8 September 2016
EMA/CAT/605735/2016
Procedure Management and Committees Support Division

Committee for Advanced Therapies (CAT)

Agenda for the meeting on 08-09 September 2016

Chair: Paula Salmikangas - Vice-chair: Martina Schüßler-Lenz

08 September 2016, 09:00 – 14:00, virtual
09 September 2016, 09:00 – 13:00, virtual

Disclaimers

Some of the information contained in this agenda is considered commercially confidential or sensitive and, therefore, not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the CAT meeting reports once the procedures are finalised.

Of note, this agenda is a working document primarily designed for CAT members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the agenda cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

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1. Introduction

1.1. Welcome and declarations of interest of members, alternates and experts

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CAT plenary session to be held on 8 – 9 September 2016. See September 2016 CAT minutes (to be published post-October 2016 CAT meeting).

1.2. Adoption of agenda

CAT agenda for the 8 - 9 September 2016 meeting

1.3. Adoption of the minutes

CAT minutes of the 13 - 15 July 2016 meeting

1.4. August Written Procedure

Report of the August 2016 Written Procedure

1.5. Technical information

2. Evaluation of ATMPs

2.1. Opinions

No items

2.2. Oral explanations

No items

2.3. Day 180 List of outstanding issues

No items

2.4. Day 120 Lists of questions

No items

2.5. Day 80 assessment reports

No items

2.6. Ongoing initial full application

No items

2.7. New applications

2.8. Withdrawal of initial marketing authorisation application

No items

2.9. Re-examination of initial application procedures under Article 9(2) of Regulation no. 726/2004

No items

2.10. GMP and GCP inspections requests

No items

2.11. Type II variations

2.11.1. Glybera – alipogene tiparvovec; *Orphan*; EMA/H/C/002145/II/56

UniQure Biopharma B.V.;
Rapporteur: Christiane Niederlaender; CHMP Coordinators: Greg Markey

Scope: quality

Action: for adoption of RSI

Document:
-RSI

2.12. post-authorisation activities

No items

3. Certification of ATMPs

Disclosure of information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

3.1. Opinions

No items

3.2. Day 60 evaluation reports

No items

3.3. Ongoing initial application

No items

3.4. New applications

4. Scientific Recommendation on Classification of ATMPs

4.1. New requests – appointment of CAT Co-ordinators

4.1.1. Autologous bone marrow-derived non-haematopoietic stem cells

Intended for the treatment of multiple sclerosis

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for nomination of CAT Coordinator

Document:
Request received

Note: CAT classified this product in October 2015 as *somatic cell therapy product* for the indications: treatment of patient with diabetes type I, diabetes type II and rheumatoid arthritis; and as *tissue engineered product* for the indications: treatment of patient after ischemic stroke and after myocardial infarction.

4.1.2. Anti-BCMA (B-cell Maturation Antigen) Chimeric Antigen Receptor T cells

Intended for the treatment of multiple myeloma and B cell lymphoma

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for nomination of CAT Coordinator

Document:
Request received

4.1.3. Wharton's jelly derived mesenchymal stem cells

Intended for the treatment of acute myocardial infarction, chonic ishemic heart failure and no-option critical limb ischemia

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for nomination of CAT Coordinator

Document:
Request received

4.1.4. Modified vaccinia virus Ankara encoding human mucin 1 and interleukin 2; H004658

Intended for the treatment of advanced non-squamous non-small cell lung cancer

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for nomination of CAT Coordinator

Document:
Request received

4.1.5. Autologous Human Adipose Mesenchymal Stromal Cells

Intended for the cardiac repair after myocardial infarction

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for nomination of CAT Coordinator

Document:

Request received

4.1.6. Autologous skin cell suspension

Intended for the treatment of burns, donor sites and other wounds

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for nomination of CAT Coordinator

Document:
Request received

4.1.7. Rilimogene galvacirepved and rilimogene glafolivec; H004657

Intended for the treatment of metastatic, castrate-resistant Prostate cancer

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for nomination of CAT Coordinator

Document:
Request received

4.2. Day 30 Co-ordinators' first reports

4.2.1. Genetically-modified *Lactobacillus reuteri* bacteria, with a plasmid containing the gene for human CXCL12-1a with an inducible promoter

Intended for wound healing of chronic ulcers in patients with diabetes

Action: for adoption

Document:
ATMP classification report

4.2.2. Autologous cells of stromal vascular fraction (SVF) and autologous adipose derived stem cells

Intended for the treatment of treatment of cutis laxa senilis

Action: for adoption

Document:
ATMP classification report

4.2.3. Tumour selectively replicating oncolytic adenovirus expressing tumor necrosis factor alpha (TNFα) and interleukin 2 (IL2)

Intended for the treatment of metastatic melanoma and other solid tumors

Action: for adoption

Document:
ATMP classification report

4.2.4. NKG2D autologous engineered T cells

Intended for the treatment of various tumour types (solid and liquid)

Action: for adoption

Document:
ATMP classification report

4.2.5. DNA plasmid vectors encoding for HPV type 16 consensus E6 and E7 antigens and human papillomavirus (HPV) type 18 consensus E6 and E7 antigens

Intended for the treatment of HPV-16 and 18 related high-grade squamous intraepithelial lesions (HSIL) of the cervix and vulva

Action: for adoption

Document:
ATMP classification report

4.3. Day 60 Co-ordinators' revised reports following List of Questions

No items

4.4. Finalisation of procedures

4.4.1. REarranged during Transfection (RET) activated human cord blood progenitor cells expanded *ex-vivo*; EMA/H0004545

Intended for the treatment of patients undergoing hematopoietic stem cell transplantion

Action: for information

Document:
ATMP classification report
The European Commission raised no comments

4.4.2. Adeno-associated viral vector serotype 8 containing the human glucose-6-phosphatase gene; EMA/H0004544

Intended for the treatment of glycogen storage disease type Ia (GSDIa)

Action: for information

Document:
ATMP classification report

The European Commission raised no comments

4.4.3. Recombinant adeno-associated virus 2 human aromatic L-amino acid decarboxylase gene; H0004546

Intended for the treatment of Parkinson's disease (PD)

Action: for Information

Document:

ATMP classification report
The European Commission raised no comments

4.4.4. Heterologous human adult liver-derived progenitor cells (HHALPC)

Intended for the treatment of liver diseases

Action: for information

Document:
ATMP classification report
The European Commission raised no comments

4.5. Follow-ups and guidance

4.5.1. Autologous concentrated bone marrow

Intended for critical limb ischemia without surgical option

Scope: Feedback from the applicant on the CAT classification of July 2016

Action: for information

Document:
Feedback from the applicant

Note: the CAT adopted in July 2016 a classification as a tissue-engineered product

5. Scientific Advice

Disclosure of information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

5.1. New requests – appointment of CAT Co-ordinators

5.2. CAT Rapporteurs' reports

5.3. List of issues

5.4. Finalisation of Scientific Advice procedures

5.5. Follow-up of Scientific Advice procedures

No items

6. Pre-Authorisation Activities

Disclosure of information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

6.1. Paediatric investigation plans

6.2. ITF briefing meetings in the field of ATMPs

6.3. Priority Medicines (PRIME) – Eligibility requests

6.3.1. Month 0 - Start of the procedure

6.3.2. Month 1 – Discussion of eligibility

6.3.3. Month 2 – Recommendation for eligibility

6.3.4. Ongoing support

7. Organisational, regulatory and methodological matters

7.1. Mandate and organisation of the CAT

7.1.1. Strategic Review & Learning meeting

CAT Strategic Review & Learning meeting will take place in Dublin, Ireland on 24-25 October 2016

CAT resources: Maura O'Donovan

Scope: agreement on topics for the agenda

Action: for discussion

Document:
Draft agenda

Note: proposed topics so far: new medical device legislation, genetically modified organism (GMO) issue including the wording for product information, use of real world data and registries.

Note: CAT members are asked to send proposals for agenda topics

7.1.2. Recommendation on criteria for competence and expertise of CAT members and alternates

Action: for discussion

Documents:
-Briefing note on competence and expertise of CAT members and alternates
-Annex B: CAT-EMA recommendation on criteria for competence and expertise of new CAT members. This annex will be added to nomination invitation letters to the Members State when a new member or alternate is to be appointed
-CAT Areas of Expertise
-CAT Criteria for Expertise and Experience

7.2. Coordination with EMA Scientific Committees

7.2.1. Committee for Medicinal Products for Human Use (CHMP)

Scope: Summary of Outcomes (SoO) for the July 2016 meeting

Action: for information

Documents:
-Summary of Outcomes

7.2.2. Review of experience with the Early Background Summary

Postponed to October 2016

Action: for information

Note: at the plenaries end of 2015, the committees agreed to perform a review of experience with the Early Background Summaries. A survey amongst CAT/CHMP/PRAC assessors was conducted following the pilot starting at the end of 2014. The data collection and analysis are completed based on a total 121 responses for the 21 products in scope of the exercise.

7.3. Co-ordination with EMA Working Parties / Working Groups / Drafting Groups

7.3.1. ATMP guideline on S&E follow-up and risk management

Scope: update on the revision

Action: for information

7.3.2. Revision of the mandate of the Scientific Advice Working Party (SAWP)

Scope: the revision covers the interaction with the EMA's scientific committees, PRIME activities and rules of procedure for the appointment of SAWP members.

Action: for information

Document:
-Mandate, objectives and rules of procedure of the Scientific advice working party (SAWP) (Doc ref: EMEA/CHMP/SAWP/69686/04 Rev 10) – revision

Note: the CHMP adopted the revised mandate at its July 2016 plenary.

7.3.3. Guideline on quality, non-clinical and clinical aspects of gene therapy medicinal products

Scope: call of interest to involve additional members in the drafting group

Action: for discussion

Document:
-Overview of comments received during the external consultation

Note: The external consultation ended in July 2015

CAT was informed that 28 comments were received during the external consultation. CAT appointed following drafting group members to review the comments and finalise the revision of this guideline:

Drafting group composition:
-Quality: M. Menezes-Ferreira, C. Niederlaender, S. Ruiz and P. Salmikangas
-Non-clinical: K. Breen, B. Sarkadi, M. Renner (tbc)
-Clinical: P. Gasparini, B. Klug, M. Hystad, O. Tenhunen (all tbc)

7.3.4. Review and update of EMA guidelines to implement best practice with regard to 3Rs (replacement, reduction and refinement of animal testing) in regulatory testing of medicinal products

CAT resources: Tiina Palomäki;

Scope: to address comments on the CAT table (pages 30 to 42).

Action: for discussion

Document:
-Reflection paper providing an overview of the current regulatory testing requirements for medicinal products for human use and opportunities for implementation of the 3Rs

Comments to be sent to by 16 September 2016

Note:
-18-19 October: for adoption at the next JEG 3Rs meeting
-July 2016: CAT agreed to the document
-July 2016: CHMP and CVMP adopted the document by for a three-month consultation.
-May 2015: Tiina Palomäki presented to CAT the Annex table for cell and gene therapies.

7.3.5. Working Party with Healthcare Professionals' Organisations (HCPWP)

Action: For information

Document tabled:
Minutes of the HCPWP meeting that took place on 15 June 2016

7.3.6. Working Party with Patients' and Consumers' Organisations (PCWP)

Action: For information

Document tabled:
Minutes of the PCWP meeting that took place on 14 June 2016

7.3.7. Working Party with Patients' and Consumers' Organisations (PCWP) and Working Party with Healthcare Professionals' Organisations (HCPWP)

Action: For information

Documents tabled:
-Draft Agenda - EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting – 20 September 2016 (EMA/428004/2016

-Agenda - EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting – Workshop on social media – 19 September 2016 (EMA/825257/2015)

-Report of a joint EMA workshop with patient and healthcare professional representatives about communication on medicines - 8 March 2016 (EMA/194543/2016)

-Minutes of the EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting - 9 March 2016 (EMA/183905/2016)

7.4. Co-operation within the EU regulatory network

7.4.1. EU Good Pharmacovigilance Practices (EU-GVP) – adoption of revised GVP modules in 2016-2017

Action: For information

Note: the EU Good Pharmacovigilance Practices (EU-GVP) has been updated on the EMA's GVP webpage (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000345.jsp&mid=WC0b01ac058058f32c#section4)

7.4.2. Analysis of European Clinical Trials Database (EudraCT)

CAT resources: Tomáš Boráň, Margarida Menezes-Ferreira, Ilona Reischl, Paula Salmikangas, Romaldas Mačiulaitis, Dariusz Śladowski, Michele Lipucci di Paola, Bernd Gänsbacher

Scope: manuscript for publication

Action: for information

7.5. Co-operation with international regulators

No items

7.6. CAT Work Plan

7.6.1. Guideline on requirements for investigational ATMPs

CAT drafting groups: Tiina Palomäki (Rapporteur), Ilona Reischl (Rapporteur), Metoda Lipnik-Stangelj, Margarida Menezes Ferreira, Maura O'Donovan, Simona Badoi, Tomáš Boráň, Christiane Niederlaender, Paolo Gasparini, Olli Tenhunen, Marit Hystad, Carla Herberts

Scope: initial draft of the guideline

Action: for discussion

Note: an outline of the structure of the guideline was provided in June 2016.

7.6.2. Questions and Answers on minimally manipulated ATMPs

CAT drafting group: Metoda Lipnik-Stangelj, Paula Salmikangas, Tiina Palomäki, Egbert Flory, Margarida Menezes Ferreira, Marit Hystad, Mikuláš Hrubiško

Scope: initial draft of the Q&A document

Action: for discussion

Note:
The Questions-and-Answers will describe the quality, non-clinical and clinical requirements for the marketing authorisation for a minimally manipulated ATMP (CD34+ cells for cardiac repair). In the answers, a practical explanation will be provided how to use the risk based approach to identify and justify deviations for the standard requirements for cell-based ATMPs as included in Annex I Part IV of Dir. 2001/83/EC.

7.6.3. CAT Workshop on cell-based cancer immunotherapies, EMA premises, 15-16 November 2016

CAT resources: Rune Kjeken, Björn Carlsson

Scope: attendance CAT members

Action: for information

Link to documents and registration

Note:
-CAT members interested to attend should complete the Registration Form
-CAT members are encourage to promote/disseminate this workshop in their NCAs

7.7. Planning and reporting

7.7.1. ATMP Expert meeting, 27 May 2016

Postponed

Action: for information

Documents:
-Regulators report and action plan

Link to the published stakeholders report:
http://www.ema.europa.eu/docs/en_GB/document_library/Report/2016/06/WC500208080.pdf

7.7.2. Management Board data gathering exercise - CAT horizontal data collection

Scope: Update on progress. The project started in March 2014 to gather evidence needed by the European Commission in drafting future legislative proposal on fees. The goal was to assemble evidence about the time spent on procedures at EMA and NCAs. The latest part of the projects relate to time spent by Committee members/alternates when not acting in their principal role as centralised product rapporteurs/peer reviewers.

Action: For information

7.7.3. Planning estimates of Q3/2016 ATMP MAAs

Action: for information

Note:
Not for public release. This report is part of the reporting cycle for the Scientific Committees. That is to say, five reports a year: four quarterly updates and an annual 'horizon scanning' which appears in April.

7.8. Others

7.8.1. Organisational adjustments to the EMA's Human Divisions to come into force on 1 September 2016

Action: for information

7.8.2. Cancer Drug Development Forum (CDDF)'s workshop on the 'Use of Real World Data to Optimise Oncology Drug Development and Access', London, 6-7 July 2016

CAT resources: Marit Hystad

Scope: session 5: 'Can Real World Data accelerate patient access to medicines'

Action: for information

Document:
Programme

8. Any other business

No items

Date of next CAT meeting:
Thursday 6th to Friday 7th October 2016

9. Explanatory notes

The Notes give a brief explanation of relevant agenda items and should be read in conjunction with the agenda.

Abbreviations / Acronyms

AR: Assessment Report

ATMP: Advanced Therapy Medicinal Product

BWP: Biologics Working Party

CAT: Committee for Advanced Therapies

CHMP: Committee for Medicinal Product for Human Use

COMP: Committee for Orphan Medicinal Products

CTFG: Clinical Trial Facilitation Group

DG: Drafting Group

EC: European Commission

ERA: Environmental Risk Assessment

FDA: Food and Drug Administration

FL: Final Letter

GCP: Good Clinical Practice

GLP: Good Laboratory Practice

GMO: Genetically-modified organism

GMP: Good Manufacturing Practice

HTA: Health Technology Assessment Bodies

HSPC: Hematopoietic Stem and Progenitor Cells

ITF: Innovative Task Force

JR: Joint Report

LoOI: List of outstanding issues

LoQ: List of questions

MA: Marketing Authorisation

MAA: Marketing Authorisation Applicant

MAH: Marketing Authorisation Holder

MSC: Mesenchymal stem cells

PDCO: Paediatric Committee

PMDA: Pharmaceuticals and Medical Devices Agency (Japan)

PIP: Paediatric Investigation Plan

PL: Package leaflet

PRAC: Pharmacovigilance and Risk Assessment Committee #

PRIME: Priority Medicines

RMP: Risk Management Plan

RP: Reflection paper

RSI: Request for supplementary information

SA: Scientific Advice

SAG-O: Scientific Advisory Group Oncology

SAWP: Scientific Advice Working Party

SR: Summary Report

SWP: Scientific Working Party

SME: Small and medium size enterprises

SmPC: Summary of Products Characteristics

TT: Timetable

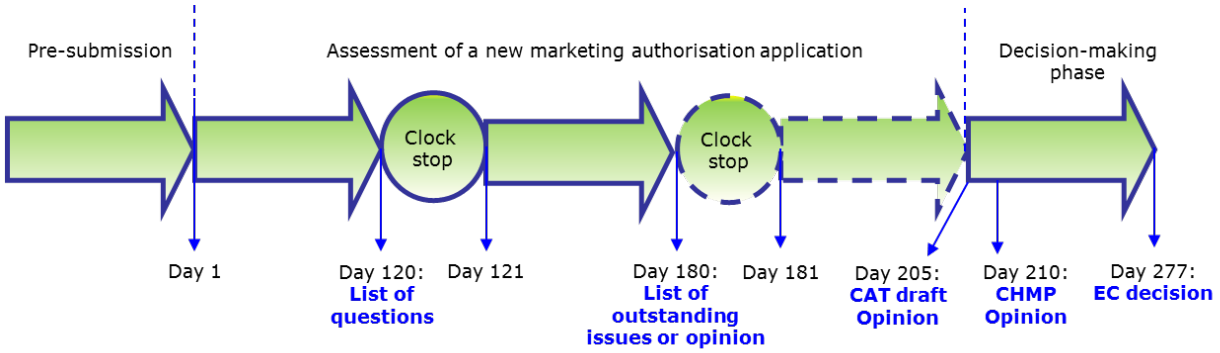
Evaluation of ATMPs (section 2)

This section lists applications for marketing authorisations of new Advanced Therapy Medicinal Products (ATMPs) that are to be discussed by the Committee. It also lists any ATMP related inspection requests (*section 2.9*) and Post-authorisation activities (*section 2.10*).

New applications (sections 2.1. to 2.12.)

Section 2.1 is for ATMPs nearing the end of the evaluation and for which the CAT is expected to adopt a draft **opinion** at this meeting on whether marketing authorisation should be granted. Once adopted, the CAT opinion is transmitted to the CHMP for final adoption. The CHMP opinion will be forwarded to the European Commission for a final legally binding decision valid throughout the EU. More information on the evaluation of ATMPs can be found here.

The other items in the section are listed depending on the stage of the evaluation, which is shown graphically below:



The assessment of an application for a new medicine takes up to 210 'active' days. This active evaluation time is interrupted by at least one 'clock-stop' during which time the applicant prepares the answers to questions from the CAT. The clock stop happens after day 120 and may also happen after day 180, when the CAT has adopted respectively a **Day 120 list of questions** (section 2.3) or a List of outstanding issues to be addressed by the company, which is listed in the agenda under sections 2.7 (**Ongoing evaluation procedures**). Section 2.7 also includes the CAT discussions at any other timepoint of the evaluation procedure of new applications.

Oral explanation (section 2.2.)

Prior to adoption of the CAT opinion, marketing authorisation applicants are normally invited to the CAT plenary meeting to address questions raised by the Committee.

Oral explanations normally relate to ongoing applications, but they can also relate to any other issue for which the CAT would like to discuss with company representatives in person.

Re-examination procedures (new applications) under article 9(2) of regulation no 726/2004 (section 2.6.)

This section lists applications for new marketing authorisation for ATMPs for which the applicant has requested a re-examination of the opinion previously issued by the CHMP. Similar to the initial evaluation of a marketing authorisation of an ATMP, CAT will adopt a draft re-examination opinion, which is transmitted to the CHMP for final adoption.

Withdrawal of applications (section 2.7.)

This section includes information on marketing authorisation applications that are withdrawn by the applicant. Applicants may decide to withdraw applications at any stage during the assessment and a CAT opinion will therefore not be issued. Withdrawals are included in the agenda for information or discussion, as necessary.

New applications (section 2.9.)

In this section, information is included on upcoming marketing authorisation applications for ATMPs, as well as information on appointment of Rapporteurs for new ATMP applications.

GMP and GCP Inspections Issues (section 2.10.)

This section lists inspections that are undertaken for ATMPs. Inspections are carried out by regulatory agencies to ensure that marketing authorisation holders comply with their obligations. Inspection can relate to good manufacturing practice (GMP), good clinical practice (GCP), good laboratory practice (GLP) or good pharmacovigilance practice (GVP).

Post-authorisation activities (section 2.12.)

This section lists type II variations, extension application according to Annex I of Reg. 1234/2008, re-examination procedures for type II variations (including extension of indication applications) for which the applicant has requested re-examination of the opinion previously issued by the CHMP and other issues concerning authorised medicines that are not covered elsewhere in the agenda such as annual reassessments, 5-year renewals, supply shortages, qualify defects. Issues that have been discussed at the previous meeting of the PRAC, the EMA's committee responsible for evaluating and monitoring safety issues for medicines, will also be included here.

Certification of ATMPs (section 3)

This section includes the scientific evaluation by the CAT of quality and non-clinical data that small and medium-sized enterprises have generated at any stage of the ATMP development process. More information on the ATMP certification procedure can be found here.

Scientific Recommendation on Classification of ATMPs (Section 4)

This section includes the scientific recommendation by the CAT on whether medicines based on genes, cells or tissues meet the scientific criteria that define ATMPs. More information on the ATMP classification procedure, including the outcomes of finalised classifications, can be found here.

Scientific Advice (section 5)

This section includes all scientific advice given to companies during the development of an ATMP. Information related to the number of ATMP related scientific advices discussed by CAT can be found in the CAT Monthly reports. Further information on SAWP can be found here.

Pre-Authorisation (section 6)

Paediatric Investigation Plan (PIP)

This section includes the discussion of an ATMP before a formal application for marketing authorisation is submitted. These cases refer for example to requests for an accelerated assessment for medicines that are of major interest for public health or can be considered a therapeutic innovation: in case of an accelerated assessment the assessment timetable is reduced from 210 to 150 days.

CAT contributes to the evaluation of a Paediatric Investigation Plan (PIPs) for ATMPs by the Paediatric Committee. These PIPs are included in this section of the Agenda.

ITF Briefing meeting in the field of ATMPs

This section refers to briefing meetings of the Innovation Task Force and International co-operations activities of the CAT

The Innovation Task Force (ITF) is a body set up to encourage early dialogue with applicants developing innovative medicines. Minutes of meetings with applicants developing ATMPs and of other ITF meetings of interest to the CAT are included in this section of the agenda. Further information on the ITF can be found here.

Priority Medicines (PRIME)

This section includes the new requests for eligibility to PRIME for ATMPs under development, the discussions in CAT of these eligibility requests and the final recommendations for eligibility of ATMPs adopted by CHMP.

CAT will appoint one of its members as the CAT sponsor for each new ATMP eligibility request who will lead the CAT discussion based on the recommendation from the SAWP.

Organisational, regulatory and methodological matters (section 7)

This section includes topics related to regulatory and procedural guidance, CAT workplan, CAT meeting organisation (including CAT membership), planning and reporting, co-ordination with other committees, working parties and scientific advisory groups.

Furthermore, this section refers to the activities of the CAT drafting groups developing scientific guidelines for gene therapy medicinal products and for cell-based medicinal products, cooperation within the EU regulatory network and international regulators as well as direct interaction with interested parties. It also includes topics of scientific interest for the Committee that are not directly related to the work of the CAT drafting groups or CAT associated working parties.

Any other business (section 8)

This section is populated with miscellaneous topics not suitable under the previous headings.

More detailed information on the above terms can be found on the EMA website: www.ema.europa.eu/