11 May 2023
EMA/193793/2023
European Medicines Agency

CAT Stakeholder meeting

16 May 2023 from 15.00 – 18.00

Location: EMA premises, Amsterdam

Meeting Agenda

14.30 – 15.00 - Coffee

15.00 – 15.05	**Start of the meeting**	
	Welcome, house-keeping notes	Ilona Reischl (CAT) and (EMA)

15.05 – 15.45	**1. ATMPs consisting of genetically modified organisms (GMO)**	**Moderator: Marcos Timon (CAT)**
	Revision of the Pharma legislation: proposal for centralised GMO/ERA evaluation in the revision of the pharmaceutical legislation	Lina Koufokotsiou (European Commission)
	Flexibilities in the current legal framework (simplified ERA, best practice document)	Marcos Timon (CAT)
	Experiences and issues: short input from the stakeholders[1]	Stuart Beattie (EFPIA/ARM) Marcello Milano (Eucope) Dolores Pérez Méndez (EUCROF)
	Discussion	

[1] CAT / EMA is not responsible for clinical trial authorisation; therefore, experience and issues with GMO clinical trials can be shared for awareness mainly.

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15.45 – 16.15	2. Predictability of marketing authorisation application submissions	Moderator: Carla Herberts (CAT)
	Feedback on the EMA focus group actions/discussions	(EMA)
	PRIME: submission readiness meetings	(EMA)
	Input from Stakeholders: particular issues for marketing authorisation application submissions for ATMPs	Jacquelyn Awigena-Cook (EFPIA)
	Discussion	

16.15– 16.40	3. Guideline on quality, non-clinical and clinical requirements for investigational ATMPs in clinical trials	Moderator: Ilona Reischl (CAT)
	Outline of the guideline following the external consultation	Ilona Reischl (CAT)
	Input from stakeholders: are further additions needed in the light of the evolution in science and products under development?; are the quality challenges with ATMP sufficiently addressed in the guideline?	Stakeholders (short inputs)
	Discussion	

16.40 – 17.10	4. The use of Registries for regulatory decision making	Moderator: Alessandro Aiuti (CAT)
	Long-term follow-up of patients treated with adeno-associated viral vector products	Carla Herberts (CAT)
	Experience at CAT: SMA Registry	Lisbeth Barkholt (CAT)
	Input from stakeholders	Julie Taccoen (EuropaBio)
	Discussion	

17.10 - 17.40	5. Implementation of the HTA Regulation	Moderator: Lisbeth Barkholt (CAT)
	Recent experience and learnings from a bilateral between EMA and EUnetHTA21 on ATMPs	(EMA) With support from Judith Fernandez (HAS)
	Optimisation of post-licensing evidence generation (PLEG) planning: stakeholders views and proposals	Paolo Morgese (ARM) Contributions by EFPIA and EuropaBio (tbc)
	Discussion	

17.40 – 17.55	**6. Platform approaches**	**Moderator: Patrick Celis (EMA)**
	Platform approaches: proposal in the revision of the pharmaceutical legislation	Lina Koufokotsiou (European Commission)
	Platform approaches for ATMPs, with focus on marketing authorisation applications	Kowid Ho (EFPIA) Maren von Fritschen (Eucope)
	Discussion	

17.55 – 18.00	**Wrap-up**	**Ilona Reischl (CAT)**
	End of the meeting	