Roundtable Discussion on SIMPLERAD Guidance Document and Recommendations

Session 5

11:20–13:00

Simplerad

This project has received funding from the European Commission under Service Contract N° ENER/2022/NUCL/SI2.869532.0

Panel statements

11:20-12:00 (3 minutes per panellist)

Georgi Simeonov, European Commission

Vanessa Fradin-Da Ros, European Medicines Agency

Ken Herrmann, nuclear medicine therapy expert

Steffie Peters, medical physics expert

Marianne Patt, radiopharmacy expert

Erik Briers, patient representative

Leonhard Schätz, industry representative

Simplerad

This project has received funding from the European Commission under Service Contract N° ENER/2022/NUCL/SI2.869532.0

Questions to Panellists

- Please share the three most important topics to be discussed during the 2-day workshop on the SIMPLERAD project.
- What is the greatest challenge in your view to providing access to high-quality and safe nuclear medicine and radiopharmaceuticals in the EU?
- Which is the first priority with respect to implementation of EU legislation regarding this topic?

Simplerad

This project has received funding from the European Commission under Service Contract N° ENER/2022/NUCL/SI2.869532.0

Roundtable Discussion on SIMPLERAD Guidance Document and Recommendations

12:00-13:00

Discussion on actions proposed and their implementation

Simplerad

This project has received funding from the European Commission under Service Contract N° ENER/2022/NUCL/SI2.869532.0

Items to be discussed

1. Insufficient linkage between EU pharmaceutical legislation/EMA guidance and BSSD
2. Interpretation and implementation of the BSSD in the context of therapeutic nuclear medicine
3. Lack of resources for dosimetry
4. Differences regarding status of MPEs between member states
5. Heterogeneity of dose constraints & patient-release criteria among member states
6. Heterogeneity of management of radioactive waste across member states
7. Differing guidance from professional societies for clinical practice
8. Differing regulatory procedures between member states for drug development & clinical trials
9. Sufficient specialist knowledge concerning nuclear medicine within various stakeholders regarding EU pharmaceutical and medicine as well as BSSD-related regulations
10. Differences between opinion of professionals concerning dosimetry and the necessity stipulated in national legislation and guidance

Simplerad

This project has received funding from the European Commission under Service Contract N° ENER/2022/NUCL/SI2.869532.0

Simplerad

Lunch break!

13:00–14:00

This project has received funding from the European Commission under Service Contract N°ENER/2022/NUCL/SI2.869532.