

## **EBA POSITION PAPER**

### **COMPETITION IN THE EU BLOOD COMPONENT MARKET**

#### **1. Introduction.**

EBA considers competition within the EU blood component market to be amongst the 2 or 3 most far-reaching issues facing European Blood Transfusion Services, their Regulators and Policy-makers over the next few years. This is because unregulated competition threatens the stability of the industry; and, consequently, both puts at risk the provision of safe and sufficient blood components for patients and prejudices the industry's ability to react to new health threats.

EBA recognises that competition can be beneficial in many areas of activity. But it is convinced that extending it to such a vital and sensitive area of healthcare without FIRST introducing proper rules and regulation to ensure that the safety of components is maintained and that the supply of all products to all hospitals and patients is preserved would create a huge risk to public health in Europe. The good news is that it is not too late to introduce a European framework for competition that would capture the benefits whilst avoiding the failure of the system. This could be introduced on a State by State level, if presently outside the competence of EU legislation and regulation. However, the bad news is that failure of the policy-makers to act will put at risk the improvements in the safety and supply of blood components that has been achieved in Europe over the last decade, through the introduction of the Blood Directives and other measures.

**This Position Paper** concentrates on examples of how unregulated competition (either within a Member State or across State borders) is putting the safe and secure provision of blood components at risk. It then describes the policies that EBA considers are necessary for the EU and Member States to avoid these risks.

**The Appendix** contains EBA's first Position Paper on this subject and demonstrates the consistency of EBA's position over the last 3 years. It also goes into the underlying issues in more detail than does the present Paper.

#### **2. Examples of how unregulated competition is putting at risk safe and secure supplies of blood components within the EU.**

2.1 In two Member States (Germany and Austria), there have been recent examples of 'for profit' companies paying donors for blood donations, processing the blood into blood components and supplying hospitals with these components and then discontinuing this service at very short notice. In both cases, the long established not-for-profit blood transfusion service (both Red Cross services) was expected to fill the gap at short notice. This meant that the Red Cross service had to re-recruit donors that it had given up when the competitor entered the market and to expand its testing and processing capacity, in order to ensure that all hospitals were provided with the full range of products that were required for

patients. In both cases, this proved possible because of the dedication of the not-for-profit blood transfusion service and because the for-profit company had not had time to take over all the donors. But, had these companies withdrawn their services later (one went bankrupt and the other decided that the hospitals concerned were not sufficiently profitable to supply), the situation would have been very serious. If the not-for-profit blood service had acted in a purely commercial manner, or it had not existed (i.e. there had not been a supplier of 'last resort'), it is likely that hospitals would have run seriously short of blood components. This would have been a hugely backward step in the health provision of an economically rich part of the EU.

2.2 The cases referred to in 2.1 above also exemplify the risks attached to allowing competition from organisations that offer to pay donors. In the economically poorer Member States and the poorer parts of the more economically developed States, it proves very hard for an existing blood service that does not pay its donors to retain these donors if there is a competing service that does offer to pay a significant amount of money for a donation. This problem will become more acute at a time of economic recession, such as we are beginning to experience in Europe. Over time this would make the EU, or part of it, reliant on paid donors. This is contrary to the intent of the EU and WHO; and creates a real risk to public health across Europe.

2.3 In other Member States, the not-for-profit blood transfusion services have had experience, for a variety of reasons, of reducing the number of blood donors that they use and then having to try to re-engage these donors at a later date. It has proved very difficult to re-engage the donors. An example is the experience of the National Blood Service in England after it had turned away donors who had travelled to malarial parts of the world. Subsequently, having introduced a test for malaria, the NBS tried to re-recruit these donors but found this very difficult to achieve. These examples demonstrate that the blood supply is dependent on the established and respected blood service developing and maintaining long-term relationships with its donors. You cannot turn donors on and off at short notice or move them between blood services, without putting at risk the security of the blood supply. This is why EBA is fully involved with the Project that is led by Sanquin and co-funded by the EU and aimed at improving the relationships between donors and their local blood transfusion service.

2.4 Experience in the US, where competition has been a feature of the supply of blood components for transfusion for many years, demonstrates some of the advantages and disadvantages of different models of competition.

All the blood components prepared for transfusion throughout the US are derived from non-remunerated donors. This was not always the case. Up to the early 1970s about 20 to 25 percent of blood components were prepared from donors who were paid to give blood.. But a national blood policy to move to an all volunteer (non-remunerated) donor supply, coupled with regulatory requirements to label prominently whether the blood component came from a 'volunteer donor' or 'paid donor' has completely replaced this practice. Nearly all the blood components for transfusion are collected, tested and processed by not-for-profit organisations (the American Red Cross supplies about 45% of the blood components for transfusion and the community blood services supply about 50%; with supplies from

hospitals and the armed forces making up the remainder). Competing blood services all operate under the same regulatory and inspection regimes.

Therefore, the major differences between competition in the US and the EU are:

i) In the US, blood services are overwhelmingly not-for-profit and all use voluntary and non-remunerated donors. Competing centres are all subject to the same legislative, regulatory and inspection standards and, therefore, blood components for transfusion are viewed mainly as generic products of equal quality.

ii) By contrast, in the EU, emerging competition comes almost entirely from for-profit companies (making decisions on who and what products to supply on a commercial basis), paying donors to receive their blood and operating under heterogeneous regulatory and inspection regimes. Therefore competition can and does arise between blood services working to different regulatory standards (see 2.5 below).

Competition in the US has centred on winning supply contracts with hospitals and on recruiting donors. The main competitors are community blood centres (typically members of the America's Blood Centers organisation) and the American Red Cross. Competition is usually based on sustainable positions, for example: a blood service will not compete for a supply contract with a hospital that it cannot supply on an economic basis for the long-term. Recently, ABC and ARC signed a national memorandum of understanding that sets an ethical framework for competition for donors. In any case, overt competition for the same donors tends to annoy the donors and may stop them from donating at all. This understanding was based on experience in the mid to late 1990s that competition without rules upset donors and caused disruption of supplies.

Evidence from the US shows that in 2006 nearly 7% of hospitals reported that elective surgery was postponed on one or more days (median 3 days; range 1-120 days) because of blood inventory shortage. Of responding hospitals, 13.5% (231/1707) experienced at least one day in which non-surgical blood needs could not be met. The total number of days reported on which blood component needs could not be met was 5,460 and the range 1 day to 365 days. This coincided with the introduction of vCJD precautions that led to the deferral of potential donors who had spent time in the UK. As this caused a loss of around 9% of donors, it is unclear to what extent any shortages of blood components were caused by this deferral and to what extent they arose from the underlying structure of the industry. Whilst the security of the supply of blood components in the US has improved greatly in recent years, in spite of a having to deal with donor exclusions relating to vCJD and other transmissible diseases, these figures suggest that competition of itself does not guarantee the levels of supply security to which much of the EU has become accustomed.

2.5 Emerging infectious diseases are regularly bringing new potential threats to the transfused patient's safety. Climate change, increased travel and migration are increasing these threats as the recent examples of West Nile Virus, Chikungunya and SARS have demonstrated. Existing blood services work closely with their national departments of health and across the EU, both through EBA and by establishing and maintaining close relations with the European Commission, so that the EC, Member States and blood services can act quickly and in a concerted fashion in the face of a threat. The above examples have shown

blood services acting quickly to introduce preventative measures such as donor selection/exclusion and/or donor testing. It is vital for the protection of patients and the European population that only those blood services that show this commitment to public health are permitted to operate in the EU. The risk was recently illustrated by an example in Germany, where the use of paid blood donors (they were paid approximately €15 per donation) from across the border in Poland had to be stopped, apparently because of epidemiological problems and because not all of the donors were traceable by the for-profit blood service involved should a look-back have been required. This is particularly serious because a threat to public health in one Member State can very quickly become a threat across the EU. At a time when so much public money is spent on making blood components safe, it seems perverse to allow a reduction in safety of this kind.

2.6 Where competition does emerge, the not-for-profit blood service would have to be permitted to charge market prices and/or reduce some of its activities or it would potentially go into deficit or out of business. This would probably mean increasing prices for specialist products and for supplying outlying hospitals. It may well mean charging one price for hospitals that buy all their blood components from the not-for profit blood service and another higher price for the hospital that spreads its purchases across different suppliers. It would also risk ending investment in such activities as Effective Use of Blood (EUB) programmes. These EUB programmes are addressing the main known safety risks of having a blood transfusion in many EU States. This is why EBA is fully involved with the project, led by the Scottish Blood Transfusion Service and co-funded by the EU that is aimed at reducing these risks.

### **3. What the Policy-makers Need to Do.**

EBA considers that competition in the collection, testing and processing of blood as well as in the provision of blood components to hospitals within the EU must be carried out in a way that safeguards the security of supply, the safety of the blood components and the efficacy of the transfusion process.

In order to achieve this, it is vital to adhere to the following principles:

3.1 The EU should continue its advocacy of the principle that donors of blood for transfusion should be voluntary and non-remunerated, as defined by the Council of Europe. This should apply to all donors of blood components that are transfused in the EU, whether the donors are resident within or outside the EU. This rule must be applied even if the blood were to be collected outside the EU. This principle is strongly supported by the EU and WHO in order to enhance blood safety, avoid past mistakes and above all minimise patient risk. If some of the blood components are derived from paid donors, product labelling should make clear whether particular blood components are derived from 'paid' or 'unpaid' donors.

3.2 Any new blood component supplier to an EU state must comply with all the terms of the EU Blood Directive. This should be enforced by the State, even when that State has not yet transposed the Directive into its law. If a State fails to do this, it could allow its blood supply service to be severely damaged and patients to be put at risk, even before the terms of the Directive become operative in the state concerned.

3.3 Any blood establishment collecting, testing or processing blood components for use in an EU State (even if the establishment is situated outside the EU) should be subject to regular inspections by the regulator in the receiving State. The regulator should be required to take account of the epidemiology of the population from which the blood is collected. If this does not happen, the safety standards enshrined in the Blood Directive would be undermined.

3.4 Any new blood component supplier to an EU State should be required to take its share of high cost hospitals and products and meet the full obligations of a normal not-for-profit blood service (e.g. meeting peak demand, providing the full range of blood components, including specialist products; providing an advice service on product use, etc.). If the new entrant cannot fulfil these obligations, it must fully remunerate the existing not-for-profit service to act as a 'supplier of last resort' and carry out these essential services on its behalf. If the State government does not ensure that this happens, the capacity of the not-for-profit service could become eroded through financial pressure, as it loses its most economic donors and hospitals. Essential products and hospitals may, under these conditions, not be supplied. This would cause deterioration of health care and long-term problems for the State government concerned.

3.5 Member States must ensure that the infrastructure required to provide both a comprehensive and modern blood transfusion service remains in place in a form that is both sustainable and capable of being updated continually in the light of new technology, medical developments and health threats.

3.6 Any blood service operating within the EU should provide a guarantee that it could meet any legal claims found against it or to fund the cost of disruption caused if it were to withdraw abruptly from the market (e.g. to fund the cost of finding new donors, etc.). If such a guarantee were not to be entered into, the State government could be left with substantial costs if the company were to enter into liquidation or to otherwise cease trading in the State concerned.

### **Conclusion**

EBA's members are fully committed to providing safe and efficacious blood components for transfusion in a cost-effective way. EBA promotes quality and cost comparisons amongst its members across the EU to facilitate the achievement of these goals. EBA recognises that there is a place for competing blood services, provided that the competition is fair, i.e. is between serious long-term players who are meeting their full obligations under the Blood Directive and State law and operate under similar regulatory and inspection regimes. EBA strongly urges the authorities at EU and State levels to examine the advantages and disadvantages of various types of competition before they occur, since once a national blood service and its donor base have been eroded or destroyed it would take years to re-establish them.

DGP

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