



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
–	<i>Registration & Welcome Coffee</i>	—	08:30
SESSION 1 – Opening & Scene Setting (Chair: Dr. Marco Cavaleri, EMA, EU)			
1	Opening Remarks & Workshop Objectives	Emer Cooke, Executive Director, EMA, EU Olga Solomon, Head of Unit, DG SANTE, EU	09:00 – 09:15
2	EU Member States Existing Pathways for Named Patient Phage Therapy and Structural Gaps for Regulatory Approval Belgian magistral framework	Dr. Jean-Paul Pirnay, Queen Astrid Military Hospital, Brussels, Belgium	09:15 – 09:35
3	EU Member States Regulatory Agencies Views on the Current Situation: BE and FR	Dr. Celine Thiry, FAMHP, Belgium Dr. Nathalie Morgensztejn, ANSM, France	09:35 – 10:00
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, Hôpital de la Croix-Rousse / CRIOAc Lyon, Hospices Civils de Lyon / Clinical Officer, ESCMID ESGNTA	10:00 – 10:20
5	<i>Q&A — Plenary Discussion</i>	Moderated by Session Chair	10:20 – 10:35
–	 <i>Coffee Break</i>	—	10:35 – 10:55

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



Order	Topics	Speaker	Time
	SESSION 2 — Scientific Foundations for Regulatory Design (Chairs: Dr. Alan Fauconnier, FAMHP, BE and Pietro Erba, DG SANTE, 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 Ceyssens, Sciensano, Belgium	10:55 – 11:15
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, EUCAST Phage Susceptibility Testing Subcommittee and Therapeutics Phage Laboratory, Hospices Civils de Lyon / Lyon 1 University, France	11:15 – 11:35
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, State Agency of Medicines (Ravimiamet), Estonia	11:35 – 11:55
9	Environmental Risk Assessment of Phage Products ERA under the proposed revised pharmaceutical legislation, including questions on AMR selection; environmental release of phages; GMO phages and proposed clinical-trial procedures	Paschalia Koufokotsiou, DG SANTE, EU	11:55 – 12:15
10	Compassionate Use and Clinical Trial Design for Platform Approaches: An Academic Perspective Combined evidence generated outside trials (incl. insights from the Israeli Phage Therapy Center) with platform trial design for phages, including paediatric development considerations	Prof. Ran Nir-Paz, Hadassah-Hebrew University Medical Center, Israel	12:15 – 12:45
11	Q&A — <i>Plenary Discussion</i>	Moderated by Session Chairs	12:45 – 13:05
–	 <i>Lunch Break</i>	—	13:05 – 13:50
	SESSION 3 — International perspectives and elements of an Adapted EU Regulatory Framework (Chairs: Dr. Pablo de Felipe, AEMPS, ES and Dr. Radu Botgros, EMA, EU)		
12	Non-EU Regulatory Frameworks: FDA and TGA (joint comparative slot) FDA: biologics classification, IND pathways, single-patient expanded access, updated USA activity data TGA: Bacteriophage regulation in Australia	Dr. Roger Plaut, CBER, FDA, USA Dr. Anna Hart, Department of Health, Disability and Ageing, Australia	13:50 – 14:20

Order	Topics	Speaker	Time
13	Platform Authorisation and Master File Concepts for Phage Libraries Moving beyond product-by-product review and lifecycle management under a platform marketing authorisation (fixed/variable components)	Dr. Vasili Dabouras, EMA, EU Dr. Alan Fauconnier, FAMHP, Belgium	14:20 – 14:50
14	EU Strategic Perspective on Phage Therapy: New Tools under the Adapted Framework Delegated and implementing acts under the revised EU pharmaceutical legislation; scientific questions for an adapted framework	Pietro Erba, DG SANTE, EU Dr. Radu Botgros, Dr. Romee Reijnsenbach de Haan, EMA, EU	14:50 – 15:20
15	Q&A — <i>Plenary Discussion</i>	Moderated by Session Chairs	15:20 – 15:40
–	 <i>Coffee Break</i>	—	15:40 – 16:00
SESSION 4 —Operational Perspectives (Chairs: Pietro Erba, DG SANTE, EU and Dr. Alan Fauconnier, FAMHP, BE)			
16	Adaptive Phage Preparation and GMP Considerations Bespoke manufacturing, hospital-based production, and proportionate quality requirements	Nicolas Dhombres, EMA, EU Karin Froidbise, FAMHP, Belgium	16:00 – 16:20
17	Industry Perspective GMP manufacturing, scale-up and batch consistency; fixed, adaptable and personalised phage products; quality and evidence requirements; evolving compositions, regulatory pathways and sustainable patient access	Dr. Frenk Smrekar, Jafra/ Phage Europe, Slovenia Frédérique Vieville, 5QBD Biotech / BEAM-Phage ACT / Phage Europe, France	16:20 – 16:40
18	Q&A — <i>Plenary Discussion</i>	Moderated by Session Chairs	16:40 – 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 and open issues: identifying agreed points, differing views, evidence gaps, proposed actions and responsible organisations	All Speakers, moderated by session Chairs	17:00 – 17:20
20	Open discussion: prioritising unresolved scientific questions and proposed next steps	All, moderated by session Chairs	17:20 – 17:50
21	Closing Remarks & Next Steps Proposed follow-up actions, publication of workshop report	Dr. Marco Cavaleri, EMA, EU	17:50 – 18:00
–	End of Workshop	—	18:00