

Homosexuals and blood donation: a delicate issue for the European Union Court of Justice

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Introduction

On 29 April, 2015, the European Union (EU) Court of Justice in Luxembourg had to rule a delicate issue: to decide on a French bylaw, banning homosexuals from eligibility to donate blood on a permanent basis as their sexual behaviour may cause a high risk of acquiring severe infectious diseases, transmitted by blood¹. The issue was delicate since such a ban categorically excludes a category of citizens from donating blood, which might be contrary to fundamental human rights such as the equal treatment and non-discrimination principle, recognised by EU law. Secondly, as the Court was requested to rule on an issue that concerns the exclusive competence of individual member states: the organisation and delivery of health services and medical care. Despite the member states' exclusive competences, the EU has some limited role in terms of blood donation by setting standards of quality and safety of human blood and blood components, as established by the so-called Blood Donation Directive^{2,3}.

This short report explains the Court's reasoning, reviewing the conformity of member states' legislation on blood donation with EU law. Secondly, the Author addresses the relevance to other EU member states.

Facts

Mr. L. attended the French Blood Agency in Metz to donate blood. The physician in charge refused the blood donation on the ground that L. stated that he was homosexual. The doctor based his decision on national law, stipulating that "the exposure of a prospective donor to a sexually transmittable infectious agent, is a permanent contraindication to blood donation for a man who has had sexual relations with another man".

L. started a legal procedure for annulment of that decision, arguing that this national rule was incompatible with the Blood Directive, as it does not distinguish between permanent and temporal deferral from blood donation for which the applicable criteria must be different. Furthermore, the decision violated his basic human rights (private life, equality and non-discrimination).

The French court decided to refer the case to the EU Court of Justice for what is called a "preliminary ruling" to clarify a point of the interpretation of EU

law, more specifically the level of risk justifying the permanent deferral from blood donation. The Court of Justice's reply is not merely an opinion, but a judgment that binds the French court and likewise other national courts before which the same problem is raised.

Judgment of the Court of Justice

By rephrasing the referring court's question, the EU Court of Justice asked whether the Blood Directive allows member states to ban homosexuals from blood donation on a permanent basis, in case they have had, or have, sexual relations with other men.

In essence, the Court concluded that such a permanent ban on blood donation can only be justified conditionally, stipulating the conditions that should be fulfilled, i.e. permanent contraindication to blood donation, high risk of acquiring severe infectious diseases, and absence of effective techniques to detect human immunodeficiency virus (HIV). Additionally, that there be no less onerous methods of ensuring a high level of health protection for recipients.

It remains to the national court to assess and decide whether these conditions are met.

Discussion

Non-discrimination and legitimate restrictions

In this case the European Court clarified existing European rules on blood donation, at least to a certain extent. First of all, the Court explained the applicable legal norms. For instance, there does not exist "a right to donate blood". Although it is obvious that the rejection of a gesture of selfless generosity and solidarity may cause misunderstanding, still, giving blood is not recognised as a right in itself.

On the other hand, the EU Charter on Human Rights prohibits any discrimination against homosexuals on grounds of sexual orientation (Article 21[1] of the Charter) expressing the equal treatment principle. In that connection, it was argued that on the basis of their homosexuality, donors who are men having sex with men (MSM) are treated less favourably than male heterosexual persons. Although it might be objected that any mechanism of selection is inherently discriminatory, it is important to ensure that differences in treatment are

properly justified and proportionate, i.e. using the least invasive mean. Ultimately, the Court was being asked to explain whether the selected French rule is legitimately justified, and secondly, whether it is appropriate and necessary in order to ensure a high level of public health protection, meaning that in the case of several appropriate measures, member states should select the least onerous, and the disadvantages caused must be proportionate to the aims pursued (Article 52[1]) of the Charter).

For reasons of clarification, the Court highlighted that the concept of "sexual behaviour" should not be understood as synonymous with "sexual orientation". It nevertheless raised a kind of irrebuttable presumption that an MSM relationship necessarily and systematically puts a person at high risk of contamination. This is however, too broad and too general. Sexual behaviour used by the EU legislature requires a specific behaviour or attitude that places the prospective donor at a high risk of contamination to be identified (in line with the authoritative interpretation of the Court's top advisor, Advocate General Mengozzi, C-528/13, para 35)⁴.

EU quality regulation on blood and blood products

As a general rule, the organisation and delivery of health services and medical care belong to the sovereign powers of the member states, meaning that the EU has limited regulatory powers in the health area. This can be explained by the fact that the EU is first and for all an economic Union. This concept is now rather obsolete given the latest Treaty amendments recognising the interconnectivity of economic and social areas, requiring a more coordinated and common European policy, fighting - for instance - border-crossing health threats. Another recent example demonstrating the increased European influence in the health sector is the patient mobility directive, facilitating patients seeking cross-border medical services⁵. However, even these regulatory initiatives do not detract from the national powers in health care issues. In the field of public health, the EU has limited regulatory powers. Based on Article 168(4)(a) TFEU, the so-called Blood Directive sets more specific standards of quality and safety for the collection, testing, processing, storage, and distribution of human blood and blood products. These measures are intended to ensure a high level of quality and safety of blood (products), through the entire blood transfusion chain in all member states. In particular, it requires that in member states only accredited establishments can carry out the activities of collection, checking, preparation, storage and distribution of blood and blood components, subject to various inspections and control measures. Moreover, the Directive establishes the principles of traceability of blood, unpaid and voluntary donation, mandatory testing of each donation, and listing eligibility criteria

for permanent/temporary deferral criteria linked with exposure to risk of acquiring a transfusion-transmissible infection. The Directive does not, however, define the concept of risk of acquiring severe infectious diseases transmitted by blood. Instead, it is up to the member states to assess the level of risk according to their own specific epidemiological situations.

Risk and identifying risk behaviour

In this ruling, the French government is of the opinion that the sexual behaviour of homosexuals in itself may justify a permanent exclusion of donation, as the Directive's overarching objective is the protection of the recipient. In that respect, it refers to statistical evidence showing that the proportion of people living with HIV in the MSM population is 65 times greater than that in the rest of the population and this is confirmed by a European Centre for Disease Prevention and Control study, concluding that the prevalence of HIV in the MSM population in France was the highest of all the states⁶. In a 2013 resolution, the Council of Europe confirmed that the risk of the MSM population transmitting severe infectious diseases by blood is high⁷. In the light of these circumstances, the French government argues that a temporary deferral is not possible. This is particularly because of the "window period" following a viral infection, during which the infection may not be detected by tests and there may, therefore, be the risk of a donor transmitting HIV to a recipient. The absence of effective risk elimination techniques under the current state of scientific knowledge would be a valid argument justifying a permanent deferral. It is, therefore, up to the court to verify whether such a satisfying technique to neutralise any risk of viral infection is available or not, without causing excessive costs.

The French interpretation of homosexual behaviour that constitutes a high risk in itself is highly disputed, as it excludes the specific circumstances of sexual relations: the conditions of those relations, their frequency, and the practices involved. In effect, it means that all male homosexuals are permanently excluded from donation. As mentioned above, "sexual behaviour should not be understood as synonymous with sexual orientation". This point therefore, requires a refinement of the criteria for permanent deferral. It has been suggested that the intake questionnaire should be modified to identify risk behaviours in the MSM population. For instance, more targeted questions - concerning the period since the last sexual relation, the number of partners, the nature of the sexual relations, whether the sexual relations were protected, attendance at certain nightspots - would make it possible to assess the level of risk that each donor individually presents on account of his own sexual behaviour, rather than simply identifying sexual orientation.

By doing so, however, any permanent deferral from blood donation must be compatible with the fundamental rights recognised by the EU, including the prohibition of discrimination on sexual orientation interpreted as incorporating sexual behaviour (Art. 21 Charter). Nevertheless, certain limitations to that equal treatment provision can be justified, as long as such restrictions are necessary and meet the public health objective. Although permanent deferral of homosexuals from blood donation constitutes a limitation of the individual's human rights not to be discriminated, it remains to be seen whether such a limitation meets the public health interest, minimising the risk of transmitting an infectious disease to recipients, and whether the measure is proportionate, i.e. cannot be realised by a less invasive alternative.

Reviewing the necessity and proportionality test of permanent exclusion, the Court recognised the legitimate aim of ensuring a high level of health protection, but questioned compliance with the proportionality criterion. Again, it left it to the referring court to verify whether there is a less invasive alternative available (temporary deferral), allowing a high level of health protection, and taking into account the economic cost of a systematic quarantining and screening for HIV for blood donations, due to the risk of the "window period".

Conclusions

Reading this relatively short ruling, it can be seen that the Court of Justice took a rather ambivalent position in excluding homosexuals from blood donation. From a legal perspective the ambivalence is not unique and can be explained by the Court's reluctance to intervene in the sovereign powers of member states in the health sector. At the same time - paradoxically - member states are bound by the EU's internal market principles (free movement of services and goods) and EU Charter rights when organising their health care systems. These underlying Union values may conflict with the legitimate health concerns of member states in the case of blood transfusion. Protecting national health interests, member states have to balance potentially conflicting interests carefully, in such a manner that they comply with the Court's "necessity and proportionality" clause. In this particular case, it seems rather difficult, if not, impossible for the French government to comply with the proportionality test, as there are equally effective techniques for detecting HIV available that are less onerous than permanent deferral, e.g., systematic quarantining of plasma, associated with virological screening. Consequently, there is no justification of a permanent deferral of homosexuals from blood donation.

Will this ruling have implications for other member states too? Yes, given that many European countries apply a similar policy of excluding homosexuals on a

permanent basis, one may expect that this ruling will urge EU member states to reconsider that approach. As an illustration, the Dutch legislature is already moving towards abolishing a permanent ban. A few days after a ruling from the Netherlands Institute for Human Rights, concluding that a permanent MSM ban is discriminatory⁸, the Minister of Health informed the Dutch Parliament she was reconsidering her position towards a more temporary deferral (between 6 months and 5 years) as there is no need to exclude the MSM population permanently for health safety reasons (risks of transmitted infections)⁹. Within this short timeframe and with concurring conclusions, the European Court's ruling strengthens the Minister's plea to lift the permanent ban and establish equal treatment in the Netherlands. As such, it will follow other countries, such as the UK, Sweden, Italy and Spain, which have already introduced temporary deferral. International consensus about the minimum risks of transmitted infections will therefore challenge the proportionality test, leaving member states no discretionary power to continue a permanent ban. This would not be the first time that the Court of Justice has behaved as an activist Court.

Keywords: eligibility blood donation, sexual behaviour, permanent deferral.

The Author declares no conflicts of interest.

References

- 1) Judgment of 29 April 2015, *L. v Ministre des Affaires sociales, de la Santé et des Droits des femmes, Établissement français du sang*, C-528/13, ECLI:EU:C:2015:288. Available at: <http://curia.europa.eu>. Accessed on 10/06/2015.
- 2) Directive 2002/98/EC on setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components of 27 January 2003. OJ, L33, 8/2/2003, p.30.
- 3) Directive 2004/33/EC, 22 March 2004 implementing certain technical requirements for blood and blood components. OJ, L91, 30/3/2004, p.25.
- 4) Opinion of Mr Advocate General Mengozzi delivered on 17 July 2014. *Geoffrey Léger v Ministre des Affaires sociales, de la Santé et des Droits des femmes et Etablissement français du sang*. Case C-528/13. Available at: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:62013CC0528>. Accessed on 10/06/2015.
- 5) den Exter A, Santuari A, Sokol T. One year after the Patients' Rights Directive: a three-country analysis. *European Law Review* 2015; 2: 279-94.
- 6) ECDC, Monitoring implementation of the Dublin Declaration on Partnership to Fight HIV/AIDS in Europe and Central Asia: 2012 progress', October 2013. Available at: <http://ecdc.europa.eu/en/activities/diseaseprogrammes/hash/Pages/monitoring-dublin-declaration.aspx>. Accessed on 10/06/2015.
- 7) Resolution CM/Res(2013)3 adopted by the Committee of Ministers of the Council of Europe on sexual behaviours of blood donors that have an impact on transfusion safety, 27 March 2013.

- 8) [Case n. 2015-46, 24 April 2015.] Available at: <https://mensenrechten.nl/publicaties/oordelen/2015-46>. Accessed on 10/06/2015. [In Dutch.]
- 9) [Letter of the Minister of Health Dutch Parliament, 6 March 2015, reference 730406-133767-GMT.] Based on the outcomes of a research study by Sanquin and University Maastricht, MSM & Blood donation, 19 January 2015, p. 2. [In Dutch.]

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