

EUROPEAN COURT OF JUSTICE WEIGHS IN ON DONOR COMPENSATION DEBATE

BY JOHN DELACOURT

IN A CASE WITH SIGNIFICANT IMPLICATIONS

for the plasma protein therapies industry, the European Court of Justice has ruled that an Austrian law banning the importation of blood products not obtained from donations made “without any payment whatsoever” violates EU rules on the free movement of goods between Member States.

In *Humanplasma GmbH v. Republik Österreich*,¹ the Court held that the health and safety concerns raised by the national authorities do not outweigh the free trade priority embodied in Article 28 of the TFEU. Although the Austrian law at issue related specifically to blood products for direct transfusion, the Court’s analysis—and ultimate rejection—of the health and safety rationales for restrictions on compensated whole blood donation applies even more strongly to donations of source plasma.

Case Background

The case emerged from Humanplasma’s efforts to supply blood products to the Wiener Krankenanstaltenverbund (Vienna Hospital Association). In November 2005, the Hospital Association sought bids on a contract to supply leukocyte-depleted erythrocyte concentrates. Humanplasma was the low bidder, and confirmed that its proposal was in compliance with all applicable provisions of the *Arzneiwareneinfuhrgesetz* (Medicinal Imports Law). However, before Humanplasma could fulfill the contract, the Medicinal Imports Law was amended.

The amended law stated that “When blood products are imported for direct transfusion they may in any case not be placed on the market unless the blood was donated without any payments whatsoever having been made.”² Because Humanplasma’s products were obtained primarily from German blood donors to whom some compensation was provided, it was unable to comply with this condition and its previously successful bid was rejected. In response, the company filed an objection with the *Vergabekontrollsenat für Wien* (Public Procurement Review Tribunal, Vienna), which concluded that the bid had been properly rejected.

Humanplasma then appealed the Procurement Tribunal’s decision to the *Landesgericht für Wien Zivilrechtssachen Wien* (Regional Civil Court, Vienna), asserting for the first time that the provisions of the Medicinal Imports Law on donor compensation violated EU law. The Regional Court, in turn, stayed the proceeding and referred the following question to the European Court of Justice for a preliminary ruling:

“Does Article 28 EC (in conjunction with Article 30 EC) preclude the application of a national provision under which the importation of erythrocyte concentrates from Germany is permitted only where the blood was donated without any payment having been made (with not even expenses being covered), that being a condition which is also applicable to the obtaining of erythrocyte concentrates within Austria?”³

The Court’s Decision

The Austrian authorities argued that the ban on donor compensation advanced an objective warranting an exemption from Article 28’s guarantee of the free movement of goods between Member States – namely, the protection of human health. The Court’s analysis therefore focused on whether the provision in question – a total ban on all forms of donor compensation – was appropriately limited or, rather, went beyond what was necessary to achieve this objective.

The Court held that the provision was *not* appropriately limited, stating with surprising directness that “the obligation that the blood donation must have been made without any of the costs incurred by the donor being reimbursed is . . . not necessary in order to ensure the quality and safety of the blood and the blood components.”⁴

The Court reasoned, first and foremost, that the principal safeguard on the quality and safety of blood products is a strict regime of post-donation testing.⁵ The Court noted that the E.U.’s own blood directive mandates such testing, and requires that it evolve to reflect the scientific and technical state-of-the-art. The Court also observed that the E.U.’s blood directive does not require that donations be “completely unpaid,” but rather contemplates such compensation as small tokens, refreshments, and reimbursement of travel costs.⁶ Finally, the Court explained that the rigidity of the Austrian law made it an outlier, as a number of other Member States – all of which regard the safety of the blood supply as a national priority – permit the reimbursement of at least some of a donor’s costs.⁷

Impact of the Decision

Although the Humanplasma decision relates to blood products for transfusion, and could have gone even further in its endorsement of compensated donation, it is nevertheless likely to prove

useful to supporters of compensation for source plasma donors. A number of the positions adopted by the Court arguably provide the legal framework for future challenges to restrictions on donor compensation, and will almost certainly influence the related legislative and public policy debates. These include the following:

- **Donor Compensation Is Not a Safety Issue** – The Court stated unambiguously that the Austrian law’s restrictions on donor compensation were “not necessary” to ensure quality and safety. This is a major blow to one of the two central justifications for restrictions on donor compensation, the other being the claim (unsupported by data) that compensated blood and plasma donations “crowd out” uncompensated donations⁸.
- **Post-Donation Safeguards Are Critical** – Much of the Court’s comfort with the safety of compensated donation stemmed from its confidence in the European-level regulatory framework for post-donation testing. This rationale applies even more strongly in the plasma therapies context, where final products are subjected to two sets of post-donation safeguards: (1) pathogen testing, and (2) pathogen inactivation. In contrast, the viral inactivation procedures that are now industry standard in the plasma therapies context are often unavailable in the whole blood context, as they may result in the destruction of critical blood components.
- **Compensation Is Not the Same as Payment** – Although the specific examples of permissible donor compensation offered by the Court included only small tokens, refreshments, and reimbursement of travels costs, and did not expressly include cash payments, the Court did appear to endorse the broader principle that reimbursement of donor costs is acceptable and non-problematic. In doing so, the Court seemed to accept a principle long advocated by supporters of donor compensation: that “payment” (for the biological materials themselves) is not the same as “compensation” (for the donor’s time and inconvenience). It remains to be seen whether the Court’s decision will be construed as going this far. To the extent that it is, this rationale also applies more strongly in the plasma therapies context, as plasma donors are encouraged to donate on a qualified, repeat basis, and each individual donation session take longer. Consequently, a typical plasma donor incurs more reimbursable costs, in terms of time and inconvenience, than a typical whole blood donor.

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¹ Case C-421/09, Humanplasma GmbH v. Republik Österreich, CELEX No. 609J0421 (Westlaw) (Dec. 9, 2010).

² *Id.* at ¶ 10.

⁵ *Id.* at ¶ 42.

³ *Id.* at ¶ 23.

⁶ *Id.* at ¶ 44.

⁴ *Id.* at ¶ 43.

⁷ *Id.* at ¶ 41.

⁸ Sybille Beck, Blood Centers and Plasma Centers: Mutual Benefit, *The Source*, Summer 2011, Page 12.