PAAB ADVISORY

Brand Advertising To Healthcare Professionals:

Prescribing Information Requirements Frequently Asked Questions

PLEASE READ FULLY AND CIRCULATE TO ANYONE IN YOUR ORGANIZATION WHO IS INVOLVED WITH ADVERTISING AND THE PAAB

This is not an exhaustive review of the PAAB code requirements that came into effect July 1, 2007. Rather, it explains the rationale for the changes and provides a useful summary of the information to be included (or excluded) in each section. This document is based on real questions we have received at the PAAB office.

1) What is the purpose of the new PAAB fair balance/disclosure requirements?

The rationale for the changes is quite simple:

1. To make advertising materials (including the P.I.) more 'user friendly' so health-care professionals can easily find, read and absorb the most important product information. This includes **benefit** and **risk** information. This will help health-care professionals accurately evaluate a product's suitability for a patient.
2. To substantially reduce display page/screen clutter, leaving more room and flexibility to communicate the product's key benefits and risks.
3. To eliminate extraneous sections like Actions and Clinical Pharmacology, Pharmacodynamics and Pharmaceutical Information from the PI. In Environics research funded by the Canadian Association of Medical Publishers, the vast majority (84%) of physicians confirmed that these sections were of very limited practical value (as long as they were still available in the CPS or online). This information is in the Product Monograph that is readily available from the manufacturer/distributor.
4. To meet all necessary legal and regulatory requirements.

The objective is to reformat the P.I., while still maintaining content in approximately the same length previously. Depending on the complexity of the claims and safety information, this will vary by product because product monographs vary considerably and the willingness of the pharma company sponsor to follow the guideline for proper editing in the PAAB code.

2) Which organizations were involved in developing, reviewing and approving the changes?

The fair balance/disclosure improvements have been under development for a number of years. Substantial input was received from Rx&D member and other branded companies; generic and OTC manufacturers; medical advertising agencies; and the Canadian Association of Medical Publishers (CAMP). Health Canada (as an observer on the PAAB board) was involved in several stages of review and has been highly supportive of these changes. Health Canada reviewed the PAAB Code in respect to federal legislation that requires advertising not to be false and misleading and they stated no objection to the new requirements.

Subsequently, one senior manager of all the stakeholder companies who deal with PAAB (manufacturers, agencies and publishers) was notified in writing of the changes being considered and asked to comment. Many of their suggestions were implemented in the final draft.

All PAAB board members, including physician, pharmacist, consumer, manufacturer, medical publisher and advertising agency associations unanimously approved the changes. (Please refer to the PAAB website *www.paab.ca* for a complete list of board members.)

3) Was any research done with medical professionals (or PAAB stakeholders) to review the changes before they were implemented?

Yes. Two independent research studies were conducted with Canadian physicians. The first, conducted by Environics, involved 48 physicians. It determined the areas where disclosure requirements could be improved, from the physician perspective.

Key findings showed that demands on physician time have expanded exponentially. There was a real need for a clearer, more succinct and focused way to receive key pharmaceutical prescribing information and important warnings. It sparked the vision to make the PI a better reference tool.

The second phase pre-tested the format and content in both copy and layout. Research involving 100 physicians was conducted by Ipsos Camelford Graham.

Results: Physicians rated the new format superior in all parameters to the old version. The new headings and titles in the Prescribing Summary section were deemed clearer and easier to read. So positive was the response, that 97% of physicians considered it to be more useful than the existing format. Almost 3 in 4 stated they would refer to the information in the new format more often than the previous design.

4) Why is a specific contact person from the sponsor's Medical and/or Regulatory department required to sign-off before initiating a PAAB review?

All APS submitted to the PAAB for review should be reviewed by medical/regulatory to ensure: accuracy with the terms of market authorization by Health Canada; that the references meet PAAB code requirements. In the past, PAAB has received some submissions from sponsors (or their suppliers) that had not been properly reviewed by the company for medical accuracy. This led to errors, confusion and wasted time during the review process. This solution should resolve this issue. Please remember that advertising always required the sign-off from medical/regulatory in most companies and they always held accountability for advertising sent to the PAAB.

5) For some products the Prescribing Summary section could be very long. Is any editing allowed?

Yes, editing of the Prescribing Summary section is encouraged to provide concise, accurate information that health professionals are looking for. To make it more concise, you can edit the grammar and style within the content requirement specified in the PAAB Code of Advertising Acceptance. Just make sure it remains consistent with the PM. The goal is to summarize the *important* patient selection criteria including the indication, safety information and administration as succinctly as possible. If necessary, additional information can still be included under the Supplemental Product Information section (in the smaller 6 on 7 type size). The full product monograph should be readily available for distribution on request. While the type size for the Prescribing Summary section is specified in the code as 10 point on 11 point leading, you can choose any

font style to reduce letter spacing as long as legibility is maintained. As in the past, the PAAB will notify sponsors of illegible PI. We suggest keeping screened-in images to a minimum to allow legibility and to provide good contrast.

Following is an example in which the 'PREVIOUS version' is compared with the 'NEW Prescribing Summary' to demonstrate the degree of editing that is suggested. In this example the advertisement promoted only the 'treatment of osteoporosis', therefore the new version allows for all other indications to be removed. This is for example purposes only and your advertising results may vary.

PREVIOUS Version:

BRANDNAME is indicated for the treatment and prevention of osteoporosis in postmenopausal women.

Treatment of Osteoporosis: In postmenopausal women with osteoporosis, BRANDNAME prevents vertebral and nonvertebral osteoporosis-related fractures and increases BMD at all measured skeletal sites of clinical importance for osteoporotic fractures, including spine, hip, and wrist.

Osteoporosis may be confirmed by the presence or history of osteoporotic fracture, or by the finding of low bone mass (for example, at least 2 SD below the premenopausal mean).

Prevention of Osteoporosis: In postmenopausal patients at risk of developing osteoporosis, BRANDNAME preserves or increases BMD at sites of clinical importance for osteoporosis.

BRANDNAME may be considered in postmenopausal women who are at risk of developing osteoporosis and for whom the desired clinical outcome is to maintain bone mass and to reduce the risk of fracture. Factors such as family history of osteoporosis (particularly maternal history), previous fracture, smoking, moderately low BMD, high bone turnover, thin body frame, Caucasian or Asian race, and early menopause are associated with an increased risk of developing osteoporosis and fractures.

Glucocorticoid-Induced Osteoporosis: BRANDNAME is indicated for the treatment and prevention of glucocorticoid-induced osteoporosis in men and women.

Paget's Disease of Bone: BRANDNAME is indicated for patients with Paget's disease of bone (*osteitis deformans*) having alkaline phosphatase levels at least two times the upper limit of normal, or who are symptomatic, or who are at risk for future complications from their disease, to induce remission (normalization of serum alkaline phosphatase).

CONTRAINDICATIONS

- Known hypersensitivity to any component of this product.
- Hypocalcemia (see PRECAUTIONS, General).

NEW Version:

Patient Selection Criteria

Indication And Clinical Use: BRANDNAME is indicated for the treatment and prevention of osteoporosis in postmenopausal women. BRANDNAME prevents vertebral and nonvertebral osteoporosis-related fractures and increases BMD at all measured skeletal sites of clinical importance for osteoporotic fractures, including spine, hip, and wrist.

Contraindications: Known hypersensitivity; hypocalcemia (see PRECAUTIONS, in Supplemental Product Information Section).

6) Will PAAB reviewers help the sponsor determine which information should go in each section?

PAAB reviewers are required to check the PI for compliance with the format requirements of the PAAB code. They will give guidance on how to adapt the content to the format. Although PAAB reviewers are not required to edit PI, they can offer suggested additions or deletions to meet the new code requirements upon request. Pharma sponsor medical/regulatory personnel should determine final content. Sponsors have always been responsible and legally accountable for the information they provide in advertising. The PAAB is not responsible for the final content of the PI. Health Canada has asked the PAAB to remind advertisers to respect the content of the Product Monograph when editing tables etc.

7) What 'fair balance' information will be required?

This is not an exhaustive review of the new PAAB code requirements. Rather, it is a summary of the most important changes to be included (or excluded) in each section. The PAAB code dictates the minimum requirement. Advertisers can choose to exceed the guideline and add more information if they believe it is necessary to do so.

Section	
Advertisement (known as 'advertising/ promotional systems' or 'APS' in the PAAB code) Type size: • Not specified but must be of sufficient size and contrast to be readable	
Required	**Not Required**
• The **Indication And Clinical Use** the advertisement is promoting. This can be edited (as long as key limitations such as age restrictions, etc. are not removed). • **Important Fair Balance SAFETY information** depending on the individual product monograph. This includes boxed and bold warnings, contraindications and serious adverse events that are specific to the drug or its class. The PAAB reviewers can provide an objective observation. • **'P-values', 'n-numbers' and dosage(s)** must be displayed on graphs. If linked to copy points, these are located in the Prescribing Summary under 'Study References'. • **Footnoted reference numbers/symbols** Cross-referenced to clinical studies used to support claims or disclaimers (now be located in the Prescribing Summary under 'Study References'). • **For Journal Advertising: 'I' icon and page location of prescribing information** Icon is usually placed at the extreme bottom lower right hand corner with the copy; See Prescribing Summary on page __. (Page numbers will be inserted by the publication as has always been done. No change in practice here).	• You can delete some safety information depending on the product monograph and the class and subject to PAAB reviewer analysis and final ruling. You may discuss changes with the reviewer during the review process. • **Non-Promoted Indications** • **Other Study Parameters** (This becomes part of the Prescribing Summary) • **Clinical Study Parameters/References** (These will now be located in the Prescribing Summary section under 'Study Reference')

Section	
Prescribing Summary Section • 10pt type size with 11pt leading. (If desired letter spacing can be condensed through flexible choice of font style.). • "Edited" means ability to change grammar and style while message of the content is maintained.	
Required	**Not Required**
• **Unedited indication** of the product that the advertisement is promoting. • **Edited 'use in special populations'** (You do not need to include unrestricted populations); • **Edited 'contraindications'.** ('Known sensitivity to ingredients' is not required) • **Edited 'drug interactions'** • **Edited 'adverse reactions'** • **Edited 'administration'** (Include starting and maintenance dosing. • **Use of Section Titles and Icons** (These have been developed to maintain consistency. If desired, they can be reduced in size) • **Study References.** ***Includes all study parameters except those required on the display page.*** 'P-values', 'n-numbers' and dosage(s) are needed for studies used in text. (Recommended format: 'Vancouver Style') • **1-800 number and/or website where full monograph can be reviewed.** • **The Health Canada adverse reaction reporting phone number and/or the company contact information** (address, phone number or web-site).	• **Non-Promoted Indications** • **Pharmacokinetic and pharmacodynamic actions** • **Clinical pharmacology**

Section
Supplemental Product Information Section: • This area is for additional information that is not critical in making a prescribing decision. • The layout is similar to the previous version of P.I. • 6pt type size with 7pt leading.

Required	Not Required
• **Additional list of less serious adverse reactions** (If not already included on the Prescribing Summary section. May not be required for all products) • **Additional dosage considerations** (If not already included on the Prescribing Summary section. May not be required for all products) • **Supplemental Subsections** This would include information from the following sections not already presented in the summary section: (a) Contraindications (b) Warnings (c) Precautions (d) Adverse Reactions (e) Symptoms and Treatment of Overdose (f) Availability May not be required for all products • **Statement that the product monograph or full prescribing information is available at…** Full corporate name of manufacturer and/or Canadian distributor, full address, web-site and/or phone number.	• **Non-Promoted Indications** • **Pharmacokinetics, pharmacodynamics, modes of action** • **Clinical pharmacology** • **Availability information**

8) Why are many of the footnotes and/or references which previously appeared on the APS moving to the new Prescribing Summary section?

Through consultation with healthcare professionals and the industry, it was determined that study references and parameters were taking up too much space on the display pages. By moving this information to the new Prescribing Summary the key benefits and risks should be communicated more effectively. In testing, 4 out of 5 physicians agreed moving this information to the new Prescribing Summary would be an improvement.

9) Is it a requirement of the code that a small reproduction of the ad be located at the beginning of the Product Summary?

No, it is not a requirement but a suggestion. This was included as part of the testing and was well received by the majority of physicians. They felt it would help them to link the P.I. to a specific product more quickly.

10) Can the size of the P.I. Prescribing Summary section logos be reduced?

Yes. Section logos on the PAAB website can be resized but the appearance cannot be altered. These standardized logos tested very well with physicians. By using them consistently on all P.I. it is hoped the icons will make key product information much easier to find.

11) How about reducing the type size of the Prescribing Summary?

No. A type size of 10 on 11 for the Prescribing Summary was determined though research to be easily readable. Decreasing the letter spacing is allowed. You also have the flexibility of choosing a font that may reduce the size and maintain legibility. As noted above, effective editing/deletion of unimportant information in the Prescribing Summary can reduce its overall size substantially. Please use an appropriate font style for the 6 point on 7 point leading requirement for the Supplementary section to allow legibility.

12) Can the French version be different from the English version?

The French translation should reflect the French version PAAB code requirements.

13) Can we move the "I" icon on different places in the ad?

No. It should appear in the lower right corner of the ad.

14) How should the page number reference appear on the ad?

The publisher will insert the actual page number on the ad at time of publication. You can add a statement "For prescribing information see page __" to help the publisher. The practice is not new and has been done for 30 years. It is a new addition to the PAAB code.

15) What happens if our Product Monograph changes between the time of getting PAAB approval on the format of the Prescribing Information and printing of the PI?

Since PAAB is only approving the format, would it just be a matter of sending you the updated prescribing information for your information and records (assuming the format did not change)?

PAAB Code section 7.3 clearly states that the sponsors are responsible for the content of the prescribing information (PI) while the PAAB will review the PI for format requirements. All initial changes to the new PI format should be submitted and reviewed by PAAB (as of July 1, 2007). Thereafter, assuming that the format has not changed from the initial PAAB reviewed PI and only the content has changed, resubmission would not be required. However, you should send us the updated version for our records.

16) Scenario:
You have a journal ad and sales aid for the same product, there are 5 study references used for the sales aid while only 3 of those 5 used for the ad. The Study References section would be different for both APS (Advertising/Promotional System).
Do we need to:

1. **Have separate PIs for both APS?**

   If you wish to have the references on the P.I., you would have to have separate versions (a generic reference copy block would be too confusing). As an option, you could place the references directly on the display page in the journal ad and the sales aid. This would allow for a generic P.I. with no references associated with it. However, this option increases display page clutter.

2. **How about a general PI for use with both APS? It would have all 5 references included.**

   This would be acceptable only if both the journal ad and the sales aid references (including all reference numbers and symbols) matched exactly.

   As has been done before, Product Monograph leaflets (with attached references or references listed on the sales aid) could be distributed with the Sales Aid.

We offer some flexibility to reduce cost, when it is possible. There is more flexibility in an APS that is not a journal ad. Ask the PAAB about your specific case.

Si vous préférez ce bulletin en français, SVP visitez notre site internet au www.PAAB.ca

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