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EU regulation of blood donation and the importation of blood and blood products

La regulación comunitaria de la donación de sangre y la importación de hemoderivados

La regulació comunitària de la donació de sang i la importació d'hemoderivats

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Abstract

The European Union recommends unpaid blood donation because it deems this to be the safest way of collecting blood and the best way of respecting the dignity of the donor as well as certain ethical principles relating to the availability of human-origin products. However, the risk of suffering shortages of blood has led EU law to authorize the importation and consequent circulation across EU territory of blood from countries where the law allows donors to be paid. This paper analyses the inconsistency this represents and mentions the alternative of blood donation becoming a civic duty. This would allow the necessary amounts of blood to be collected in a more consistent way for EU regulation than the situation as it currently stands.

Keywords: Blood donation; EU Regulation; Not-For-Profit Principle; Public Health; Human Dignity; Civic Duty.

Resumen

La Unión Europea recomienda la donación no remunerada de sangre por considerar que este tipo de donación es el método más seguro para obtener sangre y sustancias derivadas de la misma, y el que mejor respeta la dignidad del donante así como algunos principios éticos relativos a la disposición de productos de origen humano. Sin embargo, el riesgo de sufrir escasez de sangre y de otros hemoderivados, ha hecho que el Derecho comunitario autorice la importación, y consiguiente circulación por el territorio comunitario, de productos sanguíneos provenientes de países en los cuales la ley permite remunerar a los donantes. Ante esta situación, se analiza la incoherencia que supone y se alude a la alternativa de que la donación de sangre sea considerada un deber cívico a cargo de los ciudadanos, lo que permitiría obtener las cantidades necesarias de sangre y derivados de forma más coherente y menos problemática para la regulación comunitaria que la situación en la que se encuentra en la actualidad.

Palabras clave: Donación de sangre; regulación comunitaria; principio de no lucro; salud pública; dignidad humana; deber cívico.

Resum

La Unió Europea recomana la donació no remunerada de sang per considerar que aquest tipus de donació és el mètode més segur per a obtenir sang i substàncies derivades d'aquesta, i el que millor respecta la dignitat del donant així com alguns principis ètics relatius a la disposició de productes d'origen humà. No obstant això, el risc de sofrir escassetat de sang i d'altres hemoderivats, ha fet que el Dret comunitari autoritzi la importació, i consegüent circulació pel territori comunitari, de productes sanguinis provinents de països en els quals la llei permet remunerar als donants. Davant aquesta situació, s'analitza la incoherència que suposa i s'al·ludeix a l'alternativa que la donació de sang sigui considerada un deure cívic a càrrec dels ciutadans, la qual cosa permetria obtenir les quantitats necessàries de sang i hemoderivats de forma més coherent i menys problemàtica per a la regulació comunitària que la situació actual.

Paraules clau: Donació de sang; regulació comunitària; principi de no lucre; salut pública; dignitat humana; deure cívic.

1. Unpaid donation

Blood transfusion is a technique that dates back to the early 20th century¹. Despite the fact that it became a consolidated practice during that century, the EU did not regulate it until the 21st century. It did so by means of a directive that, because of its importance in this field, has become known as the *Blood Directive*, enacted on 2003. It is Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC.

Besides filling the legislative gap relating to blood donation from an EU perspective (Directive 2001/83/EC did not regulate blood donation as itself), one of the objectives of that directive was to unify national haemotherapy systems, which had developed separately until that time, with each of them following the respective country's historic, social and political tradition. An aspect that the EU wanted to unify was the one relating to the measures and requirements for ensuring high levels of safety and quality in blood collection and transfusion. As stipulated in Article 1, the first objective of the *Blood Directive* was to set “standards of quality and safety of human blood and of blood components”.

Regarding the safeguard of quality and safety in blood and blood components, one of the issues that needed to be harmonized was donor remuneration. The decision finally taken was to encourage, whenever possible, unpaid donation of blood and plasma, but without going so far as to establish prohibitive measures in that respect. Thus, Article 20.1 of the Directive invited Member States to adopt measures to encourage this type of donation “with a view to ensuring that blood and blood components are in so far as possible provided from such donations”.

EU Law therefore deems unpaid donation to be the best method of collecting blood, a method that Member States are consequently *encouraged* to use. On what grounds or principles does it assume as its own the principle of favouring unpaid donation, and why, then, does it discourage paid donation? Let us now take a look at the grounds and principles invoked.

¹ For further information about the development of blood transfusion see Starr, Douglas, *Blood: An Epic History of Medicine and Commerce*, Little, Brown and Company, London, 1998.

2. *Salus populi*

We have just seen that, by means of current Directive 2002/98/EC, EU Law recommends unpaid donation of blood. However, this is not the first and only time that the EU, or the European Economic Community (EEC) as it was prior to 1993, has spoken in favour of this type of donation. Indeed, it had already done so in Directive 89/381/EEC of 14 June 1989 extending the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products and laying down special provisions for medicinal products derived from human blood or human plasma. Yet, while it did not intend to regulate blood donation, the EEC expressed support for unpaid donation.

This Directive wanted to ensure high levels of quality and safety in medicinal products derived from human blood and blood components, and one of the measures it promoted was precisely the encouragement of unpaid donation. This was stipulated in Article 3.4, which established that “(m)ember States shall take the necessary measures to promote Community self-sufficiency in human blood or human plasma. For this purpose, they shall encourage the voluntary unpaid donation of blood and plasma and shall take the necessary measures to develop the production and use of products derived from human blood or human plasma coming from voluntary unpaid donations”. Thus, as a priority objective of its policies, the EEC set the achievement of self-sufficiency in blood and plasma exclusively from unpaid donation in the name of safety and quality of blood products.

Directive 89/381/EEC declared, moreover, that by taking that decision, the EEC had taken into account the measures recommended by the Council of Europe and the World Health Organization (WHO) to prevent the transmission of infectious diseases. What were those measures?

On the one hand, in 1975, WHO had declared that it was “aware of the higher risk of transmitting diseases when blood products have been obtained from paid rather than from voluntary donors, and of the harmful consequences to the health of donors of too frequent blood donations (one of the causes being remuneration)”². Thus, in the name of *salus populi*, it urged Member States “1) to promote the development of national donation of blood”, and “2) to enact effective legislation governing the operation of blood services and to take other actions necessary to protect and promote the health of blood donors and of recipients of blood and blood products”. This is the doctrine to which the organization has remained faithful thus far, which it has

2 WHO, WHA28.72 Utilization and supply of human blood and blood products, Twenty-Eighth World Health Assembly, Geneva, 13-30 May 1975.

expressed in multiple resolutions, declarations, reports, recommendations and other documents on blood donation.

On the other hand, the Council of Europe had also argued in favour of unpaid donations on public health grounds. In 1983, its Committee of Ministers decided to recommend that, as an objective of their policies, Member States should set self-sufficiency in blood exclusively from unpaid donors in order to minimize the risk of transmission of infectious diseases³. The following year, the organization approved a new recommendation in which it declared that it was aware of the “dangers that such practices (remuneration for donation) entail both for donors and for recipients” and, in consideration thereof, it again recommended that Member States should seek the “achievement of self-sufficiency in blood and blood products through voluntary donations” as the safest way of collecting blood and blood components⁴.

In another recommendation made in 1988, the Council of Europe once again insisted on the promotion of unpaid donation as the most appropriate way of ensuring maximum safety for donors and recipients. Specifically, it stipulated that, in this case, it was “for both ethical and clinical reasons” that donation should be “voluntary and non-remunerated”. Likewise, the recommendation stipulated that “(h)health authorities should have an obligation to promote the adoption of policies in line with the ethical principles of voluntary, non-remunerated blood donation; these principles ensure maximum security for the health of both donors and recipients.”⁵

Finally, in a recommendation made in 1990, the Council of Europe asked Member States to achieve self-sufficiency in blood and plasma through unpaid donation and, to that end, invoked “clinical reasons, in order to avoid as much as possible the risk of transmission of infection”, that is, basically health reasons.⁶

Thus, by means of Directive 89/391/EEC, the EEC legislator had joined the efforts of WHO and the Council of Europe to promote unpaid donation and, consequently, not only set self-sufficiency in blood and plasma as an EEC objective, but also backed the thesis that this type of

3 Council of Europe, Committee of Ministers, Recommendation No. R (83) 8 of the Committee of Ministers to Member States on preventing the possible transmission of Acquired Immune Deficiency Syndrome (AIDS) from affected blood donors to patients receiving blood or blood products, adopted by the Committee of Ministers on 23 June 1983 at the 361st meeting of the Ministers' Deputies.

4 Parliamentary Assembly of the Council of Europe, Recommendation 985. Supply and utilization of human blood and blood products, 1984.

5 Council of Europe, Committee of Ministers, Recommendation No R (88) 4 of the Committee of Ministers to Member States on the responsibilities of health authorities in the field of blood transfusion, adopted by the Committee of Ministers on 7 March 1988, at the 415th meeting of the Ministers' Deputies.

6 Council of Europe, Committee of Ministers, Recommendation No. R (90) 9 of the Committee of Ministers to Member States on plasma products and European self-sufficiency, adopted by the Committee of Ministers on 29 March 1990 at the 436th meeting of the Ministers' Deputies.

donation was an appropriate way of preventing the transmission of infectious diseases, thereby preserving public health.

A year after Directive 89/381/EEC had come into force, the EEC still considered the remuneration of donors of blood and plasma to be a risk factor affecting the quality and safety of substances collected by that means. Proof of that was the Decision of the Council 91/317/CEE, of 1993, adopting a plan of action in the framework of the 1991 to 1993 'Europe against AIDS' programme, in which it was assumed that the prevention of HIV transmission ought to be dealt with by promoting the EEC's self-sufficiency in blood products and encouraging voluntary unpaid donations.⁷

In 2000, while Directive 2002/98/EC was being negotiated, the Scientific Committee on Medicinal Products and Medical Devices stated that "the effects of a payment to donors on the risk of transmitting infectious diseases by blood has been extensively discussed, but it appears that voluntary, non-remunerated donations have the lowest residual risk. Therefore, voluntary, unpaid donations seem to offer a higher margin of safety than paid donations".⁸

Likewise, as Cees L. Van der Poel has mentioned, during the negotiations for the drafting of Directive 2002/98/EC, a commissioner defended unpaid donation in the European Parliament, claiming that "recent studies would still show that blood from a remunerated source is any less safe than blood from an unremunerated one"⁹. For its part, the Commission defended the position that, while it accepted the "principle of unpaid and voluntary donations as a long-term objective", it had not included the application thereof "in its original and amended proposals because of fears that it may lead to a severe shortage of plasma and derived drugs and thus create risks for the maintenance of a sufficient supply for patients". This meant that, although the EU had accepted the principle of unpaid donation, it would not go as far as to prohibit paid donation.¹⁰

Finally, recital 23 of current Directive 2002/98/EC acknowledges that unpaid blood donations "are a factor which can contribute to high safety standards for blood and blood components and therefore to the protection of human health". Based on this position, and as we know, the EU has been requiring its Member States to develop policies to encourage this type of donation.

7 Decision of the Council and the Ministers for Health of the Members States, Meeting within the Council of 4 June 1991 adopting a plan of action in the framework of the 1991 to 1993 'Europe against AIDS' programme.

8 Scientific Committee on Medical Products and Medical Devices, Opinion on the Quality and Safety of Blood, SANCO/SCMPMD/2000/0005 Final, Luxembourg, SCMDMP, European Commission, 2000.

9 Van der Poel, CL, "Remuneration of blood donors: new proof of the pudding". *Vox Sanguinis*, 2008; 98: 169.

10 European Commission, Successful Health Council on 15 November, Brussels, European Commission, 2001.

Thus, under all the aforementioned provisions, it is clear to see that EU regulation accepts the thesis that blood and plasma collected from unpaid donors are of higher quality and, therefore, are safer than those obtained from paid donors. Consequently, dispensing with paid donation, as much as possible, is recommended on health grounds. This is the position to which the EU has remained faithful thus far.

3. Ethical principles and human dignity

Besides health considerations, the EU has recommended the exclusion of paid donation because, compared to unpaid donation, it deems it to be a type of donation that is less respectful of human dignity and of certain ethical principles.

Directive 89/381/EEC was the first legal act to declare that the EEC's objective of achieving self-sufficiency in blood and plasma through unpaid donation was based not only on public health grounds, but also on ethical grounds. Specifically, it was a measure that aimed "to ensure respect for ethical principles in trade in therapeutic substances of human origin".

Five years later, the European Commission wanted to stipulate in a communication that self-sufficiency in blood and plasma through unpaid donation was based "on the fundamental principle that the human body and its parts are inviolable and should not be used for the purposes of trade", and that they should not be the source of "profit or commercialization".¹¹

The European Parliament expressed itself in similar terms in two resolutions on blood adopted in 1995 and 1996, respectively. The first asserted that "the principle that the human body and its constituent parts are inviolable and must not be the source of profit or the subject of trading", which implied that it would "prevent imports from third countries and the commercial exploitation of blood"¹². The second again insisted on "the fundamental principle of the inalienability and non-marketability of the human body and of any organs or substances obtained from it", which compelled authorities "to select voluntary, unpaid donors".¹³

This general consensus was ultimately crystallized in the Charter of Fundamental Rights of the European Union in 2000. Chapter I of the Charter is dedicated to "Dignity", and under that

11 Commission of the European Communities, Communication from the Commission on Blood Safety and Self-Sufficiency in the European Community, COM (94) 652 final, Brussels, 1994: 7.

12 European Parliament, Resolution on blood safety in the European Union, Official Journal C 249, 25/09/1995: 231.

13 European Parliament, Resolution on the communication from the Commission on blood safety and self-sufficiency in the European Community, Official Journal C 141, 13/05/1996: 131.

chapter's Article 3, entitled "Right to the integrity of the person", we find the statement that stipulates "the prohibition on making the human body and its parts as such a source of financial gain".

In 2001, Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001, on the Community Code relating to medicinal products for human use, reasserted the EU's will to achieve self-sufficiency in blood and plasma through unpaid donation in order "to ensure respect for ethical principles in trade in therapeutic substances of human origin". The appropriate means for achieving that would be "to promote voluntary unpaid blood and plasma donation".

Thus, the EU's policy of promoting unpaid donation is not based solely on public health grounds, but is also based on the thesis that unpaid donations are more respectful of human dignity and of ethical principles (without clarifying at any time or to any great extent what those principles are). In addition, precisely for those reasons, EU's policy pursue the achievement of the objective of self-sufficiency based on unpaid donation and a consequent renunciation of the importation of blood and blood products from third countries.

4. Problems of consistency

Although three decades have passed since the EEC and then the EU set self-sufficiency in blood and blood components through unpaid donation as one of the main objectives of their policies on the matter at hand, and despite every attempt to achieve that objective, today's reality is that while most Member States are now self-sufficient in blood, they are not in plasma. In fact, as far back as 1994, the European Commission itself had raised the issue of a big difference between the level of self-sufficiency in blood and that in plasma within the EU. While most countries had managed to become self-sufficient in blood, there was a general deficit in terms of plasma and its components¹⁴. Thus, the problem that has had to be confronted is that of unpaid donation being insufficient to meet the plasma needs of either the health systems.

Faced with this situation, and to prevent shortages at health centres, EU regulation entitles Member States to import from countries where donor remuneration is permitted. This applies

14 Commission of the European Communities, Communication from the Commission on Blood Safety and Self-Sufficiency in the European Community, COM (94) 652 final, Brussels, 1994: 11.

above all to prepared blood products and plasma. EU law therefore gives authorization to procure blood and blood components that are in short supply from the non-EU market.

However, if the legal provisions authorize Member States to plug that gap in the supply of plasma by buying it, is it not the case, then, that they clash with the grounds that EU regulation has invoked to discourage paid donation? In our opinion, they do; considering EU regulation, the solution is inconsistent. Indeed, if EU regulation recommends unpaid donation because, in order “to ensure respect for ethical principles”, it considers that self-sufficiency in blood and plasma by means of such donation should be based on the “fundamental principle that the human body and its parts are inviolable”, that this principle should “prevent imports from third countries and the commercial exploitation of blood” and encourage the authorities “to select voluntary, unpaid donors” and, finally, that all the foregoing aspects should respect the dignity of the donor, then we must acknowledge that the European position on this topic is marked by a certain degree of inconsistency given that it authorizes the importation and circulation of blood components collected from paid donors.

Furthermore, if EU regulation considers that blood collected from paid donors could be more dangerous to public health than blood collected from unpaid donors, that “voluntary, non-remunerated donations have the lowest residual risk” and, therefore, that “unpaid donations seem to offer a higher margin of safety than paid donations”, then it seems that the EU is assuming a risk that undeniably would not arise if such imports were dispensed with.

5. The civic duty to give blood

Faced with that problematic situation, we believe that while the letter of the Law and the principles underpinning it do not allow blood products to be imported without falling into a contradictory position, alternatives will need to be sought in order to meet the needs of health systems, which, furthermore, should be more consistent with regulation on the matter.

One alternative could be to consider blood donation as a civic duty, that is, to set up a compulsory blood donation service involving the mandatory giving of a certain amount of that substance over a limited period of time. In short, it would be a matter of maintaining unpaid donation in exchange for a temporary curtailment of the voluntary nature thereof.

Considering blood donation as a civic duty would have several advantages: first, it would be possible to meet the blood and plasma needs of national health systems that are currently

unable to become self-sufficient through unpaid donation alone¹⁵. This would ensure that all citizens had the right to receive haemotherapy treatment included within their right to health. Second, it would be a measure consistent with current legislation and the principles underpinning it: blood from paid donors would not circulate on EU territory and, therefore, there would be no risk to public health. Nor, in the eyes of the law, would the dignity of any donor continue to be violated, since human dignity is considered a fundamental value of the rights of everyone, whether EU citizens or not.

Given the advantages that our proposal would bring, would it be possible to develop a mandatory blood donation service in accordance with EU legislation? The answer is yes. We want to point out here that it could be done taking into account all the requirements that derive from a democratic legal order. There is no obstacle that makes it impossible.

The duty to donate blood would fall by all citizens. However, even if everyone has a duty to donate blood, the service would only be required of those who fulfilled a series of requirements. It would be necessary to consider the physical condition and the state of health of each donor, so that the donation would not harm the donor's health. Accordingly, the service should be provided with a regime of exemptions¹⁶. Likewise, the right to conscientious objection should be acknowledged to those who claimed that donating blood is incompatible with their religious beliefs.

In addition, the maxim *primum non nocere* (in the first place not to harm) would be respected, that is, the donor's health would be prioritized over any other interest. Moreover, informed consent requirements should be settled and respected¹⁷.

For cases of non-compliance, the law should organize a regime of sanctions, which could consist, for example, in administrative fines or community work.

With proper legislation, mandatory blood donation service could be developed respecting individual autonomy and other rights of citizens (such as the right to physical integrity) as much as possible. We must bear in mind that rights are not absolute, and that they have to be harmonized, or balanced. In that case, we believe that submitting to a moderate blood extraction

15 The very different nature of the blood and human organs prevents that a compulsory donation could be able for human organs as well. For a more detailed explanation on the differences between the regulation of blood and human organs, see Cuadros Aguilera, Pol, *La donación de sangre. Historia y crítica de su regulación*, Civitas, Pamplona, 2018: 37-48.

16 Under selection criteria of blood donors established in Annex II of Real Decreto 1088/2005, those who weigh less than 50kg, those suffering from a disease such as hypotension, anaemia, haemophilia, or diabetes, pregnant women, or those over 65, for example, should be exempt from donating.

17 The fact that people present to donate in compliance with a public obligation does not exempt health personnel from reporting, in accordance with the provisions of the laws, or from obtaining consent to the medical act.

for a limited period of time causes little harm to the value of autonomy and the right to physical integrity, a harm which would be easily justified as a way of guaranteeing a sufficient supply of blood¹⁸. Therefore, in this case, we hold that the weight of public health overcomes the weight of individual autonomy and to physical integrity, as the benefit for public health is great and the harm for these two rights is much smaller.

Paradoxical as it might seem, the organization of a mandatory service of blood donation can be made compatible with the regime of rights and freedoms set out in the law. Likewise, the organization of such a service is more consistent with the regulation and the principles underpinning it than the current situation is.¹⁹

6. Conclusion

The aim of EU Law is to achieve the objective of self-sufficiency in blood and plasma through unpaid donation, a method that it recommends to Member States and encourages them to use because it deems it to be the safest one for collecting such substances and for respecting the dignity of the donor, as well as certain ethical principles. However, since the amount of blood components collected through this type of donation is insufficient to meet the needs of health systems, EU regulation allows substances that are in short supply to be imported from countries in which donor remuneration is permitted. We consider that the expediency of imports gives rise to a lack of consistency between the letter of the law and the grounds it has invoked for favouring unpaid donation. Faced with this situation, the establishment of a compulsory blood donation service could achieve the old objective of self-sufficiency, and, in turn, would be more consistent with the regulation and the principles that underlie it than the current situation is.

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¹⁸ "It seems clear that to donate a pint of blood (...) does not jeopardize one's prospect for a minimally flourishing life, for (that) body part(s) are regenerative". Fabre, Cécile, *Whose Body is it Anyway? Justice and the Integrity of the Person*, Clarendon Press, Oxford and New York, 2006: 103.

¹⁹ For a more detailed explanation about a mandatory blood donation service would be developed according EU Law, see Cuadros Aguilera, Pol, *La donación de sangre*, op. cit., 2018.

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