



3 June 2015  
EMA/265715/2015 Corr.<sup>1</sup>  
European Medicines Agency

## Agenda - Workshop on the therapeutic use of bacteriophages

8 June 2015 (09:00-16:15), room 3E

The workshop on the therapeutic use of bacteriophages is organised by the EMA as one of the ways the Agency explores opportunities for new anti-bacterial treatment options and part of the work to facilitate the development of new tools for treatment of difficult to treat bacterial infections including those due to multi-resistant bacteria. The aim is to proactively discuss major issues related to bacteriophage therapy with stakeholders from the academic, regulatory and industrial sectors. It will provide an initial discussion on current issues and open questions and reflect on potential ways forward for this therapy with various stakeholders.

Time	Agenda	Speaker
	<b>Session 1</b>	
	<b>Overview and quality requirements for phage production</b>	Co-chairs: M. Cavaleri, S. Ruiz
09.00-09.15	- Welcome and introduction	E. Alteri, European Medicines Agency (EMA)
09.15-09.45	- A historical overview of the therapeutic use of bacteriophages	A. Gorski, Polish Academy of Sciences
09.45-10.15	- GMP phage production for clinical trials	L. Bretaudeau, Clean Cells and F. Smrekar, Amplphi Biosciences

<sup>1</sup> Updated speakers list



Time	Agenda	Speaker
10.15-10.45	- Current issues on quality of phage products	A. Fauconnier, Federal Agency for Medicines and Health Products, Belgium
10.45-11.00	Coffee break	
11.00-11.30	- Changing phage cocktails to match developing resistance	G. Verbeken, Queen Astrid Military Hospital
11.30-12.00	- Considerations on regulatory aspects	Z. Sebris, EMA
12.00-13.00	Open discussion	
13.00-14.00	Lunch break	
	<b>Session 2</b> <b>Clinical development for phage therapy</b>	Co-chairs: M. Cavaleri, M. Powell
14.00-14.30	- Current clinical evidence for the therapeutic use of bacteriophages	X. Wittebole, Université Catholique de Louvain
14.30-15.00	- Experience from the ongoing Phagoburn clinical trial	P. Jault, Percy Military Hospital and J. Gabard, Pherecydes Pharma
15.00-16.00	Open discussion: aspects to be considered for clinical trials	
16.00-16.15	Wrap up and conclusion of the meeting	Co-Chairs