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European Medicines Agency

Highlights – fourth EMA – Nuclear Medicines Europe bilateral meeting

14th June 2024 – chaired by Marie-Hélène Pinheiro

1. Welcome and introduction

The chair welcomed Nuclear Medicines Europe (NMEU) representatives to the 4th bilateral meeting. The objective of the meeting was to exchange views on topics of mutual interests and discuss how NMEU can further engage at scientific as well as strategic level with the different groups and working parties.

2. Presentation on EMA engagement with Industry stakeholders

EMA gave an holistic overview of the Agency's Industry stakeholders interactions in line with its Industry Stakeholder framework and taking into account EMA recent revised Working Party's governance, pointing out where possible Nuclear Medicines Europe engagement could be foreseen for information sharing, consultation, involvement and/or cooperation and participation.

It was clarified that, with the revised governance, radiopharmaceutical topics were included under the umbrella of the Oncology Working Party (ONCWP) activities who is also currently looking after on the Concept paper on the evaluation of therapeutic radiopharmaceuticals with a public consultation planned for Q4 2024. Additional work on the quality guidelines on radiopharmaceuticals is ongoing at the level of the Quality Working Party (QWP) and Biologics Working Party (BWP) an public consultation will also be used to gather stakeholder feedback.

NMEU was encouraged to also engage with the GMP/GDP Inspectors Working Group who is planning to initiate the revision of Annex 3 Manufacture of radiopharmaceuticals in 2025.

Lastly the activities linked to addressing shortages of medicines including the stakeholders consultation on the Union list of critical medicines, the adoption of shortages prevention and mitigation plans, the activities of the Medicines Shortages Single Point Of Contact (SPOCs) and EMA role as observers in the European Observatory on the supply of radioisotopes were outlined. NMEU was reminded of the importance of registering as Industry SPOC (iSPOC) and was invited to join the discussions of the Industry Standing Group (ISG).

NMEU expressed gratefulness for the information received.

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3. NMEU position on the reform of the EU Pharmaceutical legislation. NMEU activities including EU parliament voted package

NMEU shared their positions on the European Commission's legal proposal for the revision of the EU pharmaceutical legislation remarking the importance of ensuring a common definition for radiopharmaceuticals in order to better shape robust guidance and regulatory pathways for their use in therapeutic areas.

It was clarified that EMA, not being an official party to the legislative process, was not in position to comment on any of the proposals made. Therefore NMEU was referred to the European Commission and to National Competent Authorities.

4. A.O.B The dual nature of radiopharmaceuticals: the challenges

Topic not discussed due to time constrains.

5. Conclusions and next steps

The high interest in the topics discussed was recognised. Future discussions and collaboration through the identified fora are welcomed.