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Sufficiency of supply of blood and blood products within the European Union.

We are writing to you because of a disturbing initiative from the European Commission which can start a development which may have a profound impact on blood safety and sufficiency of supply of blood and blood products within the European Union.

On 2 July 2007 the DG for Enterprise and Industry (DGEI) wrote to the government of France doubting that the French legislation on “authorization to market” (AMM) of blood plasma derivatives (BPD) was in conformity with certain articles of EU Directive 2001/83.

The essence of the complaint from the DGEI was to ask France to change the condition laid down in the French legislation, under which an AMM for five years to the French “market” for an BPD can only be granted under the condition, that the BPD are produced from plasma from anonymous, voluntary and non-remunerated persons. Derogations from to this general condition can only be given exceptionally and only for two years, if the BPD from paid donors is more efficient or safe - or if the necessary quantity of this specific BPD is not available to satisfy the actual health needs.

The Commission specifically asks France to change this legislation in order to allow the same market access for BPD from paid donors as for BPD from non-remunerated donors.

The Treaty of Nice (in article 3) **specifically forbids any commercialisation of the human body or any part of it.** It is therefore surprising, that the European Commission, which has as its most important task to uphold the treaties of the European Union, takes an initiative which can only be seen as an attempt to further the commercialisation of a part of the human body, i.e. the products derived from human blood plasma.

Plasma products such as immunoglobulins have their medical specificity from being developed in the human body. They are developed in the human body – and they used as treatment for diseases in other human beings.

Later EU Directives – and especially Directive 2002/98 on blood safety – are based on the basic notion that the human body should not be for sale, and that all blood and plasma donated in the European Union should be collected from voluntary, non-remunerated donors.

The conditions for collecting blood and plasma are exactly the same – and EU member states, which still allow for paid donation, have to report every three years on their progress in eliminating paid donation within their territory. In fact, Directive 2002/98 specifically allows member states to stop import of blood and blood components, which stem from paid donations.

The IFBDO finds it strange, that trade with parts of the human body is not outlawed by the European Union all together, considering that the treaty of Nice clearly forbids such commercialisation.

We also find it strange, that the GIFT of blood and plasma is treated as any other piece of merchandise, covered by European market access rules. We strongly believe, that the fractionation and distribution of blood and blood products is a service, which like other services connected with health, can – but do not have to – be open for open EU-bidding.

It is a well known fact, that some countries in the European Union still are dependent on the import of BPD from other parts of the world, and that a large part of these imports stem from low-income paid American blood donors. The American/Swiss/Australian plasma fractionation industry speaks about vein to vein control, but in practice it is very hard to determine the exact source and the price considerations behind such imported plasma products.

It is a sobering fact, that a large number of patients in Europe are dependant on donations from low income Americans, and that the American government can stop the export of such products as immunoglobulins without notice, setting European patients in an impossible situation. The US Senate has already done this once – and we would see it as a main goal for the European Commission **to achieve full European self sufficiency with safe BPD stemming from non-remunerated donors.**

Opening up for “dumping” of cheap products stemming from blood from poor Americans can not be a goal for the European Commission.

Like a number of other EU member states France is striving to be self sufficient in safe BPD from non-remunerated donors – and to do so, France must be able to stop the dumping of (imported) plasma products from paid donors. All studies show, that products such as immunoglobulins should come from populations which are the same as the patients. Other studies show, that “emerging” viruses are more prevalent in paid donor populations than in non-remunerated donors. So also for medical reasons France should be allowed to keep the present system of self sufficiency in products from French non-remunerated donors.

A long term strategy for a sufficient European blood supply has to be based on non-remunerated blood donation – as indicated in the Treaty of Nice. Safety of supply of any blood product is directly linked to the respect and attachment of the donors to the national and European blood supply, which again is directly related to the ethics and safety of this supply.

The European Union has come a long way towards higher safety of the blood supply with the Directive 2002/98 and the three follow up Directives. It is difficult for the IFBDO to understand, that the very same Commission, which proposed these Directives, now try to undermine the respect, ethics and safety of the French supply of BPD by asking the French government to undermine its present legislation on AAM of BPD.

We strongly urge the Commission to reconsider its actions in this case – and we will be happy and willing to enter into consultations with the Commission on the further implementation of the European blood legislation, as foreseen in Directive 2008/98.

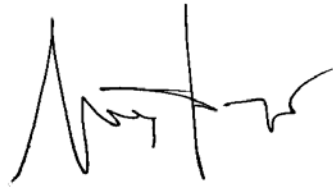
On behalf of the IFBDO



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