



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Workshop on the therapeutic use of bacteriophages

8 June 2015
Summary

- The 8 June workshop on bacteriophages was the first to be organised by the European Medicines Agency (EMA) on this topic. The objective of the workshop was for EMA to proactively discuss possible issues related to development of bacteriophage therapies for treatment of bacterial infections with relevant stakeholders including academia, industry, policy makers and patient organisations.
- Bacteriophage therapy is used in some parts of Europe, but is currently not authorised as a medicinal product. It is important for the Agency to fully appreciate the level of scientific evidence available to support this therapy, and the potential therapeutic indications for which phage products could be further developed.
- Participants at the conference presented examples of how bacteriophages may be used, and discussed the various regulatory challenges that these examples present.
- At one end of the spectrum, medical doctors are using phage therapy on a compassionate use basis to treat individual patients for difficult to treat bacterial infections. They advocate for possibilities to develop phage(s) targeting specific pathogen(s) on a single-patient basis.
- At the other end of the spectrum, pharmaceutical companies are concerned with formulating 'fixed phage cocktails' to be used in clinical trials. These fixed phage cocktails are produced under GMP conditions, in line with current guidelines for biological medicinal products. The ultimate aim is to achieve a marketing authorisation in the EU.
- In light of the growing challenge of antimicrobial resistance, many participants at the workshop stressed the importance of alternatives to currently available antibiotics. The Agency is taking steps to facilitate the development of such products. Indeed, the Agency maintains a position of openness towards exploring all possibilities for using the current regulatory framework in order to allow the further development of this therapeutic approach.
- However, at the workshop, EMA emphasised that a medicine cannot be recommended for approval before its efficacy and safety have been proven on the basis of appropriately designed clinical trials. This is not currently the case for bacteriophage therapies for which very few randomised controlled clinical trials have been conducted to date.



- The Agency is looking forward to gathering more robust evidence on the value of bacteriophage treatments and further discussing the scientific and regulatory aspects relating to the biological characterisation of the phages with stakeholders.
- The current EU regulatory frameworks are considered a suitable starting point for discussing fixed phage cocktails.
- Companies are encouraged to engage in early dialogue with the Agency by applying for scientific advice through which they can receive further guidance on how to develop their products.