Understanding EU Policies on Blood Through the Journey of Red Blood Cells

FROM DONORS TO PATIENTS IN NEED OF TRANSFUSION

Policy Milestones

1994

Prior to 1994 the European Union (EU) had little involvement in blood safety regulations and each country had its own legal framework and infrastructure of blood banks and services.

2003

Directive 2002/98/EC, adopted **in 2003** and known as the "**European Blood Directive**", was the first document transposed to national law in every EU country, supporting the effort for harmonisation of the standards and structure of hospital blood banks and blood establishments.

The aim of the Directive was to reassure the public that the framework governing the use of blood and its components in the EU was upgraded in a way to meet the same requirements in all EU countries.

The Blood Directive set standards of quality and safety for the **collection**, **testing**, **processing**, **storage** and **distribution** of human blood and blood components, addressing challenges and concerns of the time and indeed contributed significantly to improving the quality and safety of services across the European Union.

Improvements were achieved across the EU (to different levels and extents):

i. Residual risk of clinically significant pathogens (e.g. HIV, HBV, HCV) minimised;
ii. National Blood Establishments distinguished their work from the role of other blood establishments , e.g. hospital blood banks;
iii. Processing, storage, data collection, non-remunerated blood donation (NRBD) practices improved;
iv. Research in blood and blood-related processes enhanced in various areas.

Across the European Union:

1400
blood establishments

20 million
blood donations every year

25 million
transfusions to patients

Around 2/3 of red blood cell transfusions are used in medical care of anaemia related to chronic diseases

Blood and Beyond.

2019

Through the years, **shortcomings** and **gaps** in the legal framework were identified and an effort to revise it was initiated by the European Commission **in 2019.**

These were, amongst others, the following:

- Technical rules did not follow **scientific progress**.
- Protection of **donors** was inadequate.
- **Oversight** of blood establishments was not harmonised across the European Union.
- Legal **clarity** was needed to support innovation.
- **Supply disruptions** were not addressed.

Directive 2002/98/EC is available at https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32002L0098

HOW IS BLOOD OBTAINED?

From our fellow citizens, who, after a basic health check and review of other parameters related to potential risk in blood safety (e.g. travelling abroad in areas with infectious outbreaks), voluntarily and without any remuneration (for free) donate blood.

Regular, voluntary, non-remunerated blood donation contributes significantly to blood safety.

Blood services in each country decide whether a volunteer non-remunerated blood donor is eligible to donate blood, based on their response to a **questionnaire** and a basic health check.

The questionnaire establishes the potential risk of an individual donating blood in transmitting any infection. At times, some of the questions may be modified and/or new questions may be included, based on public health threats (infections), prevailing, or anticipated. It is at the EU Member States' discretion to amend the questionnaire.

- Blood from a donor naturally flows into a special bag that contains an **anti-coagulant** to stop it from clotting.
- It gently rocks to make sure the anticoagulant mixes through the whole bag.
- Besides filling the main blood bag, blood services also fill a few sample tubes for testing purposes.
- The blood donation process from the time the donor arrives to the time he/she leaves takes less than an hour.

Anti-coagulants are a groupd of medications that decrease the blood's ability to clot.

All in all, around 470 millilitres (ml) of blood, referred to as "whole blood", are taken, equal to just under an average bottle of water.

Whole blood consists of:

Red Blood Cells (RBCs) Erythrocytes	White Blood Cells (WBCs) Leucocytes	Platelets Thrombocytes	Plasma

How do EU Member States recruit NRBD Volunteers?

1. Leaflets
2. Recruitment in large companies
3. Awareness programmes in schools
4. Commercials on local radio
5. Website
6. Advertising in local newspapers
7. Small gifts
8. Volunteers
9. Recruitment information in public buildings
10. Recruitment teams at events
11. Donor-recruits-donor
12. Commercials on national television
13. Commercials on national radio
14. Cooperation with local authorities
15. Advertising in national newspapers
16. Cooperation with other non-for-profit organisations
17. Commercials on local television
18. Direct mail campaigns
19. Student recruiters
20. Cooperation with military forces
21. Cooperation with police
22. Local Red Cross
23. Recruitment information in churches
24. Advertising in magazines
25. Cooperation with rescue forces
26. Direct email campaigns
27. Telephone marketing
28. Replacement donors
29. Door-to-door recruitment

Source:

DOMAINE Donor Management in Europe

WHAT HAPPENS TO DONATED BLOOD?

Processing whole blood is essential to ensure that blood is safe to use. It involves many and multiple steps; some are common for all uses and some are specific or auxiliary to the needs of the disease for which the blood transfusion is made.

- Once in the lab, the blood goes through a process called **leucodepletion**, i.e. the removal of white blood cells which reduces the risk of infections related to those blood cells being passed to patients and in addition to certain adverse reactions, e.g. allergic, non-haemolytic pyrexial reactions.
- Following leucodepletion, **a centrifuge machine** is used to spin blood into separate components. The blood plasma is driven to the top of the bag and the red cells to the bottom and blood platelets sit in the middle. The bag is then squeezed, separating the components into three different bags.

These three components may save up to three lives!

Leucodepletion derives from the Greek word leuco- (“white”) and the Latin

Centrifuge derives from the Latin words centrum (“center”) + fugiō (“to flee”)

- The laboratory team tests for blood type/group and conditions of blood or any infections the donor may have, such as HIV1+2, HBsAg, HCV and Syphilis. All tests are done to be sure that donated blood is as safe as it can be for the person receiving it.
- These tests and others, including surrogate markers, may be implemented routinely or at times according to each country’s policies and/or infectious epidemics, e.g. West Nile virus, dengue haemorrhagic fever.
- Labels are applied and components are stored at the correct temperature, ready to be issued to hospitals.
- Red blood cells can be stored for up to 35 days, and, if in a **nutrient-additive solution**, up to 42 days.

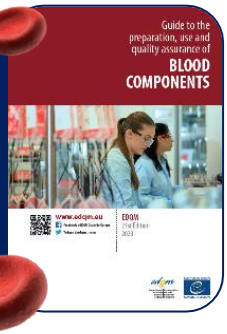
Additives are substances that offer nutritive support to the blood to keep its basic

For transfusion-dependent thalassaemia and other haemoglobin disorders, more specific testing is recommended. Blood components are safely transferred from the blood bank to hospital transfusion laboratories for such further testing.

- A second round of testing is performed at the hospital that includes **cross-matching**.
- Blood components may then be transfused to patients.

Cross-matching is the testing for compatibility of a donor's and a recipient's blood.

Donor selection criteria and technical standards for processing and testing, as well as, storage and distribution of blood components are set in *The Guide to the preparation, use and quality assurance of blood components* (“the Blood Guide”), published by the European Directorate for the Quality of Medicines & HealthCare, Council of Europe.



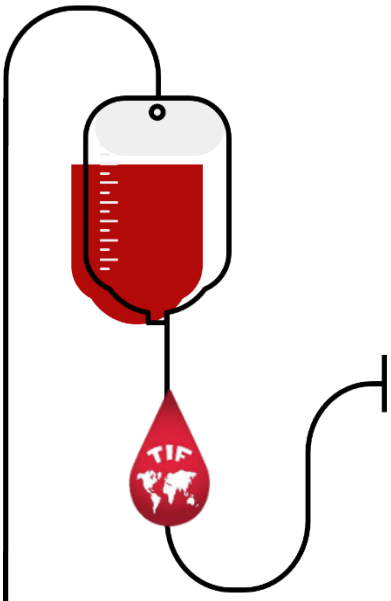
The 2002 European Blood Directive was adopted to ensure that the above process is equally implemented in all Member States and to safeguard blood safety.
But through the years, a number of challenges emerged:

- What if blood is further processed to develop new therapies?
- What if technical standards are not the same in all countries?
- What if the blood supply is disrupted?

To further strengthen blood safety and provide for the adequacy and availability of the blood supply, the European Commission has proposed a new Regulation on standards of quality and safety for substances of human origin intended for human application, also known as “SoHO Regulation”.

The proposed SoHO Regulation addresses existing but important challenges, including new therapies that require further and specialised processing of blood and its components, and the harmonisation of quality standards to allow cross-border collaboration. The Regulation also addresses blood shortages, consequent to political, environmental, and other challenges.

KEY MEASURES



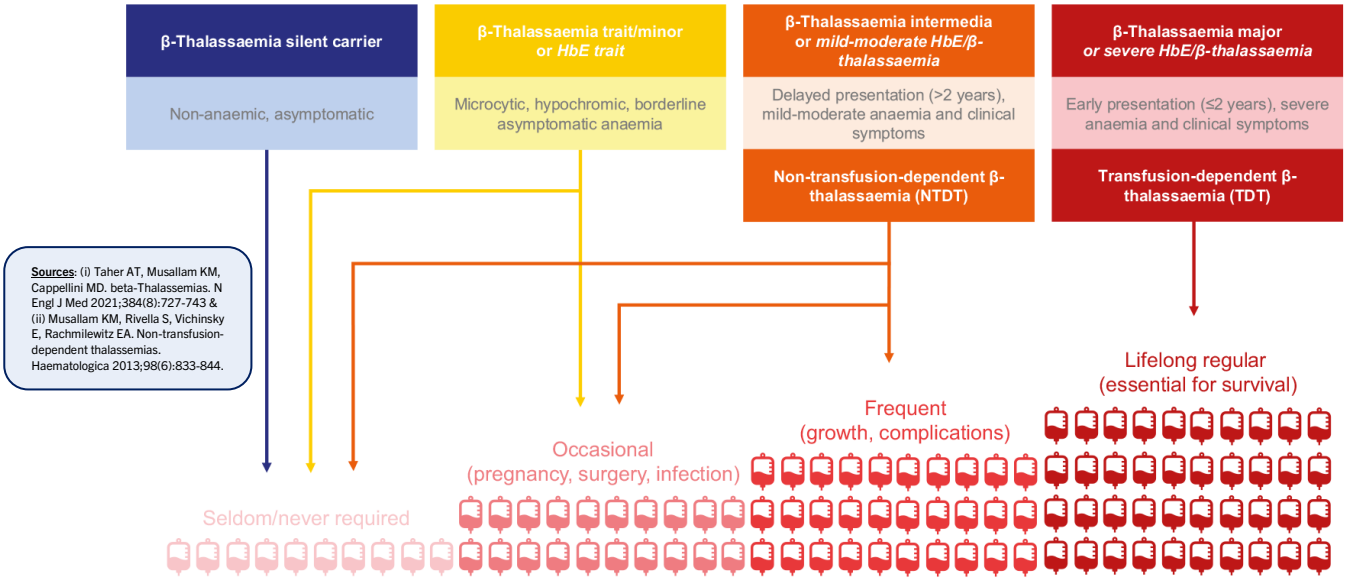
- Adoption of the same **technical guidelines and quality standards** by all EU Member States, set out in collaboration with the EDQM
- **EU oversight** of blood establishments and relevant entities by inspectors at national and European level and through mandatory registration on a common IT Platform
- Establishment of an **EU Alert System** for shortages / blood supply disruptions and facilitation of cross-border exchange of SoHO to improve patient access
- Renewed commitment to the **principle of voluntary, non-remunerated blood donation** and enhanced protection of donors

Read the EC Proposal here: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2022:338:FIN

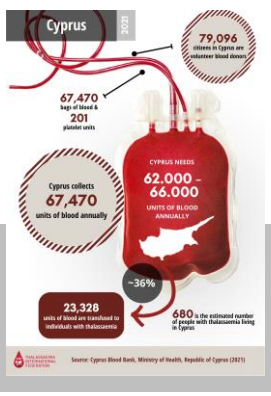
COMING UP

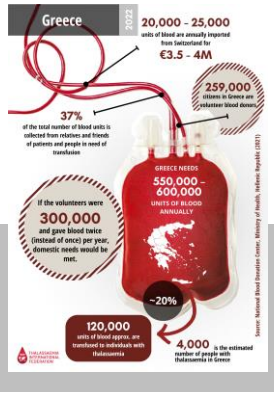
- **2020** Inception Impact Assessment of Blood Directive
- **2021** Revision of the blood, tissues and cells legal framework
- **2022** European Commission Proposal for a SoHO Regulation
- **2023** Adoption of the Proposal by the European Parliament & forwarding to the Council
- **2024** Completion of ordinary legislative procedure & adoption by EU-27

We are a community in need of a safe and adequate blood supply…

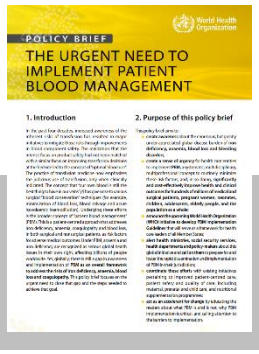


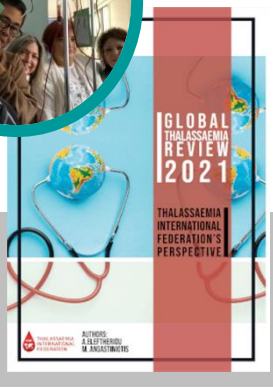
… a patient community that advocates and fights for access to safe and available blood in the European Union …





and globally!





Partners

World Health Organization

EHA EUROPEAN HEMATOLOGY ASSOCIATION

European Commission

ISBT International Society of Blood Transfusion

eba EUROPEAN BLOOD ALLIANCE

IHN International Haemovigilance Network

HNHCP Haematology Nurses & Healthcare Professionals Group

THALIA

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