# PAAB – Submission Practices for Success

Presented by:

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# What's new @ PAAB - 2007

- A new
  - "Summary Box" for study parameters
  - PI format (including a prescribing summary box and supplemental product information section)
    - More accountability for the advertiser with regards to content
  - Other languages – if translated from a PAAB approved APS should not carry the PAAB logo
    - May include disclaimer that it was approved by the PAAB

# What's new @ PAAB – 2007 – cont'd

- Advertiser must present a fair balance of risk to benefit
- Messages should include reference to the safety profile as reflected by Health Canada TMA
- Special warnings, precautions, clinical significant serious adverse events, NOC/C or use limitations cited in the PM should be included in the body copy

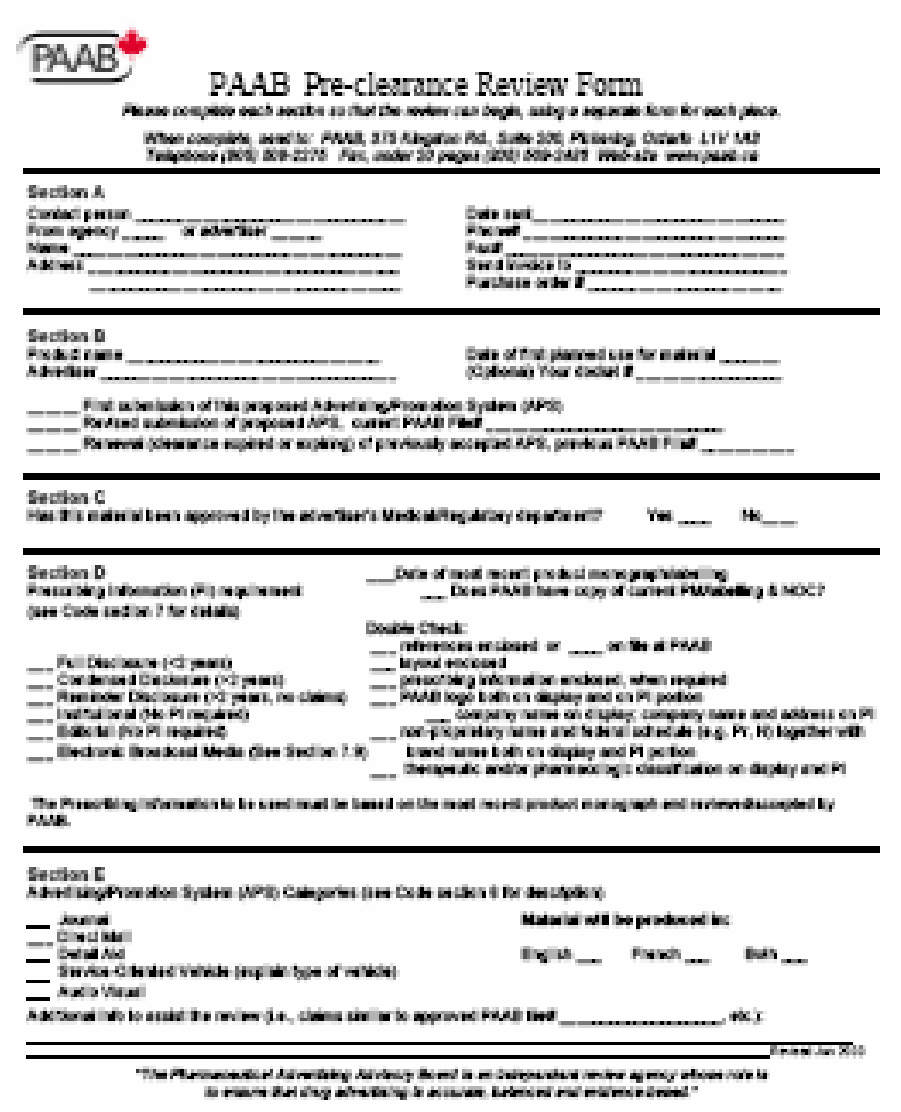
# Successful PAAB submissions

- Key areas of focus:
  - Approval process
  - Data presentations/Referencing
  - New brands
  - Existing brands
  - Submissions
  - What to expect
  - Interaction with the PAAB
  - What not to expect
  - Overall responsibility

# Approval Process

- Internal review and approval of all files prior to submission
  - Review by brand team
  - Medical/regulatory
- Inclusion of names of those who approved the initial APS submission
  - To be included in the PAAB submission form

# Approval Process



PAAB Pre-clearance Review Form

*Please complete each section so that the review can begin, using a separate form for each piece.*

*When complete, send to: PAAB, 175 Kingston Rd., Suite 305, Pickering, Ontario L1V 1A8*
*Telephone (905) 509-2170 Fax, under 20 pages (905) 509-2481 Web-site www.paab.ca*

Section A

Contact person _____
From agency _____ or advertiser _____
Name _____
Address _____
_____

Date sent _____
Phone# _____
Fax# _____
Send Invoice to _____
Purchase order # _____

Section B

Product name _____
Advertiser _____

Date of first planned use for material _____
(Optional) Your docket # _____

____ First submission of this proposed Advertising/Promotion System (APS)
____ Revised submission of proposed APS; current PAAB File# _____
____ Renewal (clearance expired or expiring) of previously accepted APS, previous PAAB File# _____

Section C

Has this material been approved by the advertiser's Medical/Regulatory department? Yes ____ No____

Section D

Prescribing Information (PI) requirement
(see Code section 7 for details)

___ Full Disclosure (<2 years)
___ Condensed Disclosure (>2 years)
___ Reminder Disclosure (>2 years, no claims)
___ Institutional (No PI required)
___ Solicited (No PI required)
___ Electronic Broadcast Media (See Section 7.8)

___Date of most recent product monograph/labelling
___ Does PAAB have copy of current PM/labelling & NOC?

Double Check:
___ References enclosed or ____ on file at PAAB
___ Layout enclosed
___ prescribing information enclosed, when required
___ PAAB logo both on display and on PI portion
___ Company name on display; company name and address on PI
___ non-proprietary names and federal id include (e.g. PI, II) together with brand names both on display and PI portion
___ Therapeutic and/or pharmacological classification on display and PI

*The Prescribing Information to be used must be based on the most recent product monograph and reviewed/accepted by PAAB.*

Section E

Advertising/Promotion System (APS) Categories (see Code section 6 for descriptions)

___ Journal
___ Direct Mail
___ Detail Aid
___ Service-Oriented Vehicle (explain type of vehicle)
___ Audio Visual

**Material will be produced in:**

English ___ French ___ Both ___

Additional info to assist the review (i.e., claims similar to approved PAAB file# _____, etc.)

Revised Jan 2010

*"The Pharmaceutical Advertising Advisory Board is an independent review agency whose role is to ensure that drug advertising is accurate, balanced and in compliance thereof."*

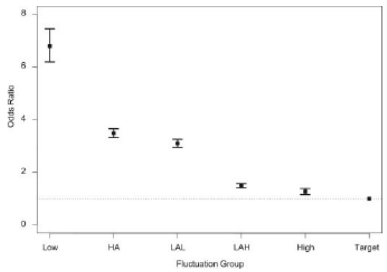
# Data Presentations

- Studies used to support claims for a specific product must be:
  - Published (or letter from the publication stating that a manuscript has been accepted)
  - Well controlled/designed
  - Must have clinical and statistical significance clearly indicated
  - Study endpoints/objectives should also be in line with the data that is being presented

# Data Presentations

- Some key things to remember about claims:
  - Comparative products and their formulations must be available in Canada
  - Claims must be supported by the product monograph
  - Study findings must be supported by the product monograph
  - Claims over and above those within the product monograph will not be accepted
  - Claims are to be past tense, not forward looking or absolute:
    - Demonstrated
    - Shown
    - Helped
  - Study parameters must accompany claims

# Referencing

| | |
|---|---|
| **Headline:** | A message that appears at the top of a page 1A |
| **Bullets:** | May be part of the headline to support the message 1B |
| **Subhead:** | Could be a line that introduces an idea that will be further supported – a quote perhaps that is consistent with the endpoints of the study 2A |
| **Chart head:** | Introducing what will be shown in the graphic 2B |
| **Chart:** |  2C |
| **Chart legend:** | As a lot of times, charts are scanned and dropped in for placement only within copy decks, so it's important that the legend, data points, x and y axis labels and legends are spelled out – so they can be reviewed against the clinical paper. |
| **Close:** | This could be a statement that closes the thought on the page; or summarizes a main idea. 3A |
| **Footnote:** | This will likely show the cross-referenced information; the additional required support for the claims that are made within the page of the APS. This may be a series of footnotes depending on what data is presented on the page. 1c, 2d, 3b |

# Referencing



*Table 2.* Hospitalization and comorbidity by hemoglobin level fluctuation classification*

| Hemoglobin | Hospital Admission (%) | Admission for Infection (%) | Average LOS (d) | Average Comorbidity (n) |
|---|---|---|---|---|
| Low | 69.2 | 29.5 | 12.7 | 2.4 |
| Target | 25.3 | 6.2 | 1.9 | 1.1 |
| High | 29.8 | 7.4 | 2.2 | 1.2 |
| LAL | 51.1 | 17.6 | 6.5 | 1.8 |
| LAH | 33.5 | 9.3 | 2.8 | 1.3 |
| HA | 54.0 | 17.7 | 6.4 | 1.8 |

*LOS, length of hospital stay.

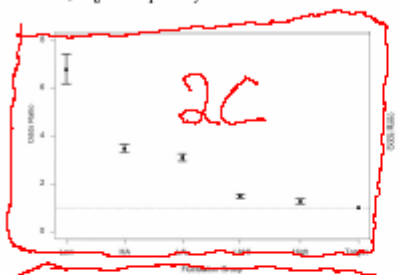



*Figure 4.* Logistic regression model showing relationship between hemoglobin level fluctuation group and hospitalization, yes versus no. All odds ratios (OR) are statistically significant.

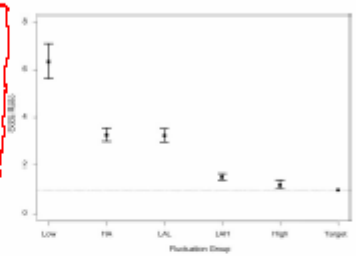


*Figure 6.* Logistic regression model showing relationship between hemoglobin level fluctuation group and infectious hospitalizations, yes versus no. All OR are statistically significant.

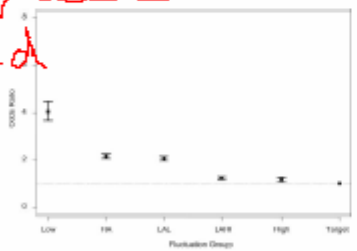



*Figure 5.* Logistic regression model showing relationship between hemoglobin level fluctuation group and number of comorbidities, 1 or more versus 0. All OR are statistically significant.

Although Fishbane and Berns (6) suggested provider practices as the main reason for the cycling of hemoglobin levels, their study also showed significant degrees of comorbidity and hospitalization, even though they assessed patients with fewer than 10 d of hospitalization during their study period. In contrast to their analyses, we found that comorbidity and hospitalization for infection play important roles as random events that may be outside the control of providers. Catheter infections, pneumonias, and gastrointestinal bleeding episodes all contribute to fluctuating hemoglobin levels and help to create the marked instability of hemoglobin levels over time. Preventing these clinical infectious events may be difficult, but attempts to do so could help to reduce both morbidity and the fluctuation of hemoglobin levels, yielding more cost-effective anemia treatment. The Fistula First program that was initiated by CMS promotes the reduction of dialysis catheter use and the attendant infectious complications and costly hospitalizations. Vaccinations for influenza and pneumococcal pneumonia potentially could reduce these complications. Unfortunately, there are few data to indicate that these measures will change the frequency of hemoglobin level fluctuations.

Our study has important limitations that should be considered. The data that are available for this large national assessment were from reported claims for epoetin treatment, which require the submission of the last hemoglobin level before the last epoetin dose of the billing period. Many providers assess hemoglobin levels weekly or every 2 wk, possibly affecting the

2A

# Referencing

- Some rules of thumb:
  - Make sure it's easy for PAAB to pick up a copy document and line it up to a corresponding reference. 1A lines up with 1A, 2B with 2B and so on
  - Calculations (% or total number):
    - indicate to PAAB how you are making the calculation. It's easier for them to check the math than try to interpret what calculation is being compiled
  - If a statement is made in the APS and it is referenced in a number of locations within a reprint, simply label the reprint accordingly even if 1A appears in the reprint 5 times
  - Tabbed, hard copy files work very well and are easy to follow.

# New Brands

Proactive with PAAB

- Upcoming NOC
- Agency involvement
- Pre-PAAB Draft PM review
- Meeting with the PAAB

# Existing Brands

- PAAB submission (post med/reg approval) of copy deck
  - Copy submission with balancing information
  - Revisions to copy
  - Layout + French copy
    - Review of comments
    - Interim discussions with the PAAB
    - Resolution of file in copy format prior to layout review

# Submissions

Layout review:

- Creative representation of the brand
- Not disparaging to the competition (ie. above and beyond what is supportable by the PM)
- Representative of the terms of market authorization
- Footnotes and balancing copy in proximity and appropriately sized for prominence
  - Layout explanation may help with this (ie. booth panels)

# What to Expect

- Preliminary review
  - Layout required
  - Page 1: Comments will be addressed on a page to page basis so that the comments clearly indicate what they are referring to
  - General comments will likely cite a section of the code (s4.2.1). This helps address the specific issue with the data presentation
  - Examples provided in order to outline the reviewers thoughts on what may be acceptable. This does not need to be followed verbatim, however, it does provide a suitable solution

# Interaction with the PAAB

- For clarity on a comment, your agency will:
  - Engage the brand team in review of the comments
    - Brand team can subsequently engage the med/reg resources within the organization
  - Make recommendations based on their experience
  - Call the PAAB and ask for the reviewer that has provided feedback on a file
  - Provide the file number (eg. DAF12345) as reference
  - Discuss the comments with the reviewer in order to obtain clarity
  - Revise the copy accordingly

# What not to Expect

- All files are reviewed in the context of their respective brand
  - PAAB will not accept comparisons of claims from other brands
  - PAAB will not accept claims from other brands in review of the file in question
- If an advertiser wants to file a formal complaint to the PAAB regarding messaging of another brand, it must be completed in isolation from a file in review

# Overall Responsibility

Brand team/agency

- Copy reviewed and in context of the brand presentation
  - In line with the messages that are to be disseminated
  - In accordance with the approved TMA
  - Properly referenced to supporting information
  - Branded and unbranded data presentations separated appropriately
  - File referencing
  - Actual submission, following med/reg review and approval

# Overall Responsibility

Medical/Regulatory

- In order for a file to go in for review, the advertiser's med/reg team will need to review and approve the APS
  - Be in the context of the brand
  - In accordance with the approved TMA
  - Properly referenced to supporting information
  - Reviewed in full prior to sign off

Questions ???