

February 17, 2017

## **PPTA Statement on the Documentary “Das Geschäft mit dem Blut”**

PPTA, with great astonishment, has read the article "Die Ware Blut" published in ARTE magazine (2.2017), which also announces the documentary film "Das Geschäft mit dem Blut." In this article, plasma donors, who donate their plasma to produce essential therapies for the treatment of patients with genetic and rare diseases such as blood clotting disorders and immune deficiencies, are being maligned. This depiction is very unfortunate and, in our opinion, the result of insufficient research.

The report is full of inconsistencies and draws false conclusions with regard to plasma, plasma donors, and the safety of plasma protein therapies. The manufacturers of plasma protein therapies fully comply with the strict regulatory requirements of the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and numerous national health authorities, as well as additional voluntary industry standards (IQPP).

First, it must be made clear that blood and blood components for transfusion differ from plasma for the production of plasma protein therapies and there are different regulations and conditions for each. Plasma obtained for the production of therapies by plasmapheresis is a starting material for further processing into plasma protein therapies and thus cannot be used for direct transfusion purposes in hospitals.

Plasma is the clear, straw-colored liquid portion of blood that remains after red blood cells, white blood cells, platelets and other cellular components are removed. Plasma makes up about 55% of the volume of blood. Plasma is 90% water while the remaining 10% contains hundreds of essential proteins.

Plasma protein therapies are used to treat a variety of diseases which occur when naturally occurring plasma proteins are missing, insufficient, or structurally damaged in the human body. For instance, a lack of blood clotting proteins can lead to bleeding disorders such as hemophilia, and the inability of the body to produce antibodies can lead to chronic infections.

Plasma is obtained from healthy, qualified donors. Before each individual donation, the donor's ability to donate is determined - both to protect the health of the donor and for the safety of the therapies ultimately made from the donated plasma. In addition to examining a donor's general state of health, a number of questions are asked of the donor, such as record of infections or illnesses in their past. In addition, certain critical measurements are determined in the laboratory.

In the case of plasma donation, a certain amount of blood is taken from the donor's arm. However with plasma donation, the blood runs in a closed circuit through a special medical device. In this device, the plasma is separated from the blood and collected in a bag or a bottle, while the remaining blood components are returned to the donor. This process is called plasmapheresis and takes about 60 minutes. Since the human body can regenerate the components of the donated plasma within a few days, plasma donations can occur more frequently than blood donations. Further, plasma donation minimally reduces the content of red blood cells from the donor.

Plasma donation is subject to high regulatory requirements. In the United States, donors must meet the requirements of the FDA. In addition, manufacturers of plasma protein therapies adhere to additional voluntary industry standards that go beyond the regulatory requirements.

Plasma donation centers in the U.S. which collect plasma for European countries are also subject to control by the national authorities of the respective countries and the EMA. **Healthy and committed donors are the basis for safe and effective therapies.**

The current need for these medicines is now largely covered by donations from the U.S. In order to meet ever-increasing demand, manufacturers support all efforts to build safe and reliable plasmapheresis programs in all European countries and are ready to cooperate with all those who wish to contribute to this goal.

Plasma protein therapies are the only medicinal product in which the source material, the donated plasma, must also be approved by the authorities.

**The foundation of safe plasma protein therapies is a healthy plasma donor population, reliable tests, technological and scientific advancement, and constantly improving manufacturing methods.**

In order to have sufficient plasma and to ensure a continuous supply, it is customary to provide a donor with compensation for his directly incurred costs (e.g., for travel and time).

The European Medicines Agency states that there is no evidence from clinical studies and pharmacovigilance that donor compensation increases the risk of viral transmission by plasma-derived medicinal products (EMA/CPMP/BWP/1818/02/Final).

Without plasma donations, the current demand for therapies could not be met, not to mention the growing clinical need due to the steady medical and scientific progress. In order to ensure the health of patients whose survival depends on plasma-derived therapies, plasma donations are needed both from the private sector as well as from state, municipal, and public sectors. Therefore, the manufacturers of these therapies support all types of plasma donation, since patient care is the top priority.

Plasma is subject to strictly controlled manufacturing procedures to ensure the safety and purity of products made from plasma. Some of these methods are an integral and essential component of the separation and purification of plasma proteins; others are specifically added

to remove potential pathogens from the plasma. The consistent application of these manufacturing processes and safety measures are extremely effective; the plasma protein industry has a record of safety from pathogens for more than 20 years.

"Das Geschäft mit dem Blut" makes faulty and disturbing statements regarding the quality, safety, and origin of plasma and plasma protein therapies without any factual basis. Such misrepresentations make patients uncomfortable with regard to the safety of their therapies and could lead to them being no longer supplied with these vital therapies.

Plasma donors are a wide-ranging group of people, with very different motivations to donate. It is very unfortunate that more than 1.5 million donors from the U.S. are being condemned on the basis of a few isolated and carefully selected examples. PPTA has great respect for all plasma donors, employees at the donor centers, and manufacturers of plasma protein therapies. Thanks to them, patients with rare diseases can be treated with medicinal products that ensure their survival and make leading a normal life possible.