

1 **Minutes of the DPTC Teleconference**
2 **on 10 February 2006**

3 **ATTENDEES**

4 Terry Tougas, *Chair* (Boehringer Ingelheim, IPAC-RS)
5 David Christopher (Schering-Plough, IPAC-RS)
6 Bob Dana (PDA)
7 Michael Golden (GlaxoSmithKline, IPAC-RS)
8 Frank Holcombe (FDA)
9 Lana Lyapustina (IPAC-RS Secretariat)
10 Chris Moreton (Idenix Pharmaceuticals, IPEC)
11 Russel Somma (IPS, ISPE)
12 Bob Wiens (Lilly, IPEC)
13 Bruce Wyka (Schering-Plough, IPAC-RS)

14 ***Absentees***

15 Tony Amann (GPhA)
16 Clyde Anthony (USP)
17 Dan Malinowski (Pfizer, PhRMA)
18 Dan Norwood (Boehringer Ingelheim, IPAC-RS)
19 Guirag Poochikian (FDA)
20 Rich Poska (Abbot, PhRMA)
21 Nakissa Sadrieh (FDA)
22 Vilayat Sayeed (FDA)
23 Robert Seevers (Lilly, PhRMA)
24 Raj Uppoor (FDA)
25 Bill Williams (University of Texas, AAPS)

26 **EXECUTIVE SUMMARY**

27 The DPTC updated on the SC discussions and the DPTC projects.

28 No new decisions were made at this teleconference.

29 **DISCUSSION**

30 ***Opening***

31 Dr. Tougas opened the meeting and read the antitrust admonition: “Our discussions today are
32 subject to the anti-trust guidance applicable in the U.S. and E.U. Nothing discussed at this
33 meeting is intended to restrict the individual decision-making of any member company or to
34 represent an agreement to coordinate marketing or sales conduct. Those participating in this
35 meeting are instructed to avoid discussion of competitively sensitive subjects, including, but
36 not limited to, confidential marketing, sales, and pricing information.”

37 The objectives of the teleconference were to update on the Steering Committee's discussions
38 and to review the progress of projects since the last DPTC meeting (on 25 January).

39 *SC Updates*

40 Dr. Tougas provided a brief updated on the Steering Committee meeting on 8 February. Dr.
41 Tougas said he had communicated to the SC the DPTC thinking on new projects, and started
42 discussing with the SC Chair the DPTC messages discussed at the 25 January DPTC
43 meeting.

44 *Leachables and Extractables*

45 Dr. Lyapustina reported that the Leachables and Extractables WG had received 4 sets of
46 comments and is expecting 1 or 2 more sets in the next few days. Compilation of comments
47 has begun. The WG hopes to begin reviewing the comments as soon as possible for potential
48 incorporation into the Recommendations. The WG encourages PQRI organizations to submit
49 comments as soon as possible. The WG had also started to discuss plans for publication of
50 its work, and a subteam of the working group is exploring the appropriate journals in which
51 to publish. Finally, she reminded the participants that several of the WG members will be
52 presenting present the L&E work (especially the development of the safety thresholds) at the
53 annual meeting of the Society of Toxicology in March, as discussed and approved by the
54 DPTC at the last meeting.

55 Dr. Tougas added that he and Dr. Norwood had contacted Dr. Sadrieh regarding the L&E
56 Recommendations. Dr. Sadrieh explained that she and Ms. Winkle would be reviewing the
57 document and responding to Dr. Tougas in the next two weeks. Dr. Sadrieh also mentioned
58 that Dr. Poochikian would be leaving the DPTC, and FDA is currently considering a
59 replacement.

60 *Profile Comparisons*

61 Mr. Christopher reported that the WG is working through the Population Bioequivalence
62 (PBE) calculations and confirming with Dr. Hauck that the code used by the WG agrees with
63 the one he had used in his work with FDA on this topic. The "Interim Progress Report" has
64 been revised and reviewed by the WG and will be resubmitted to the publisher in the near
65 future. The Working Group plans to prepare and finalize its final report to FDA by the
66 second quarter 2006 and in parallel will prepare a publication for a peer-reviewed journal.
67 Mr. Christopher underscored that upon completion of this report and publication, the WG
68 could be sunset and if any additional research is desired in this area, it should be brought to
69 PQRI as a new project.

70 *Excipients*

71 Mr. Wiens reported the following timeline proposed by the Working Group:

- 72
- Complete the report on the survey's findings by 1 March.

- 73
- Complete an executive summary and recommendations by 1 April.
- 74
- Prepare a manuscript by 1 May, submit it to the DPTC and SC by 1 June and submit for
- 75
- publication by 1 July.

76 In addition, Mr. Wiens noted that the Working Group would like to propose a PQRI
77 workshop in October 2006. The participants suggested, however, that the WG consider
78 combining this workshop with another conference (e.g., USP's Annual Scientific Meeting),
79 and in any case allow a longer lead time in order to arrange the facility, publicity, etc.

80 *Mass Balance*

81 Mr. Wyka reported that the WG is reviewing a consensus language for the guidance, as
82 suggested by Dr. Poochikian at the 4 Nov. 2005 meeting. In addition, a paper summarizing
83 justifications for one of the positions is nearing completion and will be provided to the DPTC
84 when finalized by the drafting group.

85 *New Projects*

86 Dr. Moreton reported that he had started preparing a more detailed proposal regarding an
87 expansion of the Arrhenius equation. This should be available for review by the end of
88 February.

89 Dr. Tougas reported that the specifications/stability proposal will be discussed in further
90 details during an upcoming teleconference of a small team including himself and three
91 statisticians (from DPTC, UNL and PhRMA CMC Statistics Group).

92 *Other Updates*

93 No new developments were reported for the RFID and Container Closure System WGs.

94 **NEXT MEETING/TELECONFERENCE**

95 To be confirmed by email.

96

Finalized on 6 March 2006