Member-state field report and good-practice examples

Sweden

Anna Sundlöv, Clinical Assessor
Swedish Medical Products Agency
A privileged situation

- A long tradition of high-quality research in radiation therapies, including radionuclide therapy and internal dosimetry
- Non-clinical research in quantitative imaging, radiobiology, strategies for improving treatment outcomes, combination therapies, etc
- Academic clinical trials with radionuclide therapy incorporating dosimetry as part of the trial design
- National collaboration between university hospitals in research and training
- International collaboration and participation in professional societies, research initiatives, EU-funded projects, etc
- Physicians are not bound by law to follow the SmPC ad verbatim, if experience and/or evidence indicate other safe and effective posologies.
The current national Regulation on Medical Exposure sets out the criteria which must be met in order to receive and maintain the required license:

- “For Nuclear Medicine investigations, the radiologic leadership function shall be held by a physician with specialty in Nuclear Medicine”,

- “For Nuclear Medicine therapies, the radiologic leadership function shall be held by a physician with specialty in Oncology”,

- “For [all] use in Nuclear Medicine, the radiation physics leadership function shall be held by a Medical Physicist with at least five years’ relevant clinical experience”,

- “Every Nuclear Medicine therapy must be preceded by an individual adjustment of the radiation dose to the target volume with care given to other exposed tissues”.
Despite this...

In clinical practice, the optimisation principle (dosimetry and individual dose planning) is implemented inconsistently, and mostly within clinical trials.
In 2021 a seed was sown

- A collaboration between the Radiation Protection Authority (RPA) and the Medical Products Agency (MPA) began
- Focus area #1: Radionuclide therapy and dosimetry from our respective perspectives
- How can we, as national competent authorities, collaborate with other actors on the national stage of radionuclide therapy to make it happen?
- Understanding each other’s areas of responsibility and authority
Radiopharmaceuticals

The common ground

Radiation Safety Legislation

Justification & Optimisation

Pharma Legislation

Benefit & Risk

Simplerad

This project has received funding from the European Commission under Service Contract N° ENER/2022/NUCL/SI2.869532.0
What do we do?

- Regular meetings with ad hoc agendas
- Consultations as needed
- Lectures/presentations together at conferences & meetings
- Participation in SAMIRA including planning for the future SAMIRA Joint Action

This project has received funding from the European Commission under Service Contract N° ENER/2022/NUCL/SI2.869532.0
What do we hope to achieve?

• A constructive dialogue with health care professionals, academic institutions, professional societies, industry and other public entities with an interest in radionuclide therapy

• Agree on a step-by-step plan to take us from where we are now to where we want to be:

"Every Nuclear Medicine therapy must be preceded by an individual adjustment of the radiation dose to the target volume with care given to other exposed tissues"
Thank you for your attention