



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Inspections, Human Medicines Pharmacovigilance and Committees Division

CAT monthly report of application procedures, guidelines and related documents on advanced therapies

February 2018 meeting

The Committee for Advanced Therapies (CAT) held its 101st CAT meeting on 15 – 16 February 2018.

The CAT Monthly Report includes statistical data on CAT scientific recommendations on Advanced Therapy Medicinal Product (ATMP) classification, certifications, initial evaluations, CAT contributions to Scientific Advice and Paediatric Investigation Plans, as well as variations, line extensions, renewals.

Scientific recommendation on advanced therapy product classification

Further to consultation with the European Commission, the CAT finalised 2 scientific recommendations on the classification of advanced therapy medicinal products.

The following product was classified as a somatic cell therapy medicinal product:

- Autologous dendritic cells pulsed with allogeneic tumour cell lysate, intended for the treatment of malignant mesothelioma.

The following product was classified as a tissue engineered product:

- Allogeneic mesenchymal stem cells intended for the treatment of osteoarthritis.

Organisational matters

- The CAT adopted the revision of the Guideline on quality, non-clinical and clinical aspects of gene therapy medicinal product. After adoption by CHMP at their March meeting, the guideline will be published on the EMA Website. This guideline will replace the Note for Guidance on quality, preclinical and clinical aspects of gene transfer medicinal product (CPWP/BWP/3088/99), which was published in April 2001.
- The CAT discussed the revision of the guideline on quality, non-clinical and clinical aspects of medicinal products containing genetically modified cells.
- Feedback was provided to the CAT on the workshop on registry requirements for chimeric antigen receptor (CAR) T-cells that took place on 9 February 2018.



- CAT discussed the programme of the joint CHMP/PDCO/CAT Strategic Review and Learning meeting that will take place in Oslo, Norway on 7 – 9 May 2018 under the auspices of the Bulgarian presidency of the European Union.

Overview of product-related activities

The Committee discussed ongoing evaluation procedures for ATMPs and other related procedures as summarised in the following tables:

Initial Evaluation of Marketing Authorisation Applications (MAA) for ATMP											
	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	Total
Submitted MAAs	3	1	2	3	2	2	1	1	4	0	19
Positive draft Opinion	1	0	1 ⁱⁱ	1 ⁱⁱ	2	1	1	2	2	0	11*
Negative draft opinions	1 ⁱ	0	1 ⁱⁱ	0	0	0	2 ⁱⁱⁱ	0	0	0	4
Withdrawals	1	1 ⁱ	0	0	2	0	0	0	0	0	4
Ongoing MAAs											4

* Corresponding to 9 ATMPs

ⁱ Same product (Cerepro)

ⁱⁱ Same product (Glybera)

ⁱⁱⁱ CAT adopted two negative draft opinions for the same product (Heparesc)

Variations (Type II) for authorised ATMP											
	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	Total
Positive Opinion	0	0	1	1	9	4	3	6	3	1	28

Scientific recommendation on advanced therapy classification											
	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	Total
Submitted	22	19	12	22	20	28	61	60	46	8	298
Adopted	12	27	12	16	23	29	31	87	49	4	290

Certification of quality and non-clinical data for small and medium-sized enterprises developing ATMPs

	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	Total
Submitted	1	0	0	1	3	1	1	2	2	0	11
Adopted	0	1	0	1	1	2	1	1	3	0	10

Scientific advice procedure for ATMPs

	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	Total
Number of procedures	17	19	21	19	23	33	39	46	55	9	281

Paediatric Investigation Plans (PIP) for ATMPs

	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	Total
Number of procedures	3	4	4	8	5	4	3	5	3	1	40

Prime Eligibility for ATMPs

	2016	2017	2018							Total
Discussed	22	16	4							42
Granted	8	6	0							14

Upcoming meetings following the February 2018 CAT meeting

- The 102nd meeting of the CAT will be held on 14 – 16 March 2018.

NOTE:

1. This Monthly Report, the Agenda of this meeting, the Minutes of the previous CAT meeting and other documents can be found on the internet at the following location: [European Medicines Agency - Committee meeting reports - CAT: Committee meeting reports](#)
2. Specific information related to ATMPs and the activities of the CAT (role, responsibilities and composition) can be found at: [European Medicines Agency - CAT - Committee for Advanced Therapies \(CAT\)](#)

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