EU Policy Symposium 2
EANM Policy & Regulatory Affairs Committee
Tuesday, September 12, 16:45-18:15

Session Title

Regulatory Challenges of Radiopharmaceuticals

Chairpersons
Marianne Patt (Germany)
Oliver Kiss (Germany)

Programme

16.45-16.50: Introduction by the Chairpersons

16.50-16.55: **Olga Solomon**, Head of Unit Medicines: Policy, authorisation and monitoring, DG SANTE, European Commission (Belgium) – *Video statement*

16.55-17.07: **Clemens Decristoforo**, Medical University Innsbruck, Innsbruck (Austria) – "Revision of the pharmaceutical legislation: Prospects and challenges from the radiopharmacists perspective".

17.07-17.19: **Anna Sundlöv**, Swedish Medical Products Agency (Sweden) – **"**Justification and optimisation vs benefit/risk – finding the common ground for radiation protection and medicines agencies."

17.19-17.31: **Barbara Godthelp**, Chair of HERCA WGMA, ANVS (Netherlands) – "Challenges in the implementation of the EU-BSS directive on use of radiopharmaceuticals. The Herca workgroup on medical application experience."

17.31-17.43: **Erik Verburg**, Eramus MC (Netherlands) – "SIMPLERAD: implementation of the Euratom and the EU legal bases with respect to the therapeutic uses of radiopharmaceuticals."

17.43-17.55: **Erik Briers**, Europa Uomo (Belgium) – "A patient view on radiopharmaceuticals and the regulatory environment."

17.55-18.15: Discussion and Q&A session

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.

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.

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