8 December 2017
EMA/CAT/614550/2017
Inspections, Human Medicines Pharmacovigilance & Committees

CAT work plan
2018

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The activities outlined in the work plan for 2018 have been agreed considering the respective business priorities, as well as the Agency's relocation as a result of the UK's exit from the EU and its impact on the Agency's business continuity, and may be subject to further review and reprioritisation in accordance with the business continuity plan of the Agency

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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 2018

CAT activities to achieve the objectives set for this area:

- Publication of the draft of the revised guideline for external consultation by 1Q 2018
- Finalise the revision of the guideline by 4Q 2018

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

CAT topic leader: Marcos Timon

Other Committee participants:

Member/alternate	Name	MS
CAT topic leader	Marcos Timón	Spain
CAT chair	Martina Schüßler-Lenz	Germany
Member	Ilona Reischl	Austria
Member	Olli Tenhunen	Finland
Member	Paolo Gasparini	Italy
Member	Christiane Niederlaender	UK
Alternate	Belaid Sekkali	Belgium
Expert	Tiina Palomäki	Finland
Expert	Guido Pantè	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 where applicable clinical requirements for applications for clinical trials for ATMPs.

Activities in 2018

CAT activities to achieve the objectives set for this area:

- Set up a meeting with ATMP developers (interested parties) to identify the key aspects on which guidance is required. Deadline: 2Q 2018
- Publication of the draft of the guideline for external consultation in Q4 2018
- Finalise the guideline after external consultation - completion Q3 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' organisation representative
Alternate	Margarida Menezes Ferreira	Portugal
Expert	Guido Panté	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 2018

CAT activities to achieve the objectives set for this area:

- Revisit the existing guidance to identify where clarification is missing. Deadline: 1Q 2018
- Set up a meeting with ATMP developers (interested parties) to identify the key aspects for which clarification is required. Deadline: 2Q 2018
- Develop a Questions and Answers on comparability for ATMPs. Deadline: 2Q 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	Louise Bisset	UK
Expert	Thomas Hinz	Germany (PEI)

1.2. Pharmacovigilance activities

1.2.1. Reflection on the use of Registry data for the post-authorisation follow-up of ATMPs.

Key objectives

- Development of minimum requirements for registries for CAR-T cells.

Activities in 2018

CAT activities to achieve the objectives set for this area:

- Organise a meeting with the stakeholders and CAR-T cell developers. Deadline: 2Q 2018
- Develop minimum requirements for registries for CAR-T cells. Deadline: 4Q 2018

This is a joint activity of CAT, CHMP, PRAC and SAWP.

CAT topic leader: Kieran Breen

Other Committee participants:

Member/alternate	Name	MS
CAT topic leader	Kieran Breen	Patients' organisation representative
Member	Claire Beuneu	Belgium
Member	Tomáš Boráň	Czech Republic
Member	Jan Mueller-Berghaus	Germany
Member	Paolo Gasparini	Italy
Member	Simona Badoi	Romania
Member	Marc Turner	Clinicians' representative
Member	Mariette Driessens	Patients' organisation representative
Member	Christiane Niederlaender	UK
Alternate	Erik Briers	Patients' organisation representative
Alternate	Michele Lipucci	Patients' organisation representative
Alternate	Angeliki Roboti	Greece
Alternate	Rune Kjeken	Norway
Expert	Klaus Rensing	Germany (PEI)

1.3. Other specialised areas and activities

1.3.1. Scientific and Regulatory considerations on gene editing technologies

Key objectives

- Reflection on the regulatory status of medicines based on, or produced by means of gene editing technologies
- Consideration of the scientific requirements of medicines based on, or produced by means of gene editing technologies

Activities in 2017-2018

CAT activities to achieve the objectives set for this area:

- Further to the expert meeting of 18 October 2017, prepare a meeting report or CAT document on regulatory and scientific considerations related to the development of medicines based on, or produced by means of gene editing technologies. Deadline: 2Q 2018.
- Reflect on the need to develop a dedicated guidance on medicinal products based on, or produced by means of gene editing technologies or the need to revise existing guidelines to include information on gene editing. Deadline: 3Q 2018

CAT topic leader: Paolo Gasparini

Other Committee participants:

Member/alternate	Name	MS
CAT topic leader	Paolo Gasparini	Italy
Member	Toivo Maimets	Estonia
Member	Asterios Tsiftsoglou	Greece
Member	Maura O'Donovan	Ireland
Member	Dariusz Sladowski	Poland
Member	Simona Badoi	Romania
Member	Metoda Lipnik-Stangelj	Slovenia
Member	Christiane Niederlaender	UK
Member	Bernd Gänsbacher	Clinicians' representative
Alternate	Belaid Sekkali	Belgium
Alternate	Margarida Menezes-Ferreira	Portugal
Alternate	Egbert Flory	Germany
Alternate	Rune Kjeken	Norway
Alternate	Marcos Timon	Spain
Alternate	Michele Lipucci	Patients' organisation representative
Expert	Tiina Palomäki	Finland
Expert	Silke Schuele	Germany (PEI)

1.3.2. Scientific considerations for adeno-associated viral (AAV) vector based GTMPs

Key objectives

- Consideration of the scientific requirements of gene therapy medicinal products based on AAVs.

Activities in 2017-2018

CAT activities to achieve the objectives set for this area:

- Further to the expert meeting of 6 September 2017, prepare a meeting report, publication or CAT document on scientific and regulatory considerations for AAV-based gene therapy medicinal product. Deadline 1Q 2018
- Reflect on the need for revision of the AAV reflection paper. Start: 3Q 2018

CAT topic leader: Martina Schüßler-Lenz

Other Committee participants:

Member/alternate	Name	MS
CAT topic leader	Martina Schüßler-Lenz	CAT chair
Member	Tomáš Boráň	Czech Republic
Member	Jan Mueller-Berghaus	Germany
Member	Hans Ovelgönne	Netherlands
Member	Metoda Lipnik-Stangelj	Slovenia
Member	Bernd Gänsbacher	Clinicians' representative
Member	Christiane Niederlaender	UK
Alternate	Egbert Flory	Germany
Alternate	Olli Tenhunen	Finland
Alternate	Rune Kjeken	Norway
Alternate	Björn Carlsson	Sweden

1.3.3. Addressing the Environmental Risk assessment of ATMPs containing genetically modified organisms (GMO) / genetically modified micro-organisms (GMM).

Key objectives

- Contribute to the European Commission in support of the discussions on GMO related issues in the ad-hoc group of national experts on medicines and experts from the environmental authorities.

Activities in 2018

CAT activities to achieve the objectives set for this area:

- Provide technical and scientific input to the Commission. Deadline: 4Q 2018

CAT topic leader: Ilona Reischl

Other Committee participants:

Member/alternate	Name	MS
CAT topic leader	Ilona Reischl	Austria
Member	Claire Beuneu	Belgium
Member	Violaine Closson Carella	France
Member	Krisztian Fodor	Hungary
Member	Dariusz Sladowski	Poland
Alternate	Margarida Menezes Ferreira	Portugal
Alternate	Marcos Timón	Spain
Alternate	Erik Briers	Patients' organisation representative