EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 September 2018
EMA/CAT/327664/2018
Inspections, Human Medicines Pharmacovigilance & Committees

CAT work plan 2019

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The activities outlined in the CAT work plan for 2019 has been agreed taking into consideration the Agency's business continuity plans (BCP) due to its physical move from the Agency's current premises in the UK to the new premises in the Netherlands.
The Agency is currently implementing its phase 3 BCP which may be complemented with an additional set of temporary suspensions/reductions as of 1 January 2019, the latter to be launched as part of phase 4 of the BCP. Temporary suspension/scaling back of activities is currently scheduled to last until 30 June 2019, see enclosed link for additional information.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 Facsimile +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

1. Evaluation activities for human medicines

1.1. Pre-authorisation activities

1.1.1. Revision of the guideline on genetically modified cells

Key objectives

Revision of the Guideline on quality, non-clinical and clinical aspects of medicinal products containing genetically modified cells.

Activities in 2019

CAT activities to achieve the objectives set for this area:

Finalise the revision of the guideline by 4Q 2019

CAT will collaborate with the BWP for the revision of the quality part of this guideline.

CAT topic leader: Marcos Timón

Other committee participants:

Member/alternate	Name	MS
CAT topic leader	Marcos Timón	Spain
CAT chair	Martina Schüßler-Lenz	Germany
Member	Ilona Reischl	Austria
Member	Heli Suila	Finland
Member	Una Riekstina	Latvia
Member	Paolo Gasparini	Italy
Member	Christiane Niederlaender	UK
Alternate	Belaid Sekkali	Belgium
Alternate	Olli Tenhunen	Finland
Alternate	Margarida Menezes-Ferreira	Portugal
Expert	Tiina Palomäki	Finland
Expert	Barbara Bonamassa	Italy
Expert	Giuseppa Pistritto	Italy
Expert	Matthias Renner	Germany (PEI)
Expert	Brigitte Anliker	Germany (PEI)
Expert	Marcel Hoefnagel	Netherlands

1.1.2. Development of a guideline on requirements for ATMPs in clinical trials

Key objectives

- Development of a guideline on quality, non-clinical and clinical requirements for applications for clinical trials for ATMPs.

Activities in 2019

CAT activities to achieve the objectives set for this area:

- Finalise the guideline after external consultation – completion Q4 2019

CAT topic leaders: Tiina Palomäki, Ilona Reischl

Other committee participants:

Member/alternate	Name	MS
Expert	Tiina Palomäki	Finland
Member	Ilona Reischl	Austria
Member	Tomáš Boráň	Czech Republic
Member	Heli Suila	Finland
Member	Violaine Closson-Carella	France
Member	Maura O'Donovan	Ireland
Member	Simona Badoi	Romania
Member	Metoda Lipnik-Stangelj	Slovenia
Member	Christiane Niederlaender	UK
Member	Kieran Breen	Patients' *organization* representative
Alternate	Margarida Menezes-Ferreira	Portugal
Expert	Barbara Bonamassa	Italy
Expert	Guiseppa Pistritto	Italy
Expert	Marcel Hoefnagel	Netherlands

1.1.3. Development of guidance on comparability for ATMPs

Key objectives

Development of a Questions and Answers document on comparability for ATMPs

Activities in 2019

CAT activities to achieve the objectives set for this area:

Develop a Questions and Answers on comparability for ATMPs. Deadline: 4Q 2019

CAT will collaborate with the BWP for the development of the quality related questions.

CAT topic leader: Margarida Menezes-Ferreira, Ilona Reischl

Other committee participants:

Member/alternate	Name	MS
CAT topic leader	Margarida Menezes-Ferreira	Portugal
CAT topic leader	Ilona Reischl	Austria
Member	Violaine Closson Carella	France
Member	Maura O'Donovan	Ireland
Member	Tomáš Boráň	Czech Republic
Member	Marc Turner	Clinicians' representative
Member	Bernd Gänsbacher	Clinicians' representative
Alternate	Belaid Sekkali	Belgium
Alternate	Ivana Haunerova	Czech Republic
Expert	Tiina Palomäki	Finland
Expert	Barbara Bonamassa	Italy
Expert	Giuseppa Pistritto	Italy
Expert	Thomas Hinz	Germany (PEI)
Expert	Louise Bisset	UK

1.2. Other specialised areas and activities

1.2.1. Implementation of the Medical Device and In vitro Diagnostics Regulation

Key objectives

Reflection on the implications of the new Medical Device / In vitro Diagnostics Regulations on ATMP development.

Activities in 2019

CAT activities to achieve the objectives set for this area:

Review the implications of the new Regulations on development of ATMPs. Deadline: 4Q 2019

CAT topic leader: Ilona Reischl

Other committee participants:

Member/alternate	Name	MS
CAT topic leader	Ilona Reischl	Austria
Member	Ivana Haunerova	Czech Republic
Member	Violaine Closson Carella	France
Member	Jan Mueller-Berghaus	Germany
Alternate	Giulio Pompilio	Italy
Alternate	Erik Briers	Patients' organization representative
Alternate	Michelino Lipucci di Paola	Patients' organization representative
Alternate	Margarida Menezes-Ferreira	Portugal
Expert	Christos Sotirelis	Patients' organization representative