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Council of Europe/EDQM supports draft legislative proposal for a new EU Regulation on the safety and quality of blood, tissues and cells

On 14 July 2022, the EU Commission issued its draft legislative proposal for a new EU Regulation on Blood, Tissues and Cells (BTC), in which the EU Commission proposes to leverage on the technical standards and proven expertise of the European Centre for Disease Prevention and Control (ECDC) and the European Directorate for the Quality of Medicines & HealthCare (EDQM)¹ of the Council of Europe as expert bodies.

Falling within the EU better regulation policy, this proposal comes after an [evaluation](#) and [impact assessment](#) of the current BTC legislation, which included wide consultations with stakeholders and international organisations active in the field, including the EDQM.

BTC are also referred to as substances of human origin (SoHO), and are used in highly needed treatments to improve and save the lives of millions every year in Europe.

The figures speak for themselves. Every year:

- 25 million units of blood components – red cells, platelets or plasma – are transfused during surgery, after an accident or to treat life-threatening, chronic illnesses such as cancer or haemophilia;
- there are 36 000 stem cell transplants for blood cancers, 940 000 cycles of *in vitro* fertilisation (IVF) for medically assisted reproduction and 2 000 skin transplants for burn wounds and other injuries.

The draft legislative proposal leverages on the expertise of the Council of Europe/EDQM, which has been a leader in the SoHO/BTC field for several decades, drafting and regularly updating technical standards under the aegis of its intergovernmental committees (the European Committee on Blood Transfusion, or CD-P-TS, and the European Committee on Organ Transplantation, or CD-P-TO). The work of these committees is guided by three principles: *non-commercialisation of SoHO, mutual assistance and protection of both donors and recipients.*

Under the draft legislative proposal, two of the EDQM's widely recognised standards, the *Guide to the preparation, use and quality assurance of blood components* and the *Guide to the quality and safety of tissues and cells for human application*, will become the primary means to meet EU standards of quality and safety for BTC.

The proposed regulation "... ensures that (1) technical rules for safety and quality are responsive to changing risks and technologies, (2) donors and offspring are protected,

1. The EDQM is a directorate of the Council of Europe. The Council of Europe has 46 member states, including all EU member states. The origins of EDQM date back to 1964, when the Convention on the Elaboration of a European Pharmacopoeia was adopted by the Committee of Ministers of the Council of Europe. To date, this convention has been signed and ratified by 39 member states of the Council of Europe, including the 27 member states of the European Union, and by the EU.

The EDQM is responsible for the development of technical rules for safety and quality of SoHO through dedicated experts group, then adopted by the CD-P-TS or the CD-P-TO. These committees are intergovernmental structures answerable to the Committee of Ministers of the Council of Europe. Members eligible to these committees are the members that have signed the Convention on the Elaboration of a European Pharmacopoeia.

(3) harmonisation of oversight requirements is strengthened, (4) innovation is supported, and (5) measures supporting supply resilience are introduced. ...

Both the Council of Europe/EDQM and ECDC will use their capacity and experience to adapt their guidance to scientific progress and frequently changing threats. Entities that choose to apply different technical approaches can do so when they can demonstrate that they achieve equivalent standards of safety and quality to those achieved by following the ECDC and EDQM technical guidelines.”

This proposal will further enhance the long-standing co-operation between the EDQM and the European Union, providing further proof of a mutual recognition of strengths and expertise, as well as the importance of mutualising resources to achieve an economy of scale and ensure a better response to public health needs.

Now to be discussed by the European Council and the European Parliament, the draft legislative proposal lays the foundation for a future-proof and robust legislative framework that will provide better protection for both donors and recipients of BTC.

Once the final text is agreed and adopted, it will come into force with a transition period of two years before most provisions apply and a period of three years for the remainder.

Welcoming the draft proposal, the Council of Europe’s Secretary General, Marija Pejčinović Burić, said:

“I fully support the European Commission’s draft legislative proposal for the new EU Blood, Tissues and Cells (BTC) Regulation.

In its proposal, the Commission makes clear reference to technical standards of the Council of Europe and its European Directorate for the Quality of Medicines & HealthCare (EDQM), as an international organisation working to promote public health since the 1950s.

It is the result of decades of successful co-operation between our two organisations.

We see the draft BTC Regulation as major milestone on the path towards establishing a future-proof, harmonised European Legislative framework in BTC which will benefit patients, donors and all other stakeholders in public health”.

More information about the draft legislative proposal is available at:

- [European Commission’s press release](#)
- [European Commission’s Q&A](#)

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Note for the Editor: Further information is available on the internet site www.edqm.eu.

The EDQM is a leading organisation that protects public health by enabling the development, supporting the implementation and monitoring the application of quality standards for safe medicines and their safe use. Its standards are recognised as a scientific benchmark worldwide. The European Pharmacopoeia is legally binding in member states. The EDQM also develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

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 46 member states.