Press release

28 April 2023, Strasbourg, France

EDQM publishes 21st edition of the Blood Guide, providing state-of-the-art guidance for healthcare professionals

The European Directorate for the Quality of Medicines & HealthCare (EDQM) has just published the 21st edition of the *Guide to the preparation, use and quality assurance of blood components* (Blood Guide).

The Blood Guide is a compendium of widely accepted, harmonised European technical standards providing safety, efficacy and quality requirements for the preparation, use and quality control of blood components in Europe and beyond. It is intended for all professionals working with blood and blood components – from donation, collection and testing to processing, storage, distribution and transfusion – for blood establishments, hospital blood banks and healthcare and regulatory professionals in the blood sector. It gives them a comprehensive overview of the most recent advances in the blood field, together with guidance concerning blood donation and collection. The Blood Guide also includes the Good Practice Guidelines (GPGs) which provide standards for the implementation of quality systems in blood establishments and, where applicable, hospital blood banks. Under European Commission Directive (EU) 2016/1214, the GPGs should be taken into account by EU member states in the implementation of quality systems in their blood establishments

Petra Doerr, EDQM Director, stated on this occasion, "The new edition of the Blood Guide reflects the latest scientific knowledge, data and techniques. It will support the EDQM's objective of contributing to the provision of better healthcare for all. This is why we need to ensure that the Blood Guide standards are constantly updated in a transparent manner – and are based on the most advanced scientific rationale. Bearing in mind that much of the work on this edition was accomplished during the trying COVID-19 pandemic, we thank all the experts involved for their unfailing dedication and tireless efforts."

New in the 21st edition

The latest edition of the Blood Guide introduces a number of improvements making the revision process more transparent. For the first time, all changes with respect to the previous edition have been documented in a change log, accompanied by background documents detailing the scientific rationale behind them. Both the change log and the background documents are published alongside this 21st edition. The terminology used has been standardised, harmonising in particular the use of the terms "must" and "should", and inclusive language has been introduced.

Particular highlights regarding the scientific contents of this edition include:

- new and updated standards on data-processing systems in the GPGs;
- changes in donor selection criteria related to haemoglobin, iron stores, allergy and anaphylaxis, cancer and malignancies, interventions and treatments, acupuncture, tattooing, body piercing, and aesthetic medical procedures, surgery and dental treatment;
- with regard to plasmapheresis, the same permitted annual donation frequency as in the 20th edition but a reduction in the recommended frequency for monitoring of donor IgG levels;
- the recommendation of glucose measurement instead of pH as a more appropriate quality indicator for platelets in additive solutions.

Background

The work of the Council of Europe in the area of blood transfusion began in the 1950s. From the outset, its activities were guided by the principles of promoting voluntary, non-remunerated blood donation, mutual assistance, the optimal use of blood and blood components and the protection of donors and recipients alike.

The European Committee on Blood Transfusion (CD-P-TS) is the steering committee responsible for blood transfusion activities at the Council of Europe, including the periodic revision of the Blood Guide. The CD-P-TS set up the GTS ad hoc Working Group (GTS) to accomplish this task. The EDQM provides the scientific secretariat for these activities.

Download and further information

For more information, visit the EDQM's dedicated web page and download the 21st edition of the *Guide to the preparation, use and quality assurance of blood components*.

Two other "gold-standard" guides are available for professionals working with substances of human origin:

- *Guide to the quality and safety of organs for transplantation* (8th Edition, 2022);
- *Guide to the quality and safety of tissues and cells for human application* (5th Edition, 2022)

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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.[1] The EDQM also develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

1. The European Pharmacopoeia Commission comprises 40 members: Albania, 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, North Macedonia, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Türkiye, 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 46 member states.