



22 November 2021  
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Human Medicines Division

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

### November 2021 meeting

The Committee for Advanced Therapies (CAT) held its 142<sup>nd</sup> meeting on 3 – 5 November 2021.

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<sup>1</sup>**

Further to consultation with the European Commission, the CAT finalised 1 scientific recommendation on the classification of advanced therapy medicinal products.

The following product does not fulfil the definition of an advanced therapy medicinal product:

- Autologous red blood cells chemically coupled with 12 antigenic peptides, intended for the treatment of multiple sclerosis.

### **Organisational matters**

- CAT adopted the revised procedural advice on ATMP classification. The revision is to align the document with the current process of evaluating requests for ATMP classification. The revised procedural advice will be published on the [ATMP classification webpage](#).
- In the light of the ongoing revision of the pharmaceutical legislation and the preparation of concept papers, an initial discussion took place on initial proposals of some core definitions.
- CAT discussed topics for inclusion in the CAT work plan for 2022.

### **Overview of product-related activities**

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

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<sup>1</sup> It is stressed that the scientific recommendation on advanced therapy classification does not amount to any endorsement of the plausibility of the product, including the mode of action or therapeutic indication(s) claimed by the applicant.



Initial Evaluation of Marketing Authorisation Applications (MAA) for ATMP								
	2009-2015	2016	2017	2018	2019	2020	2021	Total
Submitted MAAs	14	1	4	3	2	8	2	34
Positive draft Opinion	7 <sup>i</sup>	2	2	3	1	3	2 <sup>vi</sup>	20*
Negative draft opinions	4 <sup>i,ii,iii</sup>	0	0	0	0	0	0	4
Withdrawals	4 <sup>ii</sup>	0	0	1	1 <sup>iv</sup>	2 <sup>v</sup>	0	8
Ongoing MAAs								6

**\* Corresponding to 19 ATMPs**

<sup>i</sup> One negative draft opinion and two positive draft opinions for the Glybera

<sup>ii</sup> Negative draft opinion and withdrawal for the Cerepro

<sup>iii</sup> Two negative draft opinions for Heparesc

<sup>iv</sup> Luxceptar

<sup>v</sup> Roctavian; Artobend

<sup>vi</sup> Skysona, Abecma

Variations (Type II) for authorised ATMP								
	2009-2015	2016	2017	2018	2019	2020	2021	Total
Positive opinion	18	6	3	8	16	27	26	104

Scientific recommendation on advanced therapy classification								
	2009-2015	2016	2017	2018	2019	2020	2021	Total
Submitted	184	60	46	55	70	74	58	547
Adopted	150	87	49	43	67	87	57	570

Certification of quality and non-clinical data for small and medium-sized enterprises developing ATMPs								
	2009-2015	2016	2017	2018	2019	2020	2021	Total
Submitted	7	2	2	1	1	0	0	14

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

Adopted	6	1	3	1	1	2	0	14
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### Scientific advice procedure for ATMPs

	2009-2015	2016	2017	2018	2019	2020	2021	Total
Number of procedures	171	46	55	53	56	61	57	499

### Paediatric Investigation Plans (PIP) for ATMPs

	2009-2015	2016	2017	2018	2019	2020	2021	Total
Number of procedures	31	5	3	3	2	1	0	45

### Prime Eligibility for ATMPs

	2016	2017	2018	2019	2020	2021	Total
Discussed	22	16	14	16	23	11	102
Granted	8	6	6	10	9	5	44

## Upcoming meetings following the November 2021 CAT meeting

- The 143<sup>rd</sup> meeting of the CAT will be held on 8 – 10 December 2021.

#### NOTE:

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](#)

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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