Health Canada Santé Canada

MEETING NOTES

PHARMACEUTICAL ADVERTISING ADVISORY BOARD (PAAB)
and
ADVERTISING STANDARDS CANADA (ASC)
and
HEALTH CANADA
(HEALTH PRODUCTS AND FOOD BRANCH and HEALTH POLICY BRANCH)

Graham Spry Building, 250 Lanark Avenue, Ottawa, Room 150
Thursday April 7th, 2005 - 10:00 a.m. - 12:00 p.m.

Attendees:

PAAB:
Ray Chepesiuk, Commissioner
Dr. Reginald Perkin, Chair of PAAB Board

ASC:
Linda Nagel, CEO & President
Nicole Bellam, Director - Advertising Clearance Services
Dora Gelntis, Analyst

Health Canada:
Cindy Evans, Chair (for David Clapin), Marketed Health Products Directorate (MHPD)
Ann Sztuke-Fournier, MHPD
Christophe Roy, MHPD
Marc Lapointe, MHPD
Simon Carvalho, Legal Services
Michel Pariseau, Health Policy Branch (HPB)
Micheline Ho, Therapeutic Products Directorate (TPD)
Bruce Boulton, TPD
Elizabeth Smith-Kawasaki, Natural Health Products Directorate (NHPD)
Marianne Tang, Biologics and Genetic Therapies Directorate (BGTD)
Diana Dowthwaite, Health Products and Food Branch Inspectorate (HPFBI)
Catherine Yen, HPFBI
Marie Morrisey, HPFBI
Jenny McLaughlin, HPFBI
Kalpesh Patel, Office of Regulatory and International Affairs (ORIA)
Michelle Nicholson, Veterinary Drugs Directorate (VDD)

1. Opening Remarks

The Chair welcomed participants. Participants are informed that, as for other Branch's association meetings, records of decisions of these trilateral meetings will be posted on the Web.

2. Approval of the Agenda

The agenda was approved.

3. Approval of the Record of Decisions - June 28, 2004

Modification with respect to Item #9 - Natural Health Product (NHP) Compliance: Replace the fourth sentence to read as follows: "A product cannot be sold and advertised unless it has a Natural Product Number". The record of decisions was approved with the above-mentioned revision.

4. Legislative Renewal - Advertising Update

An update regarding the Legislative Renewal initiative, and more specifically with respect to advertising, was provided to participants. Various stakeholders were consulted in 2003-04. Policy work at HC is ongoing. Health Canada is looking at health product promotion in general. Five items are being looked at: Direct-to-Consumer Advertising, Distribution of Samples, *Section 3* and *Schedule A*, Deception, and Health Practitioner-Oriented Promotion. HC will be seeking additional input from the PAAB and ASC when drafting instructions / draft legislation is ready.

Action: The PAAB and ASC are invited to submit any studies, statistics, etc. which may assist the policy work.

5. Reminder Ads - Reference to Specialists

A number of complaints regarding branded reminder ads including references to medical specialties were received at HC. The PAAB and ASC were involved. A reference to a medical specialty in a reminder ad is a representation that goes beyond the mention of name, price and quantity (restrictions set out in *Section C.01.044* of the *Food and Drug Regulations*).

Action: HC (MHPD) to send a policy clarification letter to the PAAB and ASC in order to cease acceptance of such ads and to discontinue dissemination of current ads.

6. Consistency of Advertising Preclearance

Since manufacturers may submit consumer-directed messages related to prescription

drugs to both the PAAB and ASC for review, potential discrepancies in advisory opinions may arise. HC raises the issue to seek input from preclearance agencies on possible mechanisms to ensure consistency.

Action: The PAAB and ASC to discuss and submit proposals to HC by end of June 2005.

7. Consumer Advertising Guidelines for Marketed Health Products

ASC and HC have drafted a Consumer Advertising Guideline for Marketed Health Products (Non-prescription Drugs including Natural Health Products). The consultation draft is posted on the TPD, NHPD and HPFB Websites. A link to the document is also on the ASC Website. A consultation notice was submitted to a list of identified stakeholders in order to get feedback on the draft guidelines. The deadline for comments is April 22, 2005. ASC has received a few comments to date.

Action: ASC to collate, analyse and tabulate comments and submit revised draft to HC.

8. Industry Education and Compliance

The PAAB is offering an education program to increase industry understanding of pharmaceutical advertising and the PAAB Code of Advertising Acceptance. Since the April 12 (Toronto) and the April 14 (Montreal) training sessions are already full, a new round of workshops has been scheduled for June 7, 2005 in Toronto and June 9, 2005 in Montreal. The PAAB invites HC to attend as observers.

Action: HC to advise the PAAB by end of May 2005 as to the number of HC representatives interested in attending the June workshops.

9. HC's Interpretation of Educational Material and Press Releases

PAAB is requesting clarification as to how HC applies the principles outlined in the policy "The Distinction Between Advertising and Other Activities" with respect to press releases and educational material. There is confusion as to whether it is advertising or not. HC reiterated that material is evaluated on a case-by-case basis since the content and the context always need to be considered. Information regarding the process, from a legal perspective, was also provided.

Action: PAAB to submit to HC a package containing challenging examples to be looked at by the Advertising WG members.

10. Mechanism for Agencies to Verify Specific HC Approved Label Claims

This issue was raised at the June 28, 2004 meeting. Determining product label claims

which have been specifically authorized by Health Canada based on Category IV or Labelling Standards is a challenge for preclearance agencies. Many industry applicants have incorrectly interpreted that a full label review was done by HC when some comments were provided regarding certain label claims. ASC is wondering whether there is a mechanism in place to verify the actual authorized label claims. Full label reviews are not done for Category IV applications.

Action: HC (MHPD) to write a letter to both agencies to confirm the Submission Information Policy Division (SIPD) contact names within TPD to confirm submission type. TPD to issue a letter to industry associations and relevant stakeholders to outline the level of Health Canada review related to submissions filed under Category IV Monographs and Labelling Standard vs regular submissions.

11. HC's Interpretation of Product Monographs / Regulatory Status

Product Monograph Claims
This issue was raised at the June 28, 2004 meeting. PAAB had provided HC with examples of claims included in Product Monographs which are of concern in terms of advertising. PAAB would like to discuss with HC the inclusion of certain claims / wording in Product Monographs and the potential impact it has on advertising material. HC provided information on various initiatives undertaken by the Department with respect to approval of drugs (Good Review Practices, posting of Summary Basis of Decisions, new PM format). These may provide additional guidance to the PAAB.

Action: PAAB to submit to HC a package containing specific examples of claims included in PMs which might have an impact in terms of advertising. This will be reviewed by clinical evaluators and a special meeting is proposed to serve as a relevant training exercise to clarify questions / issues to be submitted by PAAB.

HC Clarification of its Role in Therapeutic Comparative Claims Review
ASC is now in the final stages of implementing preclearance for therapeutic comparative claims for nonprescription drugs. ASC requested clarification regarding HC's role in the review and approval of such claims.

HC clarified that it does not generally review therapeutic comparisons that are promotional in nature, e.g. brand to brand. Rather, HC reviews only the therapeutic basis for such comparisons, and includes resulting approved claims in the product's Terms of Market Authorization. It will be ASC's responsibility to use such information as the basis for reviewing therapeutic comparative claims as per the criteria set out in the HC Directive and Guidance Document for Therapeutic Comparative Advertising Claims.

12. Natural Health Product Regulatory Compliance

ASC has become concerned about violative NHP advertising that cannot be

accommodated under ASC's Drug Complaint Procedure. An example to illustrate the point was provided. The increased incidence of violative NHP advertising creates an unfair playing field for sponsors of authorized nonprescription drug products. HC is aware of this issue and reiterated that advertising of NHPs which do not have a NPN cannot occur. If advertising poses a safety concern or if ASC is unable to achieve compliance, the complaint should be submitted to HC. The PAAB indicates that they have referred to HC a number of complaints about unauthorized NHP advertising throughout the years and actions have been taken by HC to instruct advertisers to stop the advertising.

Action: HC (NHPD) to consider the possible revision of the NHP Compliance Policy to add advertising to the Risk-based Approach for NHPs (since advertising increases consumer exposure to the product, this may increase the risk posed by an unauthorized product).

At the last meeting, the possibility of developing a database similar to the drug product database was explored in order to provide updates to advertising preclearance agencies as to the regulatory status of NHPs. This presents technical challenges and preferred approach is the Market Notification policy.

Action: HC (NHPD) is drafting a policy on Market Notification which will be shared with stakeholders including PAAB and ASC. Once the policy is finalized, the information on issued product licences would be available on the Web within 60 days of issuance of product licence.

13. PAAB Membership

The PAAB Board will welcome the Best Medicines Coalition as a new member as of April 22, 2005. The Consumers Association of Canada is no longer a voting member of the PAAB Board.

14. Next Meeting

It is suggested to have the next meeting prior to the fall PAAB Board meeting which is scheduled for November 17, 2005. Thus, the next trilateral meeting will be scheduled either in October or early November 2005 (date, time and location to be determined).

Original Signed by

Cindy Evans, A/ Director, for David Clapin, A/DG, MHPD
Policy and Partnerships Division
Marketed Health Products Directorate