

## MARKETING PRACTICES REVIEW COMMITTEE

### Report on Code Infractions #51 – October 1, 2003 to December 31, 2003

#### 1. Company and Issue: Janssen-Ortho Inc. *The Pariet First Program.*

**Discussion:** According to the Company's documentation on the program, it "*was designed to assist physicians in gaining important experience with Pariet, within approved indications, so as to better understand the drug and make decisions regarding its appropriateness in their own clinical practice... The purpose of the program is to provide you with experience assessing Pariet in your GERD patients with heartburn as their predominant symptom, and to facilitate your comparison of actual versus expected outcomes when patients use Pariet... Approximately 350 physicians across Canada will be asked to evaluate Pariet in 4,000 – 6,000 patients... The program is not a clinical trial; rather, it is a means of providing you with relevant feedback, which may contribute to your experience in treating patients who are initiated on Pariet... Patients will be assessed prior to initiating Pariet. This symptom assessment will include the first day, as well as a daily assessment up to day 6 after initiation of Pariet. You will be asked to complete the Initial Assessment Form, and another one at the regularly scheduled follow-up visit.*"

Participating physicians were provided with an honorarium of \$500.00 "*to address administrative costs associated with participating in the program,*" and with an additional \$500.00 honorarium "*for preparation, and attendance, at an advisory board meeting... (at which) you can discuss with other practitioners your results from, and opinions on, this program.*"

In correspondence to the MPRC, the Company described the role of sales representatives in the program as "*only to the extent that they informed physicians of the program's availability... delivered the program kit and guidelines to physicians that chose to participate... and delivered the administration portion of the honoraria (\$500.00) to physicians.*" Notwithstanding the foregoing, the Company's documentation on the program contained the following statement: "*If you have any questions about this program, please contact your Janssen-Ortho representative.*"

**Decision:** Despite the Company's description of the program as "*not a clinical trial,*" the MPRC ruled that the program was a clinical study as defined in Section 9.1. of the Code, namely, a study carried out after the issuance of a Notice of Compliance by Health Canada, and that the information sought through the exercise is addressed in Section 9.2.1 which describes some of the goals of Post Registration Clinical Studies. As a consequence, the MPRC ruled the program to be in contravention of Section 9.2.5 as it did not comply with the requirements for the conduct of Post Registration Clinical Studies as outlined in that sub-section.

The MPRC also ruled the program to be in contravention of Section 9.2.4 which prescribes that the role to be played by sales representatives in the conduct of such studies "*must be limited to the distribution and collection of materials pertinent to the study...*"

**Further Discussion:** In providing additional comments on the program, the Company cited a decision by the MPRC that one of their previous programs – *Switch to and Assessment of Risperdal Treatment (START)* program constituted market research, and mentioned the "*close correlation between the START program and the Pariet First Program.*" Accordingly, in the Company's view, the Pariet First Program should also have been ruled to be market research.

The Company also cited an opinion expressed on Post Registration Clinical Studies by the Arbitrator of the Company's appeal of the MPRC's decision on their START program.

During their additional deliberations, members of the MPRC noted the limited information requested of participants in the START program, as opposed to the extensive information being sought through the *Pariet First Program*, for example, "*current diagnosis,*" "*current symptoms,*" "*interference with daily activities,*" "*symptom intensity,*" and "*treatment evaluation.*" The collection of such information, in the opinion of members of the MPRC, necessitated healthcare practitioners' observation and evaluation of the patients on *Pariet*, including the clinical use of the medicine. They therefore concluded that such activity cannot be deemed to be market research.

**Decision:** Contravention of Sections 9.2.4 and 9.2.5, affirmed by the MPRC.

## **2. Company and Issue:** Janssen-Ortho Inc. *The Reminyl Experience Program.*

**Discussion:** According to the "*Guidelines for Physicians...*" documentation provided by the Company, the program was designed to "*provide physicians with direct clinical experience with Reminyl for new patients; increase physician and caregiver confidence and satisfaction with Reminyl, based on its ease of use and tolerability; and collect feedback from physicians on the ease of use and on caregiver and physician satisfaction with Reminyl.*" As with the *Pariet First Program*, the Company's literature on the *Reminyl Experience Program*, contained the statement that the activity "*is not a clinical trial.*"

Participating physicians were offered an honorarium of \$250.00 "*in respect of the physician enrollment portion of the program to cover time spent in completing administrative paperwork regardless of the number of patients assessed.*"

The program required the physicians to carry out a "*Baseline Assessment*" by completing the "*Mini-Mental State Examination (MMSE), a 30-point scale designed to assess a patient's cognitive performance in a clinical setting... and recording the baseline score,*" and the documentation provided instructions for administering the MMSE. In addition, the Company's program binder contained "*all forms necessary to screen a patient for Alzheimer Disease and apply for Reminyl formulary coverage.* Physicians were then required to "*rate your satisfaction as well as your perception of the caregiver's satisfaction with memory; activities of daily living such as dressing, bathing, and toileting; behaviour such as moodiness, lack of interest, and anxiety; and overall patient status before Reminyl.*"

The Company provided four weeks supply of Reminyl, and physicians were asked to submit the formulary forms "*for at least the remaining 8 weeks of the Experience Program.*" On completion of the 12 weeks, physicians were required to complete "*the 12 week Follow-up Assessment regarding your satisfaction and ease of use of Reminyl in the patient as well as your perceptions of both the caregiver's satisfaction and the caregiver's ease of use of Reminyl in the patient.*"

Finally, the Program provided for an *Advisory Board* to be held "*to discuss the results.*" For participation in the *Advisory Board*, physicians were offered "*a \$500.00 honorarium regardless of the number of patients assessed.*"

In elaborating on its position, the Company also stated that the program was modelled after its START Program (See Item #1), cited "*the close correlation between the START Program and*

*the REMINYL Experience Program,*” and again made reference to some of the comments on the ruling of the Arbitrator in the appeal of the MPRC’s decision on the START program.

**Decision:** The MPRC ruled that the program was a clinical study as defined in Section 9.1 of the Code, namely, a study carried out after the issuance of a Notice of Compliance by Health Canada, and that the information sought through the exercise is addressed in Section 9.2.1 which describes some of the goals of Post Registration Clinical Studies. As a result of the foregoing, the Committee ruled the activity to be in contravention of Sections 9.2.3 - lack of clearly defined goal amenable to scientific review and testing - and 9.2.5 as it did not comply with the requirements for the conduct of Post Registration Clinical Studies as outlined in that sub-section.

**3. Company and Issue:** Janssen-Ortho Inc. *“Extensive market promotion using an unpublished study poster of dubious quality.”*

**Discussion:** Violations of various sections of the Code of Advertising Acceptance of the Pharmaceutical Advertising Advisory Board.

**Decision:** Violation of Section 2.2.1 of the Rx&D Code.

#### SUMMARY – REPORT #51

<b>Company</b>	<b>Category and Number of Infractions</b>	<b># Infractions 12-month period</b>
Janssen-Ortho	Post Registration Clinical Studies – 1	11
Janssen-Ortho	Post Registration Clinical Studies – 1	12
Janssen-Ortho	Advertising & Info. Dissemination – 1	1

#### MARKETING PRACTICES REVIEW COMMITTEE

##### Report on Code Infractions #52 – January 1, 2004 to April 30, 2004

**1. Company and Issue:** AstraZeneca Canada Inc. Event entitled *“International Continuing Health Education Meeting,*” held October 2- 5, 2003, Ritz Carlton, Jamaica.

**Discussion:** The Company confirmed that the scientific program took place October 3-4, 2003, and *“was an international CHE meeting in regard to both faculty and attendees.”* It further advised that *“... as per Section 4B of the Code of Marketing Practices, no physicians were invited to this meeting. Each attendee sent a letter requesting sponsorship to this meeting, and in return AZ sent a letter in response requesting the physicians to present pertinent information to a Canadian audience upon their return.”*

The Company provided the MPRC with a copy of the letter from one physician requesting support to attend the event, as well as a copy of the response by AstraZeneca to the physician in question. The former was addressed to a GI Specialist Sales Representative of AstraZeneca who was named in the correspondence, and the latter included the following statement: *“Our expectation is that upon your return you will share key learning’s through presentations to fellow healthcare practitioners.”*

AstraZeneca confirmed that “*Grants did provide for travel for the physician (that) spousal travel was not provided for (and that) if the physician chose to bring a spouse, a registration fee of \$800.00 was collected.*”

The Company further advised that “*On October 1 and 2, we had consultants address ‘frequently asked questions’ by family physicians in a video taping session. ‘This will facilitate the development of a CME program for family physicians in Canada.’ According to the Company, ‘... participants signed a written contractual agreement outlining the nature of the services to be provided. Remuneration was in the form of an honorarium in the amount of \$1,000.’*”

During further investigation by the MPRC of this matter, a physician attendee at the event confirmed that he did not approach AstraZeneca for financial support to attend but rather, that two of the Company’s representatives, whom he named, invited him to attend the event, and offered to provide financial support to facilitate his attendance.

**Decision:** The MPRC ruled that by paying the travel and accommodation expenses of attending physicians, the Company contravened Section 4A3.5 of the Code which permits such payments only to “*healthcare practitioners who speak at or moderate CHE programs.*”

**2. Company and Issue:** Aventis Pharma Inc. Item entitled “*Symposia Reporter September 2003 – ACE Inhibitors and ARBs for Risk Reduction*” (sponsored) in at least four publications.”

**Discussion:** Contravention of Code of Advertising Acceptance of the Pharmaceutical Advertising Advisory Board.

**Decision:** Automatic contravention of Section 2.2.1 of the Rx&D Code.

**3. Company and Issue:** Bayer Inc. Distribution of white pencils bearing inscription “*Avelox I.V.*”

**Discussion:** Item does not meet the definition of “*acceptable service-oriented item.*”

**Decision:** Contravention of Sections 11.1 and 11.2.

**4. Company and Issue:** Bayer Inc. “*Bayer Healthcare Cut and Go Program.*”

**Discussion:** An invitation was extended by “*The Bayer Healthcare Team... to attend our Back to School Cut and Go Program, Saturday, September 6, 2003 between 10 a.m. and 3 p.m. at The Head Shoppe located 3<sup>rd</sup> level in Brunswick Square.*” Invitees were asked to call The Head Shoppe before August 31 to arrange for an appointment “*with (an) award winning designer... for yourself, a spouse, or your children.*” The service offered included a shampoo, cut and blow-dry. The invitation also contained the following statement: “*While waiting for your appointment or for your family to finish (approximately 15-30 mins) a Bayer Healthcare Representative will talk to you about our products. ‘Our goal for this program is simple, we want to determine how our team can provide more value to your patients and practice in the future. ‘When the hair is set you’re set to go! Bayer Healthcare takes care of the cost.’*” The invitation also included the name and telephone number of a Bayer representative.

**Decision:** The program was found to contravene Section 8.2.4 of the Code – unprofessional conduct of a representative, Section 8.2.7 – payment for access to a healthcare practitioner, and Section 11.1 – conduct of an inappropriate special promotion.

(A total of two contraventions as two sections of the Code were involved).

**5. Company and Issue:** Boehringer-Ingelheim (Canada) Ltd. Distribution to healthcare practitioners of a “*lenticular pad*,” a promotional tool containing graphics of a man on a bed with the sun in the background, and bearing the tagline “*Good Morning, Micardis.*”

**Discussion:** The Company described the item in question as follows: “*A lenticular pad which is designed to detach from the leave behind. The lenticular works in the following way: when flat, a visual of a man on a bed in a field and the Micardis tagline will be displayed. When tilted, the man on the flat bed on tracks will be displayed. The back of the lenticular will provide the physician with an easy reference for the Circadian Rhythm Chart.*” In addressing the Committee’s expressed opinion that the item in question constituted a mouse pad, the Company stated that the “*tool was designed to help illustrate the circadian variation of blood pressure, highlighting specifically the morning blood pressure surge.*”

The Committee noted that the Circadian Rhythm Chart was placed on the reverse side of the pad which was, in turn, attached to the sales aid, and that the Chart could only be accessed or viewed by the healthcare practitioner if the pad were removed from the sales aid. Members also noted that an anti-skid coating was used on the reverse side of the item, and that a clear release liner was provided in order to access the anti-skid surface which would facilitate the use of the item as a mouse pad.

**Decision:** The Committee concluded that the primary intent of the item was not to provide an easy reference for the Circadian Rhythm Chart because (1) the Chart could only be accessed if the pad were removed from the sales aid, and (2) an anti-skid coating was used on the reverse side, with a clear release liner to facilitate access to the anti-skid surface, and use of the item as a mouse-pad. The “*lenticular pad*” was ruled to be in contravention of Sections 11.1 and 11.2 of the Code.

**6. Companies and Issue:** Bristol-Myers Squibb and Sanofi-Synthelabo. A mailing to pharmacists in October 2003 “*promoting the sale of Plavix.*”

**Discussion:** Contravention of Code of Advertising Acceptance of the Pharmaceutical Advertising Advisory Board.

**Decision:** Automatic contravention of Section 2.2.1 of Rx&D Code.

**7. Company and Issue:** Hoffmann-La Roche Limited. Distribution of a waist measurement tape encased in a white plastic container bearing the inscription “*Xenical – Orlistat – Roche – LI 95 63B 00.*”

**Discussion:** Members of the MPRC noted that the tape contained markings to assist in measuring weight gain, however, the view was that the tape could be used for other measuring purposes. The MPRC also discussed additional information provided by the Company to the effect that “*there is solid scientific evidence showing that waist circumference is a clinically relevant measurement...*” While respecting the Company’s position on the tapes, Committee members were unanimous in the opinion that while the tapes can be considered a “*useful*” tool for physicians, they are “*not necessary*” to diagnose the condition of obesity. Further, Committee members affirmed that healthcare practitioners have a responsibility to acquire whatever devices/ tools are necessary to the practice of their particular area of medicine.

**Decision:** The item contravenes Sections 11.1 and 11.2.

**8. Company and Issue:** AstraZeneca Canada Inc. *The Symbicort Passport Program.*

**Discussion:** According to the Company’s documentation on the program, it was designated as “a value-added compliance program for patients who are symptomatic on current doses of asthma maintenance therapy (i.e., inhaled corticosteroid) or taking a combination of inhaled corticosteroid + long-acting B2-agonist. The Symbicort Passport Program is designed to enhance compliance and satisfaction with Symbicort while helping patients gain and maintain control of their asthma.” The documentation outlined the “Steps” to be followed by participating physicians with patients and with the “Program Coordination Centre” as well as the nature of the interaction between the Program Coordination Centre and the patients involved.

In examining information and materials on the Program, MPRC members noted the following, in addition to the information given in the preceding paragraph:

- ❑ The physician is required to carry out a patient assessment at the start of the program, complete the registration form, provide the Patient Kit, samples of Symbicort, and instruct the patient in the correct use of Symbicort. There is no follow up with the physician who does not see the patient again;
- ❑ The “Program Overview” was signed by the Product Manager for Symbicort, not by a member of the medical department;
- ❑ Within 30 to 35 days, patients receive a phone call from a “healthcare professional at the Program Coordination Centre” to answer questions and to inquire about ... “compliance, satisfaction, ease of use, and current level of asthma control”;
- ❑ At the end of the call back period, the physician receives “an aggregate report with the results ... from the call back questions; and finally,
- ❑ The “Applicant Consent” form contained the following statement: “I authorize and direct my physician to provide clinical information...”

**Decision:** The MPRC ruled “*The Symbicort Passport Program*” to be a post registration clinical study as defined in Section 9 of the Code, and that the program contravened Sections 9.2.5 and 9.2.6 of the Code as it did not comply with those sections.

**Appeal:** The Company filed an appeal of the MPRC’s decision on the program and an appeal was heard on June 9, 2004. The Arbitrator rejected the position put forward by the Company, and upheld the ruling of the MPRC.

**SUMMARY – REPORT #52**

<b>Company</b>	<b>Category and Number of Infractions</b>	<b>#Infractions 12-month period</b>
AstraZeneca	Continuing Health Education – 1	1
AstraZeneca	Post-Registration Clinical Studies – 1	2
Aventis Pharma	Advertising & Info. Dissemination – 1	2

Bayer	Service-Oriented Items – 1	2
Bayer	Reps. of Pharma Companies (2 infractions within the same section of the Code) - 1	3
	SOI Special Promotion – 1	4
Boehringer-Ingelheim	Service-Oriented Item – 1	1
Bristol-Myers Squibb	Advertising & Info. Dissemination – 1	1
Hoffmann-La Roche	Service-Oriented Items – 1	1
Sanofi-Synthelabo	Advertising & Info. Dissemination – 1	1