Guidance on Branded Patient Information

The following document provides general guidance on branded patient information for prescription products and products for the treatment of schedule A diseases. Health Canada encourages the distribution of part 3 consumer information in its entirety. However, the PAAB Code allows for editing of part 3 to facilitate patient understanding of their treatment and condition as per PAAB code section 6.4.3. While not exhaustive, the 5 main sections of this document address common types of information that are submitted in patient directed material. The information provided below is in accordance with PAAB code section 6.4.3.

PAAB Code section 6.4.3

Company controlled or prepared branded patient information is information that contains non-promotional material that is consistent with, and in addition to, the consumer information section of the Product Monograph (PM). The information should focus on educating patients about particular diseases/conditions and optimal use of the product by the patient for whom it has been prescribed.

1. Drug Content

1.1 Overview

From Part III of the PM:

a. In general, information from part III of the PM may be used in patient information when presented with similar context and prominence. Such information must be non-promotional. A claim based on part III may be deemed promotional if there is undue emphasis on benefits, features or properties of the product. Considerations when assessing for emphasis and promotion may include
    i. wording/tonality
    ii. context
    iii. visual emphasis (e.g. large callouts, font changes, etc)
    iv. repetition of a message.

[Please also see section 1.2 for differentiating between non-promotional and promotional copy]

b. Multiple indications, routes of administration, and/or formulations for the product may be included in the same patient piece provided these are covered in the same part III within a PM. If there are multiple part III sections, covering different indications, routes of administration, and/or formulations, within the same PM, the client must separate the patient pieces accordingly.

c. There should be no discussion of other Rx therapies that a patient has not been currently prescribed. It may be possible to discuss two products to be used concurrently providing it is clear at the outset of the APS that the piece is intended to be distributed to patients who will be using both products concurrently.

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From Part I of the PM:

a. Cautionary messages for dosing and administration, from part I, may be considered in a patient APS even when there is no mention in part III, e.g. “Drug X should be taken with food” as per part I with no other administration instructions in part III.

b. There is an option to include the indication statement from part I.

c. Adverse event incidences from part I of the PM are NOT accepted. See the January 2011 edition of the PAAB Newsletter.

1.2 Differentiating promotional claims from non-promotional information

Non-promotional information is copy that is presented in a manner that does not alter or form the user's opinion of the medication. Promotional claims, whether implicit or explicit, intended or unintended, are not accepted. The following are general considerations when differentiating the two types of copy.

a. **Copy text:** *"Drug X offers the flexibility of dosing with or without food once daily"* vs *"You can take your Drug X tablet with or without food once daily"*. The former highlights a benefit and is considered promotional. The latter can be non-promotional when presented in an informational context. The context, visual emphasis and frequency would be determinants.

b. **Copy context:** Presenting product features in a context that attributes a benefit status or equivalent, is considered promotional. The bullet *“Drug X is taken with or without food once daily”* is rendered promotional if presented in the context of the subhead *"Benefits of Drug X"*. A subhead such as *"Things you should know about Drug X"* would be deemed informational and non-promotional.

c. **Visual emphasis:** Visual emphasis such as callouts, buttons, banners, Nabiscos, taglines, etc, on a feature of the drug which may be considered beneficial is promotional even if the feature is mentioned in part III of the PM. *e.g. Verbatim part III copy “Drug X can be taken with or without food once daily”* in a large callout is considered promotional. If it is important that the copy appear in a callout, the tone may be adjusted to be explicitly cautionary or instructional*, e.g. “Remember to take your Drug X once daily with or without food”.*

d. **Copy frequency:** Frequent repetition of a feature, which can be considered beneficial, can render a message to be promotional.

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1.3 Formulary statements

Claims such as “Now on formulary” or “Wide range of coverage”, or “Covered in many provinces” have a promotional tone. They are not accepted in patient information.

PAAB will consider formulary messages when presented in an informational context. *e.g. “Patients in Ontario, NB, Alberta, and Quebec may qualify for provincial coverage. Talk to your HCP to find out if you are eligible for coverage".* The second sentence alone may be considered as well. This message should not be a callout as the emphasis would render it promotional.

PAAB will also consider *“Call our program agents and they will try to get coverage for you”* as it highlights a patient program service rather than coverage as a feature of the product.

1.4 Safety information

The content and context of the copy will determine the requirements for safety information. The following are general guidelines for inclusion of safety information.

Examples of APS content	**Is safety information required?**
The APS includes information on how the drug works and its various features from part III.	Yes
Tracking tools and/or how to prepare, dose, and administer the drug.	No
The patient program, e.g. how the program works & enrolment form	No
Non-pharmacologic modalities to help maintain a healthy lifestyle while on the drug.	No

2. Disease information

Acceptable references for disease information include medical texts, guidelines, review papers, epidemiological studies and recognized standard setting organizations. Disease information in any section of the TMA can be presented in a non-emphasized, non-promotional manner in branded patient info. Disease information cannot be selectively presented to suggest uses or effects which exceed the TMA. The following subsections provide common topics and guidance on their presentation.

2.1 General Symptoms

Presentation of a validated list of the usual signs & symptoms of a condition, in a disease context, may be considered when the product is indicated for treatment or prevention of that condition. This may be considered even if the indication is broad, *e.g. 'Indicated for the treatment of OAB'* or if there is no mention of those symptoms in the PM. The list should not be selective such that is it extends beyond the limitations of the indication. Please see 2.2 below.

Please note that for indications that are explicitly limited to specific symptoms then the disease information is also limited in a similar manner.

2.2 Specific Symptom(s)

Emphasis on specific symptom(s) in a disease context may be considered when:

a. specified in the indication

b. specified in part III of the PM **and** presented in the piece in a similar context

c. Part II of the PM states that the drug has an effect on the symptom(s). It may also be considered when the PM includes clinical trial data that indicates an effect by showing statistical significance for the symptom(s). If this is the singular basis for inclusion in the piece it must be limited to a disease information context only. It may be not presented as a drug related effect/outcome.

For 'a' and 'b', the presentation is not limited to a disease information context and may be presented as a drug effect if this is consistent with the indication/part III.

2.3 Disease consequence(s)

Inclusion of disease consequence(s), e.g. stroke or MI in hypertensive patients, in a disease context may be considered when:

a. specified in the indication

b. specified in part III of the PM **and** presented in the piece in a similar context

c. Part II of the PM states that the drug has an effect on consequence(s) or indicates an effect on the outcome(s) by showing statistical significance. If this is the singular basis for inclusion in the piece it must be limited to a disease information context only. It may **not** be presented as a drug related effect/outcome.

For 'a' only, the presentation is not limited to disease info context unless the relevant portion of the indication/part III statement is a disease info statement.

> **Note for Vaccines:**
> As vaccines are indicated to immunize against a disease, it is acceptable to discuss disease consequences that the disease may cause, even if scenarios a, b and c above do not apply. The rationale is that the patients do not have the disease for which the product is indicated to prevent. Conveying the consequences of the disease promotes public health as it explains why a patient is being vaccinated.
>
> For such presentations, a prominent disclaimer such as *"Vaccine X is not indicated to reduce consequences of Y"*, should be included on the same page/spread. In addition, a disclaimer similar to *"Vaccine X does not prevent all cases of disease Y. Not everyone may not be fully protected by Vaccine X",* should be included somewhere prominently in the APS.

2.4 Diseases other than that which is indicated

This may be considered in the context of differential diagnosis only. The presentation must be clear regarding the drug's indication AND what it is not indicated for. *e.g. "Your doctor prescribed Drug X to help you treat your allergic rhinitis symptoms, do not use it to treat symptoms indicative of the flu. The following chart will help you differentiate between the symptoms of allergic rhinitis and flu".*

2.5 Disease continuums or stages/severities other than that which is indicated

This may be considered similar to 2.4 above with the addition of a disclaimer clearly noting what the drug is not indicated for. *e.g. "You are prescribed Drug X because you have stage 3 or 4 disease. Here are ways this stage differs from the others" and follow with disclaimer "Drug X is not used for…".*

2.6 Triggers

Triggers for the indicated disease are accepted. Triggers for specific symptoms are acceptable providing the symptoms are acceptable as per the symptoms section, 2.2, above.

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2.7 Disease Scale Descriptions

Explanations of disease scales, e.g. HAM-D for depression, may be considered provided they are not off-label AND the tool(s) are validated for health care professional monitoring of patients receiving therapy. The scales should be consistent with consensus guidelines or the PM. The content must be limited to a description of the scale, e.g. "Your doctor will use this tool to measure how the disease and treatments are affecting your depression". The claims should be non-promotional, e.g. Note the term "affecting" rather than "improving" to keep the statement directionally neutral and thus non-promotional.

2.8 Tracking tools

Tables/Graphs for patients to track signs and symptoms of the disease as treatment are considered in the context of monitoring signs and symptoms. It should not be presented as improvements in the condition as this is considered promotional. The metrics which act as the basis of the table/graph must be directly related to the indicated condition, NOT other conditions or consequences of this condition. They should adhere to the general principles in the symptoms section in 2.2 above. *e.g. For a hypertension product, there may be a table to track home reading of systolic and diastolic BP +/- heart rate but there should not be a column for blood glucose level.*

3. Case Studies

APS content	**Is the case acceptable?**
Case studies with drug outcomes	No
Case studies with disease symptoms, consequences, or triggers	Must follow the guidance provided in the relevant portion of this document's section 2.
Case studies promoting the company's services	Must follow section 4 of this document for guidance on promotion of company services.

4. Promotion of company services

Promotion of a company's services may be considered, providing there are no drug specific claims, *e.g. "Company X is proud to cover up to the difference between brand and generic price"*. A claim such as *"Price of Drug X has been reduced"* is not accepted in a patient piece as it is a direct claim of benefit for the drug and is promotional.

5. Non-Pharmacologic Lifestyle information

Non-pharmacologic lifestyle information such as diet, exercise, meditation, counselling, etc., may be included in patient information when explicitly presented as lifestyle information. The benefits and outcomes may not be extended to suggest a concurrent drug effect. *e.g. "Along with your medication, diet and exercise can help reduce your cardiovascular risk".*