



European Commission

# EUROPEAN HEALTH UNION

## REGULATION ON SUBSTANCES OF HUMAN ORIGIN

### A comprehensive EU framework for safety and quality of SoHO

CONFERENCE ON THE NEW REGULATION ON SUBSTANCES OF HUMAN ORIGIN  
24 June 2024

Venue: Auditorium BREYDEL  
(Av. d'Auderghem 45, Brussels)

## AGENDA

9.00 – 10.00

Registration and Coffee

10.00 – 10.30

**WELCOME** by Moderator for the day:  
Tamsin Rose

**INTRODUCTION TO THE PROGRAMME AND HOUSEKEEPING**

**Opening Session – Moderated by Rainer Becker**

**Welcome remarks by Rainer Becker**, European Commission, DG SANTE, Director Medical Products and Innovation

**Recorded message from Stella Kyriakides**, Commissioner for Health and Food Safety

**Welcome remarks by Javier Padilla Bernáldez**, Spanish Secretary of State for Health

10.30 – 11.45

**SESSION 1: Meeting the safety and quality standards of the new Regulation – protecting donors, recipients and offspring**

**SAFETY AND QUALITY OF SOHO MATTERS FOR CITIZENS – Impact Statement**

George Constantinou – *Thalassaemia International Federation (TIF)*

- **EU Regulation: a new approach to setting the quality and safety standards**  
Deirdre Fehily – *European Commission SoHO Team*
- **Preventing transmission of communicable diseases by SoHO**  
Marieke van der Werf – *European Centre for Disease Prevention and Control (ECDC)*
- **Ensuring quality and safety of SoHO practices**  
Laurent Mallet – *European Directorate for the Quality of Medicines (EDQM)*
- **Ensuring compliance with the Safety and quality standards in SoHO entities: the role of the competent authorities**  
Nick Van Gelder – *Belgian Federal Agency for Medicines and Health Products (FAMHP)*

**Moderated panel discussion with professional SoHO associations**

- **Carlos Calhaz-Jorge** – *European Society for Human Reproduction and Embryology (ESHRE)*
- **Françoise Rossi** – *International plasma Fractionators Association (IPFA)*
- **Marilena Vrana** – *Plasma Protein Therapeutics Association (PPTA)*
- **Sertac Arslanoglu** – *European Milk Banks Association (EMBA)*
- **Christian Hvas Lodberg** – *EurFMT*
- **Martin Börgel** – *Common Representation of SoHO Associations (CoReSoHO)*

**Safety and quality of SoHO matters for citizens – Impact Statement**

Klaudija Kordic – *Fertility Europe*

11.45 – 13.00

**SESSION 2: SoHO Innovation**

**SoHO INNOVATION MATTERS FOR CITIZENS – Impact Statement**

Christian Lodberg Hvas – *EurFMT*

- **The future of SoHO innovation: opportunities and challenges**  
Esteve Trias – *Leitat Foundation*
- **Cross-sectoral cooperation and consultation in EU legislation**  
Stefaan van der Spiegel – *European Commission SoHO Team*
- **Authorisation of SoHO preparations based on evidence**  
Giuseppe Feltrin and Vincenzo De Angelis, *Directors of Italian SoHO competent authorities and co-ordinators of GAPP-Pro Joint Action*

**PANEL: AUTHORITIES AND PROFESSIONAL ASSOCIATIONS**

- **Pia Ekborn** – *Danish Patient Safety Authority*
- **Christian Chabannon** – *Expert in haematopoietic stem cell and CAR-T transplantation*
- **Celine Druart** – *Expert in human microbiome medicines*
- **Nigel Talboys** – *President of the Blood Transfusion Association of medical device manufacturers*
- **Steffen Thirstrup** – *European Medicines Agency Chief Medical Officer*

**SoHO INNOVATION MATTERS FOR CITIZENS – IMPACT STATEMENT**

Anne Birgit Hovde – *MS patient*

13.00 – 14.30

LIGHT LUNCH – foyer outside the meeting room

14.30 – 15.45

**SESSION 3: The challenge of ensuring a sufficient supply of critical SoHO**

**SUFFICIENT SUPPLY of SoHO MATTERS FOR CITIZENS – IMPACT STATEMENT**

Jacques Allegra – *International Federation of Blood Donors (FIODS)*

- **The issues: how the new provisions address them**  
Beatrice Marquez-Garrido – *European Commission SoHO Team*
- **How to achieve EU sufficiency for plasma**  
Peter O'Leary – *European Blood Alliance (EBA)*
- **Managing SoHO in emergency situations**  
Major General Tim Hodgetts – *Chair of NATO Committee of the Chiefs of Military Medical Services*

**PANEL: SUPPLY PERSPECTIVES OF PROFESSIONALS AND AUTHORITIES**

- **Mirjam Fechter** – *World Marrow Donors Association (WMDA)*
- **Rita Piteira** – *Banc de Sang i Teixits*
- **Gilbert Verbeken** – *Brussels Military Hospital*
- **Tjonglie Ching** – *Dutch Health and Youth Care Inspectorate*
- **Linda Larsson** – *Swedish National Board of Health and Welfare*

**SoHO SUPPLY MATTERS FOR CITIZENS – IMPACT STATEMENT**

Bernd Dobbert – *Alpha-1 EUROPE*

15.45 – 16.15

COFFEE/TEA BREAK – foyer outside the meeting room

16:15 – 17:30

**SESSION 4: The SoHO Regulation – a key element of a strong European Health Union**

**SoHO MATTERS FOR CITIZENS – IMPACT STATEMENT**

Silke Mader – *European Federation for the Care of Newborn Infants (EFCNI)*

- **SoHO priorities for the European Parliament**  
Nicolás Casares – *Member of the European Parliament*
- **How ECDC contributes to protecting SoHO recipients**  
Marieke van der Werf – *European Centre for Disease Prevention and Control (ECDC)*
- **How EDQM contributes to ensuring quality, safety and effectiveness of SoHO**  
Petra Doerr – *Director European Directorate for the Quality of Medicines (EDQM)*
- **Why Spain prioritised the SoHO Regulation during its Council Presidency**  
Beatriz Dominguez-Gil – *Director General of the Spanish National Transplant Organisation (ONT)*
- **The commitment of the Member States to implement the new SoHO Regulation**  
Hugues Malonne – *CEO Belgian Federal Agency for Medicines and Health Products (FAHMP)*
- **Safe and effective substances of human origin: underpinning healthcare across the EU**  
Sandra Gallina – *European Commission Director-General for Health and Food Safety*

17.30 – 19.00

COCKTAIL

