



## **Scientific Advisory Committee for Bioavailability and Bioequivalence:**

### **Announcement of meeting and invitation to participate in associated workshop**

This notice announces a forthcoming meeting of the Health Products and Food Branch Scientific Advisory Committee on Bioavailability and Bioequivalence (SAC-BB) and associated workshop. The workshop, which is to precede the SAC-BB meeting, will be open to all stakeholders and participation is hereby invited.

#### **Mandate of the SAC-BB**

To provide on-going and timely scientific, medical and clinical advice on current and emerging issues related to the work of the Therapeutic Products Directorate (TPD) pertaining to bioavailability and bioequivalence of drugs.

For more details, please refer to the Terms of Reference of the SAC-BB at:

[http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index\\_activities\\_committees\\_e.html#3](http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_activities_committees_e.html#3)

#### **Workshop format**

The structure of the workshop on 3 June 2004 is intended to allow for more direct stakeholder involvement in policy development and greater transparency. All stakeholders are invited to attend this workshop. Only two topics will be dealt with in order to give adequate time to fully deliberate and finalize each issue. The working language of this meeting will be English.

After brief inaugural presentations, the first topic to be discussed (outliers and inadequate profiles) will be introduced. Selected invited stakeholders will make a series of 10-minute presentations on the topic, based on experience with these issues. A panel discussion (moderated by the Chair of the SAC-BB) will ensue. The panel discussion will be restricted to the SAC-BB members and invited presenters. These discussions will however be open for all to hear/observe. This will be followed by open discussion, permitting observers and members of the greater audience to provide input. The same process will be repeated for the second topic (add-on studies as described in Guideline A).

On 4 June 2004, the SAC-BB will deliberate on the issues in a closed meeting before making their final recommendations to Health Canada (HC.)

## **Agenda**

The detailed agenda for the workshop will be posted at a later date at:

[http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index\\_activities\\_committees\\_e.html#3](http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_activities_committees_e.html#3)

In preparing presentations or comments, we ask that you consider fundamental questions as outlined below.

### **OUTLIERS/INADEQUATE PROFILES**

1. What criteria should be used to define an adequately characterized concentration-time profile? When can subjects with inadequate profiles be removed from the statistical analyses of the study data without negating the validity of the study?
2. How should outliers be identified and how should data for these subjects be analysed?

### **ADD ON STUDIES**

1. Should add-on studies continue to be permitted? If so, should more stringent requirements apply?

## **Procedure**

If you wish to attend the workshop, please inform the contact person identified below, by 3 May 2004. There is no charge for registration. However, the information is necessary for planning, as the number of registrants will determine the venue for the meeting.

If you wish to make a presentation(s) please submit a brief abstract (limit one page) of your proposed presentation along with a copy of your curriculum vitae, including contact information, to the contact person identified below by 10 May 2004. Unfortunately we can only accommodate a limited number of presentations as indicated in the agenda. Presenters will be selected based on the material submitted. We will endeavour to ensure that all groups of stakeholders are represented.

It is expected that not all interested stakeholders will be able to attend the meeting. If you are unable to attend the meeting and wish to comment on the issues in writing, please do so by 17 May 2004. You may submit comments by mail or e-mail to the contact person identified below.

## **Date and times**

Workshop: 3 June 2004 (08:30 to 16:30)

SAC-BB deliberations: 4 June 2004 (08:30 to 16:00)

Deadline for registration for the meeting: 3 May 2004

Deadline for submission of abstracts to be considered for presentations: 10 May 2004

Deadline for submission of written comments: 17 May 2004

Deadline for submission of electronic presentations: 24 May 2004

Presentation times will be posted in the agenda at a later date.

## **Location**

Ottawa. The precise venue for the meeting is to be confirmed based on the number of registrants. Details of the venue will be announced on the HC website as soon as they are confirmed.

## **Contact Person**

Ms. Marilyn Davis  
Therapeutic Products Directorate  
Tower B, Holland Cross, A.L. 3102C3  
1600 Scott St.  
Ottawa, Ontario K1A 1B6

Telephone:(613) 957-6260

Facsimile: (613) 941-5035

e-mail: [Marilyn.Davis@hc-sc.gc.ca](mailto:Marilyn.Davis@hc-sc.gc.ca)

Please complete the following form (attach abstracts and CV if necessary) and return by fax or email.

## Scientific Advisory Committee for Bioavailability and Bioequivalence

| <b>WORKSHOP REGISTRATION FORM</b><br><b>JUNE 3, 2004, OTTAWA*</b>    |                                     |                          |
|--|-------------------------------------|--------------------------|
| NAME   | TITLE                               |                          |
| ORGANIZATION   |                                     |                          |
| ADDRESS  |                                     |                          |
| CITY   | PROVINCE                            | POSTAL CODE              |
| PHONE  | FAX                                 | EMAIL                    |
| <b>REGISTRATION REQUIREMENTS (PLEASE CHECK)</b>                      |                                     |                          |
| REQUEST PRESENTER STATUS   | <input type="checkbox"/>            |                          |
| REQUEST PRESENTER STATUS BUT WILL ATTEND AS OBSERVER IF NOT SELECTED | <input type="checkbox"/>            |                          |
| WISH TO PRESENT ON:<br>ATTACH ABSTRACT(s) & CV TO<br>FORM            | #1 OUTLIERS AND INADEQUATE PROFILES | <input type="checkbox"/> |
|  | #2 ADD-ON STUDIES                   | <input type="checkbox"/> |
| REQUEST OBSERVER STATUS ONLY   | <input type="checkbox"/>            |                          |
| <b>COMMENTS (ATTACH SHEETS IF NECESSARY)</b>                         |                                     |                          |
|  |                                     |                          |

\*Exact location of workshop to be determined based on number of registrations. Details will be posted on the Health Canada Website.