6 December 2021
EMA/582731/2021

Minutes of the CAT Interested Parties meeting with Industry

26 October 2021, 14:00-18:00, Virtual meeting

Co-Chairs: Martina Schuessler-Lenz and Ilona Reischl

	Items covered– presentations are available in the corresponding agenda	Time
1.	**Welcome** **Agreement on the agenda** Martina Schuessler-Lenz (CAT), Ana Hidalgo-Simon (EMA)	14:00-14:10 *10 min*
	The CAT chair (Martina Schuessler-Lenz) and the head of the ATMP Office (Ana Hidalgo-Simon) welcomed the participants from the industry stakeholders and the CAT. The topics on the agenda were introduced. Industry stakeholders were encouraged to also join other EMA-industry stakeholder interactions: some topics relevant to ATMPs are discussed in these meetings.	
2.	**CAT activities, ATMP lifecycle support and patient access** Martina Schuessler-Lenz (CAT) Q&A (All)	14:10-14:30 *20 min*
	Martina Schuessler-Lenz presented the topic, highlighting the CAT activities to support ATMP developers and the ongoing CAT work on the topic: Timely and sustainable patient access to ATMPs. This topic was further elaborated in the presentation on 'ATMPs and Real World evidence' (agenda topic 9).	

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3.	**Comprehensiveness of clinical data in marketing authorisations** Maura O'Donovan (CAT) Q&A All	14:30-14:50 *20 mins*
	Maura O'Donovan (CAT) presented the comprehensiveness criteria of clinical data, that were developed jointly by CAT and CHMP as part of their respective Work Plans. CAT has started a pilot applying these criteria to MAA assessments: the pilot will be evaluated after 6 – 12 months. A revised template of the assessment report has been prepared which includes the comprehensiveness criteria. This updated template is available on the EMA website.	
4.	**GMO/ERA in Clinical Trials** Tomas Boran (CAT) **GMO/ERA in marketing authorisations** Patrick Celis (EMA) Q&A All	14:50-15:10 *15 mins* *5 mins*
	Tomas Boran (CAT) presented the experience of assessment of GMO/ERA during the approval of clinical trial applications. He concluded that despite the effort from the European Commission (EC) for voluntary harmonisation (GMO-Pharma interplay), the approach of GMO is still not harmonised in the EU. A change of legislation is needed, and industry was encouraged to bring this topic to EC level, as part of discussions and consultations in the frame of the revision of the pharma legislation. Patrick Celis (EMA) presented the new consultation process with environmental authorities on the ERA in marketing authorisation applications of ATMPs containing GMOs.	
5.	**EMA-FDA parallel scientific advice** Anabela Marcal (EMA) Q&A (All)	15:10-15:30 *20 mins*
	Anabela Marcal (EMA) presented the procedure to apply for an EMA-FDA parallel scientific advice (PSA). The 5-year review of PSAs (2016-2020) was shown. PSA can be flexible, e.g. limited to one or more parts of the application. Industry participants considered this procedure important and relevant for international clinical trials. It would be helpful if the possibility for a follow-up PSA would exist.	

6.	**Industry feedback** **1) Challenges Randomised Clinical Trials for ATMPs** Nigel Yateman (EuropaBio) Jill Morell (ARM; Eucope) **2) Delays in ATMP marketing authorisations submissions 2021** Ana Hidalgo-Simon (EMA) *Industry speaker* Q&A (All)	15:30-15:50 *20 mins*
	Nigel Yateman and Jill Morrell presented the industry's view on randomised clinical trials (RCT) for ATMPs. Challenges and alternative trial designs were highlighted. CAT members indicated that the feasibility of a RCTs should be considered for ATMPs: a different standard for clinical data generation for ATMPs is not automatically acceptable, as this has an impact on HTAs and patient access. Ana Hidalgo-Simon presented figures on the delays of submission of marketing authorisation applications (MAA) from 2018 to 2021. Industry participants were asked to channel any feedback on the reasons of the delays in MAA submission directly or via their trade organisation to the EMA Industry mailbox.	
	Coffee break	15:50-16:10 *20 min*
7.	**The New HTA Regulation: key elements and next** Flora Giorgio (B6, DG SANTE, European Commission*)* Q&A All	16:10-16:30 *20 min*
	Flora Giorgio from the European Commission presented the principles of the proposal for a new HTA Regulation. The legal text includes a joint clinical assessment of the HTA dossier; the responsibility for the recommendations on access and price/reimbursement remains at the level of the individual member state. The new legislation is expected to be adopted in Dec 2021 and will be progressively implemented (it will only become fully applicable from Dec 2024). Questions on the HTA dossier and the restart of the EMA-HTA joint scientific advices were discussed. On the latter, the Commission indicated that this will be addressed in EUnetHTA21.	
8.	**Industry feedback** **Views, initiatives to ensure patient access to ATMPs** *Industry speaker*	16:30-16:50 *20 min*

	Topic not discussed	
9.	**ATMPs and Real World Evidence** • **Update on Real World Evidence and DARWIN EU** Gianmario Candore (EMA) • **Real world evidence (data) in CAT decision making** Kieran Breen (CAT)	16:50-17:30 *40 min*
	Gianmario Candore (EMA) presented the European Medicine Regulatory Network approach to real world evidence (RWE) and the use of RWE in marketing authorisation applications. Information was provided on the Data Analysis and Real-World Interrogation Network (DARWIN), currently being established and that will start operating in 2022. Kieran Breen (CAT) presented the use of RWE data in CAT decision making. An analysis of the use of real-world data in ATMP MAAs (2018-now) was shown.	
10.	**Question and Answer** Discussion All	17:30-17:50 *20 min*
	Questions focused on the setting up and use of registries for the generation of post-authorisation data (for PAES/PASS). A more standardised approach in the EU (regarding infrastructure, the registries itself and the use of registry data) was advocated. The interpretation of what is standard of care in the different member states (MS) could result in a study being interventional in one MS and non-interventional in another MS. The value and need for harmonisation was discussed. There was a request for more interaction between industry stakeholders and CAT (e.g. on topics such as insertional mutagenesis, life cycle questions, Guideline wording). The CAT chair and Marie-Hélène Pinheiro (EMA) indicated that EMA is organising other stakeholder meetings where topics relevant to ATMPs will also discussed: CAT is contributing to these stakeholder meetings and concerns raised will be captured and fed back to the CAT.	
11.	**Conclusions and final remarks from chairs**	17:50-18:00 *10 min*
	The meeting chairs closed the meeting and thanked the participants for their contributions.	

List of Participants

ACRO
Leanne Di Ronno
Richard Dennett
Venkat Reddy Sunkara
Susana Pereira
Carla Sterk

ARM

Jill Morrell
Michael Werner
Paolo Morgese
Mimi Choon-Quinones

EFPIA

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Stuart Beattle
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Annelie Persson

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CAT

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Ilona Reischl
Maura O'Donovan
Tomas Boran
Kieran Breen

Members and alternates of the CAT

European Commission

Flora Giorgio
Ioana-Raluca Siska
Julia Schmitz
Leslie Pibouleau
Rocio Salvador-Roldan
Daniela Marullo

EMA

Ana Hidalgo Simon
Patrick Celis
Gianmario Candore
Victoria Palmi Reig
Anabela Marcal
Marie-Helene Pinheiro
Michael Berntgen