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

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Rome

CENTRO NAZIONALE SANGUE
Istituto Superiore di Sanità

under the patronage of

Ministero della Salute

On July 17th 2024, the new European regulation on standards of quality and safety for substances of human origin (SoHO) was officially published in the EU Official Journal to strengthen the capacity of the competent authorities (CAs) to promote and carry out oversight activities and innovation in this field, without sacrificing safety and quality.
The adoption of this new legal act is the result of a challenging revision process launched by the European Commission (EC) with an evaluation of the legislation related to blood, tissues and cells, and medically assisted reproduction. The impact assessment consisted of public and stakeholders consultations, including the organisation of dedicated workshops, as well as two external studies. Commission Expert Sub-Groups on Inspections and Vigilance (IES, VES) have been set up and other European initiatives such as VISTART, GAPP, GAPP-PRO and SIGHTSoHO have been launched to improve and harmonise SoHO oversight activities. Moreover, stronger collaboration has been sought with the European Centre for Disease Prevention and Control (ECDC) and the European Directorate for the Quality of Medicines & HealthCare (EDQM), who play a key role within the new legislation.

Member States (MS) have started undertaking the necessary actions during the transitional period, which will end in August 2027. In each MS, this path is multi-level (national/regional/local) and involves several actors.
The Conference aims at:

- presenting the experience of some blood CAs in such a path, as well as the state-of-the-art of tools and means at the EU level to support MS in the implementation of the regulation;
- providing an overview of the key European initiatives and actions;
- discussing the strengths and obstacles to a common European approach in the oversight activities.

PROGRAMME

8.45 **Participants arrival and registration**

9.30 **Welcome address**

Vincenzo De Angelis
Director, National Blood Centre,
Italian National Institute of Health

Rocco Bellantone
President, Italian National Institute 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

**invited*

SESSION I

ROAD TO 2027 WITHIN THE BLOOD FIELD: THE ITALIAN AND OTHER EU MEMBER STATES ACTION PLAN

Chairpersons: V. De Angelis, J. Kurz

10.00	**Support of the European Commission to the Member States** S. Van der Spiegel
10.15	**Spain** A. de Celis
10.30	**France** I. Sandid
10.45	**Romania** A. M. Dobrota
11.00	**Greece** K. Stamoulis
11.15	**Finland** A. Puomila
11.30	**Italy** S. Pupella
11.45	**Q&A**
12.15	**Lunch Break**

SESSION II

TOOLS TOWARDS A EUROPEAN COMMON APPROACH OF THE OVERSIGHT ACTIVITIES

Chairpersons: R. Barrio, V. Plattner

13.15	**EU SoHO Platform: State-of-the-art** M. Ambrosio
13.30	**The role of the European Directorate for the Quality of Medicine & Healthcare (EDQM)** R. M. Grubovic Rastvorceva
13.45	**The role of the European Centre for Disease Prevention and Control (ECDC)** J. M. Skoglund
14.00	**Key EU initiatives: GAPP-PRO and SIGHTSoHO** U. La Rocca, L. Cannata
14.30	**Q&A**
14.45	**Coffee break**

SESSION III

CHALLENGES OF THE EUROPEAN SoHO OVERSIGHT SYSTEM

Chairpersons: V. De Angelis, G. Feltrin

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

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

15.30 **ROUND TABLE**
Common approach: are there any obstacles to its full applicability?
S. Pupella, A. M. Dobrota, I. Sandid, A. Puomila, K. Stamoulis, A. de Celis, R. Barrio, V. Plattner, F. Bariani, B. Mazzanti

16.45 **Closing remarks - Take home messages**
V. De Angelis

17.00 **End of the meeting**

SPEAKERS & CHAIRPERSONS

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, ISS, Italy

VINCENZO DE ANGELIS - Italian National Blood Centre, ISS, 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 Control

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

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GENERAL INFORMATION

Official language

The official language is English.

A simultaneous English-Italian translation service will be available.

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.