Mandate from the European Committee (Partial Agreement) on Blood Transfusion (CD-P-TS) for the GTS ad hoc Working Group

1. Background

Recommendation No. R (95) 15, adopted by the Council of Europe (CoE) Committee of Ministers on 12 October 1995 at the 545th meeting of the Ministers´ Deputies, "recommends that the governments of member states take all necessary measures and steps to ensure that the preparation, use and quality control of blood components are carried out in accordance with the guidelines set out in the appendix to this recommendation". These guidelines, written as an appendix to R(95) 15, are the "Guide to the Preparation, Use and Quality Assurance of Blood Components" (the *Guide*).

The purpose of the *Guide* is to become a widely accepted European harmonised standard for the preparation, use and quality control of blood components, to provide safety, efficacy and quality requirements for blood components in modern blood transfusion, and to facilitate the exchange of medicinal products derived from human blood or human plasma between member states of the CoE. The *Guide* summarises the scientific state of the art in the preparation, use and quality control of blood components. It also defines minimum standards for the quality and safety of blood components required by member states in the context of cross-border healthcare settings. The *Guide* does not cover issues of cost-effectiveness of blood components.

The *Guide* is regularly updated. The duty to update the *Guide* was assigned to the CD-P-TS, an intergovernmental committee, which, in accordance with Resolution CM/Res (2011) 24, entrusted a subordinate body, the "GTS ad hoc Working Group" (GTS), with the periodic revision of the *Guide*.

2. Period of validity of the mandate

The mandate is valid by tacit renewal unless the CD-P-TS takes a different decision. The CD-P-TS verifies the appropriateness of the mandate every two years and revises it when deemed necessary.

3. Tasks and responsibilities, working methods

The main task assigned by the CD-P-TS to the GTS is the periodic revision of the *Guide,*

- based on the consistent monitoring and expert evaluation of scientific progress and regulatory changes in the field, and
- supported by systematic assessment of current evidence on the aspects of preparation, use and quality control of blood components as published in recent scientific literature.

To ensure the *Guide* remains contemporary, new or modified standards can be proposed for consideration and are provided with the supporting rationale. This rationale is broadly classified as either information on any regulatory status, scientific evidence or international recommendations/practices coded as described below:

a) EU directives (reference);

b) Good Practice Guidelines (reference);

c) Scientific documentation (reference);

d) International recommendations (organisation and reference);

e) Expert opinion (consensus within the GTS).

The GTS should also liaise with other subordinate bodies/working groups nominated by the CD-P-TS to benefit from their specific fields of expertise and, where appropriate, use this knowledge to contribute to the revision of the text of the *Guide* accordingly.

The GTS will use face-to-face meetings supported by e-mail exchanges and, where necessary, telephone conferences to facilitate work progress. Face-to-face meetings might be organised in conjunction with other European meetings to avoid excessive travelling for members and to be cost-effective.

The activities of the GTS are coordinated by the EDQM's responsible scientific officer in close collaboration with the Chair. Timely scheduling of work and meetings to meet revision targets is important.

4. Process flow for the revision cycle of the *Guide*:

As illustrated in the process flow below, the revision cycle is to be completed over a period of two years at the end of which the revised version of the *Guide* is presented to the CD-P-TS for formal approval and adoption.

Year X

Publication Edition N-1 generally April

Initiate revision; first GTS meeting March - April

- Discussion on remaining comments from the stakeholder consultation (see below)
- Points to consider from other subordinate bodies
- Proposals for change from member states accompanied by supporting evidence
- Distribution of chapters to subgroups, identification of subgroup coordinators

Discussions on first draft; second GTS meeting October – November

- First draft presented and discussed
- Decisions on remaining issues
- Advice from subordinate bodies, if necessary new exchange with relevant parties
- Agreement of amendments

Year X + 1

Discussions on second draft; third GTS meeting March - April

- Discussion on second draft
- Finalisation of chapters
- Agreement on text of the *Guide* submitted for stakeholder consultation
- Progress report at CA in Brussels

Stakeholder consultation May - August

Target audience: stakeholders such as NCAs, inspectors, CD-P-TS member and observer states (USA, Canada, NZ, Australia, Singapore, etc.), blood establishments, IPFA, PPTA, EBA, EPA, PLUS and others.

Compilation of comments by EDQM and distribution to the GTS members

Discussion of comments from stakeholder consultation, fourth GTS meeting September - October

Advice from subordinate bodies where necessary

Classification of comments (see below)

Amendment of text where necessary

Agreement on final version

Feedback to commenters (here particular attention is given to NCAs in liaison with Policy Officers at DG SANTE)

Progress report at CA in Brussels

Communication of Guide to the CD-P-TS October

Adoption of the Guide by the CD-P-TS November

Year X + 2

Publication Edition N generally April

The GTS considers all comments received during the stakeholder consultation of the draft version of the *Guide* and classifies them using the following coding system:

A: Proposals to be incorporated into the text of the *Guide*;

B1: Comments accepted by the GTS and to be incorporated in the *Guide*, potentially with editorial amendments;

B2: Proposals which merit further discussion by the GTS to be deferred for a future edition of the *Guide*;

B3: Proposals to be discussed in line with the status of EDQM standards in relation to other institutions;

C: Proposals to be rejected and not incorporated into the *Guide*.

The GTS is expected to respond to all stakeholders about the status and fate of their comments in a timely manner and in particular for the comments classified "C" to provide the rationale for rejection.

5. Composition of the GTS

Members of the GTS are nominated by the CD-P-TS following proposals made by Delegations to the CD-P-TS. Nomination is based on specific expert knowledge in the field of preparation, use and quality control of blood components. Additionally, experts from states and organisations not represented in the CD-P-TS can be nominated as members to the GTS by the CD-P-TS provided they have recognised expertise in the relevant field. Nominated members must be able to commit to active participation in and contribution to the work of the GTS, including committing to one or more chapters or sections of the *Guide*. Membership can be terminated by the CD-P-TS upon request of the Delegation that proposed the expert for nomination. The GTS selects its chair from among its members.

According to the policy for handling conflicts of interest of experts nominated to committees for which the secretariat is provided by the EDQM, all members of the GTS must complete a declaration of interest and confidentiality undertaking form (EDQM Form/226). In addition, any potential interest shall be declared before each meeting and recorded in the meeting minutes.

6. Communication structure GTS – CD-P-TS

Regular progress reports, including principal questions, will be made by the GTS Chair to the CD-P-TS during its plenary sessions held in November of each calendar year.