EU Policy Symposium 1
Policy and Regulatory Affairs Council
Tuesday, October 22, 15:00-16:30

Session Title
Bridging the Gap: EU Pharma Legislation & Basic Safety Standards - Navigating Legal Complexity across Europe

Chairpersons
Wim Oyen (Milan, Italy)
Oliver Kiß (Dresden, Germany)

Programme

15:00 - 15:05 Introduction by the Chairs

15:05 - 15:20 **Georgi Simeonov** (Luxembourg City, Luxembourg): Setting the scene. (online participation)

15:20 - 15:40 **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.

15:40 - 15:50 **Marieke Van Dok** (The Hague, Netherlands): A Dutch case study.

15:50 - 16:00 **Rolf Hesselmann** (Bern, Switzerland): Switzerland: a role model for the Pharma & Radiation Protection interrelations?

16:00 – 16:10 **Anna Sundlov** (Uppsala, Sweden): Solving the issue?

16:10 - 16:30 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.

Summary

Given their unique nature, radiopharmaceuticals require a regulatory framework that addresses their specific characteristics and challenges.

The EANM is committed to advocating for a regulatory environment that ensures the safe, effective, and timely availability of radiopharmaceuticals across Europe. However, current European regulations and standards are considering radiopharmaceuticals under the same umbrella as other medicinal products. In this respect, radiopharmaceuticals' development and delivery are hampered by a complicated and fragmented regulatory environment. This session will look into this regulatory framework and propose several policy recommendations.

Key Words

Radiopharmaceuticals; EU legislations; Dosimetry; Policy