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Human Medicines Division

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

April meeting

The Committee for Advanced Therapies (CAT) held its 136th meeting on 14 – 16 April 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[1]

Further to consultation with the European Commission, the CAT finalised 5 scientific recommendations on the classification of advanced therapy medicinal products.

The following products were classified as somatic cell therapy medicinal products:

- Autologous antigen-specific cytotoxic T-lymphocytes, intended for the treatment of cancer patients that are overexpressing the specific antigen;
- Autologous dendritic cells activated against tumour peptides, intended for the treatment of cancer patients;
- Autologous M1-polarized macrophages, intended for the treatment of cancer patients;
- Autologous Cytotoxic Natural Killer cells, intended for the treatment of cancer patients;
- Autologous plasma cells producing monoclonal antibodies against specific tumour antigen, intended for the treatment of cancer patients.

Organisational matters

- CAT discussed the agenda of the upcoming Strategic Review and Learning meeting that will be held on 27 May 2021 under the Portuguese precedency of the European Union. This will be a joint meeting with the CHMP.
- CAT heard a detailed feedback of the teleconferences that took place between CAT members and colleagues from the European Commission, DG Santé on the revision of the EU legislation on blood, tissues and cells (BTC). Following this feedback CAT discussed the potential impact of

[1] 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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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this revision on ATMPs, borderline products and CAT participation to the workshops that will be organised by the European Commission in the frame of the BTC revision.

- The European Commission presented Roadmap / Inception Impact Assessment for the revision of the general pharmaceutical legislation.

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								
	2009-2015	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**Total**
Submitted MAAs	14	1	4	3	2	8	0	31
Positive draft Opinion	7 [i]	2	2	3	1	3	0	18*
Negative draft opinions	4 [i,ii,iii]	0	0	0	0	0	0	4
Withdrawals	4 [ii]	0	0	1	1[iv]	2[v]	0	8
Ongoing MAAs								6

*** Corresponding to 17 ATMPs**

[i] One negative draft opinion and two positive draft opinions for the Glybera

[ii] Negative draft opinion and withdrawal for the Cerepro

[iii] Two negative draft opinions for Heparesc

[iv] Luxceptar

[v] Roctavian; Artobend

Variations (Type II) for authorised ATMP								
	2009-2015	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**Total**
Positive opinion	18	6	3	8	16	27	15	93

Scientific recommendation on advanced therapy classification								
	2009-2015	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**Total**
Submitted	184	60	46	55	70	74	21	520
Adopted	150	87	49	43	67	87	26	509

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
Adopted	6	1	3	1	1	2	0	14

Scientific advice procedure for ATMPs								
	2009-2015	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**Total**
Number of procedures	171	46	55	53	56	61	10	452

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	7	98
Granted	8	6	6	10	9	3	42

Upcoming meetings following the April 2021 CAT meeting

- The 137th meeting of the CAT will be held on 10 – 12 May 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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