11 October 2022
EMA/775191/2021
Stakeholders and Communication Division

Second EMA – Nuclear Medicines Europe bilateral meeting

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Chair: Marie-Helene Pinheiro (EMA), via WebEx

1. Welcome and introduction

The chair welcomed Nuclear Medicine Europe (NMEU) participants to this meeting intended to provide an opportunity to engage in dialogue on key areas of mutual interest, share information, exchange views and enhance the respective mutual understanding of the needs and expectations of our respective organisations. NMEU organisation, radiopharmaceuticals' stakeholders, specificities and current regulatory environment were identified topics of common interest.

Round table introduction of EMA and NMEU delegation took place.

2. Functioning of NMEU and identification of the stakeholders in radiopharmaceuticals

- NMEU provided information about the origin of its organisation which resulted from the evolution and broadening in 2019 of the Association of Radiopharmaceutical Producers Europe (ARPE), the latter being created in 1987 following the additional provisions for radiopharmaceuticals in Council Directive 89/343/EEC in 1989.
- NMEU today has 49 members and represents the majority of radiopharmaceutical and imaging equipment companies in the field of Nuclear Medicine in Europe. Since 2021 there has been an increase of diagnostics and therapeutics companies' membership.
- NMEU explained its new governance structure with the introduction of a quality and clinical Working groups amongst other.

3. Harmonization of the quality documentation required for the radionuclide and chemical precursor in the CTD dossier

- The scope of this meeting was related to the harmonization of the quality documentation required for the radionuclide and chemical precursor in the CTD dossier.
- NMEU highlighted the different types of radiopharmaceuticals (RP) for which a Marketing Authorisation is required and re-stated the concerns with the current definitions of Radiopharmaceuticals in EU Directive 2001/83/EC linking it with the fact that it does not take into consideration the different administration type/ formulations of radionuclides: e.g. direct administration, kit reconstitution or further processing in industrial manufacturing of ready to use preparation radiopharmaceutical dosage form etc.
- The few EU guidelines dedicated for radiopharmaceuticals (quality and GMP) were also identified as needing update to better reflect current science evolution, usages and needs of radio-

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pharmaceuticals/nuclides in the medical area. It was stressed that more clarification on quality documentation requirements and further harmonization across EU Member States would be beneficial.

- NMEU highlights the need to have a set of criteria of thresholds regarding API/chemical precursor. Discussions on NMEU proposals to address the above took place.
- In addition, NMEU explains the benefits of harmonization to:

  - decreased risk of inconsistency and regulatory burden when cross-referencing is used/possible;

  - avoid Health authority double assessment of the same quality information for same radionuclide used as part of different MAA;

  - improved efficiency for all parties allowing faster access to medicines.

- Finally, mutual understanding of industry priority needs and industry stakeholders' consultation involvement was acknowledged and advice for specific and targeted engagement discussed.

4. Q&A

- EMA thanks for the submission of the radiopharmaceutical pipelines and highlights the importance to continue receiving such information in the future, yet highlighting the more specific interest on the information related to centralised scientific advice request and future MAAs for expert resources planning. It was noted that radiopharmaceuticals manufacturers submit the majority of their MAAs at national level as fee submission is a key strategic consideration when deciding on the regulatory path.
- Consideration to approach CMDh and QWP to discuss cross Members States radiopharmaceutical regulatory matters and quality priority proposals was suggested.

5. AOB

- Updates on access of isotope due to Russia/Ukraine war was shared by some present NMEU Members, highlighting that some Clinical trials were on hold in Europe due to the challenges to source isotope.

6. Conclusion and next steps

- NMEU highlighted the interest to focus the next NMEU-EMA bilateral meeting in 2023 on the clinical development of radiopharmaceuticals requirements.
- EMA Industry liaison confirmed for the time being as the primary point of contact for NMEU in the future.
- NMEU to consider contacting QWP and CMDh for some of the topics discussed during this bilateral meeting.