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2003-03-12

Therapeutic Products Directorate (TPD)

BIOAVAILABILITY and BIOEQUIVALENCE
Expert Advisory Committee

AGENDA

PURPOSE: EAC - BB Meeting
PLACE: Lord Elgin Hotel, Pearson Room
DATE: March 13th & 14th, 2003

PARTICIPANTS:
Jake Thiessen, (CHAIR) ___, Jean-Guy Besner ___, Allan Donner ___, Robert Herman ___, Fakhreddin Jamali ___, Mohamedtaki Kara ___, Jean-Norbert McMullen ___, Rama Nair ___, Eugenia Palylyk-Colwell ___, William Racz ___, Ken Renton ___, Dan Sitar ___, France Varin___, Scott Walker___

Health Canada Representatives:
Lu_ning Cui ___, Leslie Cockell ___, Gary Condran ___, Marilyn Davis ___, Christine Ficker ___, Sultan Ghani ___, Kader Kourad ___, Celia Lourenco ___, Abiola Makinde ___, Anna Melnyk ___, Arvin Naperstkow ___, Eric Ormsby ___, Conrad Pereira ___, Robert Peterson ___, Paul Roufail ___, Craig Simon ___, Andrew Tam ___, Paul Wielowieyski ___

ROLES

Chairperson: Jake Thiessen **Secondary Facilitator:** Conrad Pereira **Scribe:** Marilyn Davis

DAY 1

Start: 9:00 a.m. **End:** 4:30 p.m.

Item	Time	Topic and Discussion Leader	Type*	Outcome
1	10mins	**Opening remarks & welcome** (R. Peterson)	IS	Welcome and outline of meeting, introduction of Conflict of Interest (COI) issues, international requirements, brief summary of expectations for this meeting.
2	10mins	**Roundtable Conflict of Interest Declarations** (C. Pereira)	IP	Each member to make a verbal declaration of any relevant COI issues, all members must approve participation.
3	10mins	**Chair's address, review agenda** (J. Thiessen)	IS	Overview of agenda and format for this meeting. Adjustment of time frames due to early departures of some members.
4	10mins	**Approval of November 2002 Record of Proceedings** (J. Thiessen)	IP	Approval of final draft from members
5	15mins	**Presentation: Current requirements for non-linear drugs in other jurisdictions; HC concerns** (C. Pereira)	IP	Summary of non-linear requirements (if any) for other countries/groups; eg. US Food & Drug Administration (FDA), European Agency for the Evaluation of Medicinal Products (EMEA). Health Canada concerns and questions.
6	40mins	**Presentation: Effects of food on bioequivalence assessment: products containing drugs exhibiting non-linear pharmacokinetics** (J. Thiessen)	IP	Issues of major concern: fed studies - are they required? unique features of non-linear pharmacokinetics; how can food affect the immediate release formulations? Evidence? etc.

7	15mins	**Coffee Break**		
8	70mins	**Discussion** (EAC members)	IP	Discussions based on pre-meeting preparation, and two presentations.
9	60mins	**Lunch**		
10	90mins	**Discussion on definition of non-linear and appropriate dose for bio study** (continued) (EAC members)		
11	15mins	**Coffee Break**		
12	75mins	**Discussion and final recommendations** (EAC members)	IP	Final EAC recommendations on bioequivalence requirements for non-linear drugs
13	15mins	**Discussion on Clarithromycin** (EAC members)	IP	Is a fed study required for clarithromycin?
14	15mins	**Adjournment of day 1, brief review and adjustment of agenda for day 2** (J. Thiessen)	IS	Comments from members and suggestions for next day
		DAY 2		**Start:** 9:00 a.m. **End:** 1:30 p.m.
15	10mins	**Presentation: Bioequivalence Criteria for Levothyroxine Tablets** (L. Cockell)	IP	Presentation of issues of concern and HC questions on Levothyroxine: Is it a narrow therapeutic range drug?
16	50mins	**Discussion: Bioequivalence Criteria for Levothyroxine Tablets** (J. Thiessen)	IP	Discussions by the EAC - BB regarding the bioequivalence criteria to be applied to levothyroxine tablets, response to questions.
17	15mins	**Coffee Break**		
ITEM 18 is to be discussed, only if time permits and all other issues are finalized.				
18	105mins	**Food requirements for critical drugs** (J. Thiessen)	IP	
19	60mins	**Lunch**		
20.	25mins	**Future Agenda Item Proposals** (C. Pereira)	IS	"Heads up" notification to members of items of concern to HC to be discussed at future meetings. General discussion.
21.	5 mins	**Adjournment** (J. Thiessen)	IS	Scheduling of next meeting.

* Type

IS = Information Sharing Agenda Item: FYI items, no discussion, straightforward information giving, clarification questions are appropriate.

IP = Information Processing Agenda Items: Topics requiring discussion/debate, analysis, action planning, and/or decision making.