

# **Dublin Consensus Statement 2011**

## **Principles to apply to the collection and provision of blood components and plasma derived medicinal products**

### **Introduction**

The two major priorities for the global community in providing patients with adequate and safe blood components and plasma derived medicinal products (PDMPs) are to:

- a) Provide and maintain safe, sustainable and sufficient blood components in all countries through the development of national blood transfusion systems based on voluntary non – remunerated donors.
- b) Provide an adequate supply of PDMPs from recovered and source plasma to meet patient needs on a global level.

The following principles apply to:

- Blood establishments whose principal objective is the collection of blood for the production of blood components for transfusion purposes and, in some cases, plasma for further fractionation; and
- The plasma industry which collects plasma exclusively for subsequent fractionation into PDMPs.

PDMPs made from both non-remunerated and remunerated donations are currently essential to meet global health needs.

The donation of blood or plasma and its transformation into products that save and enhance the lives of patients are invaluable contributions to modern healthcare.

Respect for individuals, maintaining the health of blood and plasma donors and providing safe blood and PDMPs for patients are of utmost importance.

Countries and regions are entitled to have policies and practices on blood and plasma which reflect their political, cultural, ethical and economic contexts.

Blood establishments and the plasma industry must operate within stringent national, regional and international regulatory regimes that support the safe and effective collection and provision of blood components and PDMPs.

The principles outlined below provide the foundation on which blood establishments and the plasma industry should build their operations.

## **Principles**

### **1. Patients**

The absolute focus of the blood establishments and the plasma industry in health care must be the patient.

- 1.1** Meeting the health needs of patients through a sufficient supply of safe and effective blood components and PDMPs is the principal goal of blood establishments and the plasma industry. An insufficient supply is a major safety risk to patients.
- 1.2** Patients are entitled to expect that all stakeholders will support their need for access to safe and effective products.
- 1.3** Patients whose continued health is dependant on the use of blood components or PDMPs have a right, through their representative organizations, to be consulted on any issue which may have an impact on the safety, efficacy or supply of the treatment they receive. Health Authorities should ensure that robust mechanisms are in place to ensure that this happens.
- 1.4** Blood establishments and the plasma industry must ensure that their actions do not compromise the health status of those who receive blood components or PDMPs.
- 1.5** Blood establishments and the plasma industry should take all reasonable steps to eliminate the possibility of adverse reactions and events including transmission of pathogens. Benefits and risks vary from product to product and each product should be assessed individually.

### **2. Donors**

- 2.1** Blood establishments and the plasma industry must respect the intrinsic dignity of all people involved in the blood and plasma donation process.
- 2.2** Blood establishments and the plasma industry and society in general should highly value all those who donate blood or plasma for the benefit of patients, recognize that donors perform a good deed and treat donors with respect.
- 2.3** There is a limit to the capacity of blood establishments and the plasma industry to ensure the safety of blood and PDMPs through testing and processing alone. It is therefore important that measures to defer donors are based on a precautionary approach and underpinned by evidence based assessment where feasible. Deferral policies should be explained clearly to donors.

**2.4** All people may offer blood or plasma to the community and their generosity is highly valued. However, blood establishments and the plasma industry have an obligation to only accept blood or plasma where the donor selection criteria are met.

**2.5** All donors must be provided with clear and accessible information prior to their donation, which should include information on:

- The potential risks to them of donating blood or plasma,
- The intended use of their donation,
- Who might benefit from their donation, including the health benefits for patients, benefits to the blood establishment, the plasma industry and to any other party that facilitates the donation.

**2.6** All donations should be voluntary.

**2.7** All donors must give their free and informed consent prior to the donation.

**2.8** Donor identity and their personal and medical information will be kept private and confidential in accordance with relevant guidelines and legislation.

**2.9** Donors should not be exploited by any individual or organization. Measures and initiatives taken to encourage blood and plasma donations should not overwhelm the capacity of the donor to make an informed decision about whether or not to donate.

**2.10** Blood establishments and the plasma industry owe a professional duty to act in the best interests of those that donate and receive blood and PDMPs.

**2.11** The health of the donor should not be compromised by their donation.

### **3. Cooperation**

Currently two main systems exist for people who donate

- Non-remunerated donations according to current definitions
- Remunerated donations

The production of blood components and of PDMPs involve different manufacturing pathways, have access to different risk mitigation measures and the products are used to treat different diseases. There is concern that the presence of two independent collection systems, one for blood and one for plasma, in the same region or country, could create a risk of shortage in supply. Cooperation between blood establishments and the plasma industry is important to ensure that the best community outcomes are achieved including sufficiency of supply for patients.

- 3.1** Activities undertaken to support plasma collection should not compromise the ability of a nation or a region to collect adequate supplies of blood components to meet clinical needs.
- 3.2** Similarly, activities undertaken to provide adequate supplies of blood components should take into account the ability of those who collect plasma for fractionation to meet the requirements of patients who rely on these therapies.
- 3.3** Organizations involved in blood and plasma collection should cooperate with the goal of ensuring the health of the donor and potential blood component and PDMP recipients.
- 3.4** The manufacture of blood components and PDMPs to treat patients with very rare diseases should be welcomed and actively supported by all those that operate in blood establishments and the plasma industry.
- 3.5** All stakeholders in blood establishments and the plasma industry have the right to hold and express opinions and should treat each other with mutual respect.

#### **4. Global utilization of donated blood and plasma**

The products of blood establishments and the plasma industry are sometimes not needed to meet the blood and plasma product needs in that particular region. This is because a number of different products can be produced from a single blood or plasma donation. Many regions lack the capacity to collect and produce all the blood products they need, so they are reliant on blood or plasma donated in another region. Donors expect their blood or plasma to be used to benefit patients who need blood and PDMPs.

- 4.1** The needs of patients should determine the optimal collection of blood and plasma.
- 4.2** Blood establishments and the plasma industry have an obligation to donors to make their best endeavours to use that blood or plasma for the purposes for which it was donated.
- 4.3** Having satisfied the principal purpose for its collection, blood components, plasma and plasma intermediates not required for that purpose should be made available to meet the health needs of others and contribute to global health outcomes where feasible. Feasibility includes whether the costs of provision are able to be met and if the regulatory regime and healthcare systems in both regions support availability.
- 4.4** Regulation of the collection and use of plasma for manufacture should be based on appropriate risk management principles. Regulation should facilitate global movement of plasma, intermediates and PDMPs when safe and appropriate to do so.