PARLIAMENT
OF THE CZECH REPUBLIC
Chamber of Deputies
Ondřej Benešík
Chairman
Committee on European Affairs

Prague, 13th October 2022

Dear Ms. President,

I would like to inform you about the opinion of the Committee on European Affairs of the Chamber of Deputies of the Parliament of the Czech Republic

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 /Council Code 11396/22, COM(2022)338 final/.

The respective document was included in the agenda of the 15th session of the Committee on European Affairs and was scrutinized on 5th October 2022. According to the Rules of Procedure the Deputy Minister of Health of the Government of the Czech Republic was present at the session to introduce the preliminary Government's Framework Position.

After the hearing of the rapporteur's review and after the discussion the Committee has adopted the **Resolution No. 99 in the context of the Political Dialogue** which is enclosed to this letter.

Yours sincerely

Ms. Ursula von der Leyen
President of the European Commission
B r u s s e l s

Parliament of the Czech Republic, Chamber of Deputies, Sněmovní 3, 118 26 Praha 1
tel.: +420-257 173 411, fax: +420-257 173 415
http://www.psp.cz/vez

PARLIAMENT OF THE CZECH REPUBLIC
Chamber of Deputies
Committee on European Affairs

Resolution No. 99

15th Session on 5 October 2022

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 /Council Code 11396/22, COM(2022)338 final/

Conclusions of the Resolution:

Committee for European Affairs

1. **welcomes** the proposed EU legislation on blood, human tissues and cells;

2. **supports** the Government's Framework Position on this document;

3. **supports** the effort of the European Parliament and the Council to adjust the above-mentioned area following its significant development and the latest scientific findings, especially with regard to increasing the availability and safety of therapies for european patients and reducing dependence on third countries, especially in the area of supplies of blood plasma intended for the production of life-saving medicines. Recommends the expansion of compensated collection of blood plasma and other steps necessary to ensure the self-sufficiency of the EU Member States;

4. **considers it essential** for the functionality, efficiency and transparency of the system, to clearly define the roles, responsibilities and method of establishing EU expert bodies (EDQM, ECDC, EMA and the newly established Coordination Group for Substances of Human Origin) responsible for regulation, rule-making and decision-making in the area of substances of human origin, especially with regard to the competences of individual EU Member States;

5. **authorizes** the Chairman of the Committee on European Affairs to forward this resolution to the President of the European Commission **in the framework of the political dialogue**.