European Parliament
2019-2024

Committee on Petitions

21.2.2024

NOTICE TO MEMBERS

Subject: Petition No 0882/2023 by Heinz Stutzenberger (German), on behalf of Alpha1 Deutschland, Gesellschaft für Alpha1-Antitrypsinmagel Erkrankte e.V., on the proposal for a Regulation on Substances of Human Origin (SoHO)

1. Summary of petition

The petitioner calls for better consideration of the interests of recipients of blood plasma products in the ongoing revision of the blood, tissues and cells legislation. According to the petitioner, the current draft of the regulation contains provisions relating to "Substances of Human Origin" that would make it more difficult to increase the willingness of the EU population to donate plasma. It would also not reduce the dependency on imports of blood plasma products from the USA. The petitioner demands, for example, that blood plasma donation should not be classified as a health risk for the donor. The petitioner also calls for the permission of compensation options for donors' expenses in such an amount that the establishment of donation centers in the private sector becomes or remains attractive alongside the public sector centers.

2. Admissibility

Declared admissible on 8 December 2023. Information requested from Commission under Rule 227(6).

3. **Commission reply**, received on 21 February 2024

In July 2022, the Commission tabled a proposal for a Regulation of the European Parliament and of the Council on standards of quality and safety for substances of human origin (SoHO) intended for human application and repealing Directives 2002/98/EC and 2004/23/EC for which a political agreement was reached with the co-legislator on 14 December 2023. The Commission wishes to underline that the sufficiency of supply of SoHO like plasma for the

manufacturing of plasma derived medicinal products, was a key driver for the revision of the SoHO legislation. Thus, the Commission proposal includes definitions for critical SoHO and critical SoHO entities (with additional requirements for those entities or establishments carrying out activities contributing to the supply of critical SoHO), the establishment of emergency plans and of supply alerts. The Commission notes that the Council and European Parliament have, as part of the legislative procedure, recognised these concerns and have proposed further provisions to strengthen supply of critical SoHO, in particular through the development of national actions for supply.

The Commission underscores that, in its proposal for a Regulation on SoHO, donation of plasma is not considered a health risk for the donor. Instead, it is emphasised that repeated and frequent donations of plasma could potentially pose health risks for donors. The Commission maintains that an open recognition of such possible health risks for donors in some circumstances is essential to ensure public trust and foster willingness of the public to continue and increase donations. This will be even more important when pursuing a responsible increase in plasma collection, in particular, from frequent donors.

The future Regulation on SoHO will allow for compensation while respecting the principle of voluntary unpaid donation. Acceptable levels of compensation will have to be defined at national level and will have to be transparent and respected equally by public and private donation centres, who both are important contributors to supply of plasma in the European Union.

Conclusion

The Commission considers that the provisions in the future Regulation on SoHO, once adopted and entered into force, will help strengthening further donation and collection activities of plasma in the European Union. The Commission very much welcomes that the aims to increase supply of critical SoHO were largely supported by Parliament and Council.

The Commission also refers to its response to a similar Parliamentary question (E-002002/2022) (https://www.europarl.europa.eu/doceo/document/E-9-2022-002002_EN.html) and (https://www.europarl.europa.eu/doceo/document/E-9-2022-002002-ASW_EN.html