



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 and Fractionation 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

