

TAIEX Multi country Workshop on the Role and Functioning of Competent Authorities in the Field of Substances of Human Origin

**organised in co-operation with the
Ministry of Health of Montenegro**

Participant as speaker: Ms Patricia Galea Director Health Care Standards

Malta was selected by the Commission to participate in the TAIEX Multi-Country Workshop on the Role and Functioning of Competent Authorities in the Field of Substances of Human Origin held in Podgorica, Montenegro. This event was organised by the European Commission's DG Neighbourhood and Enlargement Negotiations within the framework of the TAIEX Instrument

Aim of the workshop:

The aim of the workshop was to provide the participants from the Ministries of Health, competent authorities and inspectorates in the field of substances of human origin (blood, tissues & cells, and organs) with information on the set-up and running of competent authorities in the SoHO sector.

On Day 1, the workshop started by a welcoming speech from the host Competent Authority Deputy Minister Mira Dasic (MN MoH) followed by an Introduction to the Workshop and its aims by Ms Dominique de Backer . An Overview of EU SoHO legislation and the obligations of competent authorities was then presented by Mr Richard McGeehan from the Commission. The second session consisted of Member State SoHO Competent Authority models. EU Member State experts from Malta, Portugal, Poland and Croatia presented different Competent Authority models which exist in their respective country, such as 1 Competent Authority for all SoHO, 3 separate Competent Authority s, And Competent Authority s with dedicated Competent Authority SoHO inspectors, and systems with separate Competent Authority and inspection functions. The experts shared their experiences of how and why their MS choose the systems in place and how these work in practice. Session 3 consisted of Group sessions - Exploring the Pros and Cons of Different COMPETENT

AUTHORITY models and Session 4 consisted of Feedback from the group sessions. The next day started with Session 5 which consisted of Specific oversight functions of Competent Authority's. Authorisation was addressed by Ms Patricia Galea, from Malta; Inspection was addressed by Piotr Radziwon, from Poland; Vigilance was addressed by Vanja Nikolac from Croatia and finally Reporting, Registers & Inter-country Collaboration was addressed by Margarida Amil, from Portugal. Session 6: consisted of Group sessions to discuss the topics that were presented in session 5 and each group was assisted by a Competent Authority expert. Session 7 was the Closing session and all participants discussed How to apply the findings in their respective home country.

The experts presented the detailed requirements which Competent Authority s must fulfil and explained how they go about meeting these. On both days, participants were encouraged to discuss the information presented and how it relates to their own countries. They also had an opportunity to discuss the challenges they face in establishing and running SoHO Competent Authority s.

Participants were expected to arrive at the workshop with a basic understanding of their country's current Competent Authority structure and then use the information from the workshop and the experiences gained when taking decisions on the set-up of SoHO Competent Authority s and their running, once they return to their home countries. The Beneficiaries for this workshop were Albania, Bosnia and, Serbia, Turkey, the former Yugoslav Republic of Macedonia, Kosovo Herzegovina, Montenegro. Ms Patricia

Galea presented and described the Competent Authority Set up and the process of Authorisation adopted by the Maltese Competent Authority for SoHO . Malta's representative was also rapporteur for one of the groups following a lengthy discussion on how to go about implementing the EU



requirements for SoHO Competent Authorities. Participation in this workshop identified different levels of compliance with EU laws and also highlighted several strengths, weaknesses and challenges that the Balkan countries together with aspiring countries like Turkey have to address in order to respect EU obligations. An evaluation report was forwarded to the Commission.