Survey and Expert Interviews on European Legal Requirements

Discussion: 17:15-17:45

30 minutes

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Wrap-Up and Conclusions, Day 1

Michael Lassmann

Simplerad

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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

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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

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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

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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

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