06 February 2018
EMA/37264/2018
Corporate Stakeholders Department

Report of the EMA and Alliance for Regenerative Medicine (ARM) meeting

14 December 2017, European Medicines Agency

Objectives of the meeting

- To present the organisation and activities of Alliance for Regenerative Medicine (ARM) including on-going initiatives on investment, pricing & reimbursement perspective.
- To provide an overview on EMA's activities on topics relating to Advanced Therapies Medicinal Products (ATMP).

Topics addressed

ARM gave a brief presentation of their organisation structure, objectives, membership and main activities.

- ARM activities primarily promote initiatives to accelerate the development of ATMPs. Topics of interest include: market access, regulatory requirements, manufacturing and standards, access to capital and also public engagement and education. In Europe, ARM has set up two EU-specific committees focused on market access and regulatory priorities and has published several position papers and white papers on GMO requirements, hospital exemptions and on market access.
- ARM highlighted the launch in early 2017 of the Standard Coordinating Body (SCB), aiming at supporting and improving the cost, time, and resources for ATMPs. This was mentioned as an example of ARM's achievements (link). They also informed EMA of their interest in terms of public engagement and education efforts. To increase public understanding of the field, ARM has created a foundation. The first projects of the ARM Foundation will be rolled out during 2018 and will consist of a gene medicines education programme.
- EMA presented the framework for interactions with industry stakeholders, aiming to formalise and structure interactions between the Agency and pharmaceutical industry associations together with industry stakeholders eligibility criteria.

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- Amongst other topics, the EC/EMA joint action plan on ATMPs (link), as published in October 2017, was discussed. The importance of the interaction between EMA and EUnetHTA on ATMPs to increase understanding of health technology assessment and regulatory processes within respective remits was highlighted. The EMA and EUnetHTA joint work plan for 2017-2020 was outlined as being key in that respect.
- The SME Office activities were presented, including regulatory assistance, training and education activities. The 2017-2020 SME action plan outlining a series of objectives and actions grouped by theme, was presented. Key areas include raising awareness (engaging with incubators, universities and investors), training and education, support to the development of innovative medicines and stakeholder engagement. It was noted that ATMPs could be addressed in the topics for training and education.

List of Participants

EMA	
Marie-Helene Pinheiro, ***Chair***	Industry Stakeholder Liaison, Corporate Stakeholders
Lucia D'Apote	Scientific Committees Regulatory Science Strategy
Helene Casaert Salome	SME Office, Corporate Stakeholders
Patrick Celis	Committee for Advanced Therapies Secretariat, Scientific Committees Secretariat
Ana Hidalgo-Simon,	Head of Specialised Scientific Disciplines, Human Medicines Research and Development Support
Constantinos Ziogas	Head of SME Office, Corporate Stakeholders
ARM	
Janet L. Lambert	Chief Executive Officer
Jacqueline Barry,	Chief Clinical Officer, Cell & Gene Therapy Catapult and chair of ARM EU Regulatory Committee
Annie Hubert	Senior Director, EU Section and Public Policy
Paolo Morgese	Director of EU Market Access and Member Relations
Gopalan Narayanan	Vice President, Disruptive Biologics, Voisin Consulting Life Sciences
Carmen Vieira	Director Global Regulatory Affairs – EMA Liaison, Neuroscience, Janssen Research and co-chair of ARM EU Regulatory Committee