

Survey to the delegates of the Pharmaceutical Committee on the **therapeutic use of bacteriophages**

Background

We observe an increased interest of the Belgian academic and health care sector for the therapeutic use of bacteriophages, especially in treatment of infections caused by multi resistant bacteria.

Given the very specific nature of this type of product and the specific features of bacteriophage therapies, the regulatory/legal framework to develop and/or use these products is often not fully appropriate or (partially) lacking in order to adequately ensure their overall quality, safety and efficacy. Therefore, an appropriate legal / regulatory framework is needed.

Since we have signals that other Member States are confronted with similar situations and that we are in favour of a harmonised approach, we have proposed this as an agenda point for the next Pharmaceutical Committee.

To facilitate a discussion at the meeting of the Pharmaceutical Committee in October, we would like to launch a small survey on this topic to the members states' national competent authorities. The summarised results of this survey will serve as a basis for reflection and discussion.

In addition, we would like to ask the EMA to provide an update of their activities in this domain after the workshop¹ they organised on this topic in June 2015.

¹ Workshop on the therapeutic use of bacteriophages, 8 June 2015, London
<https://www.ema.europa.eu/en/events/workshop-therapeutic-use-bacteriophages>

Questions to Member States

1. Do you agree that bacteriophages that are used in phage therapy should be considered as medicinal products, as defined in Art 1.2 of Directive 2001/83/EC? If not, please explain.
2. Do you agree that placing on the market of these bacteriophages requires a marketing authorisation, as defined in Art 6 of Directive 2001/83/EC? If not, please explain.
3. Have you granted (a) marketing authorisation(s) for bacteriophages or is/are such authorisation application(s) ongoing? If so, please add relevant references (e.g. MA numbers, composition, indications).
4. Have you approved clinical trials for phage therapy, or is such procedure ongoing? If so, please add relevant references (e.g. EudraCT numbers).
5. Can bacteriophage therapy in your country be considered as unlicensed medicinal product prepared in a pharmacy in accordance with a medical prescription for an individual patient (magistral formula), as described in art 3 of Directive 2001/83/EC? If so, please clarify under which circumstances and which requirements are in force with regard to these preparations and to the phages themselves (e.g. are they considered to be “substances for pharmaceutical use” which need to comply with the monograph “substances for pharmaceutical use” of the European Pharmacopoeia, GMP requirements, etc.)?
6. Have you authorised bacteriophage therapy by any other regulatory tool (e.g. compassionate use, named patient access)? If so, please specify.
7. Do you have national guidance(s) on bacteriophages, for example regarding Good Manufacturing Practices? If so, please specify.
8. Have you approved in your member state the use of any bacteriophage therapies that were falling under the EU definition of a genetically-based organism (GMO)?