PPTA Position Paper
The intrinsic differences between blood products and plasma therapies

Introduction

Plasma-derived medicinal therapies provide life-saving treatments for a limited range of mostly rare and serious conditions. They are used as therapy for well-defined medical conditions, replacing missing components in the blood to allow individuals with immunodeficiencies and bleeding disorders to survive and lead normal lives.

A primary objective for PPTA* and its member companies is to ensure that an appropriate supply of plasma therapies is available to the patients suffering from such conditions. Appropriate supply of these therapies directly depends on the appropriate supply of human plasma and therefore on sufficient quantities of blood and plasma donations.

It is important however to understand that ***plasma therapies are intrinsically different from blood components*** such as red cells, thrombocytes (etc.) obtained from a whole blood donation. These differences lie in the way plasma is collected as well as in the production process of plasma-derived medicinal products.

Collection

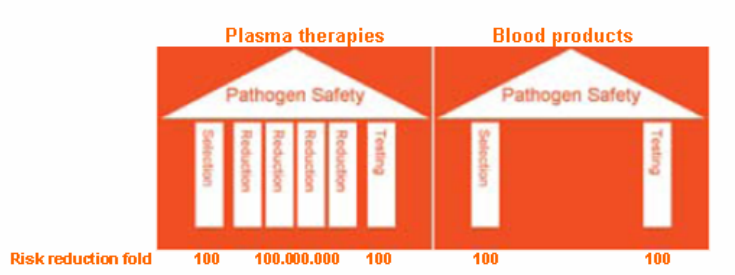
Plasma can be collected in two different ways: either through a blood donation from which the plasma is separated (recovered plasma) or through plasmapheresis, a process to collect plasma directly from a plasma donor (source plasma). Different member states have different approaches to ensure good levels of donations, all of which follow the highest quality and safety standards. There is therefore a co-existence of voluntary compensated donations and voluntary donations (based on a donor-reward system - e.g. vouchers and other consumer goods). Compensation for plasma donations is directly linked to the compensation of time, effort and related expenses (e.g. travel). ***Plasma donation through plasmapheresis is substantially longer and by far more complex than whole blood donation***. ***In addition, the frequency of donations is much higher for plasmapheresis: up to 52 times per year vs. 4 times per year for blood***. Therefore both types of collection are by no means comparable. In order to ensure an appropriate supply it is widely accepted that compensated donation schemes are needed to meet the demand for plasma-derived medicinal products. Indeed, figures show that 65% of the yearly quantity of plasma for fractionation collected worldwide comes from voluntary compensated donations.

Production

Another significant difference between plasma therapies and blood products is that once collected, ***plasma is pooled and used as a raw material from which various final products are produced after undergoing a highly sophisticated production process***. The production of plasma therapies typically takes over 6 months to produce a batch of finished product after the initial pooling of the plasma. Manufacturers and authorities constantly work to further improve the safety, quality, and efficacy of these products has resulted in a substantial change in manufacturing practices over the years. This has particularly taken place with the introduction of additional and new viral inactivation and removal techniques, new state of the art production facilities, evolving good manufacturing practices and increased auditing and inspection by government agencies.

Safety

The concept of the safety tripod is commonly used to compare the reduction of the potential risk of transmission of infectious viruses for plasma derivatives and blood products, as shown on the diagram below:



As can be seen from this diagram, ***after careful selection of donors plasma therapies undergo several virus inactivation steps (reduction steps) during their production process, thereby significantly increasing their safety profile in comparison to blood products***.

Supply of Products

Plasma products are life-saving products. The use of these products is crucial for patients. Therefore the appropriate supply of products is absolutely essential. The appropriate supply of products depends on the sufficient supply of collected plasma. The current system of co-existence of voluntary compensated donations and donations based on a reward system is a system which allows for an appropriate product supply and should therefore not be challenged.

Legislative framework

The Directive 2002/98/EC of the European Parliament and of The Council of 27 January 2003 and its daughter directives set standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components. This is the first EU-wide legislation which specifically focuses on this sector. The directives cover both whole blood and plasma for fractionation, and specifically recognize their differences, although misinterpretations are regrettably frequent.

Directive 2002/98/EC requests from the European Commission regular reports on a three-year basis on member states' promotional efforts to encourage voluntary blood donations. For the reasons outlined above, ***it is therefore extremely important to differentiate blood donations from plasma donations*** in these reports. This was unfortunately not the case in the latest report from the European Commission [*COM(2006) 217 final*, 17 May 2005].

Recommendations:

PPTA respectfully suggest the following recommendations to ensure plasma-derived medicinal therapies are appropriately considered in EU policies:

- Proper recognition of the intrinsic differences between blood and plasma from their collection to their use must be integrated into EU policies
- Proper recognition of the necessary co-existence of EU member states' plasma collection systems incorporating both the **voluntary compensated donation scheme** and the **voluntary reward-based donation scheme** to ensure the appropriate supply of life-saving plasma products to patients in need
- PPTA should be consulted and its expertise and views should be taken into account prior to and during the drafting of the relevant Commission reports, policy development and relevant legislation

** The Plasma Protein Therapeutics Association (PPTA) is the primary advocate for the world's leading producers of plasma-derived and recombinant analogue medicinal products. The medicines produced by PPTA members are used to treat patients suffering from rare life-threatening and/or life-impairing disorders and serious medical conditions including bleeding disorders (e.g. Haemophilia), immune system deficiencies (e.g. Primary Imm*