European regulatory aspects of phage therapy: magistral phage preparations

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Bacteriophages (phages) are bacterial viruses and have been used for more than a century to combat bacterial infections, particularly in Poland and in the former Soviet Union. The antimicrobial resistance crisis has triggered a renewed interest in the therapeutic use of natural phages. The capacity of phages to specifically target pathogenic strains (sparing commensal bacteria), to adapt to these strains, and to rapidly overcome bacterial resistance, makes them suitable for flexible therapeutic approaches. To maximally exploit these advantages phages offer over conventional 'static' drugs such as traditional small molecule-type antibiotics, it is important that these sustainable phage products are not submitted to the traditional (long and expensive) medicinal product development and licensing pathways. This poster discusses the Belgian 'magistral preparation' phage therapy framework and the extrapolation of this framework to the European level, enabling an expeditious re-introduction of personalized phage therapy into Europe. The magistral preparation pathway is a short and feasible pathway allowing patients' access to personalized and sustainable phage therapy products. Physicians, pharmacists, phage Active Pharmaceutical Ingredient (pAPI) producers and EDQM reference laboratories each play their specific roles. Physicians prescribe personalized (tailored) phage preparations for use in specific patients. Pharmacists prepare these phage products according to the individual prescriptions, using pAPIs. Industry and non-profit players produce these pAPIs according to a phage monograph, and reference laboratories perform the QC release testing of these pAPIs.

Industry can market these pAPIs. Pharmacists can also outsource the production of magistral phage preparations to industry. A general phage chapter, once included in the European Pharmacopoeia (Ph. Eur.), can (non-restrictively) guide the quality of the produced and released pAPIs. Further efforts are needed to incorporate general- and specific phage monographs into the Ph. Eur. This process should be driven by industry, if and when they feel the need.