Session 2 Comments

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Session description

This session will highlight examples of the recent developments and innovations with regards to radiopharmaceuticals and their expected contribution to the personalised cancer treatments of the future. The discussion will seek to identify any potential barriers to the introduction of new treatments, technologies and applications, and the structures required to support their successful development and implementation in Europe.

Session title: Health: Novel nuclear medicine to advance patient care

1. **What are the barriers to the market introduction of new medical applications using radionuclides and how can these be addressed?**

    - One barrier to the market applications is the need for increased radionuclide production. For example, therapeutic radionuclides such as Ra-223, Lu-177, Y-90 and Ac-225 as well as other newer alpha and beta emitting radionuclides. Many therapeutic radionuclides are shipped to the US from the EU for clinical trials. Radiotherapeutics is an important growth area for nuclear medicine. Currently the lack of production of radiotherapeutic radionuclides can be a barrier for increased clinical trials.

2. **What structures (physical or regulatory) need to be in place to enable the development and use of new technologies in nuclear medicine?**

    - Regulatory requirements for the clinical trials for radiotherapeutic radiopharmaceuticals—e.g. what type of preclinical toxicity needs to be provided
    - What are the requirements for the clinical trials—what dose escalation is required?
    - Guidance documents by EMA and FDA?
    - Regulatory interaction (EMA, FDA and Health Canada) among countries such as the US, EU and Canada to develop similar regulatory approaches to expedite bringing new RaPh to market, and reduce the overall cost of these RaPh

3. **What are the immediate and medium-term perspectives for the evolution of molecular imaging, in particular for SPECT and PET, in the EU and globally?**

- SPECT and PET are growing in under developed countries. Growth perspectives are good. Camera manufacturers are focusing on developing countries
- SPECT is still the primary nuclear medicine imaging procedures in the US. There is SPECT RaPh development, but not as wide-spread as in PET. But improvement in camera technology will increase the use of SPECT in nuclear medicine
- Theranostics—radiopharmaceutical labelled with diagnostic agent followed by a therapeutic agent. Good perspectives for PET in EU and US.
- Diagnostic agents can be used prior to therapy and then following therapeutic agent to assess the progress of the therapy. Allows disease management and initiation of alternate therapy if the current therapy is not working. Is a cost effective management and utilizes personalized medicine.

4. **How can we ensure best practice is implemented in the field, and that a high level of radiation protection is maintained – e.g. by upholding and implementing the principles of justification?**

- Increased radiation safety training to increase safe handling techniques including radiotherapeutic alpha and beta radionuclides
- Must offer radiation dose calculation training for radiotherapeutic radiopharmaceuticals
- In the US we are seeing medical oncologists wanting to be licensed for use of radiotherapeutic RaPh by the Nuclear Regulatory Commission. If this occurs it will require training in all aspects of nuclear medicine including radiation biology, dosimetry—which should be provided by nuclear medicine specialists. As specialties expand their focus area, appropriate training should be planned. There is a desire to restrict training to nuclear medicine, but we need to consider providing appropriate training by the experts in the field.
- IAEA is planning a radiation dosimetry conference in 2019

5. **What actions could be taken by the EU to address the issues raised?**

1. Educate the benefits of radiotherapeutic radiopharmaceuticals.

2. Public education involving radiation exposure—risk and benefit comparisons for both diagnostic and therapeutic RaPh
3. Increase therapeutic radionuclide production
4. Education in all aspects of radiotherapeutics including dosimetry and medical practice.