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EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director-General

Brussels
SANTE.D.2/SVDS/EB/(2025)11080014

Dear Director-General,

I am writing to you regarding the implementation of the EU Substances of Human Origin (SoHO) Regulation (EU/2024/1938). This Regulation will ensure citizens' future access to essential and qualitative blood, tissue and cell therapies.

More than a year has passed since adoption of the Regulation, and we now have less than two years remaining before full date of application on 7 August 2027.

We would like to thank you for all the efforts that went already into the implementation of this new legislation in your country. This first year after adoption has allowed for a strong start in our joint preparations.

The SoHO Coordination Board (SCB) has been established, along with six working groups, to develop a common understanding and practical guidance for the implementation of the new framework, in a harmonised way across the EU. A first implementing act has been adopted concerning the new digital platform and the joint development of the first digital modules (focused on registration and assessing innovations) is progressing well. All Member States have now nominated participants in the SCB and to most of the six working groups, allowing us to build on input and experience from national administrations and healthcare services. We are extremely grateful for the work your representatives perform in the SCB and its working groups.

Looking ahead, it is important to keep up this positive momentum and to deliver on our commitments in due time. For this, it will be crucial to ensure an effective coordination and communication between your different experts and representatives at national level. Furthermore, my services will continue to strengthen the coordination of the work between SoHO Expert Bodies, namely the European Centre for Disease Prevention and Control (ECDC) and the European Directorate on the Quality of Medicines and Healthcare (EDQM), where your national experts also play a key role.

During this second year, additional implementing legal acts will be adopted, and the development of the EU SoHO platform will progress. Moreover, work on compensating living donors and maximum offspring of living donors will be developed. For all these tasks we continue to count on the input of your national authorities and healthcare services, through the SCB.

I also want to take this occasion to recall the need for alignment of your national legislation with the new SoHO Regulation, particularly national legislation transposing the current Directives on blood (2002/98/EC) and on tissues and cells (2004/23/EC) whose provisions will cease to apply as of August 2027. Furthermore, in many Member States national legislation includes other elements complementary to the EU framework, such as rules on consent or funding, which may also require alignment with the new SoHO Regulation.

Amongst the first preparatory steps, it will be essential to designate an autonomous SoHO national authority, and further SoHO competent authorities as needed (as per Article 5), and to prepare for a communication strategy or other means to raise awareness towards the SoHO professionals in your Member State.

Biotechnology is a rapidly evolving sector, and the future SoHO framework must therefore interact smoothly with other frameworks, such as those for pharmaceuticals, medical devices and information/communication technologies. Several upcoming initiatives, through the SCB and through EU4Health funding, will therefore require coordinated input from your experts in all these frameworks. It will be essential for future European biotechnology to develop clear and coherent frameworks, and I count on your support to strengthen this collaboration at EU and national level.

Finally, I would like to draw your attention to the opportunities for support to your national authorities provided through EU4Health initiatives, in particular the SHARE-SoHO action which has just started. This action will offer expertise and advice to the national authorities when preparing for the new SoHO Regulation by summer 2027, including a gap-analyses, national action plan, training and exchange of know-how.

Do not hesitate to come back to my colleagues in the SoHO team, via SoHO-SANTE@ec.europa.eu in case you have further questions or would appreciate a discussion.

I look forward to continuing the good collaboration.

Yours faithfully,

Sandra GALLINA

cc.: BOIX ALONSO Lorena (SANTE.DDG1), BECKER Rainer (SANTE.D), MATHIEU-MENDES Agnes (SANTE.D.2), MCGEEHAN Richard (SANTE), BATTISTINI Luca (SANTE), MOYA DIAZ Marta (SANTE.A.2), VAN DER SPIEGEL Stefaan (SANTE.D.2), BAERT Katleen (SANTE.D.2), MARCHAND Els (SANTE.D.2), CICCARELLO Martina (SANTE.A.2)

Electronically signed on 08/12/2025 23:54 (UTC+01) in accordance with Article 11 of Commission Decision (EU) 2021/2121