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Inspections, Human Medicines Pharmacovigilance and Committees Division

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

November 2019 meeting

The Committee for Advanced Therapies (CAT) held its 120th meeting on 6 – 8 November 2019.

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.

Withdrawal of an initial marketing authorisation application

CAT noted the withdrawal by the applicant, Kiadis Pharma Netherlands B.V., of the application for marketing authorisation of their product, Luxceptar (viable T-cells). The indication sought was: adjunctive treatment in haematopoietic stem cell transplantation for a malignant disease.

The applicant's decision to withdraw the marketing authorisation application was the consideration of CAT and CHMP that the data provided where not sufficiently mature to conclude on the benefit-risk of Luxceptar.

More information can be found in the Questions and Answers.

Scientific recommendation on advanced therapy product classification

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

The following product was classified as a gene therapy medicinal product:

- Recombinant adeno-associated viral vector expressing human Factor VIII, intended for the treatment of haemophilia A.

Organisational matters

- CAT finalised the agenda of the upcoming joint CAT-COMP-PDCO Strategic Review and Learning meeting that will be held in Helsinki (Finland) on 21 – 22 November 2019 under the auspices of the Finnish presidency of the European Union.

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- CAT noted presentations on the EMA relocation to the permanent building in Amsterdam and an update on EMA organisational aspects.

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**	**2019**	**Total**
Submitted MAAs	3	1	2	3	2	2	1	1	4	3	0	22
Positive draft Opinion	1	0	1[ii]	1[ii]	2	1	1	2	2	3	1	15*
Negative draft opinions	1[i]	0	1[ii]	0	0	0	2[iii]	0	0	0	0	4
Withdrawals	1	1[i]	0	0	2	0	0	0	0	1	1[iv]	6
Ongoing MAAs												1

*** Corresponding to 14 ATMPs**
[i] Same product (Cerepro)
[ii] Same product (Glybera)
[iii] Same product (Heparesc)
[iv] Luxceptar

Variations (Type II) for authorised ATMP												
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**Total**
Positive opinion	0	0	1	1	9	4	3	6	3	8	16	51

Scientific recommendation on advanced therapy classification												
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**Total**
Submitted	22	19	12	22	20	28	61	60	46	55	61	406
Adopted	12	27	12	16	23	29	31	87	49	43	51	380

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**	**2019**	**Total**
Submitted	1	0	0	1	3	1	1	2	2	1	1	13
Adopted	0	1	0	1	1	2	1	1	3	1	1	12

Scientific advice procedure for ATMPs												
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**Total**
Number of procedures	17	19	21	19	23	33	39	46	55	53	52	377

Paediatric Investigation Plans (PIP) for ATMPs												
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**Total**
Number of procedures	3	4	4	8	5	4	3	5	3	3	2	44

Prime Eligibility for ATMPs									
	2016	**2017**	**2018**	**2019**					**Total**
Discussed	22	16	14	14					66
Granted	8	6	6	7					27

Upcoming meetings following the November 2019 CAT meeting

- The 121st meeting of the CAT will be held on 4 – 6 December 2019.
- The joint CAT-COMP-PDCO Strategic Review and Learning meeting will be held in Helsinki (Finland) on 21 – 22 November 2019 under the auspices of the Finnish presidency of the European Union

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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