DRAFT - Creative Imagery Doc

Date: Updated November 9, 2024

Creative imagery/concepts are core messages for APS. Similar to the "Guidance on the Presentation of Burdens of Disease in Advertising", 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 acceptable use of creative imagery in advertising, we are aiming for an approach that balances utility and credibility.

The focus of this guidance is to provide information on the PAAB considerations when reviewing creative imagery.

General Factors for Consideration:

When assessing creative imagery/concepts, PAAB considers the overall message and its components (e.g. copy, image, etc.) in addition the therapeutic area and supporting data. Each of these elements contribute to the context of the message and how it will be interpreted. See Appendix 1 for requirements that remain unchanged by the guidance in this document.

Main Types of Messages in APS

The following are 4 main types of messages that are seen in pharmaceutical advertising at PAAB. The list is not exhaustive, but it serves as examples to help clarifying the PAAB considerations.

1. Depiction of the indicated population without a specific setting
2. Depiction of the indicated condition or disease burden
3. Depiction of a patient in a general life setting
4. Depiction of an outcome whether explicit or implied, that suggests the outcome is the result of the product e.g. ADLs, QoL, etc.

1. Depiction of the indicated population without a specific setting:

These creative concepts are straightforward and therefore do not require further clarification in this document. Please ensure that the images do not contain elements that imply unsupported claims. Such elements may include hand gestures (e.g., thumbs up, pointing to indicate "#1"), displays of intense emotions[1] (e.g., extreme exuberance), or specific accessories (e.g., a "#1 Dad" t-shirt, ribbons, or medals).

Example 1:

Consider Drug X for your patients with condition Y

---
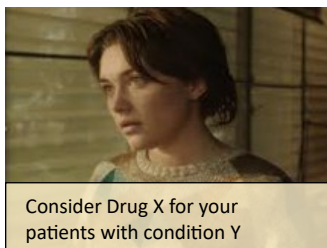
[1] In advertising, emotional extremes are depicted by showcasing highly intense emotions—either positive or negative—to capture attention and create a strong emotional response from the audience. These depictions often highlight exaggerated joy, excitement, or satisfaction to promote a product's benefits, or intense fear, sadness, or frustration to emphasize the consequences of not using a product or service.

2. Depiction of the indicated condition or disease burden:

Creatives that clearly depict the indicated condition are straightforward, such as visuals that reflects any stage of a condition reflected in the indication (e.g., "In moderate to severe RA, consider Drug X...").

For visuals that are ambiguous, PAAB may consider allowing a disclosure statement to clarify the intent of the image, along with a medical/regulatory attestation letter confirming this intent. The disclosure should be prominent and included in the body copy. Note that disclosure statements belong in the body copy.

NOTE: This document provides guidance on reviewing images and creative concepts in general; it does not cover all PAAB requirements for an acceptable APS. All relevant PAAB Code requirements will need to be met in formal submissions.

Examples:

Example 2A : In this image, a woman is shown holding or massaging her hand. This aligns with the moderate to severe RA condition which is consistent with the product's indication. Therefore, no disclosure is required.

Patient depicted is 65 years old

Meet Mary

Who has moderate to severe RA (>11 years disease duration)

Brand X is indicated to reduce the signs and symptoms of moderately to severely active rheumatoid arthritis (RA) in adults 65 and older.

Example 2B: For an indication of moderate to severe RA in patients aged 65 and older, if the age is not clearly apparent from the image alone, PAAB may consider a body copy disclosure statement, such as "Patient depicted is 65 years old."

Please note that a disclosure statement cannot offset images that clearly show patients below the indicated age, and a footnote disclaimer would not be sufficient in either case.

Meet Mary

Who has moderate to severe RA (>11 years disease duration)

Brand X is indicated to reduce the signs and symptoms of moderately to severely active rheumatoid arthritis (RA) in adults 65 and older.

*Patient depicted is 65 years old

Example 2C: This appears as a footnote disclaimer. This would not be sufficient. The copy is required to be body copy disclosure.

*Patient depicted is 65 years old

Meet Mary

Who has moderate to severe RA (>11 years disease duration)

Brand X is indicated to reduce the signs and symptoms of moderately to severely active rheumatoid arthritis (RA) in adults 65 and older.

Example 2D: The disclosure is too small.

Note: When assessing prominence, look to the PAAB Advisory - Small Space Ads document and examples for consideration of contrast, proximity, font size etc.

For creatives depicting disease burdens related to the condition but which are not specified in the indication and do not have supporting product data, please see the Guidance on the Presentation of Burdens of Disease in Advertising for further direction.

RA Fatigue is Not the Same as Being Tired

Example 2E: This image depicts fatigue as a common symptom or burden of RA; however, there is no supporting data for this product regarding fatigue and therefore it is not acceptable to place emphasis on this symptom/burden. Please refer to the *Guidance on the Presentation of Burden of Disease in Advertising* for direction on presenting disease burdens appropriately.

3. Depiction of a patient in a general life setting:

These types of creative elements can be interpreted in various ways depending on factors like therapeutic context, supporting data, and more. Images and copy may imply potential outcomes for the brand, or depict a patient in a general life setting, or sometimes be unclear.

For creative material where it is not obvious which message the image depicts, a disclosure can help clarify the intended message. To guide interpretation, PAAB may consider prominent disclosures in the body copy, such as "The visual represents a patient with condition Y and is not intended to depict a patient on product X," or similar statements where appropriate.

⚠️ Example 3A: For a product indicated for conditions whose clinical manifestations would largely preclude an untreated patient from engaging in this scenario, such as conditions with social anxiety/interactions (e.g. social anxiety disorder, agoraphobia, and so on), an image depicting a positive social interaction could imply a drug outcome of improved social functioning. Therefore, such an image would require supporting data on social functioning to be considered appropriate.

✓ Example 3B: For a condition like type 2 diabetes, this image could be interpreted as a patient in a general life setting, as it does not clearly depict a specific outcome on the condition. The image would be considered as long as it is consistent with all other aspects of the TMA.

✓ Example 3C: For a condition like depression, it may be unclear whether the image depicts a patient in a general setting or suggests a potential social functioning outcome. A disclosure statement, such as "The visual represents a patient with major depressive disorder and is not intended to depict a patient on product X," would help clarify the interpretation of the image. Contrary to Example 3A, a patient with MDD does not necessarily require treatment to engage in this scenario. This would similarly apply to conditions such as psoriasis, UC, Crohn's, acne etc.

(Please see Appendix 2 for additional examples)

4. Depiction of an outcome, whether explicit or implied, that suggests the outcome is the result of the product:

Creatives that depict an explicit or implicit outcome require substantiation and inclusion of the supporting data within the APS itself. The supporting data is required to be on the page in body copy with the creative to provide adequate qualification. 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.

4.a: Outcome messages:

In condition X,
help them walk

⚠️ Example 4A: With this image and the explicit copy of "**In condition X, help them walk**", data for improving the ability to walk would be required to appear on the same page.

*Note that the copy is to highlight emphasis on an outcome (walk). It would require revision to meet all aspects of the code.
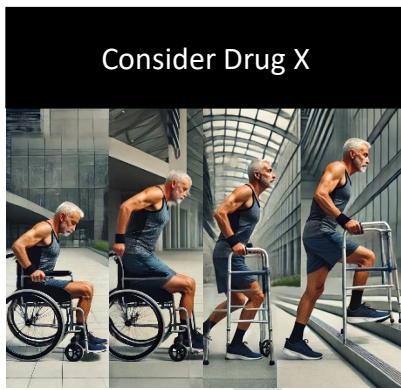
Consider Drug X

⚠️ Example 4B: If this image featured only the copy "**Consider Drug X**," there isn't an explicit copy claim.

However, the image itself implies a claim because it shows a patient progressing from a wheelchair to a walker. To support this implied claim, relevant data must be provided on the same page.

4.b: Quality of life messages:

A key challenge with creative images is that they often convey implicit messages about improvements in quality of life, functionality, activity levels, or performance. Frequently, these images go beyond simply depicting a patient in a general lifestyle setting and instead imply specific outcomes or benefits. Whether an image crosses into claiming an outcome depends on several factors described above. Below are examples of images and the contextual factors that influence their acceptability:

Example 5A	Unacceptable context
	Therapeutic area: ADHD Accompanying text: Increase concentration and productivity Perceived message: Drugs X will increase productivity multifold. TMA/ Supporting data: Indication, no productivity/work data Rationale: The image implies increased or exponential productivity without supporting data. Data would be required for such claims and the magnitude of effect conveyed would need to reflect the respective data.

Example 5B(i)	Acceptable context	Unacceptable context
	Therapeutic area: Hypercholesterolemia Accompanying text: What can Drug X do for Suzy? Perceived message: Drug X can be used in patients like Suzy. TMA/ supporting data: Indication, no work productivity data. Rationale: Having high cholesterol would not generally impact a patient's ability or desire to perform office work. The indication for hypercholesterolemia would be sufficient as support.	Therapeutic area: General Anxiety Disorder Accompanying text: Suzy's back! Perceived message: Drug X can return Suzy back to her previous functioning state. TMA/ Supporting data: Indication, no work productivity data. Rationale: Physical and mental functioning impairments are key aspects of GAD's clinical presentation and are used in outcome assessments. Any message suggesting a return to work would require specific supporting clinical data.

Combining Rationales:

In example 5B(i), the copy "Suzy's back!" sets a context that the product helped Suzy return to work (an outcome). If the context were revised to "Think Brand X" to remove the explicit link to clinical outcomes, the implicit claim can be managed through the addition of a disclosure statement per Section 3.

Example 5B(ii)

The visual represents a patient with GAD. It is not intended to be a representation of a patient on Drug X

Example 5C	Acceptable context	Acceptable context	Unacceptable context
	Therapeutic area: ADHD Accompanying text: Think Drug X for your ADHD patients Perceived message: ADHD patient in a general setting TMA/ Supporting data: Indication only Rationale: ADHD does not generally impact a patient's ability to sit in front of a computer. Importantly, the context does not convey that he has been sitting still and attentively for a substantial period. There is no inference of how the patient is using the computer or if there is a relationship to quality of life. The indication would be sufficient as support.	Therapeutic area: Carpal tunnel syndrome Accompanying text: Have you considered Drug X for their carpal tunnel syndrome? Perceived Message: Drug X can be used in this patient. TMA/ Supporting data: Indication, no function or productivity data Rationale: This is a carpal tunnel patient sitting at a computer. We cannot see their face, so we do not know if they are experiencing pain. They are existing in a general setting. The indication would be sufficient as support.	Therapeutic area: Carpal tunnel syndrome Accompanying text: Don't let carpal tunnel slow you down. Perceived message: Improved function to continue productivity TMA/ Supporting data: Indication, no function or productivity data, pain data Rationale: The visual with the heading has implications for productivity for which the product does not have data to support. The statement for "slow you down" also has implications for quality of life that would require data.

Example 5D	Acceptable context	Unacceptable context
	Therapeutic area: Thrombocytopenia Accompanying text: "Consider Drug X for their treatment journey" Perceived message: Drug X can be used in this patient TMA/ Supporting data: Indication, no data for function or quality of life. Rationale: The general presentation of thrombocytopenia does not generally impact a patient's ability to be at a group picnic and smiling. There is no overt message for improving quality of life.	Therapeutic area: Depression Accompanying text: "Support their journey with MDD" Perceived message: Drug X can improve mood and related social functioning in patients. TMA/ Supporting data: Indication, composite score for depression symptoms, no individual data for mood and no data for social function or quality of life. Rationale: Mood and mental functioning are manifestations of the condition. Quality of life and mental functioning are outcome assessments in depression. The visual and copy suggest outcomes that would require data.

Additional comments: In therapeutic areas where emotions or social interactions may relate to the clinical symptoms of a condition, even subtle imagery—such as a person looking slightly happier or shown in a small social setting—can unintentionally suggest a treatment benefit. In these cases, data to support the implied outcome would be necessary. This is different from conditions like thrombocytopenia, where social interactions or happiness aren't part of the clinical manifestation of the disease, so these images wouldn't imply a therapeutic effect.
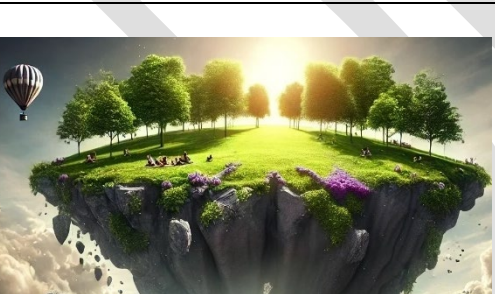
Example 5E: The following are examples of an evolving APS with varying context changes.

Example 5E(i)	Unacceptable context
	Therapeutic area: Chronic, severe constipation Perceived message: "Step up" with product B's sustained response and improve your situation. TMA/ Supporting data: Indication, response data vs. placebo, no comparative data, no quality-of-life data. Rationale: With the before and after images and copy for "Step Up", there is an implied claim for improved quality of life associated with sustained response that suggests an advantage over the current existing treatment options. The outcome message would require data to support its effects on quality of life as it relates to sustained response against all existing therapies.

When considering the factors discussed above, the following are potential revisions that may be acceptable.

Please note that each solution option should be considered on its own merits without transferring interpretations/assumptions from other solutions or to future APS.

Example 5F:

Example 5F(i)	Acceptable context
	Therapeutic area: Chronic, severe constipation Perceived message: Drug X is an option for patients. TMA/ Supporting data: Indication, response data vs. placebo, no comparative data, no quality-of-life data. Rationale: In this example, the "step up" is no longer in the APS and we've removed the before and after implications. The image would represent potential patients in a park setting.

Example 5F(ii)	Acceptable context
	Therapeutic area: Chronic, severe constipation

TMA/ Supporting data: Indication, response data vs. placebo, no comparative data, no quality-of-life data.

Proposed solution: The rocky landscape, similar to the before image in Example 5E, can represent the disease condition which the patient is on. The revised perceived message would be an appropriate patient looking for help. |

Appendix 1: Standard "lifestyle best practices" within visuals

Reminder that the Canadian Medical Association (CMA) has requested that PAAB ensures that images portrayed in APS reflect lifestyle best practices for general health and safety (e.g. helmets on bicyclists, life preservers on people in a small boat/raft).

Appendix 2: Additional examples for Section 3, "Patients in general life settings":

Example A2(i)	Acceptable Context	Unacceptable Context
	Therapeutic area: Prostate Cancer Accompanying text: "Supporting him in the fight against prostate cancer" TMA/ Supporting data: Indication, statistically significant OS, PFS data. Rationale: The copy provides context for the image and the clinical use of the product.	Therapeutic area: Schizophrenia Accompanying text: "Helping with the faces of schizophrenia" Perceived message: Drug X can help with the different symptoms of schizophrenia, potentially including social withdrawal/functioning. TMA/ Supporting data: Indication, statistically significant data for PANSS total score, no sub-score data and no social functioning data. Rationale: Physical and mental functioning impairments are integral to the clinical presentation and outcome assessments of schizophrenia. Any message suggesting improvement in social functioning would require specific supporting data, which is currently not available. Even if the copy was restricted to "Consider Drug Y", the above would remain true.

Example A2(ii):	Acceptable Context	Acceptable Context	Unacceptable Context
	Therapeutic area: Overactive bladder Accompanying text: "Need to go?" Perceived message: The OAB patient needs a washroom and Drug X can help. TMA/ Supporting data: Indication for the treatment of OAB with symptoms on urinary incontinence, frequency and urgency. Rationale: The image and copy represent the disease condition for which the product is indicated for.	Therapeutic area: Overactive bladder Accompanying text: "What did I forget? Consider Once monthly dosing" Perceived message: Once monthly dosing is convenient TMA/ Supporting data: Indication and dosing from TMA. Rationale: The image and copy identify a dosing issue and once monthly dosing frequency may be a feature of the product which addresses this issue.	Therapeutic area: Overactive bladder Accompanying text: "What's your day like?" Perceived message: The patient's OAB is affecting their day and Drug X can help. TMA/ Supporting data: Indication, no functioning or QoL data Rationale: The copy and image have implications that Drug X can help improve the patient's day. Quality of life data would be required.

Appendix 3: Additional examples for section 4, "Depiction of an outcome"

Example A3(i):	
	Unacceptable
	Therapeutic area: Any disease condition Perceived message: Breaking through or breaking free from the condition to an idyllic place. Rationale: There are absolute implications for efficacy and freedom from the condition.
	Therapeutic area: Any disease condition Perceived message: Success in managing disease and rejoining loved ones. Rationale: There are absolute implications for efficacy and improved quality-of-life.