Summary of Expertise, Experience and Affiliations and Interests for the Scientific Advisory Panel on Bioequivalence Requirements for Modified Release Dosage Forms (SAP-MRDF)

Purpose of the Summary

The following summarizes the information about expertise or experience, affiliations and interests relevant to the Scientific Advisory Panel on Bioequivalence Requirements for Modified Release Dosage Forms (SAP-MRDF) mandate declared by panel members. Health Canada considers these declarations as part of the selection process. The Health Products and Food Branch has made this summary available as part of its commitment to be transparent about the membership of its advisory bodies.

Assessment of affiliations and interests prior to each meeting

Prior to the panel meeting, Health Canada assesses members' affiliations and interests, including direct financial interests, as they may apply to agenda items for discussion. Depending on the nature of the member's affiliations or interests, the Chair of the panel in consultation with the members, may limit the participation of a member in the meeting or ask him/her to make a verbal statement of affiliations and interests at the beginning of the meeting. Members' affiliations and interests are reviewed and updated as required, based on the changes in the status of their affiliations and interests.

In accordance with the Health Products and Food Branch Review of *Regulated Products: Policy on Public Input and Guidance on Advisory Bodies*, a person with a direct financial interest in the outcome of a review of a regulated product may be a member of an advisory body whose broader mandate encompasses matters of policy, management, or program development. However, such a member would not be asked to participate in any discussion, formulation of advice, or recommendations to Health Canada relating to that review.

Indicated [Sector/Perspective]

- Health professional
- Research
- Academia

Indicated [Expertise/Experience]

- Cardiology
- Psychiatry
- Pharmacokinetics
- Pharmacology

1) **Direct financial interests**

   a) Current employment, investments in companies, partnerships, equity, royalties, joint ventures, trusts, real property, stocks, shares or bonds, with the regulated industry.

2) Indirect financial interests

a) Within the past five years, payment from regulated industry for work done or being done, including past employment, contracts or consulting; or financial support including research support, personal education grants, contributions, fellowships, sponsorships, and honoraria.[1]

b) Within the past five years, materials, discounted products, gifts, or other benefits, or attendance at meetings where all or part of the travel and accommodation costs were provided by the regulated industry.[2]

c) Within the last three years, grants or other funding from the regulated industry to any of the organizations where you are currently employed or participate in internal decision making.[3]

3) Intellectual interests

a) Within the last five years, any formal advice or opinion to industry, a government organization, or a non-government organization, on a matter of relevance to the SAP-MRDF mandate.

b) Within the past five years, any published or publicly stated point of view on issues of relevance to the SAP-MRDF mandate.

c) Current professional or volunteer affiliations such as membership of professional societies, lobbying, public interest or advocacy groups, of relevance to the SAP-MRDF mandate.

4) Other

a) Any other affiliations and interests or potential circumstances that might give a well informed member of the public reasonable grounds for concern regarding the integrity and objectivity of your participation in the SAP-MRDF.

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1 Other than from present employer.

2 Other than from present employer, over $1,000.

3 "Participate in internal decision making" means as a board member, or as an executive or non-executive director.

Name and Indicated Sector/Perspective and Expertise/Experience		Summary of Responses
Jake Thiessen, PhD (Chair)	Academia Pharmaco-kinetics	1a) No | 2a) Yes | 2b) No | 2c) No | 3a) Yes | 3b) Yes | 3c) Yes | 4a) No **Comments:** Consultant in scientific, business and regulatory issues for various pharmaceutical companies. Since 2005, has been the Chair for Health Canada's Scientific Advisory Committee on Bioequivalence and Bioavailability. Provided expert testimony to the Tax Court of Canada. Has published numerous articles on Bioequivalence and Bioavailability. Member of the Canadian Society of Pharmaceutical Scientists and the American Association of Pharmaceutical Scientists.
Robert Herman, MD, FRCPC	Health Professional Academia Pharma-cology	1a) No | 2a) No | 2b) Yes | 2c) No | 3a) Yes | 3b) No | 3c) Yes | 4a) No **Comments:** Travel and accommodation costs have been paid when attending scientific meetings for the American Society of Hypertension, the American College of Cardiology and the Aliskiren Advisory Board. Has been an expert witness for a drug product legal challenge. Volunteered as a member on the Health Canada's Scientific Advisory Committee on Bioequivalence and Bioavailability and Alberta Blue Cross/Alberta Health and Wellness Expert Committee. Currently member of the Canadian Hypertension Society, and Chair of the subcommittee on treatment of hypertension in adults without confounding indications for specific agents.
Eugenia Palylyk-Colwell, BSc, Pharm, PhD	Academia Pharmaco-kinetics	1a) No | 2a) Yes | 2b) Yes | 2c) No | 3a) Yes | 3b) No | 3c) No | 4a) No **Comments:** Has participated in panels, and has written reports, articles, clinical summaries, etc. for various pharmaceutical companies. All travel and accommodations costs were paid by pharmaceutical companies when travel was required. Member of the Pharmacokinetic Working Group, a subgroup of the Alberta Health and Wellness Expert Committee as well as a consultant for Alberta Blue Cross/ Alberta Health and Wellness and an external clinical reviewer for the Common Drug Review, Canadian Agency for Drugs and Technologies in Health.
John Parker, MD, FRCPC	Health professional Academia Cardiology	1a) No | 2a) No | 2b) Yes | 2c) No | 3a) No | 3b) No | 3c) No | 4a) No **Comments:** Guest speaker for a pharmaceutical company at a Continuing Medical Education event.
Philippe Robaey, MD, PhD, FRCPC	Health Professional Academia Psychiatry	1a) No | 2a) No | 2b) No | 2c) No | 3a) Yes | 3b) No | 3c) No | 4a) No **Comments:** as an expert in a Patented Medicine Price Review Board proceeding.
Daniel Sitar, PhD	Academia Pharma-cology	1a) No | 2a) Yes | 2b) Yes | 2c) No | 3a) Yes | 3b)Yes | 3c) Yes | 4a) No **Comments**: Has received research grants and partial reimbursement costs for a podium presentation from pharmaceutical companies. Is a continuing member for the Health Canada's Scientific Advisory Committee on Bioequivalence and Bioavailability as well as past member the Scientific Advisory Panel on Fentanyl Transdermal Delivery Systems. Participated in a Health Canada mediation panel. Is a consultant for a pharmaceutical company. Has published numerous articles relating to Bioequivalence and Bioavailability and is an active member on numerous associations.