



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 October 2026
EMA/220262/2026
Antimicrobial Resistance (AMR)

EMA Workshop on Bacteriophage Therapy

30 October 2026 @ 09:00 – 18:00 CET – Room 2A, EMA, Amsterdam, NL
and online

Connection details for online attendance will be attached to the Outlook invitation.

Order	Topics	Speaker	Time
–	Registration & Welcome Coffee	—	08:30
	SESSION 1 – Opening & Scene Setting (Chair: Dr. Marco Cavaleri, EMA, EU)		
1	Opening Remarks & Workshop Objectives (including a brief One Health framing of AMR under the revised pharmaceutical legislation)	Emer Cooke, Executive Director, EMA, EU Olga Solomon, EC, EU	09:00 – 09:15
2	EU Member States Existing Pathways for Named Patient Phage Therapy and Structural Gaps for Regulatory Approval (BE) Belgian magistral framework	Prof. Jean-Paul Pirnay, Queen Astrid Military Hospital, Brussels, Belgium	09:15 – 09:30
3	EU Member States Regulatory Agencies Views on the Current Situation: BE and FR	Dr. Celine Thiry, FAMHP, Belgium Dr. Nathalie Morgensztejn, ANSM, France	09:30 – 09:55
4	The PHAGEinLYON Clinical Programme: Building a Real-World Evidence Base Compassionate access pathways, multidisciplinary case management, regulatory interface with ANSM, and clinical outcomes in complex bone and joint infections	Prof. Tristan Ferry, MD, PhD, Hôpital de la Croix-Rousse / CRIOAc Lyon, Hospices Civils de Lyon / Clinical Officer, ESCMID ESGNTA	09:55 – 10:15
5	Q&A — Plenary Discussion	Moderated by Session Chair	10:15 – 10:30
–	☕ Coffee Break	—	10:30 – 10:50

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Order	Topics	Speaker	Time
	SESSION 2 — Scientific Foundations for Regulatory Design (Chair: Dr. Alan Fauconnier, FAMHP, BE; Moderator: Pietro Erba, EC, EU)		
6	Phage Biology and Quality Characterisation: Implications for Regulatory Standards Host range, stability, manufacturing variability, and the limits of classical pharmaceutical characterisation	Dr. Pieter-Jan Ceysens, Sciensano, Belgium	10:50 – 11:10
7	Phage Susceptibility Testing Standardisation: The EUCAST PST Subcommittee Work Programme Reference methods, phagogram interpretation criteria, quality assurance, and regulatory implications for phage selection in clinical use	Prof. Frédéric Laurent, Chair, EUCAST Phage Susceptibility Testing Subcommittee / Hospices Civils de Lyon / Université de Lyon, France	11:10 – 11:30
8	Quality Requirements for Phage Therapy Medicinal Products: The EMA BWP Draft Guideline (EMA/CHMP/BWP/1/2024) Scope, key provisions, characterisation, batch release, and implications for individualised preparations	Dr. Helerin Eiche, PhD, State Agency of Medicines (Ravimiamet), Estonia	11:30 – 11:50
9	Environmental Risk Assessment of Phage Products ERA obligations under the revised Directive, incl. AMR-selection risk across the manufacturing supply chain; environmental release of self-replicating biologicals; contained-use vs. deliberate-release analysis for engineered phages; simplified GMO clinical-trial procedures	Paschalia Koufokotsiou, EC, EU	11:50 – 12:10
10	Compassionate Use and Clinical Trial Design for Platform Approaches: An Academic Perspective Combines evidence generated outside trials (incl. insights from the Israeli Phage Therapy Center) with platform trial design for phages, including paediatric development considerations (e.g. cystic fibrosis, neonatal sepsis) and PIP implications under the revised legislation, in a single academic presentation	Prof. Ran Nir-Paz, Hadassah-Hebrew University Medical Center, Israel	12:10 – 12:50
11	Q&A — <i>Plenary Discussion</i>	Moderated by Session Chair	12:50 – 13:05
–	 <i>Lunch Break</i>	—	13:05 – 13:50
	SESSION 3 — Elements of an Adapted EU Regulatory Framework (Chairs: Dr. Pablo de Felipe, AEMPS, ES and Dr. Radu Botgros, EMA, EU)		
12	EU Strategic Perspective on Phage Therapy: New Tools under the Adapted Framework Delegated and implementing acts under the revised EU pharmaceutical legislation; mandatory centralised procedure	Dr. Radu Botgros, Dr. Romee Reijnsenbach de Haan, EMA, EU Pietro Erba, EC, EU	13:50 – 14:30

Order	Topics	Speaker	Time
13	Platform Authorisation and Master File Concepts for Phage Libraries Moving beyond product-by-product review; lifecycle management, pharmacovigilance and traceability of evolving and personalised preparations under a platform marketing authorisation (fixed/variable components)	Dr. Vasili Dabouras, EMA, EU Dr. Alan Fauconnier, FAMHP, Belgium	14:30 – 15:00
14	Q&A — <i>Plenary Discussion</i>	Moderated by Session Chair	15:00 – 15:20
–	☕ <i>Coffee Break</i>	—	15:20 – 15:35
SESSION 4 — International and Operational Perspectives (Chair: Dr. Alan Fauconnier, FAMHP, BE; Moderator: Pietro Erba, EC, EU)			
15	Adaptive Phage Preparation and GMP Considerations Bespoke manufacturing, hospital-based production, and proportionate quality requirements	Nicolas Dhombres, EMA, EU Karin Froidbise, FAMHP, Belgium	15:35 – 15:55
16	Industry Perspective On GMP manufacturing of phage therapy products — scale-up challenges, batch consistency, regulatory interface for bespoke preparations; development pathways, investment landscape, IP considerations, partnership models	Dr. Frenk Smrekar, Jafra/Phage Europe, Slovenia Frédérique Vieville, 5QBD Biotech / BEAM-Phage ACT / Phage Europe, France	15:55 – 16:15
17	Non-EU Regulatory Frameworks: FDA and TGA (joint comparative slot) FDA: biologics classification, IND pathways, single-patient expanded access, updated US activity data. TGA: GMP exemption. Translational lessons for EU framework design	Dr. Roger Plaut, CBER, FDA, US Dr. Anna Hart, Department of Health, Disability and Ageing, Australia	16:15 – 16:45
18	Q&A — <i>Plenary Discussion</i>	Moderated by Session Chair	16:45 – 17:00
SESSION 5 — Synthesis & Closing (Chairs: Dr. Pablo de Felipe, AEMPS, ES and Dr. Radu Botgros, EMA, EU)			
19	Panel Discussion: Key Principles for an Adapted EU Phage Therapy Framework Convergence, open issues, and a roadmap for regulatory development; incl. access and HTA interface	All Speakers	17:00 – 17:20
20	Open discussion on all topics, with all participants	Moderated by Session Chair	17:20 – 17:50
21	Closing Remarks & Next Steps Proposed follow-up actions, publication of workshop report	Marco Cavaleri, EMA, EU	17:50 – 18:00
–	End of Workshop	—	18:00