10 YEARS OF CO-OPERATION

WORKING TOGETHER
FOR A SAFE AND SUSTAINABLE BLOOD SUPPLY

BETWEEN THE EUROPEAN COMMISSION & THE EDQM / COUNCIL OF EUROPE

SUPPORT

COLLABORATION

REACHING GOALS

edqm

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

Funded by the European Union and the Council of Europe

EUROPEAN UNION

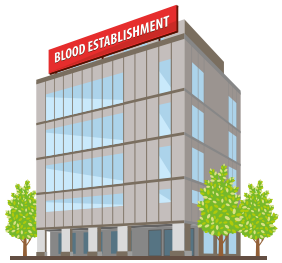
COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

Implemented by the Council of Europe

BLOOD TRANSFUSION:
A LIFE-SAVING MEASURE

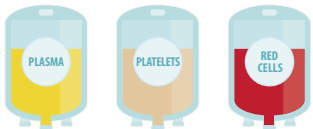
10 YEARS OF CO-OPERATION



1 400
blood establishments

FIND OUT MORE

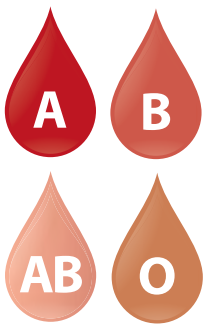
1 unit of WHOLE BLOOD
can save up to 3 lives



25 MILLION UNITS TRANSFUSED
per year**

Plasma used to produce medicinal products

LEARN MORE



15 million donors in Europe
22 donors per 1 000 inhabitants*

FIND OUT MORE

WHO NEEDS BLOOD?

- patients during **surgery**
- victims of **accidents**
- **patients with acute illnesses,** such as cancer or haemophilia

FIND OUT MORE

Learn more about the EDQM's work on blood data collection

* "The collection, testing and use of blood and blood components in Europe", 2015, EDQM/Council of Europe.
** "An EU-wide overview of the market of blood, blood components and plasma derivatives focusing on their availability for patients", Creative Ceutical report revised by the Commission to include stakeholders' comments, 2015. See also the European Commission's "Blood, tissues, cells and organs" page.

BLOOD, A PRECIOUS RESOURCE IN EUROPE

TWO ORGANISATIONS, SHARED VALUES, ONE GOAL …

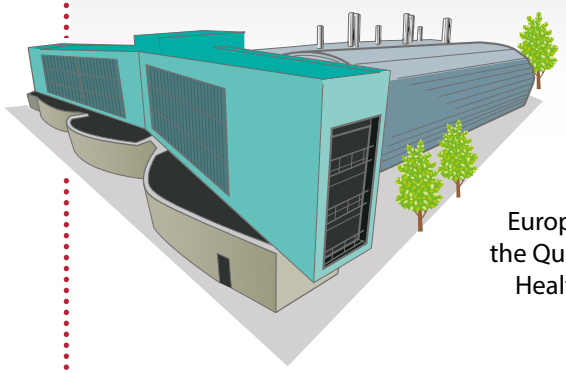
10 YEARS OF CO-OPERATION

COUNCIL OF EUROPE

47 MEMBER STATES
830 MILLION INHABITANTS

COMMITTEE OF MINISTERS · COMITÉ DES MINISTRES · COUNCIL OF EUROPE · CONSEIL DE L'EUROPE
Parliamentary Assembly · Assemblée parlementaire · COUNCIL OF EUROPE · CONSEIL DE L'EUROPE

- Statute of the Council of Europe
- Convention on the Elaboration of a European Pharmacopoeia



EDQM

European Directorate for the Quality of Medicines & HealthCare, **Strasbourg**

SoHO ACTIVITIES

- standard setting on safety and quality: *resolutions, guides, technical standards*
- monitoring
- co-operation programmes

FIND OUT MORE

Resolution CM/Res(2017)43 on principles concerning haemophilia therapies

SHARED VALUES

Democracy

Human rights

Rule of law

COLLABORATION IN THE FIELD OF SUBSTANCES OF HUMAN ORIGIN (SoHO)

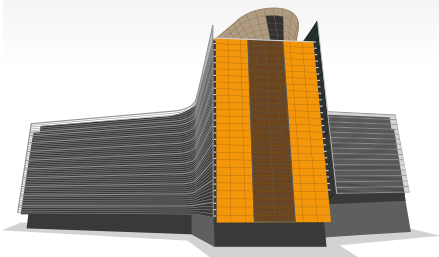
LEARN MORE

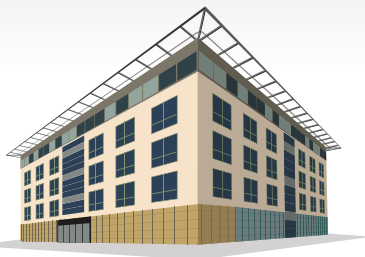
EUROPEAN UNION

27 MEMBER STATES
446 MILLION INHABITANTS

European Parliament · European Commission · European Council

- Treaty on the Functioning of the European Union > Article 168: Public health
- Treaty on European Union





DG-SANTE

European Commission Directorate-General for Health and Food Safety, **Brussels**

ECDC

European Centre for Disease Control, **Stockholm**

SoHO ACTIVITIES

- EU legislation on safety and quality
- strengthening, co-ordinating national oversight
- vigilance, alert and traceability tools
- co-operation programmes and EU-funded actions for member states
- risk assessment (ECDC, e.g. WNV)

PROTECTING PUBLIC HEALTH

10 YEARS OF CO-OPERATION

10 YEARS OF CO-OPERATION

2010-2012
1st co-operation project: blood transfusion
- *B-PTS PROGRAMME*
- *B-QM PROGRAMME*

2011-2013
2nd co-operation project: blood transfusion
- *GOOD PRACTICE GUIDELINES*

2014-2015
3rd co-operation project: blood transfusion
- *B-PTS PROGRAMME*
- *B-QM PROGRAMME*

4th co-operation project: tissues and cells
- *GUIDE TO THE QUALITY AND SAFETY OF TISSUES AND CELLS FOR HUMAN APPLICATION*

2016-2018
5th co-operation project: blood transfusion and tissues and cells
- *B-PTS PROGRAMME*
- *B-QM PROGRAMME*
- *GUIDE TO THE QUALITY AND SAFETY OF TISSUES AND CELLS FOR HUMAN APPLICATION*

2017-2018
6th co-operation project: blood transfusion and tissues and cells
- *SARE ANALYSIS*

2019-2021
7th co-operation project: blood transfusion and tissues and cells

LEARN MORE

CURRENT PORTFOLIO OF ACTIVITIES

BLOOD
- B-PTS Programme
- B-QM Programme
- Emergency and contingency planning for blood
- Plasma supply management

SARE analysis
Biovigilance training
Country assessment

TISSUES & CELLS
- Guide to the quality and safety of tissues and cells for human application
- TC QM training
- Post-mortem blood validation
- Harmonisation of collected data in tissues and cells

... BENEFITTING BLOOD ESTABLISHMENTS, TISSUES & CELLS ESTABLISHMENTS AND AUTHORITIES

TOWARDS A COMMON EUROPEAN HARMONISED SET OF STANDARDS TO ENSURE SAFE AND SUSTAINABLE BLOOD TRANSFUSION

A NECESSARY EUROPEAN REGULATORY FRAMEWORK

10 YEARS OF CO-OPERATION

KEY CHALLENGES AND TRIGGERS

- PROTECTION OF PATIENTS
- SAFETY
- QUALITY
- MUTUAL ASSISTANCE
- INFECTIOUS DISEASES
- NATURAL DISASTERS

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

GUIDE TO THE PREPARATION, USE AND QUALITY ASSURANCE OF BLOOD COMPONENTS

20 editions over 28 years
A dynamic reference which keeps pace with latest developments

1992 – 1st Edition –
Blood collection, blood components, laboratory procedures and transfusion practices

2017 – Inclusion of the Good Practice Guidelines jointly developed by the European Commission and the EDQM

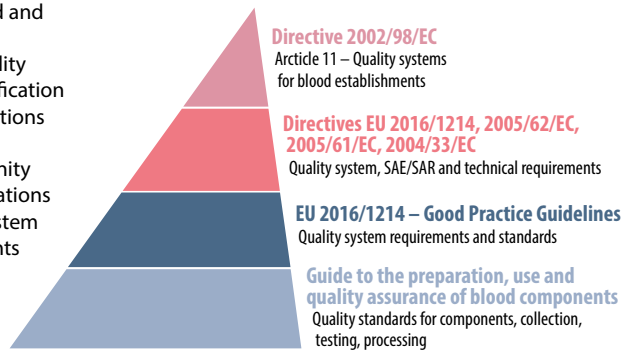
2020 – 20th Edition –
Donor selection and protection, blood collection, blood component processing, blood components monographs, immunohaematology, screening for infectious markers, haemovigilance, clinical use of blood

European Commission

2002 – A framework directive
2002/98/EC – Setting quality and safety standards for the collection, testing, processing, storage and distribution of human blood and blood components, and amending Directive 2001/83/EC

2004 – Subsequent technical directives
2004/33/EC – Technical requirements for blood and blood components
2005/61/EC – Traceability requirements and notification of serious adverse reactions and events
2005/62/EC – Community standards and specifications relating to a quality system for blood establishments

2016
EU 2016/1214 – Amending Directive 2005/62/EC quality system standards and specifications for BEs, referring to the **GPGs**



FIND OUT MORE

EU Public Health: blood, tissues, cells and organs

STAKEHOLDERS

BLOOD ESTABLISHMENTS
Donor selection and protection, collection, testing, processing, storage, distribution and clinical use, quality system requirements

NATIONAL COMPETENT AUTHORITIES
Oversight including authorisation, inspection, vigilance and traceability requirements

EUROPEAN COMMISSION
EU level support (e.g. rapid alerts)

EDQM/COUNCIL OF EUROPE
Setting standards and supporting their implementation

LEARN MORE

PROTECTING PUBLIC HEALTH

FROM STANDARDS **TO OPERATIONAL TOOLS**

10 YEARS OF CO-OPERATION

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

B-PTS Programme: a means of assessing since 2010 that the **test results** for blood donations are **reliable**

Nucleic Amplification Technique (NAT)

HBV, HCV, HIV

Serology

Anti-HCV
Anti-HIV/p24
Anti-treponema
HBsAg/Anti-HBC

Immunohaematology

ABO, Rhesus, Kell, extended phenotyping and irregular antibodies

B-QM Programme: on-site support since 2012 to **blood establishments** to develop and improve their **quality systems, towards risk-based and cost-effective quality systems**

Auditing schemes

Blood training visit (B-TV)
On-site visit and training session on technical and QMS issues based on observed non-compliances

Blood mutual joint visit (B-MJV)
Audit to check compliance with requirements
▸ *report and recommendations*

Blood mutual joint audit (B-MJA)
Audit to check compliance with requirements
▸ *report and CAPA follow-up*

Training courses/conferences

Practical guidance

- ▸ **6** studies (**300-400** participants)/year
- ▸ over **50** studies to date
- ▸ covering **33** European countries

- ▸ over **30** auditing schemes to date
- ▸ covering **17** European countries
- ▸ **4** training courses and **1** conference

LEARN MORE

PROTECTING PUBLIC HEALTH

10 YEARS OF CO-OPERATION

Géraldine Lorimier

NEUCHÂTEL-JURA BLOOD CENTRE,
SWISS RED CROSS, **SWITZERLAND**

"We were interested to have the opinion of **recognised European experts** about our procedures."

"The most beneficial aspect of the auditing scheme was **the exchange of expertise and knowledge** with auditors working in other blood establishments in Europe. The **Blood Mutual Joint Visit** allowed us **to benchmark and compare** with other blood establishments."

"The most important change was the **upgrade of our transport process**. We improved transport conditions between our different sites."

Recognised, useful and of quality

Technical supervisor at the Neuchâtel-Jura Blood Centre, Swiss Red Cross

2015
Member of Swiss Transfusion Committee for QA-Management

2002
Quality Manager at Neuchâtel-Jura Blood Centre, Swiss Red Cross

2001
Master in Biology (specialisation in Microbiology and Immunology), University of Neuchâtel

1999
Bachelor in Biology, University of Neuchâtel

Levan Avalishvili

JO ANN MEDICAL CENTRE, **TBILISI, GEORGIA**

"We applied for a **Blood Training Visit** because it was **an opportunity to gain huge experience** from highly skilled European experts. In the absence of regulatory oversight we have never been audited before."

"Friendly atmosphere, **extremely important suggestions and recommendations**. The experts are really focused on how to help you."

"Now we can start implementing the recommended action plan and protocols, set goals and start moving forward step-by-step to improve our quality system."

Free, affordable and positive

Blood Bank Director, Jo Ann Medical Centre

Since 2009
Member of the Working Group on Georgian Blood System Reformation and Strengthening (Ministry of Health of Georgia)

Since 2007
Chief expert and a leader of the National Blood Donor Database Working Group (Ministry of Health of Georgia); Member of CD-P-TS

Since 2000
Member of the American Association of Blood Banks (AABB) and the International Society of Blood Transfusion (ISBT)

1992
MD, Tbilisi State Medical Institute

Socrates Menelaou

CYPRUS BLOOD ESTABLISHMENT, **NICOSIA, CYPRUS**

"As a small country with recently reformed blood services, we required **independent assessment** and thus applied for a **Blood Mutual Joint Visit**. It was a challenging and positive experience."

"**Comments and expertise received were invaluable assets** to our recently implemented quality system."

"The **professional yet friendly approach** of the Blood Mutual Joint Visit lead to **major improvements in our service.**"

"The recommendations were the **building blocks of our quality system**, which ultimately benefited the transfused patients, many of whom are thalassemia patients."

Enlightening, invaluable and challenging

Deputy Director, Cyprus Blood Establishment

Since 2019
Member of the Cyprus National Thalassemia Committee

2016
Master in Health Service Administration and Management, Cyprus Open University

2009
Head Inspector of Medical Laboratories, Cyprus Ministry of Health

1995
Master of Science in Biomedical Sciences, Manchester Metropolitan University, UK

1992
BSc in Chemistry, Aristotelion University of Thessaloniki, Greece

Vincenzo de Angelis

ITALIAN NATIONAL BLOOD CENTRE, **ROME, ITALY**

"**We applied for a peer audit** within the Blood Quality Management Programme to get **inspiration to develop a comprehensive and structured quality system.**"

"The great professional experience gained through **the Blood Mutual Joint Visit** and the enthusiasm it generated in staff are all good reasons for recommending this programme."

"The programme has been successful in developing **a deeper insight into** and a **better knowledge in applying a risk-based approach** throughout the transfusion activities and the interaction with clinical services. This enhances safe use of blood components."

Inspiring, rewarding and commendable

Director, Italian National Blood Centre at Istituto Superiore di Sanità

Since 2019
President, European School of Transfusion Medicine (ESTM)

2008
Director, Transfusion Medicine Dept, Udine University Hospital, Italy

Since 1999
Member of different European and Italian committees and working parties on transfusion

1984 and 1988
Speciality Diplomas, Haematology and Clinical Biology, Padua University, Italy

1981
Medical Degree, Padua University, Italy

Tatjana Makarovska Bojadjieva

NATIONAL INSTITUTE FOR TRANSFUSION MEDICINE, **SKOPJE, NORTH MACEDONIA**

Head of the Department for Blood Testing at the National Institute for Transfusion Medicine

2019
Head of the Cathedra for Transfusiology, University of Ss. Cyril and Methodius, Medical Faculty

2010
PhD in Immunohaematology with doctoral thesis at the Institute for Transfusion Medicine, University of Ss. Cyril and Methodius, Medical Faculty

Since 2000
Manager of the National Blood Donor Information System

1999
Specialisation in Transfusion Medicine at the Medical Faculty

1992
Dipl. Medical doctor at the University of Ss. Cyril and Methodius, Medical Faculty

"The **Blood Proficiency Testing Scheme** is an objective and independent **means to assess and demonstrate the reliability of our data and the integrity** of our entire testing process."

"Organised in a way which is user friendly. **Results are comprehensive and educative**. Great knowledge about good laboratory practice can be learned."

"It helped us to embrace our weak points, to **implement necessary improvements** and to compare our data to other participating laboratories."

Stimulating, professional and rewarding

Alina Mirella Dobrota

REGIONAL BLOOD TRANSFUSION CENTRE, **CONSTANTA, ROMANIA**

Director, Regional Blood Transfusion Centre

Since 2016
President of the National Committee on Blood Transfusion of the Ministry of Health

Since 2005
Ministry of Health representative for competent authority regulatory meetings

Since 2004
Ministry of Health representative in CD-P-TS and GTS, EDQM/Council of Europe

Since 2010
Ministry of Health Head of Experts on blood and blood components

"The Blood Proficiency Testing Scheme is an opportunity to **contribute to the development and compliance** of the Romanian Blood Transfusion System with European regulations and good practices."

"**Genuine blood sample**s and a **broad range of tests**, covering both donor- and patient-related testing algorithms."

"It offers the possibility to identify issues related to reagents, equipment, methods and take measures where required."

Excellent organisation, accessible and user friendly

SHAPING THE FUTURE – OUTCOME OF THE EVALUATION OF EU SoHO LEGISLATION

10 YEARS OF CO-OPERATION

To stay relevant and provide the expected level of protection to EU citizens, the European Commission, in line with its Better Regulation Guidelines, conducted an evaluation of legislation governing substances of human origin (SoHO) to assess whether it achieved the original objectives and whether it was still fit for purpose. The Commission conducted its first evaluation of SoHO legislation in 2017. This multi-stage process began with the publication of a roadmap, included a study by an external contractor and involved extensive stakeholder consultation. Discussions on follow-up action are now underway in the Commission.

ROADMAP 2017

EVALUATION CRITERIA

RELEVANCE – still up to date (science, technology, epidemiology, commercialisation, new actors)?

EFFECTIVENESS – Increasing safety and quality? Negative side-effects or barriers?

EFFICIENCY – Benefits and costs for establishments, clinicians, authorities?

COHERENCE – Consistent with other legislation, any gaps or overlaps?

ADDED VALUE – Could the results be achieved better at national or global level?

SURVEY

FOCUS GROUP MEETINGS

CONFERENCES

FIND OUT MORE

Evaluation of EU blood and tissues and cells legislation

KEY SHORTCOMINGS

1. Out-of-date technical provisions in a rapidly changing sector
2. Some citizens are not adequately protected
3. Oversight provisions not adequate to regulate today's blood, tissues and cells landscape
4. Blood, tissues and cells legislation does not keep pace with innovation
5. Limited provisions to ensure efficiency

NEXT PAGE >>>

1 OUT-OF-DATE TECHNICAL PROVISIONS IN A RAPIDLY CHANGING SECTOR

Technological changes

- New donor testing possibilities – for virus, bacteria and genetic conditions
- New processing possibilities – microbial reduction (blood), vitrification (eggs), laser cutting (corneas), etc.

Epidemiological changes

- Global warming and increased travel causing infectious disease outbreaks

Societal changes

- Increased internationalisation and commercialisation
- Aging population
- Changing concepts of family

SHAPING THE FUTURE – OUTCOME OF THE EVALUATION OF EU SoHO LEGISLATION

10 YEARS OF CO-OPERATION

2 SOME CITIZENS ARE NOT ADEQUATELY PROTECTED

Limited provisions to protect blood, tissue and cell donors

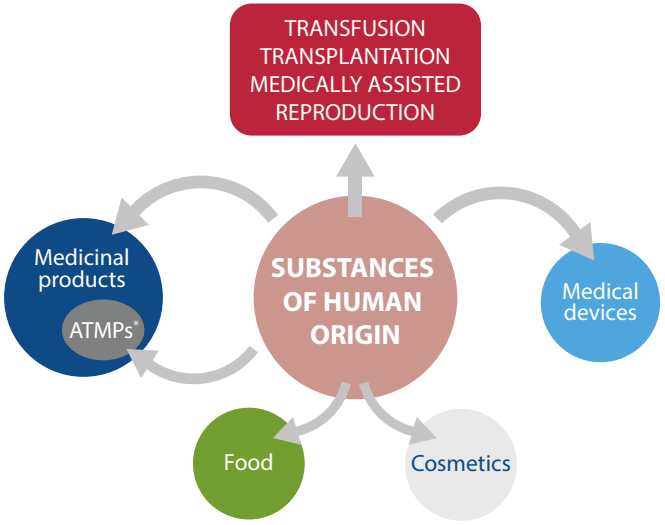
- Donors having a surgical intervention (e.g. bone marrow), hormonal treatment to stimulate production/release of cells/gametes (blood stem cells, eggs)
- Reporting of donor adverse reactions, donor eligibility
- Safety following donation – short and long term

Gaps identified in protecting the offspring born from donated gametes

- Detection of genetic conditions in donors
- Need for follow-up on children born from these donations
- Limited requirements for testing gamete donors for genetic conditions

4 BLOOD, TISSUES AND CELLS LEGISLATION DOES NOT KEEP PACE WITH INNOVATION

- Authorisation of new processing steps (including proof of effectiveness)
- Same surgical procedure and use of bedside/in-surgery medical devices for blood, tissues and cells processing
- Some lack of clarity at borderlines with other frameworks
- Requirements for blood, tissues and cells that are used to manufacture medicinal products or medical devices



* Advanced therapy medicinal products

3 OVERSIGHT PROVISIONS NOT ADEQUATE TO REGULATE TODAY'S BLOOD, TISSUES AND CELLS LANDSCAPE

- Lack of principles to ensure independence of authorities/inspectorates from the field they regulate
- No formal mechanism to verify effectiveness of inspections/ authorisations (as seen in other frameworks)
- Fixed two-yearly inspections: frequency not optimal for efficiency or effectiveness
- Clarity of provisions for activity data reporting not adequate
- Clarity of provisions for vigilance not adequate

5 LIMITED PROVISIONS TO ENSURE EFFICIENCY

- Reliance on USA for sufficient plasma for the manufacture of plasma-derived medicinal products
- Reliance on the USA for sufficiency of some tissues
- Need to facilitate international exchanges of haematopoietic stem cells
- National barriers for cross-borders exchanges, hard to overcome for (small) public establishments (patients missing out on best matching therapy)
- Dependency of the blood, tissues and cells supply on the sustainable supply of medical devices

10 YEARS OF CO-OPERATION

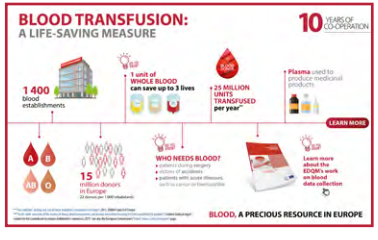
Learn more

BLOOD TRANSFUSION: A LIFE-SAVING MEASURE

There are 15 million blood donors in Europe, and 25 million blood units are transfused each year.

Plasma, red cells and platelets are used routinely to save patients' lives during surgery, after an accident or during acute illnesses, such as cancer or haemophilia.

More detailed information on the collection, testing and use of blood and blood components in Europe can be found in the EDQM's reports.



<< RETURN

TWO ORGANISATIONS, SHARED VALUES, ONE GOAL …

The Council of Europe and the European Commission (EC) are two key organisations working together in the field of substances of human origin, such as blood, tissues, cells and organs, used in a variety of medical therapies with the common, shared goal to protect public health.

The EDQM/Council of Europe sets ethical, safety and quality standards for blood, tissues, cells and organs. Through its programmes and legal instruments, it works to ensure the quality and safety of blood transfusions in the 47 member states of the Council of Europe and beyond.

The European Commission/DG SANTE undertakes a range of activities, including drafting legislation and developing guidance, assisting national authorities with their implementation, accompanied by vigilance activities and project support for its 27 member states.

These two organisations co-ordinate their efforts and resources to avoid any overlap or gap in existing regulations in the field of blood and blood components.

<< RETURN

10 YEARS OF CO-OPERATION

Since 2010, the EDQM/Council of Europe and the EC have collaborated through a succession of co-operation projects to co-ordinate activities with the common goal of ensuring the quality and safety of transfusions and transplantations in Europe. These activities have been co-funded by the EDQM and the European Commission.

Activities in blood transfusion include:

- the **Blood Proficiency Testing Scheme** (B-PTS), an external quality assessment scheme aimed at evaluating the performance of European blood establishment laboratories;
- the **Blood Quality Management Programme** (B-QM), an education and assistance programme for European blood establishments, designed to facilitate the implementation of quality management systems (QMS) through assessment schemes, training and conferences;
- the **Good Practice Guidelines** (GPGs), which comprise standards and specifications for European blood establishments in their implementation of quality management systems. The GPGs are an integral part of the Council of Europe *Guide to the preparation, use and quality assurance of blood components* ("Blood Guide") and were adopted by the European Commission in line with the Commission Directive (EU) 2016/1214.

In addition to the field of blood, since 2014, activities in the field of tissues and cells have been co-ordinated as part of the EC/EDQM co-operation projects, including the elaboration and maintenance of the **EDQM *Guide to the quality and safety of tissues and cells for human application***, setting standards and technical requirements for European tissue establishments.

The current portfolio of activities includes further work programmes relating to:

- emergency and contingency planning for ensuring continuity of blood supply;
- plasma supply management;
- tissue and cell quality management training;
- post-mortem blood validation;
- harmonisation of tissue and cells data collection;
- and transversal work programmes on vigilance and country assessment.

<< RETURN

TOWARDS A COMMON EUROPEAN HARMONISED SET OF STANDARDS TO ENSURE SAFE AND SUSTAINABLE BLOOD TRANSFUSION

The EDQM/Council of Europe regularly reviews and updates technical requirements in its *Guide to the preparation, use and quality assurance of blood components* and *Good Practice Guidelines for blood establishments*. In addition, it prepares ad hoc guidelines on different topics, in regard to the safety and quality of substances of human origin (SoHO).

The EU legal framework defining the quality and safety standards for blood and its components is set out in Directive 2002/98/EC, also referred to as the European Blood Directive. It covers all steps in the transfusion process from donation, collection, testing, processing, and storage to distribution. To help implement this main act, the European Commission proposed and adopted, in close collaboration with EU national authorities, a series of additional implementing acts (more information available on the EC web page on blood, tissues, cells and organs).

The European Commission collaborates closely with expert bodies such as the EDQM/Council of Europe and the European Centre for Disease Protection and Control (ECDC) in the development of practical guidelines that support blood establishments with the implementation of this binding legislative framework.

The ECDC prepares risk assessments and preparedness plans whenever epidemiological outbreaks are of relevance for blood, tissues, cells and organs.

<< RETURN

FROM STANDARDS TO OPERATIONAL TOOLS

Specifically, in the areas of blood quality, the EDQM has established two programmes, the **Blood Proficiency Testing Scheme (B-PTS)** and the **Blood Quality Management (B-QM) Programme**.

The **B-PTS Programme** is a form of external quality assessment (EQA) that uses inter-laboratory comparisons to determine the performance of blood establishment laboratories responsible for the testing of individual blood donations. Participation in the scheme provides laboratories with an objective means of assessing and demonstrating the reliability of their testing procedures.

Six B-PTS studies are organised each year, comprising NAT testing (HBV, HCV and HIV), serological testing (anti-HCV, anti-HIV/p24, anti-treponema, HBsAg and anti-HBC) and immunohaematological testing (ABO, Rhesus, Kell, extended phenotyping and irregular antibodies).

Since its inception, blood establishment laboratories from 33 Council of Europe and European Union member states have benefitted from participating in the B-PTS scheme.

The B-PTS continues to provide between 300 and 400 test panels each year to an average of 50 participating blood establishments per study.

The **B-QM Programme** is an education and assistance programme aimed at supporting European blood establishments in developing, implementing and improving their quality management systems (QMS), taking into account the specificities of the blood transfusion field.

The B-QM Programme delivers on-site training/assessment schemes, including Blood Training Visits (B-TV), Blood Mutual Joint Visits (B-MJV) and Blood Mutual Joint Audits (B-MJA), as well as learning tools, including training courses, conferences and practical guidance.

Since its inception, the B-QM Programme has delivered 31 on-site training/assessment schemes in blood establishments in Council of Europe member and observer states and European Union member states. Four training courses and a blood quality conference have been organised, and practical guidance for blood establishments on the development and implementation of quality management systems is currently being drafted.

<< RETURN