15 November 2013

Minutes - European Medicine Agency and European Association of Nuclear Medicine meeting

London, 5 November 2013 at 09:30, EMA Meeting room 1B

Item	Preliminary draft agenda	Initials	Mins
1.	Presentation of EANM		
2.	Overview on radiopharmaceuticals preparation and use in Europe		
3.	Status of radiopharmaceuticals • Officinalis and magistralis production • Marketing authorization		
4.	Relations with European Pharmacopeia		
5.	Endorsement of EANM documents (guidelines)		
6.	Clinical trials		
7.	Imaging biomarkers		
8.	A.O.B or Tour de Table		

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Participants EANM:

Arturo Chiti - EANM President Elect, Head of Nuclear Medicine at the Humanitas Research Hospital in Milan, Italy
Philip Elsinga - Chair of the EANM Radiopharmacy Committee, Professor in PET-radiochemistry, University Medical Center Groningen, The Netherlands
James Ballinger - Member of the EANM Radiopharmacy Committee, Head of Radiopharmacy at Guy's and St Thomas' Hospital in London, UK
Ivan Peñuelas - Member of the EANM Legislation Working Group, Head of Radiopharmacy and GMP-PET Laboratory, University Clinic of Navarra, Pamplona, Spain

Participants EMA:

Fergus Sweeney - Head of Inspection and Human Medicine Pharmacovigilance Division
Riccardo Luigetti - Senior Scientific Administrator, Manufacturing & Quality Compliance
Jose Ramon Cozar Ruiz - Senior Scientific Administrator, Quality of Medicines
Emer Cooke - Head of International Affairs
Christelle Bouygues - Regulatory Affairs Officer
Efthymios Manolis - Scientific Officer, Scientific Advice Office

INTRODUCTION
The meeting started with a round of introduction of the participants, followed by a presentation on the activities of the EANM and on the reasons that prompted EANM to request this meeting. The aims of EANM to request for the meeting with EMA were:

1. Discuss problems with respect to differences in legislation among EU Member States on magistralis and officinalis preparation and find ways for harmonization
2. Availability of EANM to be scientific advisory partner for EMA regarding use of radiopharmaceuticals

A free discussion started on the use of radiopharmaceuticals (RPh) in Europe. As per the agenda, the different forms of RPhs prepared and used in Europe were considered.

AUTHORITY OF EMA
It was clarified that the authority of the EMA encompasses only drugs for which a marketing authorization (MA) is requested via the centralised procedure and the EMA has no authority on magistralis and officinalis preparations.

It was clarified that the existing legal framework for magistralis and officinalis preparations makes pan-European harmonization of standards difficult. In order to harmonize the use of such preparations in EU, a possibility would be that EANM makes a formal request to EU authorities in Brussels to change the legislation. However, this would be a long term strategy as changing the legislation is a complex process and the results could not necessarily be in line with EANM desires. Only in case the legislation was changed to this effect EMA could become competent as regards magistralis and officinalis preparations.

It was noted that some countries are applying EMA guidelines to magistralis and officinalis RPh preparations. It was clarified that EMA guidelines apply to medicines intended for or placed on the market and not to magistralis and officinalis preparations.

GUIDELINES
EANM offered the expert advice of its members and stated that it would be important if EMA could take into account such expert advice when writing new guidelines on radiopharmaceuticals. EANM offered to send its current radiopharmacy guidelines to the EMA for information and draft guidelines for comment.

MUTUAL RECOGNITION
The issue of mutual recognition of MA of RPhs in different EU countries was raised. This is a critical issue when a small company owns the MA, with limited financial resources with respect to the budget needed to obtain mutual recognition of MA. EMA noted that there is an office available for SME devoted to help them in fulfilling the requirements for MA of medicines including RPhs. It was agreed that EANM would inform AIPES to contact SME office in the EMA Communication and Stakeholder Division.

EUROPEAN PHARMACOPOEIA
The discussion touched on the relationship between the EMA and the European Pharmacopoeia and it was explained that there is collaboration within different frameworks. In particular, there is the joint EMA-EDQM forum and the EMA has observer status in various European Pharmacopoeia groups including Group 14 Pharmacopoeia meetings.
It was agreed that EANM could forward its ideas to the EMA representatives, for them to be aware.

RPhs WITH NO COMMERCIAL INTEREST
It was discussed that RPhs used as magistralis or officinalis preparations are assessed in terms of quality when there is a Pharmacopeia monograph or an IMPD file (by Member States NCAs). EMA then explained in detail the possible use of the "qualification opinion" tool available at EMA. It was agreed that EANM will explore this route to have a qualification opinion from the EMA CHMP for RPhs without a commercial interest, i.e. which will never get a MA, primarily because of their short half lives which make local production necessary. A

favorable opinion could be used in support of the introduction of these RPhs in countries where they are not currently used.

QUALIFICATION OF BIOMARKERS
EMA representatives explained the working procedure of the Scientific Advice Working Party (SAWP) of CHMP to give either "qualification advice" or "qualification opinions" on the acceptability of a specific use of a biomarker in a clinical research environment. The overall procedure on advice and opinion on qualification and novel methodologies for a specific use could be finished in no more than 200 days. EANM representatives expressed their great interest in such a procedure as a way to get qualification opinions from the EMA CHMP.

CLINICAL TRIALS
The question of the new EU Regulation on clinical trials was also raised and discussed. EANM was informed that the amendments proposed to the Regulation by ENVI are currently being discussed between the Council and the Parliament. The EANM representatives stated the importance that the specific considerations of RPh in the current text are preserved through the final approval steps.

When the difficulty of conducting a clinical trial within multiple countries was raised, the EMA described the Voluntary Harmonization Procedure (VHP) for centralized evaluation of clinical trial applications, leading to approval in multiple countries. The secretariat for VHP is located in the clinical trials facilitation group at the Paul Ehrlich Institute. EMA advised EANM to contact the VHP secretariat.
http://www.hma.eu/fileadmin/dateien/Human_Medicines/01-About_HMA/Working_Groups/CTFG/2013_04_CTFG_VHP_v3.pdf

It was finally agreed to have regular meetings to follow-up the discussion and face common problems.