European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

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Department of Biological Standardisation, OMCL Network & HealthCare (DBO)
Organ Transplantation

Strasbourg, 26 May 2020

Ref: RZ/PH/2020-02793L
MLF/spc

Dear colleagues,

Within the framework of cooperation EU Grant Agreement 2018 53 01 between the European Commission and the Council of Europe/EDQM, the EDQM will be coordinating a project entitled **"Understanding post-mortem blood testing practices for tissue donation**". This letter, addressed to member states and relevant professional societies, is aimed at calling for nomination of experts in microbiology testing and post-mortem blood testing to join the bespoke working group that will work on this topic.

EU Directive 2006/17/EC establishes that blood samples from donors should be obtained prior to death or, if not possible, within 24 hours after death. Certain sample characteristics can cause false positive and negative test results (e.g. partial haemolysis) or lead to rejection of samples for testing (e.g. complete haemolysis). In addition, growth of microorganisms and release of enzymes (including products of tissue and cell death) can interfere with testing results. There is a direct correlation between the post-mortem blood sampling time and macroscopic abnormal findings. Other issues that may affect testing results include the site from which a sample was collected, the time of sample collection post-mortem, haemodilution due to massive and/or rapid transfusion/infusion prior to death and the presence of any underlying chronic conditions.

While blood donor testing laboratories are usually highly automated and specialised in large-scale standardised testing, deceased donor samples are usually tested at small scale and by laboratories not usually specialised in donor screening. Furthermore, testing regimes for the detection of infectious diseases in deceased donor samples vary widely between countries and tissue establishments. Some tissue establishments use external testing laboratories (public or private) to perform the tests, while others use in-house testing facilities located at the tissue establishment or within the hospital. However, it is believed that, nowadays, the infrastructure for the selection, approval and validation of testing kits is limited or non-existent.

This activity will aim at providing an overview of the post-mortem blood testing practices in Europe (kits used, sensitivity, validation of kits in tissue establishments prior to their use to test post-mortem samples, etc.). Following a landscape analysis, a technical meeting to discuss the results and develop tailored recommendations to improve post-mortem testing practices in Europe will be organised.

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An ad hoc working group of experts in microbiology testing and post-mortem blood testing will support the EDQM in producing a tailored survey that will be distributed among European tissue establishments. The EDQM will compile and analyse the results and draft a landscape analysis report, which will be used as the basis for discussion during the subsequent technical meeting.

The meetings of the ad hoc working group for the development of the survey and the analysis of the results will be held by virtual means. The final technical meeting will last 2 days and, if the COVID-19 situation allows, will be held at the EDQM premises in Strasbourg (France). Travel costs for up to 15 participants will be covered by the EDQM according to the usual Council of Europe reimbursement rules. Should it not be possible to meet face to face, sufficient advance notice will be provided and alternative virtual means to discuss the results and draft recommendations will be put in place.

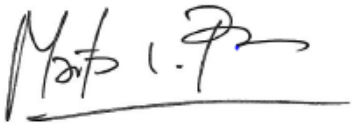
The landscape analysis of the post-mortem testing practices in European tissue establishments will provide the scientific and regulatory community with valuable data about post-mortem blood testing strategies and methodologies in place, including their strengths and limitations.

In addition, during the subsequent technical workshop tailored recommendations will be drafted to support the improvement of post-mortem testing practices by addressing the detected knowledge gaps.

Ultimately, the conclusions and recommendations from this activity could be used to support future regulatory and technical decisions during potential updates of relevant EU Directives.

To nominate experts, please fill in the attached form. Completed forms should be sent to transplantation@edqm.eu **no later than 12 June 2020**.

Best regards,



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Enc:
- Nomination form