SAMIRA Study on the Implementation of the Euratom and EU Legal Bases with Respect to the Therapeutic Uses of Radiopharmaceuticals

Programme

Monday, 11 December 2023

Session 1 **Opening & Setting the Scene**
Moderator: M. Lassmann
Rapporteur: EIBIR office

13:00-13:10 Welcome by the EC and consortium (G. Simeonov, DG ENER; M. Lassmann)

13:10-13:20 Introduction to the SIMPLERAD project (B.J. Krause)
- Overview of project scope and workplan
- The underlying issues, including status of the use of therapeutic radiopharmaceuticals

13:20-13:45 Presentation of the European framework relevant to therapeutic radiopharmaceuticals
- Euratom framework (G. Simeonov, DG ENER)
- Pharma framework
  - European pharma legislation (P. Erba, DG SANTE)
  - Clinical trials legislation (A.M. Janson Lang, Clinical Trials Coordination and Advisory Group)
  - Guidance and posology (V. Fradin-Da Ros, European Medicines Agency)

13:45-14:00 Perspectives of international organisations
- World Health Organisation (L. Gwaza)
- International Atomic Energy Agency (A. Korde)
- International Commission on Radiological Protection (A. Giussani)

14:00-14:15 Discussion

Session 2 **Interrelations among Legal and Regulatory Frameworks [WP1]**
Moderator: M. Lassmann
Rapporteur: M. Patt

14:15-14:35 Results of analytical work and identified regulatory and implementation issues [WP 1] (M. Bardiès)

14:35-14:55 Presentation of the outcome of comparative analysis of the legal bases in the United States, United Kingdom and EU [WP 1] (M. Lassmann)

14:55-15:05 Legal basis in the United Kingdom (L. Fraser, UK Administration of Radioactive Substances Advisory Committee)

15:05-15:15 Discussion

15:15-15:45 Coffee break

Session 3 Survey and Expert Interviews on European Legal Requirements [WP2]
Moderator: C. Decristoforo
Rapporteur: S. Peters
15:45-16:30 Presentation of survey methodology and results of questionnaires and expert interviews (J. Gear)

16:30-17:15 Member-state field reports and good-practice examples
Germany (A. Drzezga, German Commission on Radiological Protection)
Sweden (A. Sundlöv, Swedish Medical Products Agency)
Czechia (P. Solný, Czech Society of Nuclear Medicine)

17:15-17:45 Discussion

17:45-18:00 Wrap-up and conclusions, Day 1 (M. Lassmann)

Tuesday, 12 December 2023

09:00-09:10 Welcome to Day 2 and introduction of programme (M. Lassmann)

Session 4 Recommendations to Advance Coherent Implementation of European Legal Requirements [WP3]
Moderator: M. Lassmann
Rapporteur: J. Gear
09:10-09:40 Identification and prioritisation of issues (F. Verburg)

09:40-10:30 Identified actions to be implemented as part of the project and proposed for the future (M. Lassmann; M. Bardiès)

10:30-10:50 Discussion

10:50-11:20 Coffee break

Session 5 Roundtable Discussion on SIMPLERAD Guidance Document and Recommendations [WP3]
Moderator: M. Lassmann
Rapporteur: C. Stokke
11:20-12:00 Round table panel statements
European Commission (G. Simeonov, DG ENER)
European Medicines Agency (V. Fradin-Da Ros)
Nuclear medicine therapy expert (K. Herrmann)
Medical physics expert (S. Peters)
Radiopharmacy expert (M. Patt)
Patient representative (E. Briers, Europa Uomo)
Industry (L. Schätz, Novartis Pharma AG)

12:00-13:00 Open discussion on actions proposed and their implementation

13:00-14:00 Lunch break

Session 6 Summary
Rapporteur: EANM office
14:00-15:00 Conclusions and recommendations per proposed action (M. Lassmann)

15:00-15:30 Summary and wrap-up per project task (M. Lassmann)

15:30-16:00 Next steps in the project (M. Hierath)

16:00 Closing (G. Simeonov, DG ENER; M. Lassmann)