Resistance of bacteria against antibiotics just keeps growing. Each year, 25,000 European citizens die because of this. Industry’s pipeline does not contain much new antibiotics. Before the pharmaceutical development of antibiotics, e.g. natural bacteriophages (= bacterial viruses) were commercialized and used to kill pathogenic bacteria. This therapeutic application of natural bacteriophages was called “bacteriophage therapy”. Today, countries like Poland, Georgia and Russia are still practicing bacteriophage therapy. The European Union and “modern” medicine as a whole needs an urgent return of bacteriophage therapy as part of its armamentarium to fight bacterial resistance to antibiotics. A European regulatory frame to make a smooth and (tailored) qualitative return of bacteriophage therapy possible is actually lacking. The first goal of this doctoral study is to propose a regulatory frame that could fit the re-introduction of bacteriophage therapy without losing sight of the safety, quality and efficacy aspects related to the therapeutic use of bacteriophages.