EU Policy Symposium Session 1

Policy & Regulatory Affairs Council
Tuesday, October 7, 08:00 – 09:30

Session Title

From Policy to Patients: Building Readiness for Nuclear Medicine Innovation in Europe

Chairpersons

Wim Oyen (Radboud, Netherlands)
Paola Erba (Bergamo, Italy)

Programme

08:00 – 08:05 Introduction by the Co-Chairs

08:05 – 08:25 **SIMPLERAD Meets PRISMA: From Recommendations to Implementation**

- 08:05 – 08:15: **SIMPLERAD Legacy: Regulatory Lessons**
  Key recommendations and regulatory insights from the study.
  Michael Lassmann, University of Wurzburg (Germany)
- 08:15 – 08:25: **Carrying the Torch: PRISMA Vision**
  How PRISMA is translating recommendations into policy and practice.
  Sampsa Kaijaluoto, Finnish Radiation and Nuclear Safety Authority (Finland)

08:25 – 09:10 **From Policy to Clinical Practice: Can systems keep up with the pace of innovation?**

- 08:25 – 08:40: **Anticipating the Wave: How Many Patients, How Soon?**
  Forecasting the number of eligible patients and expected growth.
  Uwe Holzwarth, Joint Research Centre - European Commission, Ispra (Italy)
- 08:40 – 08:55: **Growing the capacity of healthcare systems for Radioligand Therapy**
  Addressing main barriers and challenges.
  Karolien Goffin, KU Leuven (Belgium)
- 08:55 – 09:10: **Right Patient, Right Time: Streamlining Access to Innovation**
  Highlighting urgent bottlenecks and opportunities in patient access and referral.
  Anne-Laure Giraudet, Centre Léon Bérard, Lyon (France)

09:10 – 09:25 Open Forum

- Panel discussion
- Q&A with the audience

09:25 – 09:30 Conclusions by the Co-Chairs

- Concluding remarks
- Call for action

Educational Objectives

1. Understand the key regulatory recommendations from the SIMPLERAD study and their relevance to EU policy.
2. Describe how the PRISMA Joint Action will support the implementation of these recommendations across Member States.
3. Analyse projected trends in patient eligibility for radioligand therapies and their implications for healthcare planning.
4. Identify current challenges and opportunities in patient referral pathways for radioligand therapies.

Summary

As radioligand therapies innovation accelerates across Europe, the challenge shifts from policy development to real-world implementation. This symposium explores how the regulatory groundwork laid by the SIMPLERAD project is being carried forward through the PRISMA Joint Action, and how healthcare systems must now prepare to meet the growing demand for advanced radioligand therapies.

The first part of the session highlights the regulatory journey—from the recommendations of SIMPLERAD to the implementation strategies of PRISMA. The second part turns to healthcare system readiness, focusing on projected patient demand, system capacity, and referral pathways. The session concludes with an open forum to engage the audience in shaping the next steps for policy and practice.

Key Words

Radiopharmaceuticals; EU legislations; Healthcare systems readiness; Policy; Referral pathways