

## PhageEU position on Pharmaceutical Package “Bringing phages closer to EU patients”

On 26 April 2023 the Commission adopted a Pharmaceutical Package, including proposal for a new Directive and a new Regulation which revise and replace the existing general pharmaceutical legislation.

PhageEU welcomes this initiative, as it aims at creating a future proof regulatory framework and supporting the industry in promoting research and technologies that reach patients to fulfil their therapeutic needs while addressing market failures. PhageEU is especially happy to see, that two out of four main pillars of the Pharmaceutical Package include:

- addressing **unmet medical needs** in the areas of antimicrobial resistance and rare diseases and
- supporting **competitiveness, innovation and sustainability** of the EU's pharmaceutical industry and the development of high quality, safe, effective and greener medicines.

Against this context PhageEU, as a coalition of like-minded stakeholders representing phages in industry, academia and civil society, believes that **it is of utmost importance, that the Pharmaceutical Package also covers innovative and alternative treatments such as bacteriophages**. In cases of infections and maladies caused by multi-drug resistant bacteria, phages offer solutions that address AMR, control the number of bacteria in the environment and support the One Health approach due to their human, animal and plant applications.

**PhageEU recommendations to the Pharmaceutical Package aim at ensuring, that phage therapies are recognised within key areas like antimicrobial incentives, regulatory flexibility, and streamlined approval pathways.**

In particular, PhageEU is calling on EU legislators to:

- **Introduce a new definition for bacteriophages and expand the definition of antimicrobials.**
- **Include phages in Priority Antimicrobial Incentives & Transferable Rights:** ensuring phage therapies qualify for Article 40 incentives as priority antimicrobials.
- **Establish Regulatory Sandboxes for phage therapies:** establishing an adaptive framework under Article 113, covering phage banks and personalized phage therapies.
- **Create streamlined phage cocktail updates:** creating a variation process under Article 47, allowing phage compositions to be modified without requiring full reauthorization.



#### PhageEU Coalition

Boulevard Saint Michel 47,  
1040 Etterbeek, Brussels, Belgium  
📧 [contact@phageurope.eu](mailto:contact@phageurope.eu)

These proposals align with existing EU strategies to tackle antimicrobial resistance and draw on regulatory precedents (e.g., biologicals, magistral preparations, real-world evidence frameworks).

European Parliament has already recognised the potential of bacteriophages in fighting AMR, in its [position](#) on the *Proposal for Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing European Medicines Agency* as well as in its [resolution on EU action to combat antimicrobial resistance](#).

**Given the urgent need for antibiotic alternatives, PhageEU sees its targeted amendments to the Pharmaceutical Package as a practical way to integrate phages into the EU regulatory framework and make the Pharmaceutical Package fit for future developments.**

---

### About PhageEU

Phage EU is a coalition of likeminded stakeholders who represent phages in industry, the scientific community and civil society. We want to realise the full potential of phages in Europe. <https://phageurope.eu>

### Contact

Margareta Przybyla, PhageEU Secretary General, [mprzybyla@phageurope.eu](mailto:mprzybyla@phageurope.eu), Tel: 0032 476 591 091