



## EU Policy Symposium 1

Policy and Regulatory Affairs Council

**Tuesday, October 22, 15:00 - 16:30**

### Session Title

**Bridging the Gap:**

**EU Pharma Legislation and Basic Safety Standards - Navigating Legal Complexity in Member States**

### Chairpersons

**Wim Oyen**

15:00 - 15:15 Introduction by Chairperson

15:15 - 15:25 **Georgi Simeonov**, European Commission (Luxembourg)  
*Setting the scene*

15:25 - 15:45 **Bernd Krause** (Rostock, Germany)  
*Focus on SIMPLERAD: Recommendations and Proposed Measures to foster the interrelations between EU pharmaceutical legislation and Council Directive 2013/59/Euratom.*

15:45 - 16:00 **Marieke Van Dok**, Dutch Ministry of Health, Welfare and Sport (Netherlands)  
*Dutch case study*

16:00 - 16:15 **Anna Sundlov**, Swedish Medical Products Agency (Sweden)  
*Solving the issue?*

16:15 - 16:35 Q&A, discussion

### Educational Objectives

1. Discussing measures to strengthen the interrelations between EU pharmaceutical legislation and Council Directive 2013/59/Euratom related to radiopharmaceuticals,
2. Discuss the outcomes and recommendations of the SIMPLERAD project.
3. Discuss the legal complexities derived from the above interrelations at the national level.

### Key Words

Radiopharmaceuticals; EU legislations; Dosimetry; Policy