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Live Biotherapeutic Products (LBPs): European Pharmacopoeia Commission sets unprecedented quality requirements

At its 160th Session, the European Pharmacopoeia (Ph. Eur.) Commission achieved an important milestone in the setting of quality requirements for Live Biotherapeutic Products (LBPs) with the adoption of quality standards for LBPs for human use: a general monograph on *Live biotherapeutic products for human use (3053),* as well as two general chapters: *Microbial examination of live biotherapeutic products (LBP): test for enumeration of microbial contaminants (2.6.36)* and *Microbiological examination of live biotherapeutic products: test for specified microorganism (2.6.38).*

LBPs are medicinal products containing living micro-organisms such as bacteria or yeasts, which have a positive influence on the health and physiology of the host. The most common species are the bacteria *Lactobacilli*, *Bifidobacteria*, some Streptococcal species, *Bacillus clausii* and the yeast *Saccharomyces cerevisiae var boulardii*. However, while many LBPs are available on the European market, no Ph. Eur. standards were available to ensure their quality until now.

In order to close this regulatory gap, the Ph. Eur. Commission has approved a general monograph laying down harmonised requirements for LBPs for human use and two general chapters addressing microbiological contamination of LBPs. These general chapters describe methods for the enumeration of contaminants and for the detection of specified microorganisms, and in addition provide decision diagrams (in both chapters) describing how to establish a suitable testing method, a supplementary tool to control the quality of LBPs.

Requirements include a full morphological, biochemical, serological and molecular characterisation of the strains used (since the therapeutic characteristics are strain-specific), as well as ensuring the absence of antimicrobial resistance or any other virulence factors in LBPs. Verification of the potency by enumeration and microbial contamination detection are also important requirements.

These three new texts will be published in Ph. Eur. Supplement 9.7 and will become effective in April 2019.

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Note for the Editor: Further information is available on the internet site **https://www.edqm.eu/**
The EDQM is a leading organisation that protects public health by enabling development, supporting implementation, and monitoring the application of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark worldwide. The European Pharmacopoeia is legally binding in member states[1]. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

[1]There are thirty-nine members of the European Pharmacopoeia Commission: *Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Republic of Moldova, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, "the former Yugoslav Republic of Macedonia", Turkey, Ukraine, United Kingdom and the European Union.*