SoHO oversight system: the implementation of the new EU regulation with a focus on the obligations for competent authorities

April 8th, 2025

organized by

ISTITUTO SUPERIORE DI SANITÀ
Italian National Blood Centre

under the patronage of

Ministry of Health*

**requested*

N° ID: 040D25-P

Rationale

The European directives on blood, tissues and cells (2002/98/EC and 2004/23/EC) have significantly helped to ensure safety and quality of care in the blood transfusion, cell and tissue transplantation and medically assisted reproduction fields. Despite this, the need for this legislation to be more responsive to new scientific and technological developments has emerged. In this context, in 2019 the European Commission (EC) initiated a process of critical evaluation of the impact of the directives. This process highlighted the need for a regulation proposal on the quality and safety of Substances of Human Origin (SoHO), which would strengthen the capacity of the competent authorities to promote and support innovation in this field, without sacrificing safety and quality.

On July 17th, 2024, the new European regulation on quality and safety standards for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC was officially published in the EU Official Journal.

Within this context and since 2010, the Italian system has been adapted accordingly.

The new national legislation (November 5th, 2021) aimed at strengthening the oversight system at a regional level, and at improving its independence and impartiality.

Simultaneously, the EC has promoted European key initiatives to strengthen and harmonise Member States (MSs) SoHO oversight activities: VISTART (Vigilance and Inspection for the Safety of Transfusion, Assisted Reproduction and Transplantation), GAPP (FacilitatinG the Authorization of Preparation Process for blood, tissues and cells), GAPP-PRO (Piloting Gapp model approach for assessing and authorizing novel substances of human origin preparation process). VISTART and GAPP developed a guideline for the conduction of inspections for the authorisation/accreditation/licensing of Blood and Tissue Establishments as well as guidelines for the authorisation of processes and products based on SoHO, with particular reference to innovative products/processes, respectively. The primary goals of GAPP-PRO, which started in February 2024 and will end in June 2027, are to test the GAPP methodology and to verify its feasibility in the Member States also where sometimes blood, tissues and cells (BTC) novelties may fall within the scope of different regulatory frameworks.

Given the above, and in consideration of the new European legislative framework, MSs started undertaking the necessary actions during the transitional period that will end in August 2027. In each MS, this path is multi-level (national/regional/local) and multi-actors.
Essentially, the event is to be intended both as a step of the dissemination of the application process of the new EU regulation until it becomes legally binding in 2027, and as an opportunity to discuss the benefits and challenges for SoHO Competent Authorities (CAs) and national oversight systems coming from the new legislative framework.

Aims
Conference aims at both presenting the experience of some CAs and providing an overview of the tools and key EU initiatives towards a European common approach of the oversight activities.

PROGRAMME

8.45 Registration

9.30 Welcome address
Vincenzo De Angelis, Director, Italian National Blood Centre, Italian National Institute of Health (ISS)
Rocco Bellantone, President, Italian National Institute of Health (ISS)
Maria Rosaria Campitiello, Head, Department of Prevention, Research and Health Emergencies, Ministry of Health *
Sergio Iavicoli, Director, General Directorate of Communication, Ministry of Health
Stefaan Van der Spiegel, Directorate General for Health and Food Safety, European Commission
Orazio Schillaci, Minister of Health, Italy* *(invited)*

SESSION I - ROAD TO 2027 WITHIN THE BLOOD FIELD: THE ITALIAN AND OTHER EU MEMBER STATES ACTION PLAN
Chairpersons: **Vincenzo De Angelis**, **Johann Kurz**

10.00 *Support of the European Commission to the Member States*
Stefaan Van der Spiegel

10.15 *Spain*
Aránzazu de Celis

10.30 *France*
Imad Sandid

10.45 *Romania*
Alina Mirella Dobrota

11.00 *Greece*
Konstantinos Stamoulis

11.15 *Finland*
Anu Puomila

11.30 *Italy*
Simonetta Pupella

11.45 Q&A

12.15 Lunch Break

SESSION II - TOOLS TOWARDS A EUROPEAN COMMON APPROACH OF THE OVERSIGHT ACTIVITIES
Chairpersons: **Ruth Barrio**, **Verena Plattner**

13.15 *EU SoHO Platform: State-of-the-art*
Massimo Ambrosio

13.30 *The role of the European Directorate for the Quality of Medicine & Healthcare (EDQM)*
Rada Milos Grubovic Rastvorceva

13.45 *The role of the European Centre for Disease Prevention and Control (ECDC)*
Jenny Mohseni Skoglund

14.00 *Key EU initiatives: GAPP-PRO and SIGHTSoHO*
Ursula La Rocca, **Livia Cannata**

14.30 Q&A

14.45 Coffee break

SESSION III - CHALLENGES OF THE EUROPEAN SOHO OVERSIGHT SYSTEM
Chairpersons: **Vincenzo De Angelis**, **Giuseppe Feltrin**

15.00 *Working group on Inspection of the SoHO Coordination Board (IES)*
Sandra Tomljenovic

15.15 *Working group on Vigilance and Traceability of the SoHO Coordination Board (VES)*
Jo Wiersum

15.30 ROUND TABLE - *Common approach: are there any obstacles to its full applicability?*
Simonetta Pupella, **Alina Mirela Dobrota**, **Imad Sandid**, **Anu Puomila**, **Konstantinos Stamoulis**, **Aránzazu de Celis**, **Ruth Barrio**, **Verena Plattner**, **Fiorenza Bariani**, **Benedetta Mazzanti**

16.45 Closing remarks - Take home messages
Vincenzo De Angelis

17.00 End of the meeting

SPEAKERS, CHAIRPERSONS and participants in the Round Table

Massimo Ambrosio - Directorate-General for Health and Food Safety, European Commission
Fiorenza Bariani - Italian National Transplant Centre, ISS, Italy
Ruth Barrio - Catalan Transplant Organisation, Spain
Livia Cannata - Italian National Blood Centre, Italy
Vincenzo De Angelis - Italian National Blood Centre, Italy
Aránzazu de Celis - Ministry of Health, Spain
Alina Mirella Dobrota - Regional Blood Transfusion Centre, Costanza, Romania
Giuseppe Feltrin - Italian National Transplant Centre, ISS, Italy
Rada Milos Grubovic Rastvorceva, European Directorate for the Quality of Medicines & HealthCare
Johann Kurz - EU projects, regulatory bodies in the field of inspections, audits and regulatory compliance of SoHO, Austria
Ursula La Rocca - Italian National Blood Centre, ISS, Italy
Benedetta Mazzanti - Italian National Transplant Centre, ISS, Italy
Jenny Mohseni Skoglund - European Centre for Disease Prevention and Control (ECDC)
Verena Plattner - Austrian Agency for Health and Food Safety, Austria
Anu Puomila - Finnish Medicines Agency, Finland
Simonetta Pupella - Italian National Blood Centre, ISS, Italy
Imad Sandid - National Agency for the Safety of Medicines and Health Products, France
Konstantinos Stamoulis - Hellenic National Blood Transfusion Center**,** Greece
Sandra Tomljenovic - European Inspection Expert Subgroup, European Commission
Stefaan Van der Spiegel - Directorate-General for Health and Food Safety, European Commission
Jo Wiersum - European Vigilance Expert Subgroup, European Commission

Scientific Coordinator

VINCENZO DE ANGELIS
Italian National Blood Centre
Istituto Superiore di Sanità, Rome

Scientific Board

SIMONETTA PUPELLA, LIVIA CANNATA, DANIELA STORANI
Italian National Blood Centre
Istituto Superiore di Sanità, Rome

Organizing Secretariat

IVAN DENARO, LAURA DI MARCO, FRANCESCA MARTINI, SERENA PAPPAGALLO, TONINO SOFIA
Italian National Blood Centre
Istituto Superiore di Sanità, Rome
Tel. 06 4990.4953/4963
e-mail: segreteriagenerale.cns@iss.it

GENERAL INFORMATION

Conference venue
Aula Pocchiari, Istituto Superiore di Sanità
Viale Regina Elena, 299 - Roma

Official language
The official language is English.
A simultaneous English-Italian translation service will be available.

Target audience
The Conference is addressed to CAs, but also to representatives (director or a delegate) of the Italian or other EU MS national/regional offices in charge of the authorisation and accreditation systems; assessor/inspector/vigilance officers of the Italian and other EU MS blood System; Italian regional coordination structures; national and European scientific societies; national/international donor associations; Italian and other EU MS Ministries of Health; other national authorities and international organizations.
Maximum number of attendees: **220**.

Registration and selection
Participation is free of charge.
Attendants are kindly requested to fill out the registration form available online at the following link REGISTRATION FORM by **March 28th, 2025**.
Participants should belong to the above target audience and will be selected on a first-come first-served basis.
Participants admitted to the Conference will receive a confirmation via e-mail.

Satisfaction questionnaire
At the end of the conference, all participants will be asked to complete a quality assessment survey.

Certificates
At the end of the meeting, a Certificate of attendance will be provided to all the attendees, upon request.
A Certificate of participation, instead, will be provided upon request only to those who have attended at least 75% of the event.

This event does not provide any CME credits.

For any further information about the conference, please contact the Organizing Secretariat.

[Electronic signature of ISS Legal Representative]