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Corporate Stakeholders Department

Report of EMA-Nuclear Medicine Europe bilateral meeting

23 September 2021, European Medicines Agency

Chair: Marie-Hélène Pinheiro, EMA

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.

1. 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 represents the majority of radiopharmaceutical and imaging equipment companies in the field of Nuclear Medicine in Europe.

2. Potential and uniqueness of Radiopharmaceuticals

- NMEU highlighted that historically radiopharmaceuticals were developed at academic level with variable standards and local member states legislation in Europe. Nowadays, there is an increase in R&D development with industry-led multinational Phase 1-3 studies mainly in the diagnosis and treatment of cancers in the medical area. It was stated that support for development and equitable uptake of novel radiopharmaceuticals for diagnosis and targeted treatment and a more favourable and harmonised European environment is needed.
- Nuclear Medicine in general, diagnoses and treats 10 million patients per year in EU of which 65% are in the oncology area. Brain imaging, stroke imaging, epilepsy, imaging of thyroid and thyroid diseases therapy, Leukaemia, blood and cardiac studies, breast cancer, prostate cancer are other leading therapeutic areas of development.
- Theranostics Nuclear Medicines, therapeutic radionuclides and radioligands are other types of nuclear medicines for which a clearer Regulatory framework would be beneficial in view of their high potential in precision medicine for cancer or in neuroimaging applications.

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3. Manufacturing models and logistics challenges

- Half-life (long (3-14 days) and short (less than 12hours)) has implications for logistics, storage and distribution of nuclear medicines. Most of them also need multiple manufacturing sites for a single product and the product is being produced in response to patient demand, for a specific injection time and at specific dose.
- Manufacturing is challenging also in terms of global clinical studies and there are key differentiating factors between targeted radiopharmaceuticals and standard imaging agents.
- To complement the information shared NMEU was asked to share addition non- confidential information on nuclear medicines future and/or expected pipeline.

4. Impact of the current Regulatory Environment for radiopharmaceuticals

- NMEU highlighted the challenges on the existing nuclear medicines guidance (updates/lack of) in Europe, the CMC development, multi-language labelling requirements and dual governance between Health Authorities and Radioprotection Agencies in terms of safety for their industry-led trials with radiopharmaceuticals as well as for marketed radiopharmaceuticals . EU regulatory environment for radiopharmaceuticals should be reviewed to support the development and equitable uptake of novel radiopharmaceuticals for diagnosis and targeted treatments. Considerations should also be given to the safe development of the products but also to the protection of the people working with them.
- Nuclear Medicines stresses the fact that guidelines (quality and non-clinical in particular) should be specific instead of requirements being imbedded in non-radiopharmaceuticals/diagnostics guidance or non-existent especially for novel targeted radiotherapy, radiodiagnostics, RLI when use as precision tool.
- NMEU also highlighted the need to review and or develop new definitions e.g. radionuclide or radioactive precursor, radionuclide precursor etc. in the legislation. In addition, labelling requirements (specific, simplified and or exemptions) and specific or updated guidance to support specific radiopharmaceutical changes andcorrect assesment for CMC variations would also benefit in being reviewed and adapted to these types of medicinal products;
- The challenges of dual governance of radiopharmaceuticals to Regulatory Agency and Radioprotection Agencies was highlighted and a call for fostering dialogue, mechanism and/or process to be established to assist development of RLTs in particular;
- Claims were made that EU legacy, variable local requirements are slowing down EU market access of radiopharmaceuticals (vs USA).

Conclusion and next steps

- It was recognized that radiopharmaceuticals are showing promise in oncology with many novel products entering clinical development;
- EMA thanked NMEU for this timely sharing of information and positions in view of the on-going discussions of the pharmaceutical legislation review; recommendations were made to share these, where relevant, with the European Commission as part of the Pharmaceutical strategy stakeholder's consultation once available;

- EMA emphasised and advised industry to consider applying for scientific advice, when considering the development of a new radiopharmaceutical product and when guidance are non-existent as this helps the regulatory network to reflect on new products requirements and guidance needs;
- Finally, it was clarified that due to EMA pandemic Business Continuity Planning (BCP), EMA is not in the position to hold a specific multi-stakeholders event on radiopharmaceuticals in 2021/2022.EMA participation to external industry led conferences could be considered on case-by-case basis.
- NMEU was advised to actively contribute to all possible and relevant scientific consultations to highlight nuclear medicines specificities.
- Regular dialogue was considered important to be kept in the future in order to continue to keep NMEU and EMA mutually informed of on-going activities in the field of radiopharmaceuticals and this especially in the context of the EMA Working Parties Governance re-organisation, where radiopharnceiticals/Nuclear medidines industry specificities should be considered, as appropriate.
- EMA Industry liaison confirmed as the primary point of contact for NMEU in the future.