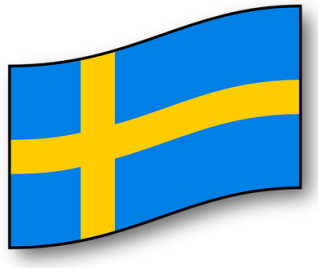
Member-state field report and good-practice examples

Sweden



Anna Sundlöv, Clinical Assessor
Swedish Medical Products Agency

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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.

A unique situation?

The current national Regulation on Medical Exposure sets out the criteria which must be met in order to receive and maintain the required license:

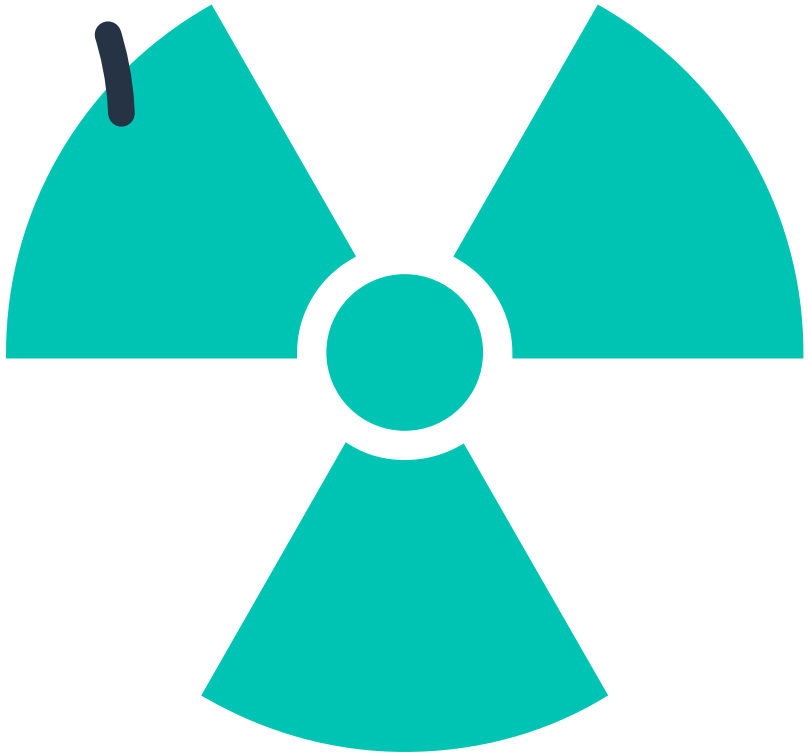
- *"**For Nuclear Medicine investigations**, the radiologic leadership function shall be held by a physician with **specialty in Nuclear Medicine**",*
- *"**For Nuclear Medicine therapies**, the radiologic leadership function shall be held by a physician with **specialty in Oncology**",*
- *"For [all] 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

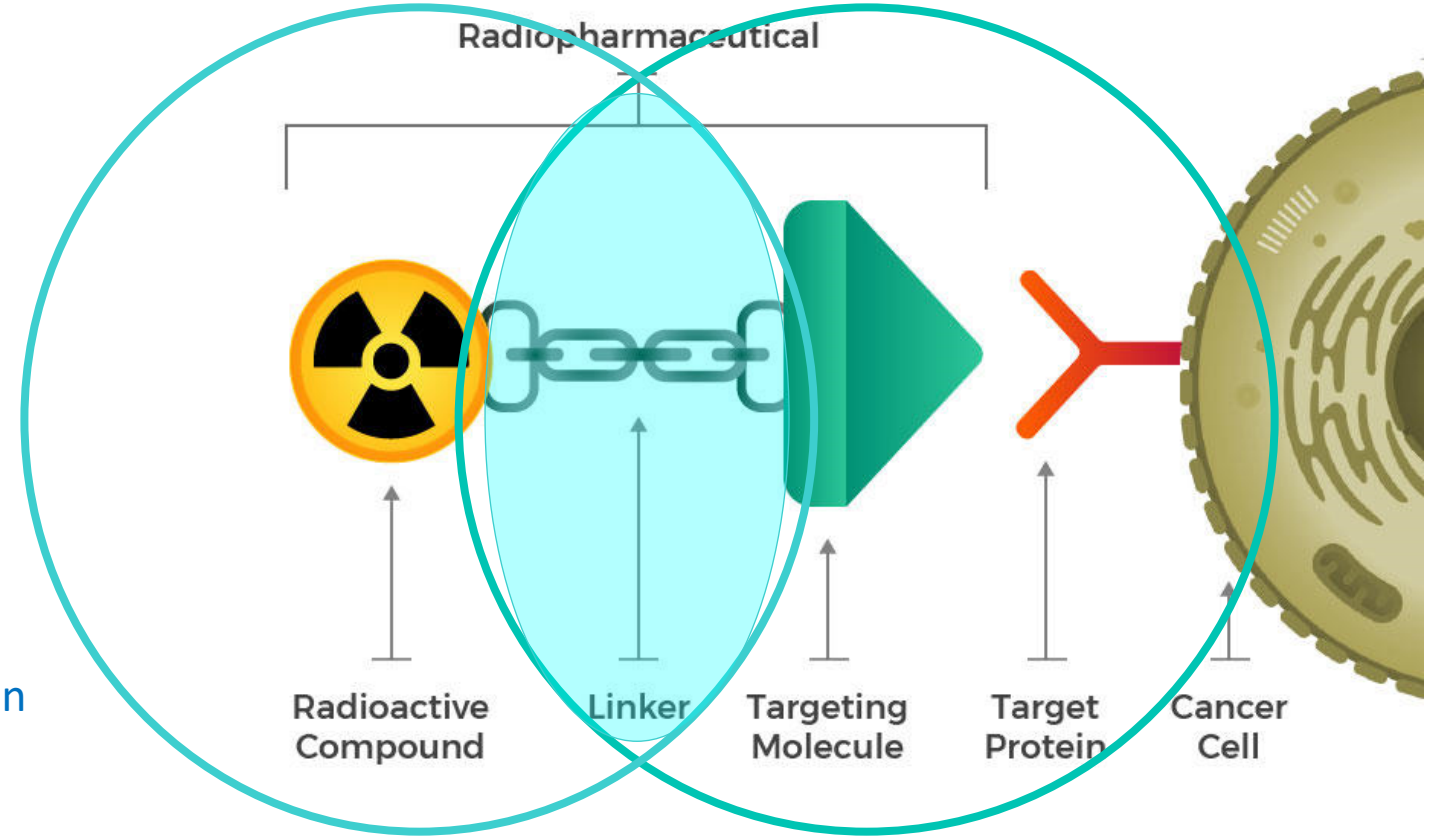


Radiopharmaceuticals

The common ground

Radiation Safety Legislation

Justification & Optimisation



Pharma Legislation

Benefit & Risk

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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

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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”

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Thank you for your attention