



*FÉDÉRATION INTERNATIONALE DES ORGANISATIONS DE DONNEURS DE SANG  
INTERNATIONAL FEDERATION OF BLOOD DONOR ORGANIZATIONS  
FEDERACIÓN INTERNACIONAL DE ORGANIZACIONES DE DONANTES DE SANGRE*

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## **Self sufficiency in safe blood in Europe**

### **Role of the IFBDO:**

The International Federation of Blood Donor Organisations (the IFBDO or FIODS in French) – is the only international organisation representing voluntary blood donors at the international level, and our main goal is sufficiency of blood from safe voluntary non-remunerated donors to all patients in all countries of the world.

We also work to enhance safety of receiving patients and of donors. As volunteers we work for humanitarian reasons, but also to keep donor loyalty. Safety and sufficiency of supply depends on continued regular blood donation. Voluntary blood donors only come back to the blood centres if they have trust in the blood supply – and regular blood donation is the key to safety in all blood services.

We work to combat all commercial exploitation of blood and blood donors for reasons of safety and for ethical reasons, but non-remunerated donation also enhances the respect for the blood supply, thereby increasing donor loyalty.

### **Self sufficiency in safe blood to all Europeans**

We have developed this new approach to a blood policy for the European Union, because we see some very important challenges to the blood supply in Europe.

Since the Amsterdam treaty established European competence in the field of blood, we have tried to promote a safe blood supply to all European patients. We work for full sufficiency of blood from safe donors in all countries of the world. This is an enormous challenge – but it is possible as a number of European countries such as Finland, the Netherlands, Denmark, Belgium, France and others are in fact self sufficient in all blood products.

Most EU countries have opted for voluntary non-remunerated blood donation

This is recommended by the WHO and the Council of Europe, ISBT, the Red Cross and the IFBDO

- For safety reasons, as paid blood is less safe than donated blood.
- To enhance the respect for the donor and the blood supply (for frankly, who can respect a person who for a small sum of money wants to sell a part of his body?)
- For ethical reasons, as no one should be forced to sell a part of their body.

Non-remunerated donation is clearly in line with provisions in the Nice Charter on Fundamental Rights (and included in the Lisbon treaty,) which forbids all profit making from the human body or parts of it.

Non-remuneration is also emphasized in the Directive 2002/98 from the Council and Parliament on Blood Safety, e.g. in Article 20, where all member states shall strive to obtain non remunerated blood donation, and in “Whereas 20” – which states, that modern blood services are based on non remuneration of donors and the absence of profit for blood establishments.

### **Non-remuneration of blood and plasma donation is a key factor**

Non-remuneration as the basis of all blood products is NOT a question of religion, faith or ideals.

It is a very practical question: How do we best guarantee enough safe blood products to all patients in all 27 members states of the European Union?

All studies show, that a stable blood supply has to be build up over a long period of time. But some have jumped to the easy solutions, as they pay the “donors” or import the products from paid “donors”. Especially the private plasma fractionating industry is pushing for paid plasma “donation” and import of medicinal products from paid “donors”. They push for an “inner market” solution, which allows for free import and commerce of plasma derivatives from paid blood.

But paying for blood is not a good long term solution! A recent study from Lithuania (published in Vox Sanguinis) shows clearly that is it much safer to use unpaid donors than paid “donors” (the study is based on a uniform donor population with no geographical or other differences except that some donors accepted payment after the donation). Paid blood is not as safe as unpaid blood, not even when used for plasma products. The European countries, which have the most stable and sufficient supplies of blood, only use only non- remunerated donors and base their plasma derivatives on plasma from non-remunerated donors.

### **Two systems for collection of plasma for plasma-derivatives in the European Union:**

Unfortunately we have in 2008 two competing systems in the European Union covering human blood contained in Directive (2001/83) on medicinal products and the later Directive (2002/98) on blood safety. The administration of these directives lays within two different directorates in the European Commission, and we see this as the classical conflict between the Market Europe versus the Citizens Europe.

As for plasma products we have a very strange system in Europe under Directive 2002/98. All plasma collection within the EU has to follow the rules in Directive 2002/98, and from this fact they become more costly than plasma from outside Europe. The strict European rules (which we support) give rise to an unfair competition to European plasma products from plasma products imported from third countries.

A large import of plasma derivatives continues to countries such as the UK, Italy, Spain and Germany. This is not a healthy situation, especially since there is no real traceability from the third country donors to the European patients.

***We demand that all plasma derivatives distributed within the European Union are produced from plasma collected in a manner conforming to Directive (2002/98).***

### **European patients depend on import of plasma products from the United States:**

Many European patients are still totally dependent on import of plasma products from the United States. The American Senate has already once temporarily stopped for export to Europe of vital immunoglobulines. This gave reason for panic in some European hospitals – and a rise in prices of plasma derivatives. The European authorities have to work for a sufficient supply from within Europe. It is totally unacceptable, that European patients depend on sudden changes in American policy for their life-saving provision of plasma derivatives.

Right now the FDA is hindering the licensing of new plasma collection centres in the US. Again the plasma price is going up, leading the commercial plasma-derivatives producers to look for paid donors in Eastern Europe and in the developing world. Depending on third country plasma collecting is clearly not a good system for safety of products and sufficiency of supply in Europe.

*In view of the overall wish for a safe and sufficient supply of blood products the Commission should stop promoting the access to European hospitals of plasma products from paid (poor) donors in third countries.*

### **Products developed within the human body**

We should always remember that blood products are effective in a treatment, because they have been developed within a human body. Very few blood products can be substituted by industrial products, so for many years to come there simply is no alternative to blood in the treatment of a large number of illnesses. Each year scientific research comes up with new properties in donor blood, which may eventually help new groups of patients. This research into the properties in blood plasma is so very important for many groups of patients, and Europe must take part in it – and not leave this research to companies from third countries only.

Of course we must allow temporarily – when absolutely needed - for the necessary import of products to European patients, but if we will, Europe can be self sufficient in all blood products. This demands a very minor investments in donor recruitment and retention, and luckily the Commission has taken a first small step by supporting the DOMAIN project for developing Donor Management, a project in which the IFBDO also takes part.

**The member states and the European Union should agree to have as a goal within 5 to 10 years where Europe shall be self sufficient with all products coming from blood, including plasma derivatives.**

### **Donated blood is gift, which is not covered by the Inner Market rules.**

This view is supported in the Nice Charter and in “whereas 20” of Directive (2002/98).

Accordingly, the Commission should stop to demand that fractionation of European blood plasma is opened for public bidding. The non-remunerated blood donor remains the owner of any products from his blood until his gift has been transfused into another human being. The process between the donor and the patient is a service, rendered to the gift of blood. As we all know, a service within the medical field can, but does not have to be made open for commercial bids.

*We feel that the Commission should stop to push for commercial bidding in this field, allowing for Australian, Swiss and American companies to undermine the European plasma fractionation, making us all dependent on research and development of new plasma products outside Europe.*

### **The European goals of the IFBDO**

We would like to European Parliament, the Member States and the European Commission to consider these goals:

*All 27 member states and the European Union shall be self sufficient in all blood products, including plasma derivatives, from voluntary non-remunerated blood donors.*

*The European health programme should include measures to enhance blood safety and sufficiency of supply. Some of the member states still need support for implementing the Blood Directives - and the European Union should expand its programmes to include support for promotion of recruitment and retention of voluntary non-remunerated blood donors.*

*The European Union and its member states shall stop using paid or compensated blood – and that they stop pressing family members and relatives to give blood to specific patients.*

*To allow for the development of self sufficiency in all blood products, article 4, 2 of Directive (2002/98), which allow a member state to stop for import of blood and blood components from paid “donors”, should include permission to member states to stop for import of all blood products from paid “donors”.*

*The rules about full traceability should cover all blood products (including plasma derivatives) in Article 14, 1 of Directive (2002/98).*

*Interested parties such the IFBDO should (in line with Art 8 B of the Lisbon Treaty and art 25 of Directive 2002/98) be consulted as an interested party when the blood directives are being updated. The important role of voluntary donor associations should be recognized by the European union and by its Member States.*

*The European Parliament should call for a continued reporting from the European Commission in the progress of voluntary non-remunerated blood donation, as foreseen in Art 20,2 of Directive 2002/98, under which member states every three years must report on their progress towards achieving full voluntary non remunerated blood donation. The Commission should also inform to the Council and the Parliament of necessary complementary measures, it intends to take to achieve this goal.*

*The European Union should coordinate collection of data about blood donation and donors in Europe - using the definitions from the Council of Europe. Data collections are done right now by the Council of Europe, the EBA, the IFBDO and the European Commission (even though the latter has not presented much data up to now, even if this is foreseen in the Directive 2002/98).*

*The commission should in cooperation with the Council of Europe work for harmonizing the guidelines for blood donor deferrals in Europe, and make sure that the deferrals are done on rational medical grounds. Donor deferral should be based on rational decisions, based on the principle to harm neither donor nor patient, and there should be access to the scientific evidence leading to the deferral rules, so that interested donors can obtain this information.*

*The number of donor deferrals is very much influenced by the information-level of the donors. The blood services are obliged to inform the donors according to the European directive, but there should be data from different countries on deferrals rate and number of donors in quarantine. There is a need for additional obligatory information to all donors in Europe.*

*Europe should work for a harmonization of the rules for deferral for taking medicines, and a list of drugs leading to donor deferral could be included in the Guide from the Council of Europe (and made available at an internet site). The rules should take into consideration: Why the drug is taken, the effect on the donor and possible allergies in the patients toward the drug. The procedure for permission to market a drug in the European Union should include the possible effect on donor deferral, when a new drug is allowed to be marketed.*

*Insurance for blood donors, who have accidents before, during and after their donation, should be a public obligation – and it should be mentioned in the Directive directly. All potential donors must be informed that there is a (small) risk connected to giving blood – and that this risk is somewhat compensated by the insurance offered.*

*(As adopted by the Executive Council of the IFBDO 25.10.2008)*