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

COUNCIL OF EUROPE
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INTERGOVERNMENTAL COMMITTEES AND NETWORKS
DEPARTMENT (ICND)

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EUROPEAN COMMITTEE (PARTIAL AGREEMENT) ON BLOOD TRANSFUSION (CD-P-TS)

European Committee on Blood Transfusion (CD-P-TS) - Work Plan

1 Jan 2025 – 31 Dec 2027

Updated following the 24th CD-P-TS Plenary Meeting (March 2025)

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

Work Plan

1 Jan 2025 – 31 Dec 2027

Version: Updated following the 24th CD-P-TS Plenary Meeting (March 2025)

Purpose

This work plan is intended to complement the Terms of Reference for the European Committee on Blood Transfusion (CD-P-TS) by outlining practical aspects related to the composition and working methods of the committee, as well as clarifying roles and responsibilities concerning key deliverables, ongoing projects and priority areas.

This work plan is a working document and will be updated following each CD-P-TS plenary meeting to reflect the latest developments, decisions and priorities.

Its aim is to promote transparency, ensure continuity and strengthen mechanisms for monitoring and evaluating progress over time.

The CD-P-TS Terms of Reference (1 January 2024 - 31 December 2027) provide further information on the main tasks, deliverables and composition and working methods.

A consolidated summary table of key dates and actions drawn from across the work plan is included in Appendix 1.

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

Background

The work of the Council of Europe in blood transfusion is carried out under the aegis of the CD-P-TS.

The European Directorate for the Quality of Medicines & HealthCare (EDQM), working under the European Pharmacopoeia Partial Agreement, provides the scientific secretariat for these activities.

Mission

The work of the Council of Europe in blood transfusion is to ensure the protection of public health by elaborating, promoting and actively contributing to the implementation of high safety and quality standards.

The principles guiding this work are:

- promotion of voluntary, non-remunerated blood donation,
- mutual assistance,
- optimal use of blood and blood components,
- protection of both donor and recipient.

Considering ethical, legal and organisational aspects of blood transfusion and new scientific developments in this sector, the ultimate aim of all blood transfusion activities is to ensure the quality and safety of blood and blood components and their optimal use, increase their availability and avoid wastage.

Composition

The CD-P-TS is composed of representatives nominated by Council of Europe member states that have signed and ratified the European Pharmacopoeia Convention (n = 39)[1].

The CD-P-TS includes regular participating representatives from Australia, Canada, New Zealand and the USA, from the European Commission (DG SANTE), the European Medicines

[1] Albania, Andorra, Armenia, Austria, Azerbaijan, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Republic of Moldova, Monaco, Montenegro, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, San Marino, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Republic of Türkiye, Ukraine, United Kingdom

Agency (EMA), the European Centre for Disease Prevention and Control (ECDC) and the World Health Organization (WHO). Steering Committees of the Council of Europe that are engaged in related work also participate, where relevant, including the European Committee for Organ Transplantation (CD-P-TO) and the Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO).

Observer requests may be submitted to the CD-P-TS by organisations relevant to the blood transfusion field, including civil society organisations and other public, private and academic actors who wish to contribute to the work of the CD-P-TS. At this time, there are no additional observers to the CD-P-TS.

Chair and Vice-Chair

The CD-P-TS elects a Chair and Vice-Chair. The term of office for both positions is one year and may be renewed once.

The Chair and Vice-Chair are members of the CD-P-TS Bureau (see below). The Chair presides over plenary meetings and sums up the conclusions, when necessary. The Vice-Chair replaces the Chair should the Chair be absent.

The CD-P-TS is chaired by Johanna Castrén (Finland). The term of office will conclude in January 2026.

The position of Vice-Chair is currently vacant.

The election for both the Chair and Vice-Chair of the CD-P-TS will be held during the 25th Plenary Meeting of the CD-P-TS (10 and 11 December 2025).

Chair and Vice-Chair – Election Schedule

Election	Meeting	Date
Election – Chair and Vice-Chair	25th Plenary Meeting CD-P-TS	10 and 11 December 2025
Renewal of Terms – Chair and Vice-Chair	27th Plenary Meeting CD-P-TS	Q4 2026 (date TBC)
Election – Chair and Vice-Chair	29th Plenary Meeting CD-P-TS	Q4 2027 (date TBC)

Election timings are subject to change based on committee needs and other procedural considerations.

CD-P-TS Bureau

The CD-P-TS has an appointed Bureau to facilitate more regular and timely contact with the CD-P-TS Secretary.

The functions of the Bureau are as follows:

- to ensure continuity between CD-P-TS plenary meetings, as necessary;
- to provide guidance and advice in developing strategic objectives for the CD-P-TS and its areas of work;
- to support the preparation of CD-P-TS plenary meetings;
- to represent the CD-P-TS, where required, in meetings, at conferences, etc.

The Bureau has no decision-making power and cannot replace the full CD-P-TS in this regard. All matters that require decision are brought to the committee for approval.

The CD-P-TS Bureau is composed of the CD-P-TS Chair and Vice-Chair, and the Chair of the Blood Guide Working Group (GTS Working Group). A limited number of additional committee members may also be appointed, via election, in the same manner as the Chair and Vice-Chair.

The Bureau has monthly meetings (via videoconference) and meets in person twice a year, where suitable, in conjunction with the CD-P-TS plenary meetings.

CD-P-TS Bureau members are Johanna Castrén (FI), Betina Soerensen (DK), Stephen Thomas (UK) and Aranzazu de Celis Miguelez (ES).

Rapporteurs

The CD-P-TS has an appointed Gender Equality Rapporteur (GER), Martina Brix-Zuleger (Austria).

CD-P-TS Plenary Meetings

CD-P-TS plenary meetings are held twice a year. One meeting is held via videoconference and the other is held in person at the premises of the Council of Europe in Strasbourg.

Plenary Meeting Schedule

Event	Location	Date
24th Plenary Meeting of the CD-P-TS	Strasbourg (in person)	25 March 2025
25th Plenary Meeting of the CD-P-TS	Virtual	10 and 11 December 2025
26th Plenary Meeting of the CD-P-TS	Strasbourg (in person)/virtual (TBC)	Q1/Q2 2026 (date TBC)
27th Plenary Meeting of the CD-P-TS	Strasbourg (in person)/virtual (TBC)	Q4 2026 (date TBC)
28th Plenary Meeting of the CD-P-TS	Strasbourg (in person)/virtual (TBC)	Q1/Q2 2027 (date TBC)
29th Plenary Meeting of the CD-P-TS	Strasbourg (in person)/virtual (TBC)	Q4 2027 (date TBC)

The dates and formats listed are indicative and subject to change.

Priority Areas of Work

1. Blood Guide

The CD-P-TS is responsible for the elaboration of quality and safety standards for the collection, preparation, testing and use of blood and blood components.

Specifically, the CD-P-TS is responsible for updating and publishing, on a regular basis, the technical appendix to Committee of Ministers Recommendation R(95)15, also known as the *Guide to the preparation, use and quality assurance of blood components,* "the Blood Guide", and promoting its implementation.

To fulfil this requirement, the CD-P-TS established and appointed the GTS Working Group (GTS) to revise the Blood Guide. The Chair of the GTS periodically reports to the CD-P-TS on the progress of revision at plenary meetings.

The revision is based on the monitoring and expert evaluation of scientific progress and regulatory changes in the field and the assessment of current evidence on the quality and safety of blood and blood components as published in recent scientific literature, with the aim of setting high standards of quality and safety for donors and recipients of blood and blood components.

The CD-P-TS is responsible for the technical and strategic oversight of the GTS and the Blood Guide.

This oversight is maintained through the participation of the GTS Chair in the CD-P-TS Bureau, the periodic reporting of the GTS Chair to the committee and, within the EDQM, through the CD-P-TS Secretary in co-ordination with the EDQM Standards Section.

The CD-P-TS is responsible for the following tasks:

Terms of Reference

The CD-P-TS approves the Terms of Reference of the GTS.

The current GTS Terms of Reference provide further information on the main tasks, composition and working methods for the 23rd Edition of the Blood Guide.

Nomination of Experts

The GTS is composed of experts nominated by CD-P-TS members and observers. Nominations are based on specific expert knowledge in the field of preparation, use and quality assurance of blood and blood components, and are made in response to calls for nominations.

The composition of the GTS is decided by the CD-P-TS Bureau, the GTS Chair (if not a member of the CD-P-TS Bureau), and the EDQM Secretariat, based on the recommendation of an appointed "GTS Core Group" (chapter group leaders), considering:

a) the elaboration needs (critical revision of the content, identification of revision needs, drafting and input for digitalisation);
b) the technical and scientific expertise needs;
c) an optimal ratio of newly appointed experts and those who have already actively participated in the development of previous editions of the Guide (to ensure continuity and sustainability in the elaboration process);
d) broad and balanced geographic representation;
e) willingness of the candidate to take active part in the GTS in a timely manner.

Working Groups/Projects

Where there is an identified need, the CD-P-TS can establish working groups or projects in specific areas to complement the work of the GTS and support the revision of the Blood Guide.

Scope of Revision

The CD-P-TS is responsible for approving the scope of revision of the Blood Guide.

The CD-P-TS can contribute to the scope of revision by identifying needs and specific areas of priority.

Adoption

The CD-P-TS is responsible for the adoption of the Blood Guide prior to publication by the EDQM.

Blood Guide Revision Processes

The CD-P-TS supports the EDQM, where required, by providing input and advice to support the modernisation of Blood Guide revision processes, including the consultation on the

digitalisation of the Blood Guide (expected launch 2025) and digital transformation of the Blood Guide (expected launch 2026).

EU Regulation on Substances of Human Origin (SoHO) (EU) 2024/1938.

The CD-P-TS supports the EDQM, where required, by providing technical and scientific advice to facilitate their role as an expert body under the EU SoHO Regulation (EU) 2024/1938.

The Blood Guide is referenced in the regulation as the primary technical guideline to be followed to demonstrate compliance with, among other requirements, EU standards related to the protection of blood donors and recipients.

Notwithstanding this, the foundational premise of the Blood Guide remains unchanged. It continues to be regularly updated as a technical appendix to Council of Europe Recommendation No. R (95)15, under the aegis of the CD-P-TS.

The Guide remains governed by the intergovernmental framework of the Council of Europe and will continue to serve as a key source of technical standards for the preparation, use and quality assurance of blood and blood components across Council of Europe member states and internationally.

Work Plan – Blood Guide

Output	Action	Date
22nd Edition of Blood Guide	Publication	May 2025
23rd Edition of Blood Guide GTS Working Group – Terms of Reference	Adopted	March 2025
23rd Edition of Blood Guide – Scope of Revision	Adopted	March 2025
23rd Edition of Blood Guide – Consultation	Consultation	Q2 2026 (TBC)
23rd Edition of Blood Guide – Adoption	For Adoption	Q4 2026 or Q1/Q2 2027 (TBC)
23rd Edition of Blood Guide	Publication	Q2 2027 (TBC)

The dates listed are indicative and subject to change.

2. Data Collection and Reporting

The CD-P-TS collects annual activity data for the preparation of reports on the donation, collection, testing and use of blood and blood components. Each report provides activity data from the CD-P-TS member states and highlights new or changed practices, addressing trends in the blood sector in Europe.

The reports are available here: https://www.edqm.eu/en/reports-blood

The CD-P-TS annual questionnaire is composed of two parts:

A. *Fixed, general part*

- Collect core data – minimum data set
- Repeated every year

Aim: To collect all essential information needed to obtain yearly data and monitor trends over time.

B. *Flexible, specific part*

- Collect more detailed data on hot topics
- Can be tailored to requests from CD-P-TS/working groups to gain increased knowledge/background for future changes in the Blood Guide or CD-P-TS activities
- Interchangeable

Aim: To address and monitor new or changed practices.

Work Plan – Data Collection and Reporting

Output	Date
The collection, supply and use of blood and blood components in Europe 2020 – 2023 Report	June 2025 – Publication
2024 Activity data collection exercise	December 2025

The dates listed are indicative and subject to change.

Data Harmonisation

A collaborative project on harmonised activity data collection and reporting is being co-ordinated under the aegis of the CD-P-TS, and co-funded by the EDQM under its 2025–2027 co-operation agreement with the European Commission (EC).

A working group has been established comprising experts nominated by the following member states: Estonia, Finland, France, Italy, North Macedonia and the Netherlands. Membership of the working group is extended to professional associations and independent experts, and additional stakeholders can be involved, as required. The project is being co-ordinated in close co-operation with EC DG SANTE and the SoHO Coordination Board (SCB).

The objective of the project is to develop a minimum activity data set and proposal for reporting on blood and blood component activities in Europe. This will include defining a minimum activity data set for blood and blood components to fulfil the requirements of Article 41 of the EU SoHO Regulation and developing a supporting glossary of terms/definitions to ensure a clear, consistent understanding and format for all reporting entities.

Work Plan – Data Harmonisation

Output	**Date**
Working Group Meeting (in person)	7 and 8 October 2025
Minimum activity data set – Initial Draft	January 2026
Minimum activity data set – Consultation	March2026
Working Group Meeting (in person)	March/April 2026
Minimum activity data set – Proposal	June 2026

The dates listed are indicative and subject to change.

Other Areas of Work

Donors and Donation – Inclusive Blood Donation

A project is planned to be co-ordinated under the aegis of the CD-P-TS focusing on inclusive blood donation practices. This could include an examination of donor selection questionnaires and the use of inclusive language regarding sex and gender, supporting development of technical guidelines in the Blood Guide and the development of a draft recommendation/resolution to support member states in promoting equitable and inclusive approaches to blood donation. As part of this work, the existing standards within the Blood Guide relating to sex and gender in donor selection will be further considered and developed.

The scope and objectives of this project are currently at a preliminary stage and will require further consideration and development in consultation with stakeholders.

Work Plan – Inclusive Blood Donation

Output	Date
Preliminary phase – Project scope and deliverables to be defined	December 2025

The dates listed are indicative and subject to change.

Blood and Plasma Supply Continuity

Work is planned under the aegis of the CD-P-TS to strengthen blood and plasma supply continuity. This initiative will be co-funded by the EDQM under its 2025–2027 co-operation agreement with the European Commission.

As part of this work, the CD-P-TS will assume a co-ordinating and collaborative role, supporting the exchange and implementation of best practice and facilitating communication and co-operation among stakeholders.

In this context, a Plasma Supply Continuity stakeholder event was held on 26 and 27 March 2025. Outcomes from this event will be documented in a manuscript/report and will inform concrete actions to be taken forward by stakeholders. More information can be found here: https://www.edqm.eu/en/edqm-stakeholder-event-plasma-supply-continuity.

Building on the outcomes of this event, the CD-P-TS will explore the development of a draft recommendation/resolution to member states on national plasma programmes, with the aim of

supporting member states in establishing or strengthening action plans and co-ordinated efforts to secure sustainable supply of plasma and plasma-derived medicinal products (PDMPs).

In addition, specific activities will build upon the committee's previous deliverables, including the blood supply contingency and emergency plan (B-SCEP) project, considering strengthening blood supply continuity through military/civilian co-operation, contributing to the development of emergency preparedness and contingency guidelines, supporting work related to the supply of plasma for fractionation and contributing to the development of standards in the Blood Guide and improvements in data collection and reporting.

To further support the implementation of these actions, the organisation of targeted workshops on key issues related the collection, use and supply of blood and plasma is also planned.

Specific activities and actions will be further explored by the CD-P-TS as the work progresses.

Work Plan – Blood and Plasma Supply Continuity

Output	Date
EDQM Plasma stakeholder event	26 and 27 March 2025
EDQM Plasma stakeholder event Manuscript/Report	September 2025
Council of Europe recommendation/resolution on plasma supply continuity	Q1 2026

The dates listed are indicative and subject to change.

Anti-D Immunoglobulin

The EDQM IgG anti-D webinar series helped raise awareness of the challenges surrounding the collection of anti-D plasma, the manufacture of plasma-derived anti-D immunoglobulin products, and the development and use of alternative or complementary therapies.

Building on the outcomes of the webinar series, the CD-P-TS and the European Blood Alliance (EBA) launched a joint survey to assess the current status and potential for initiating or resuming anti-D plasma collection across Europe.

A report is in preparation to consolidate the outcomes generated over recent activities, focusing on scientific, technical, regulatory and operational considerations to support the

development of a common European Anti-D Programme aimed at sustainably re-establishing anti-D plasma collection in Europe. The report will inform the development of a common European Anti-D Programme, with the objective of supporting co-ordinated, sustainable anti-D plasma collection efforts across member states.

Work Plan – Anti D Immunoglobulin

Output	Action	Date
European Anti-D Programme – Report	Draft for publication	December 2025

The dates listed are indicative and subject to change.

Rare Blood Provision

The provision of rare blood requires a co-ordinated and collaborative effort from different regional, national and international stakeholders, as well as resourcing, standardisation, education and innovation.

Since 1968, the Council of Europe has worked in national and international rare blood provision. The CD-P-TS established the European database on Frozen Blood Units of Rare Blood Groups in 2008.

Further to the CD-P-TS decision to close this database and redirect users to the International Rare Donor Panel (IRDP), originally conceived under a World Health Organisation (WHO) and International Society of Blood Transfusion (ISBT) initiative and currently managed by NHSBT in the UK, a dedicated webpage on rare blood provision will be placed on the EDQM website which will refer to the IRDP. The EDQM will liaise with relevant colleagues to finalise the information on the webpage to ensure that an appropriate reference is made.

Work Plan – Rare Blood Provision

Action	Date
Endorsement and promotion of the WHO/ISBT International Rare Donor Panel (IRDP)	October 2025

The dates listed are indicative and subject to change.

Blood Quality Management

The CD-P-TS supports the EDQM in the organisation of quality management programmes for European blood establishments, including:

- the Blood Proficiency Testing Scheme (B-PTS) to measure the performance of testing laboratories in European blood establishments;
- the Blood Quality Management (B-QM) Programme to assist European blood establishments in the implementation of harmonised quality management systems and the standards laid down in the Blood Guide.

Progress on these activities is periodically reported by the EDQM Secretariat to the CD-P-TS at plenary meetings.

The CD-P-TS is responsible for the following tasks:

Terms of Reference

The CD-P-TS approves the Terms of Reference of the B-PTS Advisory Group and B-QM Working Group.

The current Terms of Reference for both groups are valid from 1 January 2024 to 31 December 2025.

Nomination of Experts

The B-PTS Advisory Group and B-QM Working Group are composed of experts nominated by CD-P-TS members following a call for nominations.

The composition of the groups is decided by the CD-P-TS Bureau and the EDQM Secretariat, taking into account the technical and scientific expertise of the proposed nominees.

Work Plan – Quality Management

Action	Date
Call for nominations – B-QM Working Group and B-PTS Advisory Group	May 2025
Terms of Reference – B-QM Working Group and B-PTS Advisory Group	December 2025

The dates listed are indicative and subject to change.

Project Proposals

CD-P-TS members are encouraged to propose new projects for consideration by the committee.

Projects may be established, for example, to support the revision of the Blood Guide, or to develop recommendations, scientific articles or publications that strengthen the evidence base.

A project proposal form is available to assist with the process of proposing and establishing CD-P-TS projects/working groups. Members who wish to propose a specific project can complete the project proposal form and submit it to the CD-P-TS Secretary.

Project proposals are put forward for discussion at the CD-P-TS plenary meetings. The committee can then consider the relevance and interest of members in participating before a decision is taken to include projects in the CD-P-TS portfolio of activities.

Events and Training

The CD-P-TS supports the EDQM in the co-ordination of blood transfusion training and events (e.g. conferences/symposia) by identifying topics of interest, nominating and contributing to scientific committees, and identifying speakers.

The EDQM co-ordinated a Blood Conference in Strasbourg on 14 and 15 January 2025, centred on the theme "Innovation in Blood Establishment Processes." The event explored how advancements in blood donation and component preparation can be translated into practice to support the continuity of blood supply. The two-day conference welcomed over 250 participants.

Outcomes from this event will be documented in a manuscript/report. All related materials, including the abstract book, presentations and programme, are available for download on the EDQM website: https://www.edqm.eu/en/blood-conference.

Annual SoHO quality management training will also be co-ordinated through the EDQM SoHO Quality Section. An online training session is scheduled for Autumn 2025, with trainers drawn from the B-QM Working Group and experts from the tissues and cells field. In addition, in-person training programmes focusing on specific topics are planned for 2026 and 2027.

Events and Training – Schedule

Action	Date
EDQM Blood Conference – Innovation in Blood Establishment Processes	14 and 15 January 2025
SoHO Quality Management Training	August – October 2025

The dates listed are indicative and subject to change.

Contribution to the dialogue and engagement with stakeholders and external parties

The CD-P-TS supports the EDQM, where required, by providing technical oversight and advice to support dialogue and engagement with stakeholders and external parties, this includes:

- Co-operation with Council of Europe bodies – including the European Committee on Organ Transplantation (CD-P-TO) and the Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO);
- Co-operation with the European Union and its bodies – the European Commission (EC), the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC);
- Co-operation with international partners – including the World Health Organization (WHO), the Food and Drug Administration (FDA) and Health Canada (HC);
- Co-operation with professional associations;
- Co-operation with donor and patient organisations;
- Co-operation with scientific societies and bodies.

Appendix 1 – Summary Table of Actions

A consolidated summary table of key dates and actions drawn from across the work plan is provided below.

Work Area	Output/Action	Date
Chair and Vice-Chair – Election Schedule	Election – Chair and Vice-Chair (25th Plenary Meeting)	10 and 11 December 2025
	Renewal of Terms – Chair and Vice-Chair (27th Plenary Meeting)	Q4 2026 (TBC)
	Election – Chair and Vice-Chair (29th Plenary Meeting)	Q4 2027 (TBC)
Plenary Meeting Schedule	24th Plenary Meeting	25 March 2025
	25th Plenary Meeting	10 and 11 December 2025
	26th Plenary Meeting	Q1/Q2 2026 (TBC)
	27th Plenary Meeting	Q4 2026 (TBC)
	28th Plenary Meeting	Q1/Q2 2027 (TBC)
	29th Plenary Meeting	Q4 2027 (TBC)
Blood Guide	22nd Edition – Publication	May 2025
	23rd Edition – Terms of Reference Adopted	March 2025
	23rd Edition – Scope of Revision Adopted	March 2025
	23rd Edition – Consultation	Q2 2026 (TBC)
	23rd Edition – For Adoption	Q4 2026 or Q1/Q2 2027 (TBC)
	23rd Edition – Publication	Q2 2027 (TBC)
Data Collection and Reporting	2020–2023 Report – Publication	June 2025
	2024 Activity data collection exercise	December 2025
Data Harmonisation	Working Group Meeting (in person)	7 and 8 October 2025
	Minimum Data Set – Initial Draft	January 2026
	Minimum Data Set – Consultation	March 2026

	Second Working Group Meeting	March/April 2026
	Minimum Data Set – Proposal	June 2026
Inclusive Blood Donation	Preliminary Phase – Scope & Deliverables	December 2025
Blood and Plasma Supply Continuity	EDQM Stakeholder Event	26 and 27 March 2025
	Event Report	September 2025
	Council of Europe recommendation/ resolution on plasma supply continuity	Q1 2026 (TBC)
Anti-D Immunoglobulin	European Anti-D Programme – Report (Draft for Publication)	December 2025
Rare Blood Provision	Endorsement and promotion of IRDP (WHO/ISBT)	October 2025
Quality Management	Call for nominations – B-QM and B-PTS Groups	May 2025
	Terms of Reference – B-QM and B-PTS Groups	December 2025
Events and Training	EDQM Blood Conference – Innovation in Blood Establishments	14 and 15 January 2025
	SoHO Quality Management Training	August – October 2025