EUROPEAN COMMISSION

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Dear Chair,

The Commission would like to thank the Poslanecká sněmovna for its Opinion on the proposal for a Regulation of the European Parliament and of the Council on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC {COM(2022) 338 final}.

The revision of the legislation on substances of human origin, that the Commission initiated with this proposal in July 2022, aims at updating the legislation to allow for a more flexible alignment of the regulatory framework to scientific and technological developments. By proposing to increase the safety and quality rules for substances of human origin, the Commission takes a further step towards a strong European Health Union. Citizens would benefit from a safer environment when donating or receiving vital substances of human origin, such as blood, tissues and cells, as well as breast milk and microbiota. The new Regulation would also facilitate cross-border circulation of critical health therapies. It would reinforce solidarity between public health authorities, while ensuring that the sector can manage the supply of critical substances and promoting innovation with the same high standards of quality and safety for all.

The Commission is pleased that the Poslanecká sněmovna shares the view that action at EU level, as envisaged in the proposal, is required to adapt the rules on safety and quality for substances of human origin according to the latest scientific developments, and to ensure supply monitoring of critical substances of human origin, such as plasma intended for the production of live-saving medicines.

The Commission also welcomes the opportunity to provide further clarifications regarding its proposal. As regards the recommendation to expand the collection of plasma to ensure the self-sufficiency of Member States, the proposal addresses the

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continuity of supply of plasma, as well as of other critical substances of human origin. In this regard the proposal sets out the obligation for Member States to make all reasonable efforts to encourage donation; obligations for continuous monitoring of donations, exchanges between Member States, imports and exports; and obligations related to supply alerts and emergency plans. The Commission also supports non-legislative actions and other forms of cooperation between national authorities. This is in line with the Member States retaining the competence for organising their own health systems, including their blood and plasma services.

On the comment regarding the definition of the roles, responsibilities, and methods of EU expert entities, the added value of the Commission proposal is to ensure full use of the high level of scientific and technical expertise already available, while respecting the competences of the Member States. This concerns for example the European Centre for Disease Prevention and Control (for the prevention of communicable disease transmission through substances of human origin) and the European Directorate for the Quality of Medicines & HealthCare within the Council of Europe (for the donors, recipients and offspring protection other than from transmission of communicable diseases). On the Substances of Human Origin Coordination Board, a newly established expert group, the proposal defines the rules for Member States' participation and foresees implementing acts for further measures regarding its functioning. The proposal does not modify the functioning rules of EU agencies such as the European Centre for Disease Prevention and Control and the European Medicines Agency. It neither amends rules applicable to the European Directorate for the Quality of Medicines & HealthCare, given that the latter is not an EU entity. As the Substances of Human Origin Coordination Board would promote coordination between Member States in the implementation of the Regulation, it would also liaise with expert entities to exchange experiences and good practices. This would contribute to enhancing the efficiency and transparency of the system.

The proposal is now being discussed as part of the ordinary legislative procedure by the co-legislators. The Commission is hopeful that an agreement will be reached within a reasonable time. The Poslanecká sněmovna's Opinion has been made available to the Commission's representatives in the ongoing negotiations of the co-legislators, the European Parliament and the Council, and will inform these discussions.

The Commission hopes that the clarifications provided in this reply have addressed the points raised by the Poslanecká sněmovna and looks forward to continuing the political dialogue in the future.

Yours faithfully,

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Vice-President

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Member of the Commission