Insights on PAAB Review and Evaluation of Creative Imagery

Creative imagery/concepts are among the core messages of an APS.

The PAAB endeavours to ensure the credibility of evidence-based drug advertising and it is important that benefits that have not been demonstrated by a drug product are not implicitly imputed to it. In our effort to expand the range of creative imagery in branded advertising, we are aiming for an approach that balances utility and credibility.

This document is not intended to provide a set of prescriptive rules for creative imagery. We recognize that there must be room for nuance and creativity and remain open to conversation and collaboration around creative ideas within the review process.

The clarification and guidance provided in this document are intended to help illuminate the ways the PAAB intakes and reviews creative imagery to help inform the Sponsor and Agency's creative process.

Key changes from current PAAB review practice in this document include an updated approach toward depictions of patients in general life settings and the potential use of disclosures as an option to help move previously unacceptable visuals towards acceptance. These new approaches create greater flexibility with regards to acceptance of creative concepts.

Review Scenarios

When assessing creative imagery/concepts, the PAAB considers the overall message and its components (e.g. copy, image) in addition to the therapeutic area and supporting data that meets PAAB evidentiary requirements. Each of these elements contribute to the context of the message and how it can be interpreted.

During the initial layout review, the PAAB will determine which scenario the creative concept depicts. This process informs how the creative will be evaluated, as well as possible solutions that can be provided to help move the concept to approval. During the initial review process, multiple PAAB Reviewers will assess the new creative to help ensure that multiple perspectives are considered. Please note that this document presents 3 common and challenging scenarios seen at the PAAB. The scenarios described in the pages that follow do not provide an exhaustive list of all possible scenarios and there may be creative imagery concepts that continue to remain unacceptable in spite of the changes listed within this document.

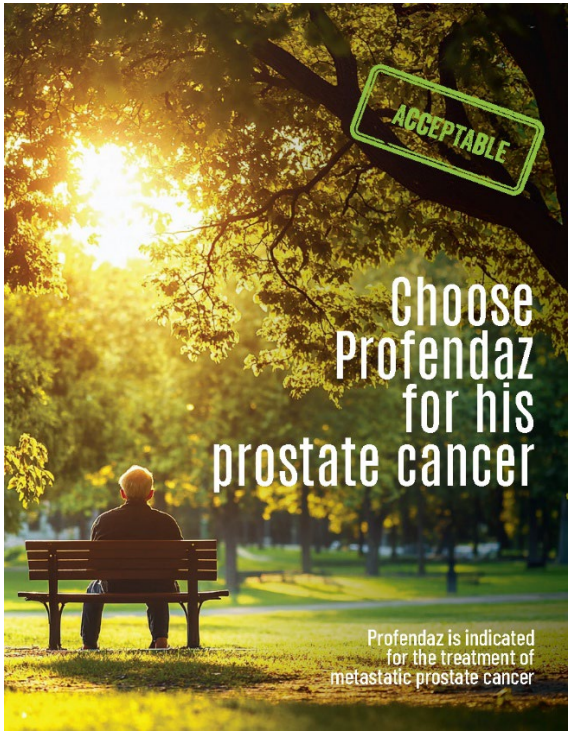
NOTE: The examples provided herein are included strictly for illustrative purposes. They do not cover all PAAB requirements for an acceptable APS.

Scenario 1: Depiction of patients in a GENERAL LIFE SETTING

This scenario shows patients existing in their daily lives. Specific clinical outcomes are typically not connected to these visuals through evidence or data. However, images and copy may still imply potential outcomes for the brand.

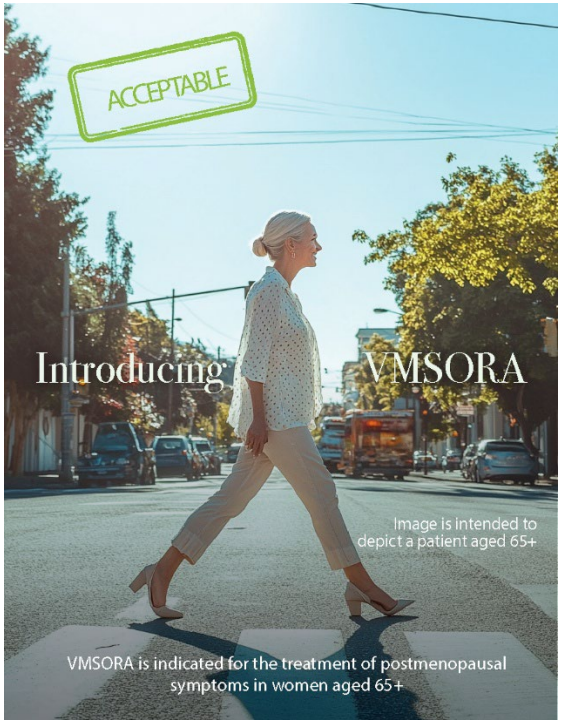
When a creative visual could convey multiple meanings, one of which extends beyond the terms of marketing authorization (TMA) (e.g., suggesting an unapproved indication), and/or implies a clinical outcome, a disclosure statement may be used to clarify the intended message. A disclosure statement may serve as an option when other solutions, such as modifying the imagery or the accompanying copy, are not preferred and an impasse arises regarding the visual's interpretation. **However, disclosure statements cannot be used to justify overtly misleading or off-label messages.** To ensure clarity and accessibility, the disclosure must be placed **in direct proximity to the visual** and presented **with equal or greater prominence** than the balance copy.

In most cases, depicting a patient in a general life setting is acceptable.



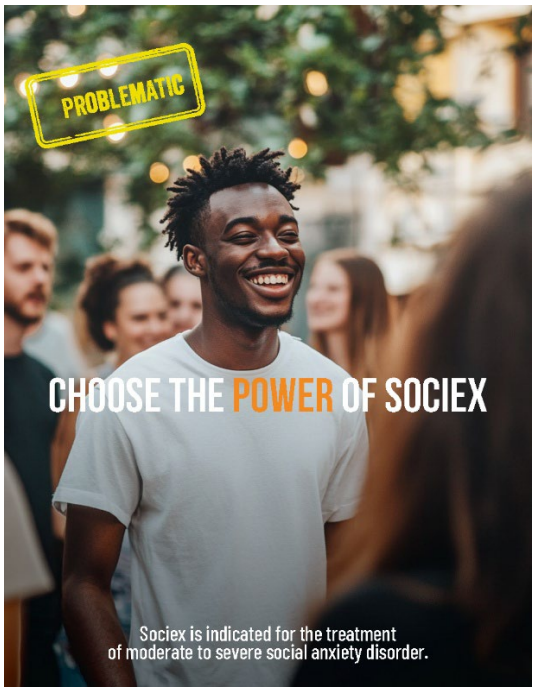
NEW

If the creative imagery is unclear with respect to the intended patient population or patient selection limitations, the PAAB can consider a disclosure to assist the reader with interpretation.



Note: The disclosure should be placed in direct proximity to the visual, in a size and prominence equal to or greater than balance copy.

In some cases, the therapeutic category may have inherent implications for clinical outcomes or quality of life, even in a general life setting (particularly mental health). In these cases, the PAAB will collaborate with the Sponsor to ensure the image is interpreted in accordance with the TMA and supporting data.



In the above example, the Sponsor could elect to modify the creative imagery to lessen the implied claim for improved social interactions (e.g., remove some people from scene, crop closer to the patient). Should any implied claims remain, the creative imagery would then fall under **Scenario 2** below.

Scenario 2: Creative imagery with IMPLIED outcomes

The evaluation of creative imagery is inherently subjective. Often, the audience can derive multiple interpretations from a concept. When a concept does not explicitly visualize an outcome, it can still be perceived to carry an implicit claim. These implied claims are often the result of category or context, and not just the image itself.

Below are three examples of solutions when dealing with implied claims.
Note: The examples are for illustrative purposes only. They are not the only solutions.

NEW

In cases where an outcome is implied through the nature of the therapeutic category or the surrounding headline/message, the PAAB may consider including a disclosure to help mitigate that implication. The PAAB will work with the Sponsor to ensure that any perceived implication is not interpreted as an indirect claim of therapeutic benefit or claim of merit.

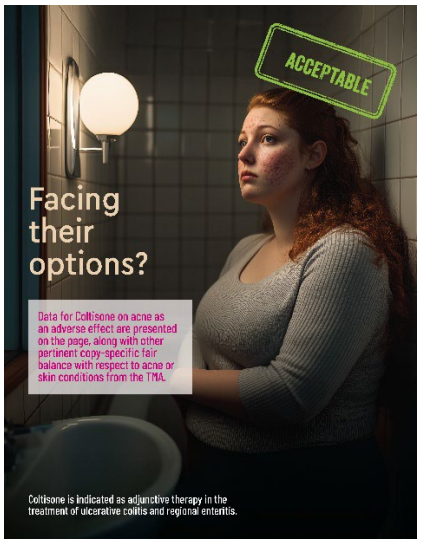
Note: The disclosure should be in direct proximity to the visual, in a size equal to or greater than balance copy.

NEW

In cases where the product has qualifying data to support an implied claim for quality of life (QOL) but the Sponsor elects not to include this in direct proximity to the creative imagery, the PAAB can consider a prominent disclosure directing the reader to the data within the APS. This is applicable for quality of life endpoints only.

Note: The claim neutral disclosure must appear in body copy for adequate prominence to the reader. Should the Sponsor elect to include data on the same page, the disclosure is not required.

In cases where the product has qualifying data, and there are important considerations with respect to its limitations or interpretation, the PAAB will continue to require this be presented in direct proximity to the creative imagery.



Note: In this case, the qualifying data must be disclosed with the creative. The PAAB may also ask for disclosures or disclaimers that are relevant to the therapeutic landscape.

Note: Products with NOC/c or other label limitations are required to provide supporting data in direct proximity to all creative imagery with implied outcomes. Advertisers should be mindful of creatives in banner/small space ads

Scenario 3: Creative imagery with EXPLICIT outcomes

A creative that explicitly depicts an outcome requires substantiation and inclusion of the supporting data that meets the PAAB requirements.

Clearly presenting the extent of benefits demonstrated in studies allows health professionals to make informed risk–benefit assessments, essential for rational prescribing or recommending of treatments. All messages in HCP advertising, whether conveyed through text or imagery, must be evidence-based. The PAAB will not approve imagery that is misleading or which misrepresents the evidence.

In cases where the creative imagery and/or accompanying claims convey an explicit claim of merit, the PAAB will continue to require supportive data be presented in direct proximity for qualification and/or quantification.

As a helpful reminder, the PAAB accepts general study parameters to appear on other pages of the APS, such as the References listing. Important study limitations must still be presented with qualifying data on the same page.

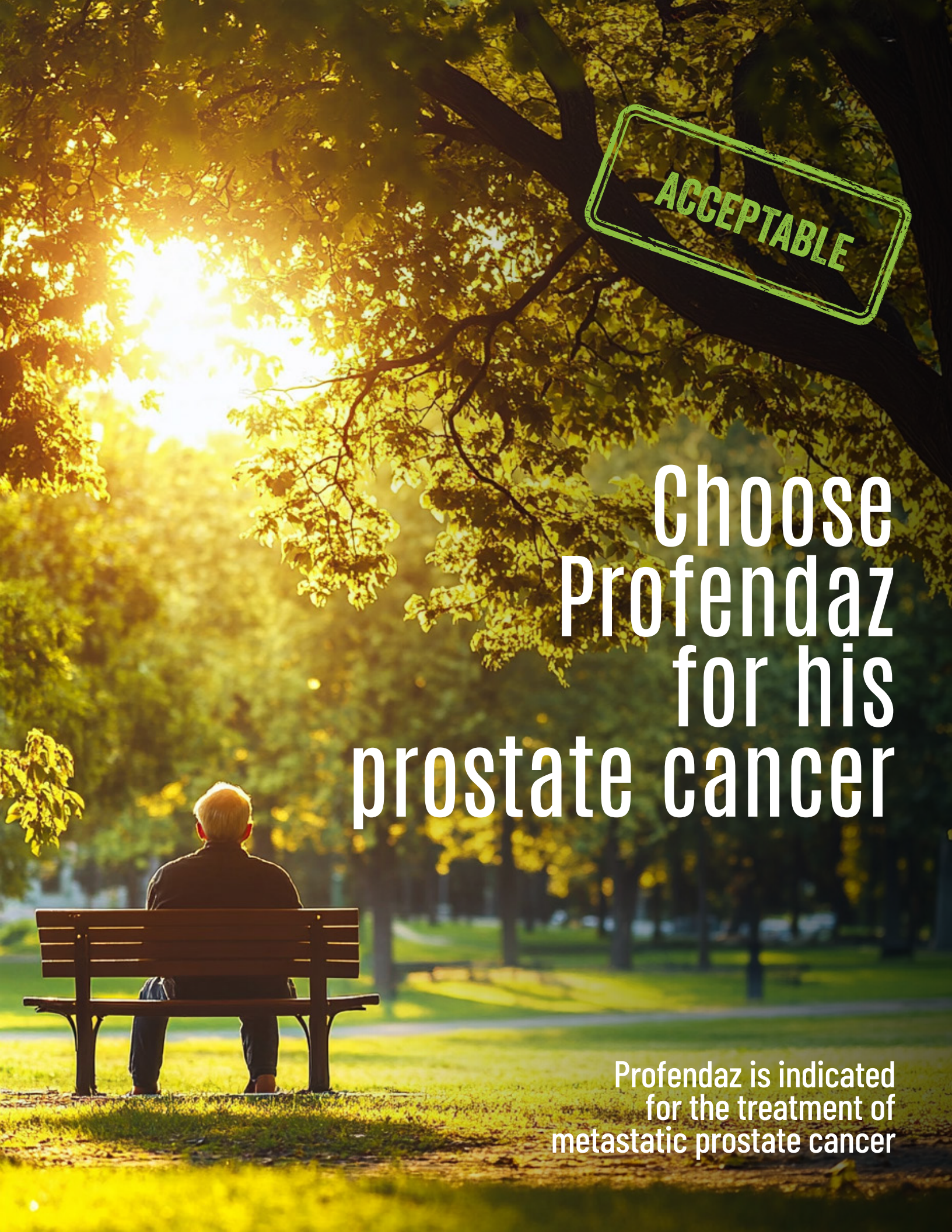
NEW

In some instances, exaggeration or metaphor is used in creative imagery to emphasize an explicit claim. In cases where the depicted effect exceeds the qualifying data, the PAAB may consider a strongly worded disclosure to help mitigate the effect.

Note: The disclosure must appear in body copy for adequate prominence to the reader. Use of such disclosures will be highly dependent on the therapeutic category and product label. The PAAB will work with Sponsors to ensure APS remain truthful and balanced.

In cases where an exaggerated visual clearly misleads the reader such as by extending the measured outcome or overstating the magnitude of effect of a treatment, the PAAB will continue to question such creative imagery, even in the presence of qualifying evidence.

As a helpful reminder, the PAAB opinion process can help gauge the preliminary acceptability of new creative, including pre-NOC.


ACCEPTABLE
Choose Profendaz for his prostate cancer
Profendaz is indicated for the treatment of metastatic prostate cancer


ACCEPTABLE
Introducing VMSORA
Image is intended to depict a patient aged 65+
VMSORA is indicated for the treatment of postmenopausal symptoms in women aged 65+.


PROBLEMATIC
CHOOSE THE POWER OF SOCIEX
Sociex is indicated for the treatment
of moderate to severe social anxiety disorder.

Consider Rafortus

Rafortus is indicated for the treatment of mild to moderate rheumatoid arthritis.

Image represents a patient with mild to moderate RA and is not intended to depict an outcome for Rafortus.


ACCEPTABLE
Share the journey with Adipogo!
Adipogo is indicated for chronic weight management in obese adults ≥30kg/m² .
Data for Adipogo on QOL are presented elsewhere in this piece.

Facing their options?

Data for Coltisone on acne as an adverse effect are presented on the page, along with other pertinent copy-specific fair balance with respect to acne or skin conditions from the TMA.

Coltisone is indicated as adjunctive therapy in the treatment of ulcerative colitis and regional enteritis.

Could Taxavere give him more time?

Taxavere improved Overall Survival by 25% vs. placebo [HR: 0.75 (95% CI:0.60, 0.90), events: 100/200 Taxavere, 150/175 placebo]

Taxavere is indicated for the treatment of early-stage pancreatic cancer.


ACCEPTABLE
GO FOR LAXAFORE
In a 4-week / open-label trial, Laxafore improved bowel frequency vs. placebo by 50%, 4 vs. 2 bowel movements per week, p=0.049
Laxafore is indicated in conjunction with oral laxatives for the medical management of severe constipation associated with late-stage chemotherapy.
Image is not intended to depict clearance of constipation.
Laxafore has not been evaluated for this outcome.

Is Vortec part of her treatment journey?

Vortec improved Progression-Free Survival by 10% vs. placebo [HR: 0.90 (95% CI:0.85, 0.95), events: 100/150 Vortec, 100/125 placebo.

Vortec is indicated for the treatment of adults with relapsed or refractory multiple myeloma.