



## Scientific Advisory Committee on Respiratory and Allergy Therapies (SAC-RAT) Agenda

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**Place:** 1600 Scott Street, Ottawa, Ontario  
Holland Cross, Tower B, Room 2048

**Date and Time:** March 14, 2012/8:30am-4:00pm

**Chairperson:** Irvin Mayers

**Science Advisor:** Bob Li

**Science and Regulatory Officer:** Erica Harnett

**Participants:** SAC-RAT Members, Health Canada representatives

**SAC-RAT members:** Don Cockcroft, Myrna Dolovich, Allan Donner, Alan Kaplan, Redwan Moqbel, Parameswaran Nair, William Racz, Don Sin, Robert Schellenberg, William Swan, Susan Waserman

**Health Canada representatives:** Kimby Barton, Jatinderpal Raj Deol, Gail Grant, Dominique Heon, Barbara J. Sabourin, Ajaykumar Thaker, Violina Thomas, Jun Zhang

- 8:30am - 9:00am    **Refreshments**
- 9:00am - 9:05am    **Opening Remarks** (Barbara J. Sabourin, Therapeutic Products Directorate)
- 9:05am - 9:15am    **Review of the Agenda, Declaration of Affiliations and Interests, Introduction of New Member, Announcement of *ad hoc* member change to core member status** (Chair/SAC-RAT Members)
- 9:15am - 9:25am    **Review and Acceptance of Terms of Reference** (Chair/SAC-RAT Members)
- 9:25am - 9:30am    **Introduction of issues** (Ajaykumar Thaker, Bureau of Cardiology, Allergy and Neurological Sciences)
- 9:30am - 10:30am    **Review of Kelly *et al's* paper: Eosinophilic bronchitis in asthma: A model for establishing dose-response and relative potency of inhaled corticosteroids** (J Allergy Clin Immunol, 2006)
- a) Presentation (Bob Li, Yongmin Yu, Bureau of Policy, Science and International Programs)
  - b) Questions and Discussions (SAC-RAT members and Health Canada representatives)

10:30am - 10:45am **Break**

10:45am - 11:30am **Sputum Eosinophils: Review of comments from 60-day consultation period and questions to the committee [*Draft Guidance Document: Data Requirements for Safety and Effectiveness of Subsequent Market Entry Inhaled Corticosteroids Products for Use in the Treatment of Asthma (SME ICS)*]**

- a) Introduction
- b) Discussions (Chair/SAC-RAT Members)

11:30am - 12:30pm **Lunch**

1:00pm - 1:45pm **Other issues: Review of comments from 60-day consultation period and questions to the committee (*Draft Guidance Document: Data Requirements for Safety and Effectiveness of Subsequent Market Entry Inhaled Corticosteroids Products for Use in the Treatment of Asthma*)**

- a) Introduction
- b) Discussions (Chair/SAC-RAT Members)

1:45pm - 2:45pm **Committee Recommendations: Response to Questions concerning safety and efficacy requirements for SME ICS in the treatment of Asthma (Chair/SAC-RAT members)**

2:45pm - 2:55pm **Break**

2:55pm - 3:55pm **Committee Recommendations (cont'd): Response to Questions concerning safety and efficacy requirements for SME ICS in the treatment of Asthma (Chair/SAC-RAT members)**

3:55pm - 4:00pm **Next steps, Closing Remarks and Adjournment of Meeting**

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