Pharmaceutical Advertising Advisory Board
Conseil consultatif de publicité pharmaceutique
375 Kingston Rd., Suite 200, Pickering, Ontario L1V 1A3

IMPORTANT NEWS FROM THE PAAB

PAAB Code Clarification – Implementation April 2002

At the November 9, 2001 Board meeting, the PAAB members unanimously approved a revision to the PAAB Code. PAAB Commissioner Ray Chepesiuk presented the following backgrounder to the members. "Currently PAAB Code section 6.6.f allows for exemption from preclearance review for 'Patient information from product monographs and patient education material'. There are no explanatory notes to accompany that section. Prior to the 1993 Code revision, patient education materials created by pharmaceutical companies and distributed through health professionals did require PAAB preclearance review. It may have been believed that the 'information for the Consumer' section of the Product Monograph would be distributed by drug companies and those items would not require PAAB review. The intent of the Information to the Consumer is to provide adequate directions for use of a product to achieve optimal therapeutic results. We have seen a recent proliferation of these items and a rise in the number of complaints regarding violations of the Food & Drugs Act because the items were perceived to be 'advertising' and not 'information'. Sponsors were incorrect in their assessment of the regulatory status of the material. Companies have viewed these items as an opportunity to communicate product-specific messages directly to patients and to the general public. In my opinion, this activity is leading to the perception that this type of item is a loophole in the regulatory framework and may contribute to mistrust of the pharmaceutical industry."

The members approved the following revisions:

Section 6.6f will read as '***Patient Information direct from and consistent with the product monograph [see 6.4 for regulations]***'.

Section 6.4 will read as '***Service-oriented vehicles are designed to contribute to the healthcare professional's/ patient's understanding of a condition or its treatment. Such materials include Educational APS and patient information [see 6.6f for exemptions] that are prepared or controlled by the manufacturer of its agent [11.10]…***'.

Section 6.4.2 will read as '***Examples of patient information vehicles are company-controlled patient brochures, internet and other electronic presentations, and 1-800 number scripts.***'

Newly created Section 6.4.3 will read as '***Company controlled or prepared patient information is information that contains editorial material that is in addition to the patient information section of the product monograph***'.

You should note that this is a clarification of the current wording to show the necessity of formal review of company created and/or controlled patient material distributed through health professionals. It does not cover items created under the full control of a third-party organization such as a patient advocacy association. The members agreed to an implementation date of April 1, 2002. We look forward to your full cooperation with the PAAB Code of Advertising Acceptance.

Pharmaceutical Advertising Advisory Board
Conseil consultatif de publicité pharmaceutique
375 Kingston Rd., Suite 200, Pickering, Ontario L1V 1A3

IMPORTANT NEWS FROM THE PAAB

December Holiday Schedule

The PAAB office will close at 3 p.m. December 24, 2001 until Wednesday January 2, 2002. Best Wishes for the Holiday Season to all of our clients.

PAAB FEE SCHEDULE

Effective for material received after **January 1 2002**

		English **or** French	English **and** French
All APS		$350	$410
except			
a)	additional APS within series with slight variations, submitted same day:	$140	$190
b)	product reminder (section 7.6)		

Consultative Meeting or Written Opinion to Help Distinguish Between Advertising and Information (unless requested by PAAB) $350

Extended review fee *chargeable for all reviews and advisories when:*

		additional
i)	three or more resubmissions are required	$105
ii)	APS is more than 10 pages and less than 21 pages in length **or** with more than 15 references	$105
iii)	APS is more than 20 pages in length	$210

Fees are invoiced after the first review letter has been sent. Fees are for the cost of the review and not for the acceptance of the APS. Once a piece has an approval number, we consider the approval process to have been completed for the fee that was assessed. Any revisions after that will be treated as a new submission with a new file number and billed a full fee. A review of prescribing information at launch or when revised will be billed an “All APS” fee.

Invoices are payable within 30 days; advertisers with outstanding balances may be required to clear their accounts before new reviews can begin. GST at 7% is applied to the above rates, GST#R104174743.

Questions about fees should be directed to the PAAB office: E-mail: review@paab.ca