Guidance on Base Fair Balance Level Selection and Placement (HCP Advertising)

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Preamble:

In alignment with section 9.1 of the Food and Drugs Act, the PAAB code sections 2.1, 2.4, and 3.5 require that risk information be:

- presented within the APS among the claims
- comprised of content type & quantity which adequately balances the claims
- accurate
- clear
- prominent

This present document provides guidance developed by a committee of industry experts on how to meet the above requirements in the context of changes to PAAB code section 7.3. This guidance was designed to address Health Canada's questions about fair balance while offering flexibility for the manufacturers.

Scope of guidance provided herein:

This document applies only to healthcare professional advertising/promotion systems (APS) that require fair balance per PAAB code sections 2.1, 2.4, 3.5, and 7.3.

Overview:

The sister document "Guidance on Generating the Three Base Fair Balance Levels" demonstrated how to generate the highest, the middle, and the lowest level of base fair balance. This present document will now explain how to determine which level would satisfy PAAB code sections 2.1, 2.4, 3.5, and 7.3 in any given APS and where to position that selected level. This assessment is based on the type of content in the APS rather than the amount of content. The basis for the three levels is best explained through discussion of the following three scenarios:

Scenario #1: An APS containing therapeutic claims (e.g. extent of reduction of heartburn) is essentially describing beneficial aspects of the interaction between the drug and the body. This should therefore be balanced with a description of the risks associated with the interaction between the drug and body. The fair balance for that APS would therefore include disclosure of the conditions of clinical use and data limitations conveyed in the "Indication and Clinical Use" in addition to descriptions of the most serious warnings and precautions (i.e. two of the key differentiating features of "highest" level fair balance).

Scenario #2: An APS containing pharmacokinetic claims (e.g. the beta blocker with the longest half-life) but no therapeutic claims[1] is also describing aspects of the interaction between the drug and the body. However, these aspects are non-clinical in nature (i.e. we don't know that they are clinical "benefits" per se). As the interaction between body and drug is described without discussion of the clinical benefits of that interaction, it is sufficient to simply identify even the most serious warnings and precautions and refer the reader to the product monograph for information relating to clinical use (i.e. key features of "middle" level fair balance).

Scenario #3: An APS containing no pharmacologic claims[1] (whether therapeutic or non-therapeutic) does not discuss the interaction between the drug and the body. It is therefore

[1] Other than the required indication and fair balance.

sufficient to convey that the product has risks and that the HCP should read about them in the product monograph (i.e. “lowest” level fair balance).

Determining which level of fair balance to use in the APS

All claims whether explicit or implicit (e.g. visuals) are considered in determining which of the three levels to use. This section has a series of questions which, when answered objectively, help you with this assessment.

It is helpful to answer the questions in the provided order. They are boxed for your convenience. Please note that manufacturers have the option to use a higher level than that which is derived by answering these questions.

Question 1: Are there one or more of the following?

- ✓ Therapeutic claim (e.g. efficacy, safety, tolerability)
- ✓ Compliance/adherence claim
- ✓ Place in therapy claim (e.g. 1st line treatment)
- ✓ Pharmacoeconomic claim
- ✓ Beneficial aspects of risk/burden profile from TMA*

**Includes claims like “Minimal risk of CYP3A4 interactions” or “No need to monitor INR” from the TMA. Also includes cross-TMA comparisons relating to risks/burdens or to limitations of use (e.g. indications, contraindications, warnings, precautions, interactions and overdose). Although the incremental difference between products in such comparisons is not typically clinically significant, the content relating to each individual product’s risk/burden profile is clinically significant. Excludes non-pharmacological aspects such as instructions for use, dosage and or administration information (whether comparative or non-comparative) provided the claim does not allude, in any way, to efficacy or safety or other messaging listed above as requiring highest level fair balance (in which case lowest level fair balance can be used).*

If you’ve answered **“NO with exception of the indication”**, go to Question 2.
If you’ve answered **“YES”**, the APS requires the highest level of base fair balance.

Question 2: If the answer to question 1 is no (aside from the indication), are there one or more of the following?

- ✓ pharmacologic claims other than any of those listed in question 1 (e.g. pharmacokinetics/pharmacodynamic),
- ✓ presentations describing predefined measured endpoints from clinical trials without disclosing results (e.g. ongoing studies)?

If you’ve answered **“NO”**, go to Question 3.
If you’ve answered **“YES”**, the APS requires the middle level of base of fair balance:

Question 3: If the answer to question 2 is also no, are there one or more of the following?

- ✓ non-pharmacologic claims[‡]
- ✓ healthcare product messages other than marketing benefit claims (e.g. cautionary content)
- ✓ messages which do not relate to the healthcare product (e.g. disease information)

[‡] *For example tablet characteristics without implications on pharmacokinetics, market positioning/experience, sensory characteristics such as taste/smell, cost comparisons, cosmetic/packaging/device characteristics, study characteristics without mention of endpoints (e.g. "largest published RCT in diabetes"), plea to choose/prescribe the product or plea to write "do not substitute" if physician wants to ensure patient receives brand X. Also includes claims relating to instructions for use, dosage and or administration information (whether comparative or non-comparative) provided the claim does not allude, in any way, to topics discussed in question 1.*

If you've answered **"NO"**, the advertisement may be exempt from preclearance (i.e. if there are no messages other than drug name +/- claims listed in the PAAB code s6.6). If exempt, the APS should not contain fair balance. If you're uncertain about the exemption status, take advantage of the PAAB's opinion service. The fee schedule is available on the PAAB website.
If you've answered **"YES"**, the APS qualifies for the lowest level of base fair balance.

Placement & visual treatment of selected fair balance level

As drug products have both risks and benefits, promotional materials can be misleading if they emphasize the benefits without emphasizing the risks in a similar fashion. Risk information may not be treated in such a way as to interfere with the reader's perception of the relative importance or utility of the information. Complete separation of benefits and risk information is one example of inappropriate prominence.

> *i.e. Risk information should be where the claims are (meaning in the same parts of the APS). Additionally, risk information should be accorded a degree of prominence which is similar to the claim content.*

When compared to the promoted benefits, the risks/burdens conveyed within fair balance shall always be of visually comparable type size, duration, pace, shade, and location where these considerations are applicable. The proportion of 75% versus the main body copy is a rough guideline often used by review staff to help advertisers meet the requirement of "visually comparable type size". However, other variables such as positioning, spacing, contrast, font type, and readability are critical factors in evaluating acceptability of prominence.

Fair balance should generally not be presented below product logos (+/- tagline), references, legal mice type and/or footnotes as these tend to mark the end of the advertising message portion on a surface.

Consider option to direct HCP elsewhere for more detailed balance

When the answers to the three questions above indicate use of the highest level of fair balance, the manufacturer has the flexibility to include middle fair balance within the main advertising message and direct the reader to another location for the complete and comprehensive highest level.

This is particularly worthwhile when the product has:

- many clinical use considerations (as the reader is simply instructed to refer to the TMA for clinical use considerations)
- complex or numerous bolded/boxed warnings and precautions (as these are simply identified in a list within a single bullet for middle fair balance)
- a long list of other relevant warnings and precautions (as these are listed in a single bullet for middle fair balance)

In order to ensure that PAAB code sections 2.1, 2.4, 3.5, and 7.3 are satisfied, consider the following when exercising the option of using middle level to direct to highest level fair balance.

With respect to the highest level content:

i. The highest level information must be within the same tool (or directly attached to it) **AND** in the same media.

e.g. A print tool cannot direct the HCP to visit an internet address for this information. However, on an electronic banner ad (on a gated site), middle level fair balance may direct the HCP to highest level through an electronic link.

e.g. Print tool X cannot direct the HCP to the separate print tool Y for the highest level

ii. This information must be easily accessible in normal day-to-day use.

e.g. It would not be acceptable to direct the HCP to the bottom inside panel of a sample holder (as this would require him/her to remove the samples from the container). The exterior bottom panel is also not acceptable (as this would need to be read from an awkward angle to avoid spilling the samples). On the other hand, the HCP can be directed to the exterior back panel. Although this panel is not part of the main advertising message, it can be accessed with relative ease by lifting the holder from the shelf.

iii. This information must appear on a surface which is conducive to easy legibility.

e.g. Not a very curved or bumpy/rippled surface on a 3D model

iv. Minimum font size when highest level fair balance is not on the face of the ad:

Minimum of 8.5 point font with 10 point leading for text and 8 point font with 10 point leading for bold headings. Note that there is no minimum font size guidance for fair balance required to appear on the face of the ad (i.e. font size must be comparable to claim copy).

With respect to the middle level:

i. It must be within the main advertising message

ii. Adjust the wording so as to reflect the fact that you are directing the reader to a more comprehensive risk presentation. See figures 1 & 2 below.

Figure 1: The example middle level fair balance for Toviaz created in the document "Guidance on Generating the Three Base Fair Balance Levels (HCP Advertising)". Recall this example is for training purposes only. It has not been approved by Pfizer.

Consult the product monograph at www.toviaz.ca/PM1583 for important information about:

- Contraindications in patients with urinary retention, gastric retention, uncontrolled narrow-angle glaucoma, hypersensitivity to tolterodine L-tartrate, soya, peanuts, lactose.
- Relevant warnings and precautions regarding increased heart rate, interaction with potent CYP3A4 inhibitors, patient at risk of gastric retention, patient at risk of urinary retention, patients with impaired hepatic function, angioedema, patients with myasthenia gravis, patients with controlled narrow-angle glaucoma, patients with impaired renal function, and use of contraception in women of childbearing potential.
- Conditions of clinical use, adverse reactions, drug interactions, and dosing instructions.

The product monograph is also available by calling us at 1-800-XXX-XXXX.

The adjustment is as simple as changing the first line to read "Click here for additional safety information and for a link to the product monograph discussing:" and removing the last line with the phone number as information about how to access/obtain the TMA will be conveyed within the highest level fair balance. Figure 2 is the adjusted middle fair balance.

Figure 2: Example of middle level fair balance modified to direct to highest level fair balance

Click here for additional safety information and for a link to the product monograph discussing:

- Contraindications in patients with urinary retention, gastric retention, uncontrolled narrow-angle glaucoma, hypersensitivity to tolterodine L-tartrate, soya, peanuts, lactose.
- Relevant warnings and precautions regarding increased heart rate, interaction with potent CYP3A4 inhibitors, patients at risk of gastric retention, patients at risk of urinary retention, patients with impaired hepatic function, angioedema, patients with myasthenia gravis, patients with controlled narrow-angle glaucoma, patients with impaired renal function, and use of contraception in women of childbearing potential.
- Conditions of clinical use, adverse reactions, drug interactions, and dosing instructions.

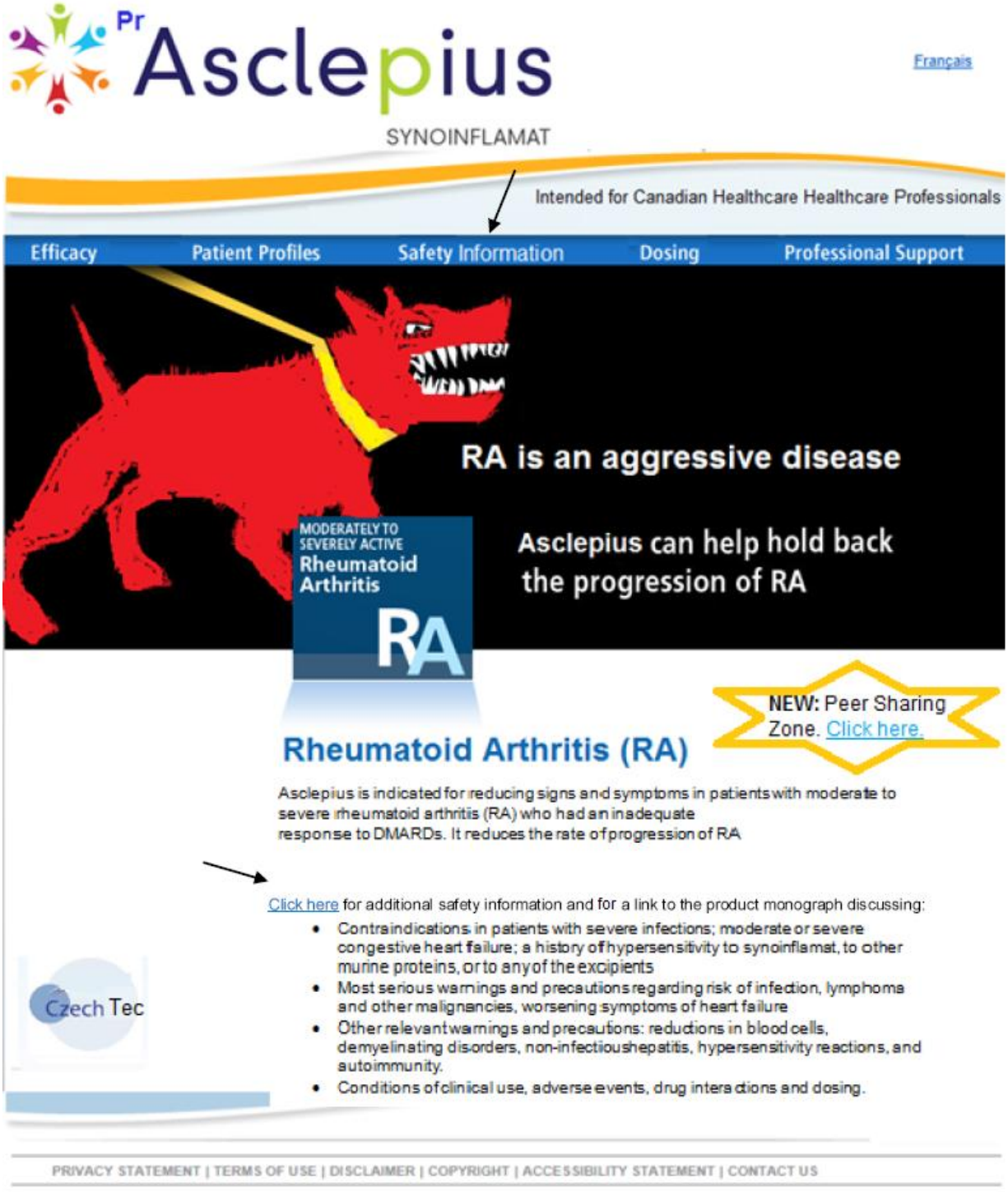
Note that "Click here for" would have read "Pull out the inside panel for" on a slide ruler, "tear here for" on a bellyband...etc.
The instruction will vary between APS types to so as to accurately reflect which steps the HCP needs to take in order to access the highest level fair balance containing the link to the product monograph.

Detailed non-linear tools (e.g. Websites and Apps)

The use of middle level fair balance to lead to highest level fair balance is also particularly useful for websites and apps. For the majority of APS, the appropriate base fair balance level can generally appear anywhere within the main advertising message (i.e. early or late within the presentation). However, particular care is required for tools like websites and apps as it is often difficult to predict the path of information consumption. Additionally, the content is not typically consumed entirely within one sitting. In such cases, the fair balance should appear on the home

page/surface. Also, a prominent “Safety Information” menu item visible from any screen on the site should lead to the highest level fair balance. Figure 3 depicts a home page containing the indication (as required by PAAB code section 2.10) and the middle level fair balance. Whether the reader presses the “click here” link within the middle fair balance or the “Safety Information” menu item, he/she is taken to the highest level fair balance.

Figure 3: Homepage for Asclepius (post-gate)



Journal Ads

PAAB was asked to create an icon specifically for journal ads that contain middle level fair balance directing the reader to highest level fair balance elsewhere within the publication.

The icon reads “See additional safety information on page xx”. It must appear in the extreme bottom-right corner of the spread containing the middle level fair balance. The icon will be available for download from the resources menu item on the PAAB website.
For journal ads containing the icon, the middle fair balance copy format must take one of the following three forms.

- **Scenario 1: When study parameters and references appear on the face of the ad.**
  The copy “Refer to the page in the bottom-right icon for additional safety information and for a web link to the product monograph discussing:” followed by the middle fair balance bullets.

- **Scenario 2: When study parameters and references appear elsewhere within the publication (i.e. with the highest level fair balance)**
  The copy “Refer to the page in the bottom-right icon for additional safety information and for a web link to the product monograph discussing:” followed by the middle fair balance bullets. The middle fair balance bullets are then followed by the copy “In addition, the page contains the reference list and study parameters relating to this advertisement”. See figure 4 on next page.

- **Scenario 3: When study parameters and references appear on the web link destination.**
  The copy “Refer to the page in the bottom-right icon for additional safety information and for a web link to the product monograph discussing:” followed by the middle fair balance bullets. The middle fair balance bullets are then followed by the copy “In addition, the web link contains the reference list and study parameters relating to this advertisement”.

Figure 4: study parameters and references appear elsewhere within the publication (i.e. with the highest level fair balance)