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Committee on Social Affairs, Health and Sustainable Development

Sub-Committee on Public Health and Sustainable Development

Minutes

Exchange of views on the position statement of the European Committee on Organ Transplantation of the Council of Europe (CD-P-TO) on “Risk of commodification of substances of human origin”, held in Strasbourg on Thursday, 26 January 2023

The PACE Sub-Committee on Public Health and Sustainable Development held an exchange of views on the position statement of the European Committee on Organ Transplantation of the Council of Europe (CD-P-TO) on “Risk of commodification of substances of human origin”, with the participation of **Ms Beatriz Domínguez-Gil** from the National Transplant Organisation of Spain (*Organización Nacional de Trasplantes – ONT*).

Ms Nigar Arpadarai (Azerbaijan, EC/DA), **Sub-Committee Chairperson**, introduced the topic and the invited speaker and then gave her the floor for her presentation.

Ms Beatriz Domínguez-Gil took the floor and screened her presentation on the “Risk of commodification of substances of human origin. A position statement of the European Committee on Organ Transplantation of the Council of Europe”.

The expert addressed the issue of commodification of substances of human origin (SoHO), such as tissues and cells, and noted that it could be done with organs in the future. Most treatments for humans depended on the usage and the modification of these substances. Within the European Union, the scientific development in the field had led to the production of SoHO-derived medicines as advanced therapies medicine and products (ATMs). These derived from substantial manipulation of multiple functions of cells. However, this procedure was not clearly defined in the regulatory framework.

In the ongoing context, concrete and dangerous implications arising from the lack of a clear and comprehensive regulatory framework meant that substances of human origin, instead of being categorised as transplants, were overclassified as medical products or devices, and their usage underwent labelling and commercialisation by the pharmaceutical industry. For example, bone marrow mononuclear cell fraction was rich in hematopoietic stem cells and could be effectively used in numerous treatments and therapeutical purposes without substantial manipulation. However, the regulatory framework categorised it as a transplant in higher risk treatments and as an ATMP in lower risk treatments. This categorisation appeared highly questionable, from scientific, economic, organisational, and ethical perspectives.

There was a proposal for a regulation on substances of human origin, which was under discussion at the European Union level. The World Health Organization was examining the possibility to adopt recommendations on the potential development of a global regulatory framework for cell and gene therapy products, and a public consultation process. Both processes should be recognised in the future as important occasions to raise public awareness on the issue of commodification of SoHO and, ultimately, as an opportunity to change the existing regulatory framework.

The expert then gave an overview of the risks derived from the commercialisation of substances of human origin. One risk was increased costs, which in turn undermined the sustainability of healthcare systems that faced higher costs for SoHO-derived treatments when they were labelled as ATMPs or medical devices. This was in part due to commercialisation that sought profits. The price did not directly reflect the costs and investments made by pharmaceutical companies in their development, manufacture and marketing. The high price for ATMPs and SoHO-derived medical devices could compromise the accessibility to patients. Thus,

¹ The minutes were approved and declassified by the Sub-Committee on Public Health and Sustainable Development at its meeting on 25 January 2024.

there was a serious risk of violations of fundamental ethical principles set out in the relevant articles of the Oviedo Convention. These included the principle of voluntary and unpaid donation of SoHO (article 21), the principle of equity in access to SoHO-based therapies (article 3), the principle of prohibition of financial gain of the human body (article 21), and the principle of informed consent, if donors did not receive explicit information on the destination of the donated material and the possibility of subsequent profit for a third party, which was sometimes disproportionate (article 19).

The abovementioned risks could challenge altruistic donation of SoHO, which was needed for patients whose survival or quality of life depended on such donation. The danger stemmed from the fact that the general public could believe that altruistic donation would in certain cases result in a disproportionate financial gain for pharmaceutical and biotech companies, which could lead to potential donors turn away.

The expert then highlighted several proposals detailed in the position paper adopted by European Committee on Organ Transplantation of the Council of Europe (CD-P-TO), with the aim to help bring new treatment opportunities to all patients. These included proposals to preserve and reaffirm the principle of non-commercialisation of SoHO and prohibit any remuneration of subjects who donated SoHO; to establish mechanisms to guarantee transparency with regard to the final use of donated SoHO; to improve coordination between the various bodies and health authorities; to establish transparent and scientifically sound quality and safety standards for donation, procurement and clinical use of SoHO that could be the same regardless of its final use; to regulate clinical research with SoHO in accordance with the level of complexity and innovation and potential risks for patients; to establish criteria and transparent mechanisms to assess and ensure the quality, safety and efficacy of new SoHO-based therapies; and to promote mechanisms to foster development and innovation within tissue and blood establishments.

The Chairperson thanked the expert for the interesting and detailed presentation and closed the hearing.

List of presence / *Liste de présence* (27 seats / 27 sièges)

Chairperson / *Président(e)* :

Ms Nigar Arpadarai	Azerbaijan / <i>Azerbaïdjan</i>
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Vice-Chairperson / *Vice-Président(e)* :

Zz...	
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Members / Membres**Alternates / Remplaçant(e)s**

1.	Mr	Armen Gevorgyan	Armenia / <i>Arménie</i>		Zz...
2.	Ms	Nigar Arpadarai	Azerbaijan / <i>Azerbaïdjan</i>	Ms	Konul Nurullayeva
3.	M.	Simon Moutquin	Belgium / <i>Belgique</i>	Ms	Els Van Hoof
4.	Ms	Minna Reijonen	Finland / <i>Finlande</i>		Zz...
5.	M.	Alain Milon	France	Mme	Nathalie Serre
6.	Mr	Levan Ioseliani	Georgia / <i>Géorgie</i>		Zz...
7.	Mr	Andrej Hunko	Germany / <i>Allemagne</i>	Ms	Martina Stamm-Fibich
8.	Ms	Theodora Tzakri	Greece / <i>Grèce</i>	Ms	Foteini Pipili
9.	Mr	Joseph O'Reilly	Ireland / <i>Irlande</i>		Zz...
10.	Mr	Edmunds Cepurītis	Latvia / <i>Lettonie</i>		Zz...
11.	M.	Max Hengel	Luxembourg		Zz...
12.	Mr	Miloš Konatar	Montenegro / <i>Monténégro</i>		Zz...
13.	Mr	Andrzej Szejna	Poland / <i>Pologne</i>		Zz...
14.	Mr	Bolesław Piecha	Poland / <i>Pologne</i>	Mr	Tomasz Latos
15.	Mr	Nuno Carvalho	Portugal	Ms	Jamila Madeira
16.	Mr	Andi-Lucian Cristea	Romania / <i>Roumanie</i>	M.	Ion Prioteasa
17.	Ms	Carmen Leyte	Spain / <i>Espagne</i>	Ms	Belén Hoyo
18.	Ms	Susana Sumelzo	Spain / <i>Espagne</i>		Zz...
19.	Ms	Sibel Arslan	Switzerland / <i>Suisse</i>	Mme	Ada Marra
20.	Mr	Halil Özşavli	Türkiye		Zz...
21.	Ms	Larysa Bilozir	Ukraine		Zz...
22.	Mr	Geraint Davies	United Kingdom / <i>Royaume-Uni</i>		Zz...
23.					
24.					
25.					
26.					
27.					

ex officio: Ms Selin Sayek Böke (Chairperson / *Présidente*, Türkiye)

Other Parliamentarians present / Autres Parlementaires present.e.s

Ms / Mme Zdravka Bušić Croatia / *Croatie*

Secretariat of Delegation or of Political Group / Secrétariat de Délegation ou de Groupe politique

Ms / Mme Handan Karakaş Demir, Delegation Secretary, Turkish delegation to PACE / *Secrétaire de délégation, délégation turque auprès de l'APCE*

Experts / Expert.e.s

Ms / Mme Beatriz Domínguez-Gil, National Transplant Organisation of Spain / *Organisation nationale espagnole de transplantation* (Organización Nacional de Trasplantes – ONT)

Council of Europe staff / Secrétariat du Conseil de l'Europe

Mr / M. Lorenzo Montrasio, Human Rights Directorate, Bioethics Unit / *Direction des Droits de l'Homme, Unité de Bioéthique*

Committee on Social Affairs, Health and Sustainable Development /
Commission des questions sociales, de la santé et du développement durable

Ms / Mme Tanja Kleinsorge Head of the Secretariat / *Cheffe du Secrétariat*
Ms / Mme Aiste Ramanauskaite Secretary to the Committee / *Secrétaire de la commission*
Ms / Mme Anita Gholami Co-Secretary/ *Co-Secrétaire*
Mr / M. Guillaume Parent..... Co-Secretary/ *Co-Secrétaire*
Ms / Mme Sylvie Elter Assistant / *Assistante*
Ms / Mme Claire Fabre Trainee / *Stagiaire*
Ms / Mme Teresa Andreani Trainee / *Stagiaire*
Ms / Mme Federica Peseri..... Trainee / *Stagiaire*