

1 **Minutes of the DPTC Teleconference**  
2 **on 13 July 2005**

3 **ATTENDEES**

Terry Tougas, <i>Chair</i> (Boehringer-Ingelheim, IPAC-RS)	Dan Norwood (BI, IPAC-RS)
David Christopher (Schering-Plough, IPAC-RS)	Guirag Poochikian (FDA)
Bob Dana (Elkhorn Associates, PDA)	Rich Poska (Abbott, PhRMA)
Sylvia Gantt (PQRI Executive Secretary)	Rajendra Uppoor (FDA)
Frank Holcombe (OGD/FDA)	Chris Moreton (Idenix Pharmaceuticals, IPEC)
Lana Lyapustina (IPAC-RS Secretariat)	Bob Wiens (Eli Lilly, IPEC)
Lee Nagao (IPAC-RS Secretariat)	Bruce Wyka (Schering-Plough, IPAC-RS)

4 **AGREEMENTS**

- 5 1. The Excipients WG will provide regular updates on the survey to DPTC.
- 6 2. Dr. Tougas will check with Dr. Seevers regarding the status of RFID WG.
- 7 3. DPTC will respond to the Container Closure WG's plan (emailed by Ms. Gantt on 7/13)
- 8 within two weeks if possible.
- 9 4. Since Dr. Poochikian was not informed of the previous DPTC decision and was unaware of
- 10 the discussions, he will provide comments later on the approach and the proposed notes for
- 11 MB WG presentations.
- 12 5. DPTC face-to-face meetings are useful for in-depth updates on WGs. Dr. Tougas will
- 13 consider the possibility of starting face-to-face meeting earlier than 10 AM to allow more
- 14 time for such updates.

15 **DISCUSSION SUMMARY**

16 *Opening*

17 Dr. Tougas opened the teleconference and read the following antitrust admonition: "Our

18 discussions today are subject to the anti-trust guidance applicable in the U.S. and E.U.

19 Nothing discussed at this meeting is intended to restrict the individual decision-making of

20 any member company or to represent an agreement to coordinate marketing or sales conduct.

21 Those participating in this meeting are instructed to avoid discussion of competitively

22 sensitive subjects, including, but not limited to, confidential marketing, sales, and pricing

23 information."

24 The objective of the teleconference was to update on all of the DPTC Working Groups.

25 ***The Excipients Working Group***

26 Mr. Wiens reported that the survey had been finalized and within 24 hours would be  
27 forwarded to the Steering Committee for distribution to member organizations. In response  
28 to questions, he clarified that there would be an internet link to the survey, and he is working  
29 with AAPS to have the survey posted on AAPS website. The survey will continue until  
30 October 12, after which the data will be assembled and analyzed. The Working Group plans  
31 to send monthly reminders to all interested parties to have the survey completed; technical  
32 help-line will also be provided. The group will keep DPTC informed of the survey's  
33 progress. The DPTC Chair and members congratulated Mr. Wiens and his Working Group  
34 on reaching this important milestone.

35 ***The Leachables and Extractables Working Group***

36 Dr. Norwood reported that the WG had been diligently working to complete their  
37 Recommendations for L&E chapter by chapter, and in parallel preparing a technical report on  
38 all laboratory work to date. In response to questions, he clarified that the Recommendations  
39 should be available for the DPTC review by the end of the summer, and the technical report  
40 by December 2005, prior to the L&E Workshop. Dr. Nagao reminded the participants that  
41 the PQRI L&E Workshop is scheduled for 5-6 December. She clarified that publicity is  
42 handled through AAPS and that basic information about the workshop should soon be  
43 available through the PQRI website. Ms. Gantt added that a "Save the Day" email had been  
44 sent to all PQRI participants, and another email would be sent in the near future.

45 ***The RFID Working Group***

46 No updates were available on this WG due to Dr. Seevers' recent vacation. Dr. Tougas  
47 committed to contact Dr. Seevers separately.

48 ***The Container Closure Working Group***

49 Dr. Moreton reported that the Container Closure WG is preparing a paper about moisture  
50 vapor transmission for unit dose packages. USP had indicated that the group's earlier  
51 theoretical paper on this topic did not receive any comments and now the paper would be  
52 developed into a more practical document. The WG is considering bracketing studies and  
53 different packaging but still needs more consultation to finalize the protocol. The WG is  
54 seeking DPTC's approval to move forward with the pilot study; details have been circulated  
55 by Ms. Gantt to DPTC on 7/13/05 by email. It was agreed that DPTC members would  
56 respond within approximately two weeks, depending on their summer schedules. The results  
57 of the pilot study will be used to define a full-scale study. Beyond the full-scale study, the  
58 WG is considering the potential impact of the results on bracketing of stability studies, and  
59 other Guidances.

60 ***The PSD Profiles Comparisons Working Group***

61 Mr. Christopher reported that the WG is working to plot and verify realistic scenarios based  
62 on the descriptions provided through a confidential survey. These scenarios will then be

63 used to evaluate the chi-square ratio test along with the additional (impactor-sized mass) test.  
64 To generate the sets of scenarios and have them confirmed by the sponsors will take several  
65 weeks, so after today's teleconference the Working Group will likely not hold any meetings  
66 until after Labor Day. The WG is currently in line with the projected timeline, planning to  
67 have the substance of recommendations finalized by the end of 2005, and have the document  
68 prepared and submitted to FDA in the first half of 2006.

### 69 *The PSD Mass Balance Working Group*

70 Mr. Wyka reminded the DPTC that the MB WG had met on 6 April to further discuss the  
71 proposal prepared by WG in the fall of 2004. At that meeting, some of the FDA members  
72 requested that the WG review an alternate proposal. The WG evaluated this alternate  
73 proposal during the month of April and reported the results during a teleconference on April  
74 29. On that teleconference, some of the FDA representatives proposed a hiatus for an  
75 indefinite time. Dr. Tougas added that this situation was discussed by the Steering  
76 Committee and the SC recommended that the two proposals be presented to the DPTC for a  
77 technical evaluation and that Ms. Winkle committed to communicate this decision to the  
78 relevant FDA representatives. Dr. Poochikian noted that Ms. Winkle briefly mentioned this  
79 to him but the Agency had not had a chance to discuss this issue in detail due to scheduling  
80 difficulties. Dr. Tougas requested Dr. Poochikian's input on the proposed date of the  
81 technical presentations (currently planned for September 14).

82 Mr. Wyka and Dr. Tougas further reported that at the last DPTC meeting, it was suggested  
83 that DPTC provide guidelines to the subgroups preparing technical presentations. (It should  
84 be noted that during the afternoon session, when PSD MB presentation and discussion took  
85 place, the FDA DPTC liaison to this working group, Dr. Poochikian, was absent due to  
86 urgent scheduling conflict.) These guidelines were drafted by Dr. Tougas and Mr. Golden  
87 and forwarded to the DPTC for comment on June 29. Dr. Tougas asked whether that  
88 document was appropriate for distribution to the full MB WG. Several DPTC members  
89 replied that the prepared outline would be helpful in guiding a scientific discussion and  
90 should be provided to the full WG. Dr. Uppoor also proposed that the two subgroups make  
91 their respective technical presentations to each other first, before they are brought to the  
92 DPTC. Dr. Poochikian noted that he was not aware of the DPTC's decision, and he had not  
93 reviewed that document so he could not comment on it but he plans to do so in the next day  
94 or two. Dr. Uppoor clarified that Dr. Poochikian's insight would be helpful due to his  
95 current responsibilities and his previous position as pulmonary team leader within ONDC.

### 96 **NEXT MEETING/TELECONFERENCE**

97 To be confirmed by email  
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Finalized on 8 August 2005