



# Medicines & Healthcare products Regulatory Agency

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10 June 2025

Chi Onwurah MP  
Chair, Science, Innovation and Technology Committee  
House of Commons  
London  
SW1A 0AA

## By email only

Dear Chair

## Regulatory considerations for therapeutic use of bacteriophages in the UK

I am writing to notify the Science, Innovation and Technology Committee of the publication of the Medicines and Healthcare products Regulatory Agency (MHRA) guidance on '[Regulatory considerations for therapeutic use of bacteriophages in the UK](#)'.

The publication clarifies which regulatory guidelines should be followed, and which apply, in the development of bacteriophage therapeutic products. In line with the then-government's response to the committee's recommendations in its 2024 report 'The antimicrobial potential of bacteriophages', the published guidance sets out the type of quality, safety and efficacy data needed for the evaluation of applications for licensed and unlicensed phage products intended for the treatment of patients with difficult to treat infections.

The MHRA guidance aims to assist researchers and companies in developing phage-based medicines that meet UK safety, quality and efficacy standards, so they can be made available to patients who need them most. It covers both combined phage products designed for common infections and circulating strains, as well as personalised phage therapies that are tailored for individual patients with rare or highly resistant infections.

We have worked in consultation with the Innovate UK Phage Innovation Network (PIN) and remain supportive of the important role the network plays in assisting the development of the regulatory considerations outlined in the guidance. We continue to actively engage with the PIN to support knowledge exchange between innovators and regulators and facilitate the development of regulatory frameworks that evolve in step with scientific advancements.

The publication supports the UK 2024-2029 National Action Plan to confront Antimicrobial Resistance (AMR) and the MHRA's wider role in enabling innovative, science-led regulation that meets public health need while maintaining high standards for quality and safety. We are committed to delivering predictable, optimised, and sustainable services, across all our functions, in ways that put patients and public health outcomes first.

Our work on phages reflects our wider ambition to be a forward-thinking, enabling regulator. We want to create a clear and proportionate regulatory environment that supports the safe development of new treatments – not just for phages, but across a range of novel therapies, such as advanced therapeutics, personalised medicines, and genomics-based products.

We continue to review our regulatory considerations in consultation with the phage research and development community as products and their associated methods and technologies mature, as well as to reflect regulatory experience that continues to develop in this field.

Yours sincerely,

A handwritten signature in dark ink, appearing to read 'Julian Beach', with a stylized, cursive script.

Julian Beach  
Executive Director of Healthcare Quality and Access  
MHRA

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