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2003-06-19

Therapeutic Products Directorate (TPD)

BIOAVAILABILITY and BIOEQUIVALENCE
Expert Advisory Committee

WORKSHOP AGENDA (DRAFT)

PURPOSE: EAC - BB
PLACE: Lord Elgin Hotel, Pearson Room
DATE: June 26th, 2003 **Start:** 8:30 a.m. **End:** 4:00 p.m.

PARTICIPANTS:

Core Members:
Dr. J.J. Thiessen, (CHAIR) ___, Dr. A. Donner ___, Dr. R. Herman ___, Dr. F. Jamali ___, Dr. E. Palylyk-Colwell ___, Dr. K. Renton ___, Dr. D. Sitar ___

ad hoc Members:
Dr. R. Nair ___, Dr. W. Racz ___, Dr. W. Riggs ___, Dr. F. Varin___, Mr. S. Walker___

Health Canada Representatives:
Dr. M.M. Bernard ___, Ms. L. Carter ___, Ms. L. Cockell ___, Dr. L.N. Cui ___, Ms. M. Davis ___, Ms. C. Ficker ___, Dr. J. Gordon ___, Dr. K. Kourad ___, Dr. C. Lourenco ___, Dr. A. Makinde ___, Dr. A. Melnyk ___, Mr. E. Ormsby ___, Dr. C. Pereira ___, Dr. P. Roufail ___, Dr. C. Simon ___, Ms. S. Stojdl ___, Dr. A. Tam ___, Ms. S. Wagner ___, Mr. P. Wielowieyski ___

Stakeholder Presenters:
Ms. M. Belisle ___, Dr. W. Curatolo ___, Dr. P. Keown ___, Dr. M. Lefebvre ___, Dr. I. McGilveray ___, Dr. K. Midha ___, Dr. C. Toal ___

ROLES

Chairperson: Dr. Jake Thiessen **Primary Facilitator:** Dr. Conrad Pereira **Scribe/Timekeeper:** Ms. Marilyn Davis

AGENDA

Item	Time	Topic and Discussion Leader	Type*	Outcome
1	15 mins 8:30 - 8:45	**Chair's address & opening remarks, adjustment of agenda** Dr. J. Thiessen, Chair	IS	Welcome and outline meeting.
2	30mins 8:45 - 9:15	**Presentation: Bioequivalence Requirements: Comparative Bioavailability Studies Conducted in the Fed State** Dr. E. Palylyk-Colwell	IP	Presentation of discussion paper & overview of issues surrounding requirements for food effect studies.
3	60mins (total)	**Stakeholder Presentations: Requirements for Food Effect Studies** moderated by Dr. J. Thiessen	IP	
	10mins 9:15 - 9:25	**Presentation # 1** Dr. W. Curatolo Pfizer Global Research & Development	IP	Allows stakeholder input and suggestions on development of Policies, leading to debate. Strict adherence to time lines necessary.
	10mins 9:25 - 9:35	**Presentation # 2** Dr. M. Lefebvre Algorithme Pharma Inc.	IP	
	10mins 9:35 - 9:45	**Presentation # 3** Dr. I. McGilveray University of Ottawa	IP	

	10mins 9:45 - 9:55	**Presentation # 4** Dr. K. Midha Pharmalytics Research Institute	IP	
	10mins 9:55 - 10:05	**Presentation # 5** Dr. C. Toal Bayer Inc.	IP	
4	25mins 10:05 - 10:30	**Coffee Break**		
5	90mins 10:30 - 12:00	**Open Discussion on Requirements for Food Effect Studies** moderated by Dr. J. Thiessen	IP	Opportunity for EAC members, presenters, stakeholders and observers to participate in discussion on food requirements.
6	60mins 12:00 - 1:00	**Lunch**		
7	30mins 1:00 - 1:30	**Presentation: Bioequivalence Requirements: Highly Variable Drugs & Highly Variable Drug Products: Issues & Options** Dr. K. Midha	IP	Presentation of discussion paper & overview of issues surrounding highly variable drugs.
8	40mins (total)	**Stakeholder Presentations: Highly Variable Drugs** moderated by Dr. J. Thiessen		
	10mins 1:30 - 1:40	**Presentation # 1** Ms. M. Belisle Canadian Generic Pharmaceutical Association	IP	Allows stakeholder input and suggestions on development of Policies, leading to debate. Strict adherence to time lines necessary.
	10mins 1:40 - 1:50	**Presentation # 2** Dr. P. Keown Vancouver General Hospital	IP	
	10mins 1:50 - 2:00	**Presentation # 3** Dr. I. McGilveray University of Ottawa	IP	
	10mins 2:00 - 2:10	**Presentation # 4** Dr. C. Toal Bayer Inc.	IP	
9	20mins 2:10 - 2:30	**Coffee Break**		
10	75mins 2:30 - 3:45	**Open Discussion on Highly Variable Drugs** moderated by Dr. J. Thiessen	IP	Opportunity for EAC members, presenters, stakeholders and observers to participate in discussion on highly variable drug issues.
11	10mins 3:45 - 3:55	**Open Discussion on BB Priorities** moderated by Dr. J. Thiessen	IS	Opportunity for observers and stakeholders to participate in discussion on other BB priorities from list posted on HC Website.
12	5mins 3:55 - 4:00	**Adjournment of day 1, brief comments regarding day 2** Dr. J. Thiessen	IS	Thanks to presenters and stakeholders and comments on what the EAC members will attempt to do on day 2.

Presentation times indicated are to be used as a guide and are approximate.

DAY 2				
PURPOSE: EAC - BB **PLACE:** Lord Elgin Hotel, Pearson Room **DATE:** June 27th, 2003			**Start:** 8:30 a.m.	**End:** 4:00 p.m.
13	10mins 8:30 - 8:40	**Change of Name from Expert Advisory Committee to Scientific Advisory Committee** Dr. C. Pereira	IP	Rationale behind this change, and its implications. Approval of amended TOR.
14	80mins 8:40 - 10:00	**Requirements for Food Effect Studies** Dr. J. Thiessen	IP	Discussion and deliberation stemming from presentations on day 1.
15	15mins 10:00 - 10:15	**Coffee Break**		
16	90mins 10:15 - 11:45	**Requirements for Food Effect Studies** Dr. J. Thiessen	IP	Recommendations for finalization of draft policy.
17	60mins 11:45 - 12:45	**Lunch**		
18	75mins 12:45 - 2:00	**Highly Variable Drugs** Dr. J. Thiessen	IP	Discussion and deliberation stemming from presentations on day 1.
19	15mins 2:00 - 2:15	**Coffee Break**		
20	75mins 2:15 - 3:30	**Highly Variable Drugs** Dr. J. Thiessen	IP	Recommendations for finalization of draft policy.
21	15mins 3:30 - 3:45	**Future Agenda Item Proposals** Dr. J. Thiessen	IP	General discussion by members and HC regarding priorities that should be discussed at next meeting.
22	10mins 3:45 - 3:55	**Workshop Format** Dr. J. Thiessen	IS	General discussion by members about workshop format…comments what went well, what needs improvement.
23	5mins 3:55 - 4:00	**Adjournment** Dr. 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.