EU Policy Symposium 2
EANM Policy & Regulatory Affairs
Tuesday, September 12, 16:45 – 18.15

Session Title
Regulatory Challenges of Radiopharmaceuticals

Chairpersons
Marianna Patt
Oliver Kiss

Programme
16:45 – 16.50  Introduction by the Chair and Co-Chair on the rationale and background of the session

16:50 – 17:00  Olga Solomon, Head of Unit Medicines: Policy, authorisation and monitoring, DG SANTE, European Commission (Belgium) (invited)

17:00 – 17:12  Anna Sundlöv, Swedish Medical Products Agency (Sweden)

17:12 – 17:24  Clemens Decristoforo, Medical University Innsbruck, Innsbruck (Austria) - Revision of the pharmaceutical legislation: Prospects and challenges from the radiopharmacists perspective

17:24 – 17:36  Barbara Godthelp, Chair of HERCA WGMA, ANVS (Netherlands)

17:36 – 17:48  Bernd J. Krause, University Medical Center Rostock, Rostock (Germany) – SIMPLERAD: implementation of the Euratom and the EU legal bases with respect to the therapeutic uses of radiopharmaceuticals

17:48 – 18:00  Erik Briers, Europa Uomo (Belgium) - A patient view on radiopharmaceuticals and the regulatory environment

18:00 – 18:15  Discussion and Q&A session
Educational Objectives

- Discussing measures to strengthen the interrelations between EU pharmaceutical legislation and Council Directive 2013/59/Euratom related to radiopharmaceuticals, with a focus on the SIMPLERAD project.
- Discussing how the pharmaceutical legislation under revision will support reinforced equal access to nuclear medicine services across Europe.

Summary

The session aims at gathering information including insight experiences from regulators, and experts in the field of radiopharmacy on current regulation of radiopharmaceuticals and potential requirements for the future. The quality of radiopharmaceuticals is important, but radiopharmaceuticals are also special in the way they are prepared, whether it is within the marketing authorization track, for use in clinical trials or as in-house preparations, e.g., in hospital (radio)pharmacies. In parts, current regulation has not been revised for more than 20 years in particular for radiopharmaceuticals despite significant changes in the field of Nuclear Medicine and the way how radiopharmaceuticals are prepared. With the success of the theranostic approach in Nuclear Medicine (e.g. neuroendocrine tumors, prostate cancer) the potential of radiopharmaceuticals is there and a closer look is given into the needs of potential adaptions in current legislation within the EU pharmaceutical strategy.

Key Words
Radiopharmaceuticals; EU legislations; Dosimetry; Policy; Marketing authorisations