

A Question of Balance



The Pharmaceutical Advertising
Advisory Board

REVIEW

Ray Chepesiuk,
Commissioner

In May 2004, after it had become apparent that the Code Committee required a lot of work to be done on just one topic, the PAAB struck a task force to study the fair balance/prescribing information (PI) requirements of the PAAB Code of Advertising Acceptance. PAAB chose Paul Hickey as the chair and he was "... charged with the task of improving the quality of pharmaceutical communication (both content and format) across all major types of media, starting with the most high profile medium, medical journal advertising."

Stage I consisted of defining the problem and identifying a definition of medical journal advertising. This was done by committee members Praveen Chawla (NDMAC), Ron Weingast (CGPA), Elgin Cameron (Rx&D), Gloria Bowes (CAMP), Dr. Jeff Blackmer (CMA) and Paul Hickey (AMAA). It was agreed that it was indeed very difficult to do a one-page journal advertisement that included all of the fair balance information that the PAAB Code required and that the current format of the PI was almost useless. During this period, the Canadian Association of Medical Publishers conducted research, involving 48 physicians in six centers across Canada, to assess what was important to them regarding the PI. The physicians ranked the different sections in order of importance to them. An important finding was that physicians said they only "referred" to the PI rather than actually "reading" it. So, the committee agreed that it would be a good thing to revise the format of the PI to make it a better reference document.

A group consisting of two PAAB Directors, Paul Hickey and Gloria Bowes and two creative consultants, Gord Schwab and Rob Vosburgh, developed format options. These options were assessed and narrowed down to one.

The next step was both a consultation and a refinement process by a

group consisting of Hickey, Bowes and Schwab, joined by Ray Chepesiuk and John Wong of the PAAB staff. To refine the chosen format, the group sought stakeholder input through CAMP, AMAA, Procter & Gamble Pharmaceuticals Regulatory department, Bristol-Myers Squibb Regulatory department and the Allergan Pharmaceuticals Regulatory department.

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Then, a committee composed of Paul Hickey and Ray Chepesiuk evaluated the request for proposal bids from three market research firms. The committee chose Ipsos Camelford Graham (ICG) because of the unique approach they offered, within the approved budget, to reach 100 physicians.

Based on the results of the survey, the Board approved a motion to incorporate this format into the PAAB Code. A Code committee was struck and hopefully a proposal for a Code change will be accepted by the Board in November 2006, with implementation scheduled for 2007. The normal wide stakeholders consultation will take place this year.

Survey objectives

The research objectives were as follows: assess physicians' reactions to a new and improved format for advertising and PI within Canadian medical journals vis-à-vis the existing format. But more specifically, to:

- Identify which format is most effective at clearly communicating the most important, most relevant information about the medication
- Assess if the new PI is an improvement over the current format
- Determine if the information that has been removed from the ad display portion of the advertising/promotion system is acceptable
- Understand the opinion of physicians on whether the new modified format has compromised, in any way, the communication of the product's strengths and precautions
- Gauge overall acceptance of this new format and understand what specific parts of the new format are considered improvements and which are not

Survey methodology

The perspective of Health Canada was sought through three individual qualitative interviews with assessment division personnel. The following reviews the survey methodology:

- Telephone interviews were conducted with 100 physicians (70 family physicians and 30 specialists) in both Toronto and Montreal (in English and French)
- Test materials were sent to the physicians to be opened at the time of the individual interview
- Mock ads and prescribing information, using Actonel® (risedronate) as the example to provide realism, were used*
- A mix of endocrinologists and rheumatologists were contacted for the specialists group

Survey results

The following are the survey results

- Ninety eight per cent (74% much improved + 24% slightly improved) of physicians reported that the proposed new format and prescribing

* We would like to thank Procter & Gamble for permission to use their product for the test advertising.

information pages were an improvement over the existing format

- Ninety seven per cent (59% much more useful + 38% somewhat more useful) reported that in comparison to the current format, the new format would be useful as a communication tool for their profession
- Ninety six per cent (31% very valuable + 65% somewhat valuable) reported that the proposed changes would be of value to their daily practice
- Seventy three per cent (20% a lot more + 53% a little more) reported that they would refer to the PI pages more often in the new format.

Twenty seven per cent said there would be no difference (Figure 1)

The new format also scored better in terms of overall communication; effectiveness in communicating what a physician needs to know about the product; ease of finding important information and the amount of infor-

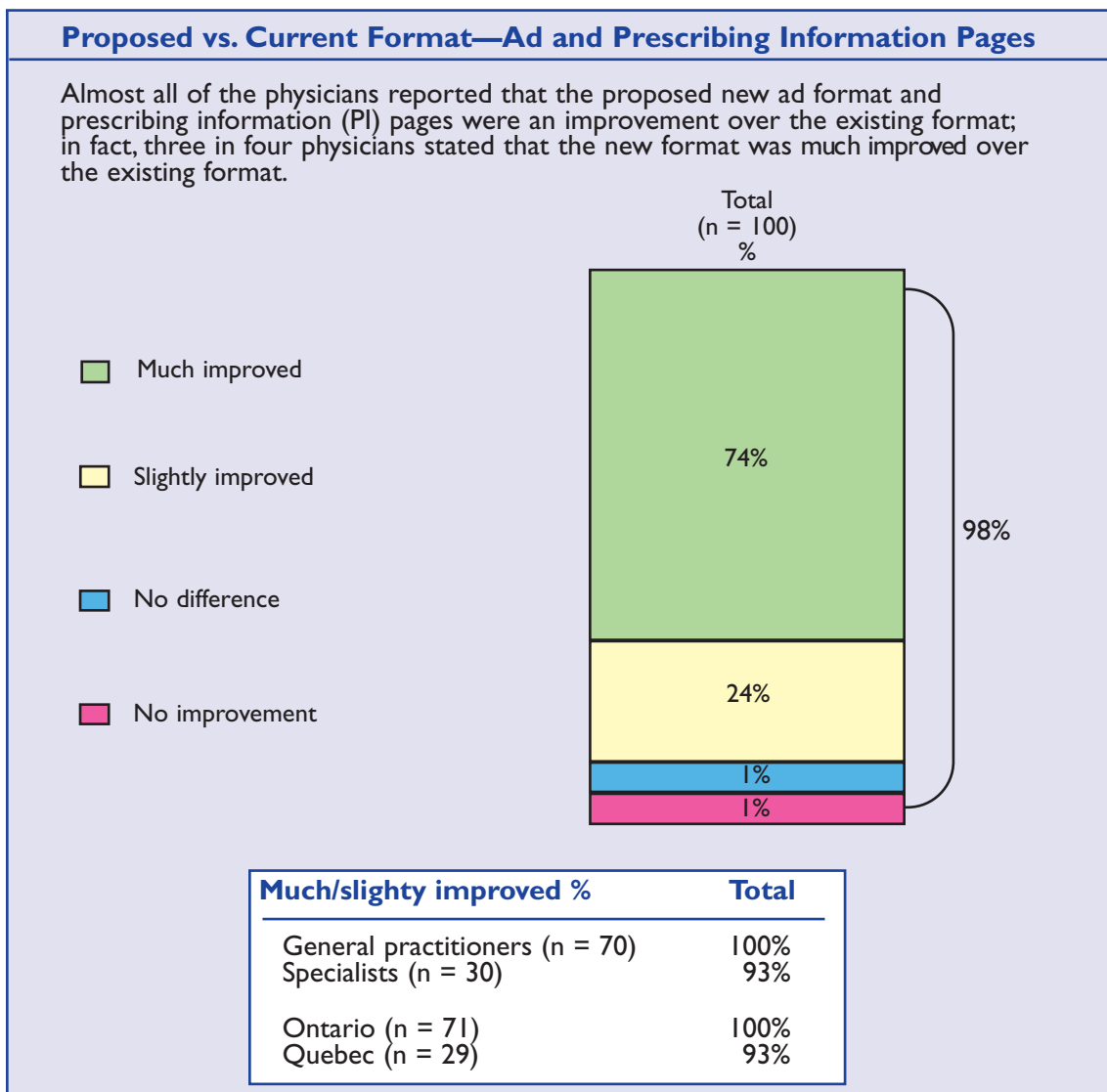


Figure 1. Proposed vs. current format—ad and PI pages.

Side-By-Side Comparison of Ads				
The group of physicians found that:				
<ul style="list-style-type: none"> • The proposed format was considered superior to the current format. It was “easier on the eyes” and was considered to be the ad that would most likely get physicians to stop and read • Most physicians also selected the proposed format as the one that most clearly communicates Actonel®’s main message, specific indications and safety indications 				
(n = 100)	Current %	Proposed %	Both %	None %
Is easier on the eyes	-	98%	2%	-
Most likely to get you to stop and read	5%	87%	6%	2%
Most clearly communicates Actonel®’s main message	2%	87%	10%	1%
Most clearly communicates specific indications for which Actonel® is used	8%	70%	19%	3%
Most clearly communicates safety information pertaining to Actonel®	16%	70%	12%	2%
Format preferred as industry standard	6%	93%	1%	-

Figure 2. Side-by-side comparison of ads.

Side-By-Side Comparison of PI Pages			
Physicians selected the proposed PI pages over the current pages because:			
<ul style="list-style-type: none"> • The proposed PI pages had “easier to read” type size and the organization of the information was more useful • It was easier to find important information, specifically pertaining to safety issues, type of patient and dosage and administration 			
(n = 100)	Current %	Proposed %	Both %
Easier to read type size	2%	96%	2%
Easier to find information on safety issues pertaining to Actonel®	5%	95%	-
Easier to find information on type of patient for which Actonel® is appropriate	5%	94%	1%
Organization of information is more useful	8%	91%	1%
Easier to find information on Actonel®	9%	91%	-
Easier to find information on dosage and administration of Actonel®	8%	88%	3%
Format preferred as industry standard	7%	93%	-

Figure 3. Side-by-side comparison of PI pages.

mation being communicated.

The proposed ad format was preferred primarily because it was seen as: less cluttered, clearer and easier to read and easier to find information. Physicians appreciated the reduction in fine print and in the amount of text. The four icons and boxed warnings are seen as positive elements of the new format (Figure 2).

Preference for the proposed PI pages is primarily led by the bigger type size and the new headings and titles which made the pages clearer and easier to read. Physicians also appreciated that the pages were categorized into sections, were more concise and that the important information was up front. The icons, the framed-boxes and the focus on important information were other aspects that led to the preference (Figure 3).

Recommendations

The ICG researchers made the following recommendations:

1. The results of the study clearly support a decision to adopt the proposed ad format and PI page within Canadian medical journals
2. Most physicians are unconcerned that information on actions and clinical pharmacology, pharmacodynamics and pharmaceuticals has been removed from the PI pages and they are satisfied that it is available in the Compendium of Pharmaceuticals and Specialties or online. Health Canada representatives want to see all of the information in one location. ICG recommended the inclusion of a highlighted box directing physicians to the CPS or the website for additional details related to those categories
3. Most physicians consider the ad references to be useful. Health Canada representatives suggested a change of heading to literature or study references
4. The icons have general approval as part of the industry standard for prescribing information. Some further attention appears warranted to ensure optimal clarity and understanding
5. Even though some physicians did not find the miniature reproduction of the ad in the PI pages as being particularly useful in helping them link the PI and the ad, it is an element that should be retained within the pages, as it is unlikely to detract from communication effectiveness, as seen in the results
6. The 1-800 number or a website to report adverse events would be a welcome addition and should be highlighted so that physicians can easily find it

The PAAB directors approved, in principle, to incorporate the new format as part of the Code. A lot of work by the Code Committee remains to be done to bring a Code revision to a vote by PAAB members.

I would especially like to thank Paul Hickey, Gord Schwab and Gloria Bowes for their effort to bring this project to this stage.

CPM

Stay tuned...