Guide to the preparation, use and quality assurance of BLOOD COMPONENTS

European Committee (Partial Agreement) on Blood Transfusion (CD-P-TS)

EDQM
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Guide to the preparation, use and quality assurance of blood components

Why a European guide?

This guide is a compendium of harmonised requirements designed to ensure the safety and quality of blood components used in transfusion.

In the field of blood transfusion, co-operation among Council of Europe member states started back in the 1950s. From the outset, the activities were inspired by the following guiding principles: promotion of voluntary, non-remunerated blood donation, mutual assistance, optimal use of blood and blood products and protection of the donor and of the recipient.

Work on Recommendation No. R (95) 15 started in 1986, when the Select Committee of Experts on Quality Assurance in Blood Transfusion Services published proposals on quality assurance in blood transfusion services. Based on these proposals, the Select Committee produced a more comprehensive guide on blood components in 1995. The immediate success and acceptance of this document was such that the Committee of Ministers adopted the *Guide to the preparation, use and quality assurance of blood components* as a technical appendix to its Recommendation No. R (95) 15.

The recommendation requires that the guide be updated to keep it in line with scientific progress and regulatory changes. Co-ordinated by the European Directorate for the Quality of Medicines & HealthCare (EDQM, Council of Europe), the European Committee on Blood Transfusion (CD-P-TS) acts as the Steering Committee in charge of blood transfusion activities for the Council of Europe. The CD-P-TS is entrusted with the regular update of the guide.

This revision process includes a stakeholder consultation and comments are solicited from national health authorities, as well as all actors involved in blood transfusion or plasma-derived medicinal products before a new edition is released for publication.

What information does the guide contain?

The guide contains harmonised standards and recommendations on blood collection, preparation and the use of blood and blood components, as well as elements of quality management for blood establishments and hospital blood banks. It represents the basis for the establishment of national regulations and certain European Directives.

What is new in the 20th edition of the Blood Guide?

New presentation – This edition introduces a major change in the organisation of the guide. The pre-existing "Principles" and "Standards" sections have been merged in the 20th edition. These changes were favoured by Blood Guide users and will facilitate its use, as standards are now better identified.

Good Practice Guidelines – This edition contains an updated version of the Good Practice Guidelines (GPGs) fully reflecting the most recent changes in good manufacturing practice relevant for blood establishments. The GPGs were prepared through ad hoc co-operation between the EDQM and the European Union Commission. These GPGs are mandatory requirements within the European Union as per Directive (EU) 2016/1214.

Standards chapter – The Blood Guide now proposes a set of standards which are developed to support high-quality transfusion practice in Council of Europe member states. They may also be of benefit to other jurisdictions or organisations involved in blood transfusion activities outside Europe. The guide includes recommendations for minimum standards for blood establishments and hospital blood banks that are required to comply with EU Directives 2002/98/EC, 2004/33/EC, 2005/61/EC and 2005/62/EC as amended by Directive (EU) 2016/1214.

Monographs chapter – This chapter contains monographs on blood components, mirroring the structure used in the European Pharmacopoeia. These monographs describe requirements that are to be regarded as harmonised standards for the quality and safety of blood components across Europe.

Who is the guide designed for?

The guide is a tool specifically designed for all professionals working in the field of blood transfusion, including regulatory authorities, blood establishments and hospital blood banks.

Publication and purchase of the guide

The guide is available in English. Translations into other languages may be produced under the responsibility of external parties and with the agreement of the EDQM.

The guide can be downloaded in electronic format free of charge: go.edqm.eu/dl

Paper copies are available for purchase at the EDQM Store: www.edqm.eu/store

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