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ÉTABLISSEMENT FRANÇAIS DU SANG
Du donneur aux patients

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Position of the French Blood Establishment (EFS) on the future revision of the Blood, Tissues and Cells legislation*

KEY OBJECTIVES FOR THE REVISION OF THE DIRECTIVE

» **Maintain** a collection model of substances of Human origin (SoHo) based on the principle of **voluntary non-remunerated donation (VNRD), whatever their destination.**

» **Leave each Member State free to:**

- Organise its **collection model** to answer the needs of its patients
- Adopt **supplementary measures to protect its donors**
- Fully base its collection **on voluntary non-remunerated donations**

» In this framework, **increase collection of plasma for fractionation.**

* in line with the note of the French authorities

CONTEXT

The revision of the Blood, Tissues and Cells directives is a key component of the ambition of building a **stronger European Health Union.** The Covid-19 health crisis has highlighted the challenges for health sovereignty. Regarding the field of blood transfusion, it underlined **the efficiency of the model based on anonymous, and voluntary non-remunerated donations.** During this period, no patient lacked blood products in France. The model must be strengthened and promoted in the framework of the revision of the blood legislation.

European dependence on the United States for plasma as a raw material for the manufacture of plasma-derived medicinal products (PDMPs) remains a key issue. In 2019, almost 70%[1] of plasma used around the world for manufacturing PDMPs was collected in the United States. Decreasing this dependence is an essential challenge for **the strategic autonomy of the European Union** at a time when the Covid crisis has emphasised the difficulties of both the commercial and ethical models to maintain their level of collection of plasma for fractionation. A strong mobilisation of EU resources to improve plasma collection will be key to meet this major challenge.

Blood, plasma, what are we talking about?

Blood is mainly composed of red blood cells, platelets, and plasma. These three components can be administrated separately to patients by blood transfusion. **Plasma can also be used to produce medicines, called plasma-derived medicinal products (PDMPs).** Plasma then undergoes a process of fractionation (separation, purification, and concentration of the contained proteins). Plasma can be extracted either by separation from other blood components after a whole blood donation or by collection on its own (apheresis).

While the vast majority of European countries succeed in being self-sufficient in blood products for transfusion, Europe is experiencing difficulties in achieving self-sufficiency in plasma for the manufacture of plasma-derived medicinal products, resulting in European dependence on plasma as a raw material from the USA.

Who collects and how?

In the European Union, **whole blood collection** is ensured by **blood establishments** that do not remunerate donors (EFS and its counterparts, members of the European Blood Alliance - EBA). These establishments also organise collection of plasma for fractionation along the same principle of **voluntary non-remunerated donation.**

However, some European Member States also allow **private entities to collect plasma** (Austria, Czech Republic, Germany, and Hungary). In these countries, plasma fractionation companies regularly get around the principle of VNRD and **offer generous compensation to donors.**

What is the state of European legislation?

Currently, **on a regulatory level**, collection of all components falls under the blood directive (2002/98/CE). The plasma fractionation process and the commercialisation of PDMPs fall under the directive on medicinal products for human use (2001/83/CE).

Promotion of **voluntary non-remunerated donations is a central principle** of the current European directives and also of the Council of Europe and the World Health Organization (WHO).

The European Commission plans **to revise the blood** (2002/98/CE) **and tissues & cells** (2004/23/CE) **directives. The proposal is due for Spring 2022.**

POSITION OF THE FRENCH BLOOD ESTABLISHMENT (EFS)

The directives must:

☑ **Keep within the scope of the directive the collection of all blood components whatever their destination** (transfusion or production of medicines).

☑ Reaffirm and reinforce the principle of **voluntary non-remunerated blood donation** by integrating **the definition**[2] and the **acceptable compensations**[3] defined by **the Council of Europe.**

☑ **Reinforce the protection of donors** by integrating provisions to set up a **European-wide donor hemovigilance system.**

☑ **Set as a priority the great general principles**, that will form an unbreachable core: voluntary non-remunerated donation, anonymity, monitoring of donor health. More detailed and more technical rules concerning **safety and quality** should be defined after thorough consultations in the framework of European expert bodies (EDQM & ECDC).

☑ Call for an **optimal use of scarce resources of human origin**, like blood and blood components, including PDMPs, through Patient Blood Management (PBM).

☑ Ensure the security of supply in PDMPs (including in times of pandemic) by **promoting a plasma collection system that relies on a large donor base donating at a low frequency.**

☑ Encourage European Member States to **collect more plasma in an ethical way**. Plasma supply is a **real challenge for Europe, but it cannot be resolved at the expense of security and ethics.**
N.B. The current directive sets a framework that is based on the human origin of blood components. It should not be changed. The increase in demand in PDMPs does not alter the framework. The European Union and its Member States must fulfil their obligations and give themselves the means to collect blood, and particularly plasma, in sufficient quantity to meet patient demands.

The European Union should also:

☑ Support Member States in setting up plasmapheresis programmes and campaigns to raise public awareness about the critical importance of PDMPs and the necessity of donating plasma.

The directives should not:

☒ **Differentiate plasma used for transfusion and plasma used for producing PDMPs.** The sole purpose of such a proposal is to transfer the collection of plasma for fractionation to the directive on medicinal products for human use. It is not justifiable from an ethical, legal, or practical point of view. Whatever their destination, blood and its components are substances of Human origin. The transfer of plasma collection to the directive on medicinal products would pave the way to the **commercialisation and commodification of elements of the Human body, in contradiction with the ethical principles of the European Union.** In addition, differentiating plasma according to its destination would be legally and practically absurd. When donating whole blood, part of the components (red cells and platelets) would be regulated under the blood directive when the rest (plasma) would have to comply with the obligations of the directive on medicinal products.

☒ **Promote the coexistence** between non-profit blood and plasma collection centres that do not remunerate donors and private lucrative plasma collection centres that remunerate donors.

☒ **Encourage remuneration of donors** and leave space for interpretation of the principle of "prohibition on making the human body and its parts as such a source of financial gain"[4] . In the absence of precise provisions in European legislation, the compensations applied in some countries look more like remunerations, especially when they are combined with high frequency of donations. In Hungary for example, "compensation" can reach 25€ (excluding loyalty or recruitment bonuses) for a 90-minute plasma donation when the Hungarian minimum wage amounts to 2,68€/hour.

Such changes in the legislation would constitute risks for the:

✘ **Health and safety of donors:** Commodification of the human body is already a reality in the United States, especially among **the younger generations and the most vulnerable**. Donors can give their plasma up to twice a week (for a possible retribution of 1.000$ per month), thus taking risks for their health[5] ;

✘ **Quality of collected plasma:** plasma collected from a frequent donor contains less proteins than plasma collected from an occasional donor[6] ;

✘ **Security of the blood and plasma supply:** a large donor base can minimize the impact of a pandemic on blood and plasma stocks.

ABOUT THE FRENCH BLOOD ESTABLISHMENT (EFS)

The French Blood establishment (EFS) is **the unique civil blood transfusion operator in France.** It operates under the administrative supervision of the Ministry of Health. Its duty is to collect, prepare, qualify, and distribute blood products (blood, plasma, platelets). Each year, **it provides for the needs of a million patients, thanks to the generosity of donors, the professionalism of its staff and the help of a large network of volunteers.**

On the European level, the EFS is member of the *European Blood Alliance* (EBA) which defends and represents not-for-profit blood transfusion establishments across Europe.

[1] Marketing Research Bureau. (2021). Plasma flows on a global level – why it travels so far. p5.

[2] Council of Europe (1995). Recommendation R(95)14 of the Committee of Ministers to Member States on the protection of health of donors and recipients in the area of blood transfusion. Article 2

[3] Council of Europe (2018). Guide for the implementation of the principle of prohibition of financial gain with respect to the human body and its parts from living or deceased donors. pp 6-7 et 9-10.

[4] European Union (2000). Charter of fundamental rights of the European Union. Article 3.2. Council of Europe (1997). Convention on Human rights and Biomedicine (Oviedo Convention). Article 21.

[5] MÖLLER, A. (2014). Der Einfluss der präparativen Plasmapherese auf den Immunglobulin G-, Gesamteiweiß- und Flüssigkeitshaushalt des Plasmaspenders. Universität des Saarlandes.

[6] LAUB, R., BAURIN, S., TIMMERMAN, D., BRANCKAERT, T. & STRENGERS, P. (2010). Specific protein content of pools of plasma for fractionation from different sources: impact of frequency of donations. Vox Sanguinis. 99. p220-231.

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