows completion of the peer review process and approval for publication (but often prior to copyediting and typesetting).

Where a reference within those listed exceptions has not been published at the time of use in advertising, the sponsor is still required to make the reference available to a healthcare professional on request per PAAB Code s3.2. The healthcare professional may be asked to sign a non-disclosure agreement where required.

Abstracts, posters, and slides presented at congresses are not acceptable. If the data has been peer-reviewed and accepted for future publication, then the manuscript that has been accepted for publication must be used as the data source (not the abstract/poster/slides).

1.3 Reference provides transparent disclosure of methodologic information

Transparency is a key characteristic of high-quality research. The evidentiary source must provide comprehensive details on how data was collected and analyzed. The following two-part litmus test is a fair guide for advertisers on comprehensiveness.

Litmus test: The published paper contains sufficient methodologic information to likely enable:

- the PAAB to identify key study limitations (as these are required to be listed in the APS)
- healthcare professionals to assess the study and determine if it is sufficiently robust for them to consider incorporating the findings into their clinical practice.

Manufacturers are *encouraged* to assess studies according to recognized national or international reporting standards where appropriate/relevant (e.g., the STROBE checklist or the upcoming CADTH guidance *or equivalent*), ***particularly regarding criteria relevant to the research question and methodology***.

1.4 Pre-planned methodology

The methodology is predefined. Any amendments to the methodology should be justifiable (i.e., are required and have scientific merit) and will be disclosed in the APS when warranted. Data derived from data-mining activities must be based on pre-defined research questions to be considered acceptable in advertising. This is in addition to all other standards outlined herein.

Note that this does not necessarily preclude use of retrospective analysis with pre-defined methodologies.

Pre-planned secondary endpoints must clearly be identified as secondary endpoints per PAAB Code s3.1.10.

1.5 Data is collected from empirical observation

Health product data is collected from empirical observation as opposed to being generated in silico through predictive modeling and/or simulation.

1.6 Findings are relevant to medical practice in Canada

In RWE/RWD, clinician decisions can potentially be impacted by factors that are local to the study's jurisdiction (e.g., the healthcare system structure, the manner in which clinical care is practised, distribution of co-variables relating to patient/disease characteristics) to a larger extent than they would be in RCTs by virtue of the fact that clinical decisions in RWE/RWD tend to be less protocol driven. Consequently, although RWE often has the benefit of generalizability to the corresponding real-world clinical context, it can be perilous to generalize the study's findings to other jurisdictions.

For RWE from other jurisdictions, the sponsor should provide an attestation letter signed by personnel from the medical/regulatory department confirming that the study is relevant to Canadian practice. It is understood that the letter will be signed by personnel considered by the sponsor to have sufficient knowledge and authority to make such an attestation. This attestation is required the first time a particular reference for the non-Canadian RWE/RWD is submitted.

The APS explanatory statement (accompanying the icon discussed below) will include prominent disclosure of the non-Canadian study jurisdiction(s).

1.7 The study groups are treated in a comparable manner

Where the study includes one or more comparators (whether active or inactive), the methodology must be equivalent for each study group. Inferential statistical analysis is required for comparative studies. The p-value and/or confidence interval must be included in the APS presentation.

All comparators included in the APS presentation must have been evaluated in a manner consistent with their respective TMA's. The principles outlined in section 1.1 above apply to both the sponsor's products and the comparator(s).

1.7.1 Single arm trials:

Single arm trials can be considered as the basis for data presentations pertaining to adherence/compliance, persistence/retention, safety and effectiveness. The explanatory statement (i.e., the statement next to the icon) must identify that this is a single arm study.

For such a study to be considered as the basis for presentations relating to safety and effectiveness, it must be published and peer-reviewed. Additionally, for effectiveness endpoints, the disclosure of key study limitations must also specify that the methodology may make it difficult to differentiate between:

- drug effects and the natural history of the disease
- drug effects and placebo effects

Please note that this requirement is in addition to the identification of the source as a single arm study in the explanatory statement.

For single arm studies, sample size and a measure of sample dispersion (e.g., standard deviation) must always be presented within the body of the presentation along with the sample size (as opposed to among the study parameters in a footnote). For elaboration on the rationale, CLICK HERE.

1.8 Disclosure of contradictory data (specifically for active comparisons versus another health product)

While there is no requirement for sponsors to perform systematic analyses prior to including RWE in APS, where a published contradictory statistical inference for a comparison versus another health product is known to exist, the RWE presentation should disclose that fact in body copy of the APS. If this contradictory data is uncovered after creation of the APS, that APS shall be updated with the disclosure accordingly. Alternatively, the sponsor has the option of removing the RWE presentation from the APS.

Example case in which this disclosure provision applies:

The sponsor's study demonstrated that Drug A is statistically superior to Drug B on endpoint ABC while a separate study demonstrated that Drug B was statistically superior to drug A for a similar endpoint and population.

Example cases in which this disclosure provision does not apply:

Had the separate study in the above case demonstrated that Drug A was statistically non-inferior to Drug B (or that Drug B was statistically non-inferior to Drug A), this disclosure provision would not apply. Additionally, the disclosure provision would not apply if the separate study had instead demonstrated that p=NS with respect to that comparison (i.e., a failure to attain statistical significance).

It is not anticipated that this standard will introduce significant burdens onto health product manufacturers. Particularly given the scope of this standard outlined above (i.e., published head-to-head comparative studies demonstrating that the competitor's product was statistically superior for the endpoint and population in which the sponsor's APS is presenting superiority data). Manufacturers already have a vested interest in maintaining awareness of published studies demonstrating that a competitor was statistically superior to their product in relation to endpoints and populations that are featured in the manufacturer's ongoing advertising campaigns.

If the PAAB is made aware of credible contradictory data after approval of the APS, the PAAB will request that the APS to be updated with the relevant disclosures accordingly.

Where the contradictory data comes from a published and peer-reviewed, well-controlled RCT, the contradictory data should be presented prominently for balance (so as to avoid an overly selective presentation of data). The studies must appear as separate and distinct presentations so as not to appear to be a cross-study comparison. The study parameters for the contradictory study must not draw a direct comparison to the study parameters of the sponsor's study.

Where the contradictory data comes from a published and peer-reviewed RWE or a meta-analysis, it is sufficient to include a disclosure statement indicating the existence of the contradictory RWE or meta-analysis with a cross-reference to the citation list item identifying the reference. However, the sponsor is welcome to exceed this minimum disclosure standard.

1.9 Inform PAAB of review by other Canadian bodies

The advertiser is expected to inform PAAB during initial review of any study included in the APS that has undergone review by an authoritative Canadian body (e.g., CADTH, INESSS, Health Canada). The initial submission should include the relevant conclusions from the review of the RWE.

1.10 Transparency in how RWE/RWD presentations are formatted in APS

Therapeutic presentations of RWE/RWD in APS are required to align with the standards for presentation format/structure outlined in section 2 of this document. Those standards are designed to ensure that health professionals can easily differentiate between therapeutic presentations of RWE/RWD and other evidentiary forms such as RCTs. Additionally, they promote efficient transmission of the key limitations of each featured RWE/RWD such that health professionals can quickly determine whether the information in the APS is relevant to their practice and whether they would like to obtain and read the entire study.

2. HOW TO FORMAT RWE/RWD 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

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.

The RWE 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 RWE Disclaimer 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.

An example of an explanatory statement is "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".

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).

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 from the observational study 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 RWE icon uses the same font size as the copy, and is bolded black.

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.

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Key limitations perspiciatis unde omnis iste natus error sit voluptatem accusantium doloremque laudantium, totam rem aperiam.

The grey box colour composition is C0 M0 Y0 K8.

Except for the RWE 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 text is adjusted to reflect the fax layout.

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 observational study. It should be interpreted cautiously as it is not a randomized controlled trial or in the Product Monograph.

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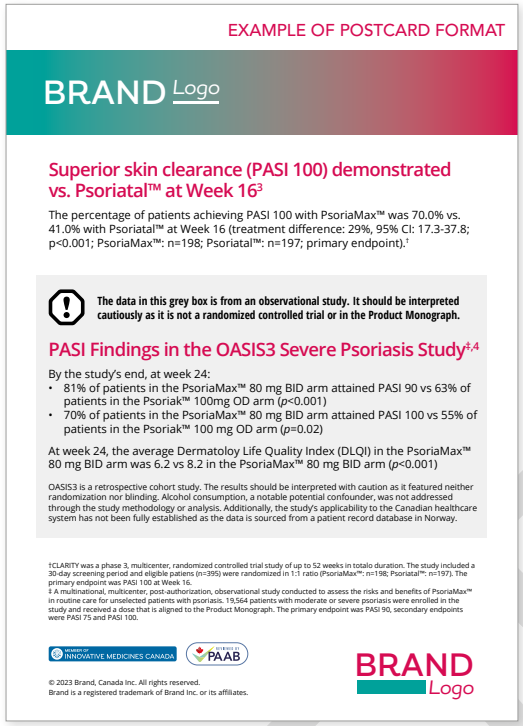
Postcard example*,†


EXAMPLE OF POSTCARD FORMAT

BRAND Logo

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).†

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 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, 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

*Gold-standard RCT precedes or is presented in combination with the RWE boxed copy.
†Presentation of the RWE content alone assumes prior presentation of gold-standard RCT data.

EXAMPLE OF POSTCARD FORMAT

BRAND Logo

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).†

Minimum 225% of the main body copy cap-height

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.

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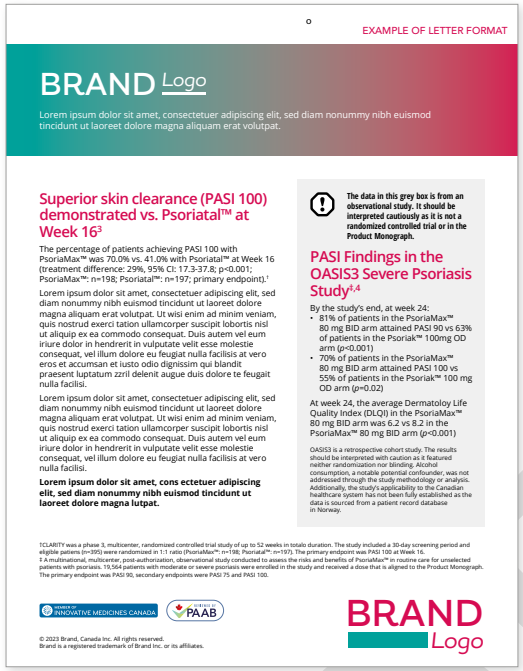
BRAND Logo

Letter example*



EXAMPLE OF LETTER FORMAT

BRAND Logo

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*Assumption that a data presentation meeting PAAB's standards for marketing benefit claims precedes or is presented in combination with the RWE boxed copy.

EXAMPLE OF LETTER FORMAT

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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 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)

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Fax and Black and White layout Examples

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Alternative to Boxed RWE Data*†

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.

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ACKNOWLEDGEMENTS

PAAB would like thank the RWE Committee members for their time and invaluable contributions to the development of this guidance:

Amyn Sayani (AstraZeneca)
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Matt Slipek (Havas Health and You)
Nina Hemery (Fisika)
Virginie Giroux (Merck)

PAAB would also like to thank Lemieux Bédard for their design services.

GLOSSARY

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.

GLOSSARY

APS

Advertising/Promotional Systems

PSP or PAP

Patient Support Program or Patient Assistance Program

Programs that exist to provide patients with timely access to medication, information, and resources intended to help patients stay on track of their therapy.

Real World Data (RWD)

Real world data are data relating to patient status and/or the delivery of health care routinely collected from a variety of sources in real-world settings.

Real World Evidence (RWE)

Real world evidence is the evidence regarding the usage, and potential benefits or risks, of a medical product derived from analysis of real-world data.