Survey and Expert Interviews on European Legal Requirements

Discussion: 17:15-17:45
30 minutes
Wrap-Up and Conclusions, Day 1

Michael Lassmann
Opening and Setting the Scene

Session 1

• The SIMPLERAD project and its objectives, major actions and timeline were introduced

• The European framework and pharma legislation and guidance relevant to therapeutic radiopharmaceuticals were described

• The perspectives of important international organisations in this field were given
Interrelations among Legal and Regulatory Frameworks

Session 2

• The work of WP1 to analyse literature and national legal frameworks and identify regulatory and implementation issues was outlined

• A comparison of the legal frameworks in the EU, UK and US showed important similarities and indicated differences that might be adopted

• More information specific to the UK and the role of ARSAC was presented
Survey and Expert Interviews on European Legal Requirements

Session 3

• The methodology of WP2 to collect information on the current practice and challenges of therapeutic nuclear medicine in Europe was described
• The analysis of the pre- and main survey responses and expert interviews and overall conclusions were given
• Field reports on the practice of therapeutic nuclear medicine and good examples were presented for Germany, Sweden and Czechia
SAMIRA Study on the implementation of the Euratom and the EU legal bases with respect to the therapeutic uses of radiopharmaceuticals

End of day 1