



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Focus Group Meeting on Bacteriophages

11 May 2023, Amsterdam/virtual

Chair: Jacqueline Poot

Programme

- 09:30** **Introduction and welcome (5')**
Jacqueline Poot (Chair of Novel Therapies and Technologies Working Party)
- 09:35** **Setting the scene: introduction on the background and expected outputs for the meeting (10')**
Susana Casado (Vice-chair of Novel Therapies and Technologies Working Party)
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Session I: Guideline on quality, safety and efficacy of veterinary medicinal products specifically designed for phage therapy

- 09:45** **Presentation on quality aspects (30')**
Martin Bronislaw Oleksiewicz (Danish Medicines Agency)
- 10:15** **Open discussion**
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- 10:45** *Coffee break*
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- 11:00** **Presentation on safety aspects (30')**
Sandra-Maria Wienhold (Federal Office of Consumer Protection and Food Safety)
- 11:30** **Open discussion**
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- 12:00** *Lunch break*
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- 13:15** **Presentation on efficacy aspects (30')**
Belén Gutiérrez Soriano (Spanish Agency of Medicines and Medical Devices)
- 13:45** **Open discussion**
- 14:15** **EDQM perspective on Ph. Eur. activities on bacteriophages (20')**
Olga Kolaj-Robin (European Directorate for the Quality of Medicines & HealthCare)
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- 14:35** *Coffe break*
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Session II: Case studies on bacteriophages

14:50 **Case studies on bacteriophages (30')**

Frédéric Klein (Federal Agency for Medicines and Health Products)

Susana Casado (Spanish Agency of Medicines and Medical Devices)

15:20 **Open discussion**

15:50 **Conclusions and closing remarks (40')**

Jacqueline Poot (CBG-MEB Medicines Evaluation Board)

Speakers

Belén Gutiérrez Soriano	Scientific assessor at the Spanish Agency of Medicines and Medical Devices; Member of the Operational Expert Group on bacteriophages
Frédéric Klein	Scientific expert at the Federal Agency for Medicines and Health Products; Coordinator of the Operational Expert Group on bacteriophages; Member of Novel Therapies and Technologies Working Party; Alternate member of the EMA Committee for Medicinal Products for Veterinary Use
Jacqueline Poot	Clinical assessor at the CBG-MEB Medicines Evaluation Board; Chair of Novel Therapies and Technologies Working Party; Member of the EMA Committee for Medicinal Products for Veterinary Use
Martin Bronislaw Oleksiewicz	Head consultant at the Danish Medicines Agency; Member of the Operational Expert Group on bacteriophages
Olga Kolaj-Robin	Scientific officer at European Directorate for the Quality of Medicines & HealthCare; Coordinator of the European Pharmacopoeia Groups of Experts and Working Parties in the area of Biological and Biotechnological Substances, Antibiotics, Gene Therapy Products and Phage Therapy
Sandra-Maria Wienhold	Scientific assessor at the Federal Office of Consumer Protection and Food Safety; Member of the Operational Expert Group on bacteriophages
Susana Casado	Head of Unit of Immuno-Bio Veterinary Medicines at the Spanish Agency of Medicines and Medical Devices; Coordinator of the Operational Expert Group on bacteriophages; Vice-Chair of Novel Therapies and Technologies Working Party