Expert Advisory Committee on Bioavailability and Bioequivalence:

Announcement of meeting and invitation to participate in associated workshop

Ottawa, Ontario
June 26, 2003

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

MANDATE OF THE EAC-BB

To provide on-going and timely medical, scientific and clinical advice on current and emerging issues related to HC's work pertaining to bioavailability and bioequivalence of drugs.

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

http://www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/advcomm_eacbb.html

WORKSHOP FORMAT

The structure of the workshop on 26 June 2003 is intended to allow for more direct stakeholder involvement and greater transparency in policy development. All stakeholders are invited to attend this workshop. Only two topics will be dealt with in order to give adequate time to fully address and deliberate each issue. The working language of this meeting will be English.

There will be an introductory presentation on the first topic to be discussed (***highly variable drugs***). Selected invited stakeholders will then make a series of 10-minute presentations on the issue. A facilitated discussion open to all present will ensue permitting observers and members of the audience to provide input. The same process will be repeated for the second topic (***requirements for food effect studies***).

On 27 June 2003, the EAC-BB will deliberate the issues *in camera* before making their final recommendations to HC.

AGENDA

The detailed agenda for the workshop has not yet been finalized. The brief summaries below outline the current status of the issues to be discussed. Once completed, the agenda and all relevant discussion papers will be posted on Health Canada's web site (URL above.)

Highly variable drugs

Health Canada does not currently have any specific guidance or make any specific allowances with respect to bioequivalence requirements for highly variable drugs. It is expected that the study design, for example the number of subjects, will take variability into consideration. It is Health Canada's intention to explore the need for special bioequivalence requirements with respect to highly variable drugs. A discussion paper on this issue is currently being developed and will be posted on this website before the June meeting.

Requirements for food effect studies

This discussion is intended to examine the need for food-effect comparative bioavailability studies in general (all submissions types), with a view to developing a general guidance document on this issue. Currently, comparative bioavailability studies under fed conditions are normally required, in addition to studies under fasted conditions, for modified-release products, highly toxic and narrow therapeutic range (critical dose) drugs and drugs exhibiting non-linear pharmacokinetics. In some cases it may also be possible to justify conducting a study under fed conditions in lieu of a fasted study. A discussion paper on this issue is currently being developed and will be posted on this website before the June meeting.

PROCEDURE

Based on feedback and comments received after our first workshop in November 2002, there will be some changes to the procedure, and **DEADLINES WILL BE ENFORCED**. If you wish to attend the workshop as an observer, please inform the contact person identified below before **30 May 2003.** There is no charge for registration, however the registration form must be completed as the information is necessary for planning and accommodation purposes. Registration is limited to 60 persons, and will be accepted on a first-come, first served basis. However, in order to allow the widest possible representation, registration may be limited to one individual per organization.

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 **30 May 2003**. Unfortunately we can only accommodate a limited number of presentations based on available time. Presenters will be selected based on the material submitted. We will endeavour to ensure that all groups of stakeholders are represented. If we do not receive your abstract by the due date, you will not be allowed to present. An electronic copy of your final presentation must be submitted to HC before end of day, **20 June 2003**. There will be **NO EXCEPTIONS**.

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 discussion papers in writing, please do so by **20 June 2003**. You may submit comments by mail or e-mail to the contact person identified below. In preparing presentations or comments, we ask that you consider the above summaries and the discussion papers which will be posted on the HC web site.

Registration will be confirmed by email to as many applicants as we can accommodate (limited by room size.)

DATE AND TIMES

Workshop: 26 June 2003 (08:30 to 16:30) (times approximate)
EAC-BB deliberations: 27 June 2003 (08:30 to 16:00) (times approximate)
Deadline for registration for the meeting: 30 May 2003
Deadline for submission of abstracts to be considered for presentations: 30 May 2003
Deadline for submission of written comments: 20 June 2003
Deadline for electronic copy of presentations to reach HC: 16:00 (Eastern time) 20 June 2003

Please see the agenda to be posted on HC website for approximate presentation times.

LOCATION

Lord Elgin Hotel, Pearson Room
100 Elgin Street
Ottawa, Ontario
K1P 5K8
Tel: 613-235-3333
Fax: 613–235-3223
http://www.lordelginhotel.ca/

Additional details will be announced on the HC website as soon as they are confirmed.

CONTACT PERSON

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http://www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/advcomm_eacbb.html

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

Expert Advisory Committee for Bioavailability and Bioequivalence

WORKSHOP REGISTRATION FORM
JUNE 26, 2003, OTTAWA*

NAME	TITLE	
ORGANIZATION		
ADDRESS		
CITY	PROVINCE	POSTAL CODE
PHONE	FAX	EMAIL

REGISTRATION REQUIREMENTS (PLEASE CHECK) ✔

REQUEST PRESENTER STATUS (WILL ATTEND AS OBSERVER IF NOT SELECTED)		
WISH TO PRESENT ON: ATTACH ABSTRACT(s) & CV TO FORM	#1 HIGHLY VARIABLE DRUGS	
	#2 REQUIREMENTS for FOOD-EFFECT STUDIES	
REQUEST OBSERVER STATUS ONLY		

COMMENTS (ATTACH SHEETS IF NECESSARY)

* Further details will be posted on the Health Canada Website as they become available.