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Ph. Eur. consults on new quality standards for Live Biotherapeutic Products

The European Pharmacopoeia (Ph. Eur.) is consulting the public on three new texts, which for the first time in Europe, propose harmonised quality standards for Live Biotherapeutic Products (LBPs) used in human healthcare.

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 boulardi.* However, while many LBPs are available on the European market, there are currently no standards at European level ensuring their quality and thus protecting the health and safety of patients across the Ph. Eur. Member States.

In order to close this regulatory gap, the scientific experts of the Ph. Eur. Commission have set out to finalise a general monograph laying down harmonised requirements to define the quality of LBPs for human use. The Ph. Eur. Commission has also agreed on the need to prepare two general chapters addressing the risk of microbiological contamination of LBPs, hence providing additional tools to control the quality of LBPs.

The requirements proposed by the Ph. Eur. experts include the need for a full morphological, biochemical, serological and molecular characterisation of the strains used, as a way of ensuring the absence of antimicrobial resistance or any other virulence factors in LBPs, since the therapeutic characteristics are strain-specific. Verification of the potency by enumeration and detection of microbial contaminants is also an important requirement.

The Ph. Eur. Commission is now seeking public feedback on the proposed monograph and chapters. Comments can be submitted to the publication Pharmeuropa, edition 29.2 of April-June 2017[1], where the public can find the general monograph *Live biotherapeutic products for human use (3035),* as well as the two 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).*

Interested parties will be able to leave their feedback until June 2017, as per the procedure described in the online publication Pharmeuropa[2].

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Note for the Editor: Further information is available on the internet site **www.edqm.eu**
The EDQM is an organisation that leads the protection of public health by enabling development, supporting implementation, and monitoring the application of quality standards

[1] *Pharmeuropa* 29.2 of April 2017. *Pharmeuropa Online*: http://pharmeuropa.edqm.eu/home/
[2] More information on public enquiries is published in *Pharmeuropa Online* under "Useful information".

for safe medicines and their safe use. Our standards are recognised as a scientific benchmark world-wide. The European Pharmacopeia is legally-binding in member states. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

There are thirty-eight 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, 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.*

A political organisation set up in 1949, the Council of Europe works to promote democracy and human rights continent-wide. It also develops common responses to social, cultural and legal challenges in its 47 member states.