



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

12 May 2015  
EMA/CAT/750592/2014  
Procedure Management & Business Support Division

## Agenda – CAT Hearing with Interested Parties

Thursday, 11<sup>th</sup> December 2014 – 15:00hrs – 18:30hrs, room 3-E

**Coffee break with CAT members:** 15:00 – 15:30 (open area on 3<sup>rd</sup> floor)

Chair: Paula Salmikangas

Item	Agenda topic	timeslot
1.	Welcome of all participants by CAT chair and CAT secretariat	Start at 15.30
2.	Agreement of the agenda	
3.	<b>Reflection paper on classification of ATMPs:</b> <ul style="list-style-type: none"><li>CAT's current considerations on the following criteria for classification of ATMPs: 'substantial manipulation' and 'non-homologous use';</li><li>Discussion and exchange of views;</li><li>Questions from the interested parties on ATMP classification (EuropaBio, EBE, BIA).</li></ul>	45'
4.	<b>The application of the concept of Risk-based approach (RBA) during the development and marketing authorisation of ATMPs.</b> <ul style="list-style-type: none"><li>Introductory presentation from CAT;</li><li>Discussion and exchange of views;</li><li>Questions from the interested parties on the application of RBA (EuropaBio, EBE, BIA)</li></ul>	45'
5.	<b>CAT workplan and CAT interested parties focus groups</b> <ul style="list-style-type: none"><li>Presentation of the CAT Workplan 2015-2016</li><li>Questions from interested parties (EuropaBio)</li></ul>	15'



Item	Agenda topic	timeslot
6.	<b>Discussions on other procedures and support to ATMP developers</b> (ATMP certification, adaptive licensing, one-stop-shop initiative) (CAT, BIA, IML)	15'
7.	<b>Other issues and questions from the interested parties:</b> <ul style="list-style-type: none"> <li>• Possible revision of ATMP regulation (Eucomed, EuropaBio)</li> <li>• Interactions with other stakeholders such as Competent authorities for tissues and cells, European Pharmacopoeia (EuropaBio)</li> <li>• Assessment of combined ATMPs (BIA)</li> <li>• Starting materials for ATMPs (BIA)</li> </ul>	30'
8.	<b>Open forum discussion on any topic</b>	30'
9.	<b>Close of meeting</b>	<b>End at 18.30</b>