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Inspections, Human Medicines Pharmacovigilance and Committees Division

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

May 2017 meeting

The Committee for Advanced Therapies (CAT) held its 93rd CAT meeting on 10 – 12 May 2017.

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.

CAT recommends the granting of the marketing authorisation for Spherox

Spherox is a tissue engineered product containing as active substance 10 to 70 three-dimensional spheroids/cm², each composed of a cartilage matrix with the patient's own chondrocytes, isolated from healthy cartilage and cultured *in vitro.* Spherox is intended for the repair of symptomatic articular cartilage defects of the femoral condyle and the patella of the knee.

Following an in-depth review of the dossier submitted by the applicant, co.don AG, CAT concluded during its May meeting that a positive benefit risk profile has been demonstrated. CAT adopted the positive draft opinion recommending the granting of the marketing authorisation for Spherox. The CHMP subsequently adopted the positive opinion for Spherox during its May 2017 meeting.

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 gene therapy medicinal product:

- Natural killer cells transduced to express high-affinity non-cleavable CD16 (hnCD16) Fc receptor, intended for the treatment of advanced solid tumour malignancies.

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

- Allogeneic haptenized, stimulated and irradiated non-proliferative colorectal tumour whole cells derived from 3 colorectal cell lines, intended for the treatment of colorectal cancer.

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Organisational matters

- CAT finalised the agenda of the Strategic review and learning meeting that will take place in Gozo, Malta on 1-2 June 2017.
- CAT discussed the comments received by the European Commission on their proposal for revision of the definition of orphan similarity (Art 3.3.c of Regulation (EC) No 847/2017) and finalised its input to the European Commission on the definition of orphan similarity for ATMPs.
- CAT discussed the concept paper on the revision of the Guideline on quality, non-clinical and clinical aspects of medicinal products containing genetically modified cells.
- Information was provided to the CAT on the EMA framework of collaboration with academia, as agreed by the EMA management board.

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**	**Total**
Submitted MAAs	3	1	2	3	2	2	1	1	1	16
Positive draft Opinion	1	0	1[ii]	1[ii]	2	1	1	2	1	10*
Negative draft opinions	1[i]	0	1[ii]	0	0	0	2[iii]	0	0	4
Withdrawals	1	1[i]	0	0	2	0	0	0	0	4
Ongoing MAAs										2

*** 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**	**Total**
Positive Opinion	0	0	1	1	9	4	3	6	1	25

Scientific recommendation on advanced therapy classification										
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**Total**
Submitted	22	19	12	22	20	28	61	60	27	271

Scientific recommendation on advanced therapy classification										
Adopted	12	27	12	16	23	29	31	87	16	253

Certification of quality and non-clinical data for small and medium-sized enterprises developing ATMPs										
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**Total**
Submitted	1	0	0	1	3	1	1	2	1	10
Adopted	0	1	0	1	1	2	1	1	2	9

Scientific advice procedure for ATMPs										
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**Total**
Number of procedures	17	19	21	19	23	33	39	46	24	241

Paediatric Investigation Plans (PIP) for ATMPs										
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**Total**
Number of procedures	3	4	4	8	5	4	3	5	1	37

Prime Eligibility for ATMPs									
	2016	**2017**							**Total**
Discussed	22	9							31
Granted	8	4							12

Upcoming meetings following the May 2017 CAT meeting

The CAT strategic review & learning meeting under the auspices of the Maltese Presidency of the Council of the European Union will be held in Gozo, Malta on 1 – 2 June 2017.

The 94th meeting of the CAT will be held on 15 – 16 June 2017.

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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