EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 February 2011
EMA/354785/2010
Committee for advanced therapies (CAT)

Procedural advice on the evaluation of combined advanced therapy medicinal products and the consultation of Notified Bodies in accordance with Article 9 of Regulation (EC) No. 1394/2007

Discussion at CAT	**July 2009**
Discussion at EMA/CAT-NB Coordination Group	23rd March 2010 21st April 2010 2d June 2010
Presented to CAT for 1 month consultation	June 2010
Adoption by CAT for release for external consultation	16th July 2010
End of consultation (deadline for comments)	29th October 2010
Discussion at EMA/CAT-NB Collaboration Group	24 November 2010
Presented to CAT for 1 month consultation	January 2011
Adopted by CAT as final version	11 February 2011

Keywords	*Combined Advanced Therapy Medicinal Products (ATMPs), Notified Body, Medical Devices, Consultation*

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1. Introduction

Advanced Therapy Medicinal Products (ATMPs) are medicinal products for human use, including gene therapy, somatic cell therapy and tissue engineered products. ATMPs may incorporate, as an integral part of the product, one or more medical devices, in which case they are referred to as "Combined ATMPs" as defined in Article 2 of the Regulation (EC) No 1394/2007 on Advanced Therapy Medicinal Products .

ATMPs offer new treatment opportunities for diseases and injuries of the human body. The regulatory framework established by the new legislation on ATMPs is designed to ensure the free movement of these medicines within the European Union (EU), to facilitate their access to the EU market, and to foster the competitiveness of European pharmaceutical and medical technology companies in the field, while guaranteeing the highest level of health protection for patients.

All ATMPs are evaluated *via* the centralised procedure as defined in Article 8 of Regulation (EC) No 1394/2007, thus ensuring that they benefit from a single evaluation and authorisation procedure applicable across the EU. This makes it easier for companies to market their products and for patients in the different Member States to gain access to these products.

The Committee for Advanced Therapies (CAT) following its evaluation, drafts an opinion on the quality, safety and efficacy of each ATMP subject to marketing authorisation application (MAA). This opinion is then sent to the Committee for Medicinal Products for Human Use (CHMP), the committee responsible for human medicines at the European Medicines Agency (EMA). Based on the CAT opinion, the CHMP adopts a recommendation on the granting, variation, suspension or revocation of a marketing authorisation. The recommendation is then sent to the European Commission for a decision binding in all Member States. Such evaluation is done in line with the "*Procedural Advice on the Evaluation of Advanced Therapy Medicinal Product in accordance with Article 8 of Regulation (EC) No 1394/2007*" (EMEA/630043/2008) published in EMA website:
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2010/02/WC500070340.pdf

Regulation (EC) No 1394/2007 states that ATMPs may incorporate medical devices or active implantable medical devices as defined in Directive 93/42/EEC and 90/385/EEC respectively. In order to ensure an appropriate level of quality and safety, those devices should meet the essential requirements laid down in the relevant Directive. A Notified Body (NB) for medical devices may be or may have been involved in the assessment of the medical device part of a combined ATMP. As the CAT prepares the draft opinion on a combined ATMP, it will therefore be this Committee who primarily interacts with a NB in the context of the procedure described in this document.

Further information on various scenarios for the provision of NB assessments is provided in section 4 of this document.

2. Scope

This document describes the procedure for interactions between the Agency (EMA) and CAT and Notified Bodies for medical devices in relation to the evaluation of combined ATMPs by the CAT and provides details of possible scenarios and timelines for such interaction within the context of Article 9 of Regulation (EC) No 1394/2007.

This procedure is put in place in order to establish timely and effective interactions between NBs and the CAT, in conjunction with the Applicant and to facilitate the availability of the required assessment of the conformity of the medical device component of the combined ATMP with the essential requirements provided in the relevant medical device Directives during the centralised evaluation of a combined ATMP. Such interaction, when required, should enable the CAT to perform an adequate benefit-risk assessment and to adopt a draft opinion for the combined ATMP.

This document should be read in conjunction with the "*Procedural Advice on the Evaluation of Advanced Therapy Medicinal Product in accordance with Article 8 of Regulation (EC) No 1394/2007*"(EMEA/630043/2008) published in EMA website:

http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2010/02/WC500070340.pdf

This procedure **does not concern:**

- The **procedure for classification of an ATMP**, for which the procedure is described in the "*procedural advice on the scientific recommendation on classification of ATMPs"* (EMA/CAT/99623/2009).
- **post-approval procedures/interaction between CAT and NB** (guidance will be developed at a later stage).

3. Legal basis

Article 1(d) of Regulation (EC) No 1394/2007 defines combined ATMPs as follows:

> *"(d) 'Combined advanced therapy medicinal product' means an advanced therapy medicinal product that fulfils the following conditions:*
> *— it must incorporate, as an integral part of the product, one or more medical devices within the meaning of Article 1(2)(a) of Directive 93/42/EEC or one or more active implantable medical devices within the meaning of Article 1(2)(c) of Directive 90/385/EEC, and*
> *— its cellular or tissue part must contain viable cells or tissues, or*
> *— its cellular or tissue part containing non-viable cells or tissues must be liable to act upon the human body with action that can be considered as primary to that of the devices referred to."*

Article 9 of Regulation (EC) No 1394/2007 provides that:

> *"1. Where a combined advanced therapy medicinal product is concerned, the whole product shall be subject to final evaluation by the Agency.*
>
> *2. The application for a marketing authorisation for a combined advanced therapy medicinal product shall include evidence of conformity with the essential requirements referred to in Article 6.*

3. The application for a marketing authorisation for a combined advanced therapy medicinal product shall include, where available, the results of the assessment by a notified body in accordance with Directive 93/42/EEC or Directive 90/385/EEC of the medical device part or active implantable medical device part.

The Agency shall recognise the results of that assessment in its evaluation of the medicinal product concerned.
The Agency may request the relevant notified body to transmit any information related to the results of its assessment. The notified body shall transmit the information within a period of one month.
If the application does not include the results of the assessment, the Agency shall seek an opinion on the conformity of the device part with Annex I to Directive 93/42/EEC or Annex 1 to Directive 90/385/EEC from a notified body identified in conjunction with the applicant, unless the Committee for Advanced Therapies advised by its experts for medical devices decides that involvement of a notified body is not required."

4. Specific considerations for combined Advanced Therapy Medicinal Products

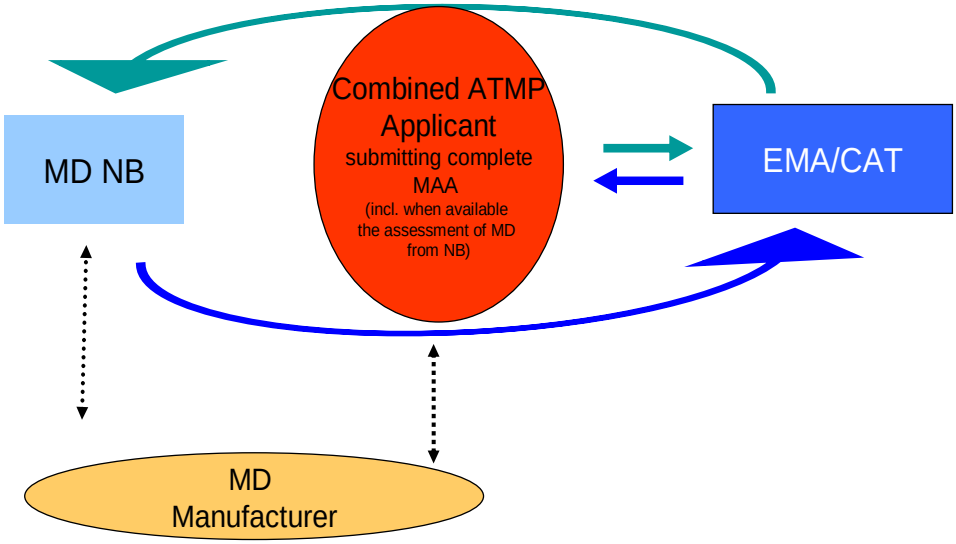
4.1. Combined ATMP Applicant

The Applicant of a combined ATMP is the person legally responsible for submitting a Marketing Authorisation Application (MAA) for a combined ATMP to the Agency. The applicant, if successful and following grant of Marketing Authorisation by the European Commission will become the holder of a marketing authorisation for the combined ATMP. The Marketing Authorisation Holder (MAH) shall be responsible for the placing on the market of the medicinal product, whether he does it himself or via one or more persons designated to that effect, in accordance with Article 2 of Regulation (EC) No. 726/2004. (Further details of the applicant's responsibilities can be found in Annex II to Chapter 1 of Volume 2A of the European Commission Notice to Applicants (ec.europa.eu/health/files/eudralex/vol-2/a/vol2a_chap1_2005-11_en.pdf).)

The combined ATMP applicant will be responsible for any fee payment direct to the NB for the work performed by the NB for the EMA/CAT.

It should also be noted that any interaction between the EMA/CAT and the NB(s) will be done in conjunction with the Applicant, which in practice will imply that that Applicant will always be involved/copied/informed of all contact(s) the EMA/CAT may have with the NB. However, for expediency communication may be sent directly from the EMA/CAT to the relevant NB.

CAT CONSULTATION OF A MD NB IN CONJUNCTION WITH THE COMBINED ATMP APPLICANT



4.2. Data requirements for combined ATMPs

- **Data provided for a combined ATMP** must be in accordance with Annex I, Part IV of Directive 2001/83/EC, as amended and other relevant EMA guidance(s) *.

- Regarding the **information to be provided on the device**, in accordance with Article 6 of Regulation (EC) No. 1394/2007, any medical device (active implantable or not) which forms part of a combined ATMP shall meet the requirements of laid down in Annex I to Directive 93/42/EEC and Directive 90/385/EEC, as amended (see also **section 4.3**).
    - It is expected that the evidence of conformity with essential requirements with the Medical Device Directives to follow Part 2 of the guideline set up by GHTF for devices classified as high risk devices i.e.: GHTF SG1 N11: 2008 Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED): (http://www.ghtf.org/documents/sg1/sg1final-n11.pdf), including an Essential requirements checklist to the relevant medical device Directive and may for example include a description of the interaction and compatibility between genes, cells and/or tissues and the structural components.

* Further details would be provided in a separate document which is under development. See EMA/CAT and Medical Notified Bodies Collaboration Group 2011 Work program: http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/CAT/people_listing_000086.jsp&murl=&mid=

- In case the NB assessment of the device part of combined ATMP is available, it is proposed that NBs would ideally use the format and principals of the NBOG guidance on Design – dossier examination and Report Content (http://www.nbog.eu/resources/NBOG_BPG_2009_1.pdf).

The information on the device part of the combined ATMP and the NB assessment, if available, should be submitted in Module 3, section 3.2.R of the CTD under the "medical device" section. The information provided by the Applicant in this section should be adequate and sufficient for him to demonstrate conformity of the device part with Annex 1 to Directive 93/42/EEC or Annex 1 to Directive 90/385/EEC.

Further guidance may be developed on the format and specific content of data that should be submitted.

4.3. Consultation of a Notified Body

Consultation of a NB on a medical device part of a combined ATMP will be done further to identification by the CAT of a need to consult a NB within the remit of Article 9 of Regulation (EC) No 1394/2007.

The scope of such consultation by the CAT will depend on whether or not the results of the NB assessment on the device part of the combined ATMP are included in the MAA (see also above section 4.2). If available at the time of MAA submission, this assessment shall be recognised by the CAT insofar as it is relevant for the evaluation to the combined ATMP subject to the application.

In either case, a pre-submission meeting at the EMA is strongly recommended before a MAA for a combined ATMP is submitted to the Agency using information available on http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000157.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac058002251f.

It should be noted also that if and when required by the CAT, the consultation may include a request of an Opinion on the conformity of the device part with Annex I to Directive 93/42/EEC or Annex 1 to Directive 90/385/EEC from a NB identified in conjunction with the Applicant, unless the CAT advised by its experts for medical devices decides that involvement of a NB is not required. In practice, this will include a list of questions drafted/adopted by the CAT addressed to NB.

An illustration of the above request from the CAT to the NB could be the case when the results of the assessment on the device part performed by a NB relates to the use of the device, which is now combined with an ATMP, but in a different intended use. In such case, further opinion on the suitability of the device for the intended use proposed when in combination with an ATMP may be sought from a NB.

It is also acknowledged that combining a medical device with an ATMP may have an effect on the original technical, clinical and biological characteristics of the device as a result of the addition of the ATMP. Therefore, evaluation of combined ATMPs may require assessment of this effect on the characteristics of the device part. Potential interactions and the effect of the combination of the ATMP on the device part may require assessment, in particular on the safety and performance of the device part. In such cases, within the remit of Article 9 of Regulation (EC) No 1394/2007, the CAT may seek an opinion on the effect of the combination on the device part from a NB.

4.4. Identification of a Notified Body

When a need for consultation by the EMA/CAT is identified, it is the responsibility of the EMA in conjunction with the Applicant for marketing authorisation of the combined ATMP to identify a NB to which the consultation may be addressed.

Therefore, to facilitate such consultation by the CAT, the Applicant for the combined ATMP:

- will be requested to always identify a NB in the centralised MAA Application form published by the European Commission on the EudraLex - Volume 2B - Pharmaceutical Legislation Notice to applicants and regulatory guidelines medicinal products for human use (http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/vol-2/index_en.htm).

  This information is required even in the case where NB assessment of the device component has not yet taken place. The NB specified may be consulted in the event that CAT determines that advice on the conformity of medical device is required (see Section 5.1).

- should ensure the identified NB is appropriately notified for assessment of the type of medical device included in the combined ATMP and in identifying a suitable NB, might take into consideration the experience of that NB in similar assessments e.g. medical devices incorporated with medicinal substances, medical devices incorporated with stable human blood derivatives, medical devices incorporated with tissues of animal origin.

For this purpose, the **Nando** (New Approach Notified and Designated Organisations) Information System available on the European Commission website (http://ec.europa.eu/enterprise/newapproach/nando/index.cfm) lists medical device NBs as well as the tasks for which the NB has been notified. The lists of NB are given for information only and are valid at the date indicated on EC Website.

Note: For further explanation see also NBOG guideline on "*Designation Authorities to Define the Notification Scope of a Notified Body Consultation Medical Devices Assessments*" (http://www.nbog.eu/resources/NBOG_BPG_2009_3.pdf).

4.5. Access by the EMA/CAT to data concerning the medical device component and confidentiality

It is the responsibility of the Applicant to submit a complete MAA in accordance with the relevant legal basis of the Directive 2001/83/EC, as amended and data requirements.

Following the submission of such an MAA, the EMA/CAT can request at any time – i.e. during the evaluation procedure, the Applicant to provide any information related to the device component.

The Applicant will be liable for the content and timely submission of any such information requested as well as the provision of any clarifications with regard with such information. It is therefore the responsibility of the Applicant to ensure that any necessary agreements for access to any data relating to the medical device(s) that may be requested by the EMA/CAT are in place between the combined ATMP Applicant and the medical device manufacturer (s), in the case that they are separate legal entities.

These agreements should include provisions to allow the exchange of information on a continuous basis so that the Applicant is fully aware of any changes of the medical device component or safety issues related to the device which may have an impact on the combined ATMP Benefit Risk assessment.

Also, it should be noted that, as part of the EMA standard transparency policy, once the European Commission issues a Marketing Authorisation for the combined ATMP, a European Public Assessment Report (EPAR) will be published by the Agency, which may include some information relating to the medical device part.
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/epar_search.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001d125

In this context, the combined ATMP applicant will be requested to comment on the proposed EPAR prior to any publication in accordance with standard EMA policy on EPAR publication for medicinal products.

5. Procedure to consult a Notify Body

5.1. Timetable for the consultation of a NB when the results of the assessment of the medical device(s) have not been provided

5.1.1. Pre-submission meeting at the EMA

During the pre-submission meeting, the EMA will encourage Applicants to provide results of the assessment from a NB of the Medical Device(s) in the Marketing Authorisation Application (MAA).

During the pre-submission meeting, the EMA in conjunction with the Applicant may already identify potential Notified Bodies to be consulted in case the CAT will determine that such a consultation is necessary upon their evaluation of the application. In any case, these should be specified in the Application Form (module 1 of CTD MAA, see section 4.3).

5.1.2. Identification of need to consult a Notified Body at day 1

During validation, in those cases where the results of the assessment of the medical device by a NB have not been provided as part of the MAA, the EMA will inform the CAT accordingly in order to allow the CAT to consider the need to consult a NB at day 1 of the procedure.

The EMA/CAT in conjunction with the combined ATMP Applicant identifies the NB(s), see section 4.3

5.1.3. Identification of need to consult a Notified Body at Day 80

In the Assessment Reports at Day 80, the CAT (Co)-Rapporteurs, the CHMP Co-ordinators and the assessment team may identify the need to consult a NB.

This may be the case when the need to consult a NB was not identified by the CAT at day 1, when there are still questions regarding the assessment performed by the NB or if there are any additional queries regarding the medical device(s).

At the next CAT meeting following the provision of the CAT (Co)- Rapporteurs Assessment Reports, the CAT may decide on the need for further consultation of a NB and if there is a need to identify a different NB in conjunction with the Applicant. Such consultations will include an explicit List of Questions (LoQ) to be addressed by a NB. Once the CAT has agreed on the LoQ to be addressed to the NB, the EMA Project Team Leader (PTL) sends the LoQ to the NB. The Applicant will always be informed of all correspondence exchanged with the NB(s). Similarly the NB responses will also be made available to the Applicant and the EMA/CAT Rapporteurs.

A timetable should be proposed by the CAT and when agreed with the Applicant and the NB(s) will then be sent to all parties involved.

5.1.4. Consultation with the Notified Body at Day 120

If the responses from the NB are not provided by day 120, the request is added to the CAT LoQ, the clock is stopped and will only restart once an appropriate response to the LoQ is received from the NB through the combined ATMP Applicant.
If additional questions are identified following the receipt of the NB's responses, a third consultation with the NB may exceptionally take place.

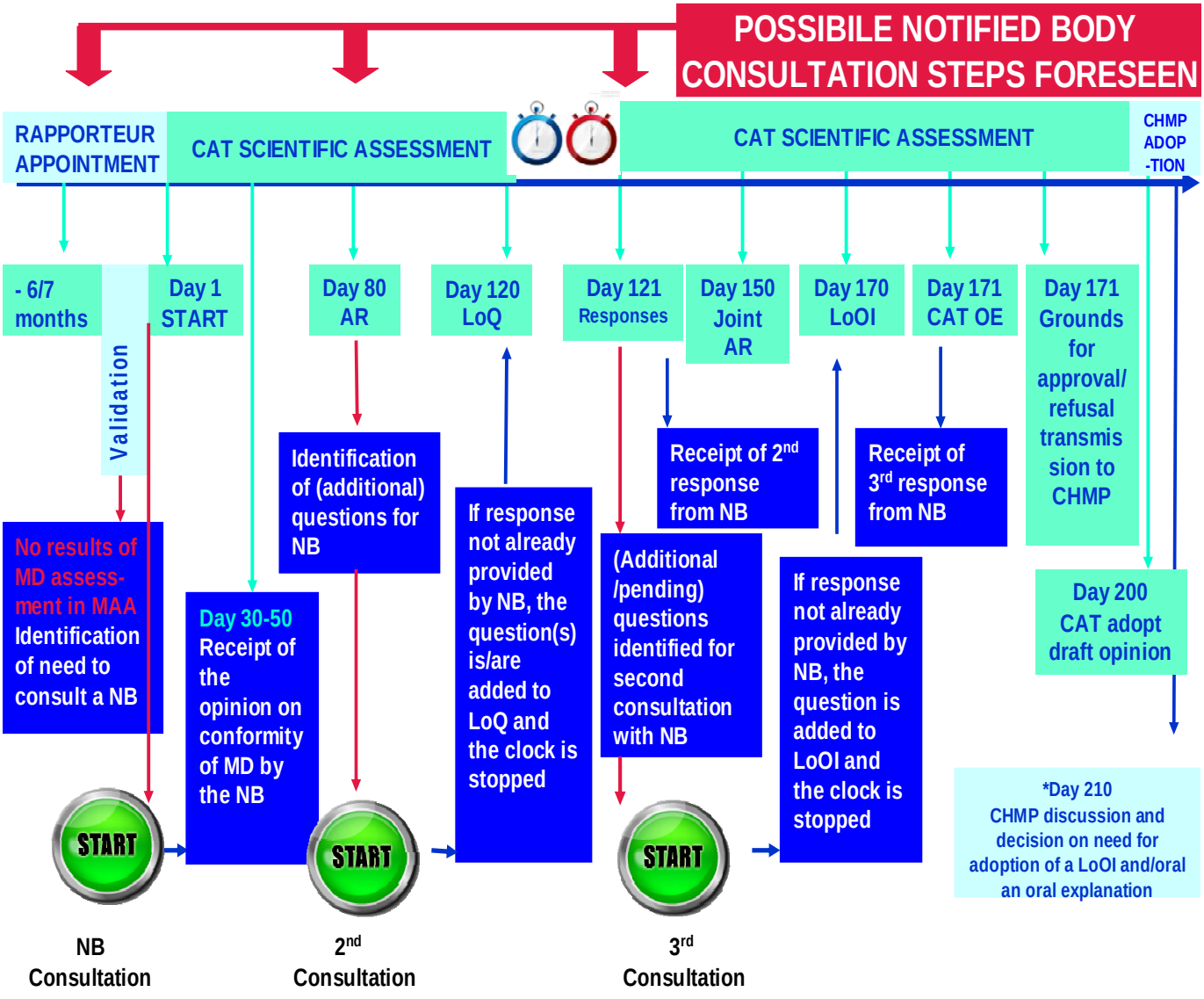
The CAT should consider the need and adequacy of any request from the combined ATMP Applicant for a further clock stop in line with the principles of the EMA procedural advice on the "Time allowed for applicants to respond to questions and issues raised during the assessment of new marketing authorisation applications in the centralised procedure "(EMEA/75401/2006 Rev. 2). These should be adhered to, as far as possible.

If the CAT decides on the third consultation of the NB and another LoQ to be addressed by the NB, with copy to the Applicant will be sent by the EMA PTL together with a timetable that should be proposed by the CAT and agreed with the NB and the Applicant.

5.1.5. Consultation with the Notified Body at Day 170

If the responses from the NB are not provided by day 170, the request will be added to the List of Outstanding Issues (LoOI), the clock is stopped and only restarts once an appropriate response to the LoOI is received from the NB.

Scenario 1: Consultation of the Notified Body in order to get the results of the assessment of the medical device(s)



5.2. Timetable for the consultation of a Notify Body when the results of the assessment of the medical device(s) have been provided

5.2.1. Pre-submission meeting at the EMA

The EMA will advise combined ATMP Applicants to provide at the time of submission of a Marketing Authorisation Application (MAA) of a combined ATMP, the results of the assessment of the medical device(s) part by a NB.

It should be kept in mind however that upon assessment of the application by the CAT it might be determined necessary to consult a NB to get additional information regarding the medical device part of the combined ATMP.

5.2.2. Validation of the Marketing Authorisation Application

At the time of the validation, the EMA acknowledges that the results of the NB assessment of the medical device(s) have been provided.

5.2.3. Identification of need to consult a Notified Body at Day 80

The need to ask further questions of a NB is identified by the Rapporteurs and their assessment teams **as soon as possible** in the evaluation procedure. When providing the Assessment Reports at Day 80, the CAT (Co)-Rapporteurs, the CHMP Co-ordinators and the assessment team may identify the need to consult a NB in those cases where there is a need to get additional information on the assessment of the NB or any additional query regarding the medical device(s).

At the next CAT meeting following the provision of the CAT (Co)- Rapporteurs Assessment Reports, the CAT decide on the consultation of the NB and the LoQ to be addressed by the NB.

Once the CAT has agreed on the LoQ, the EMA in collaboration with the Applicant sends the LoQ to the NB.

A timetable should be proposed by the CAT and agreed with the NB and the Applicant.

5.2.4. Consultation with the Notified Body at Day 120

If the responses from the NB are not provided by day 120, the request is added to the LoQ, the clock is stopped and only restarts when an appropriate response to the LoQ is received from the NB..

If additional questions are identified following the receipt of the NB's responses, a second consultation with the NB can take place.

The CAT decides on the second consultation of the NB and the LoQ to be addressed by the NB.

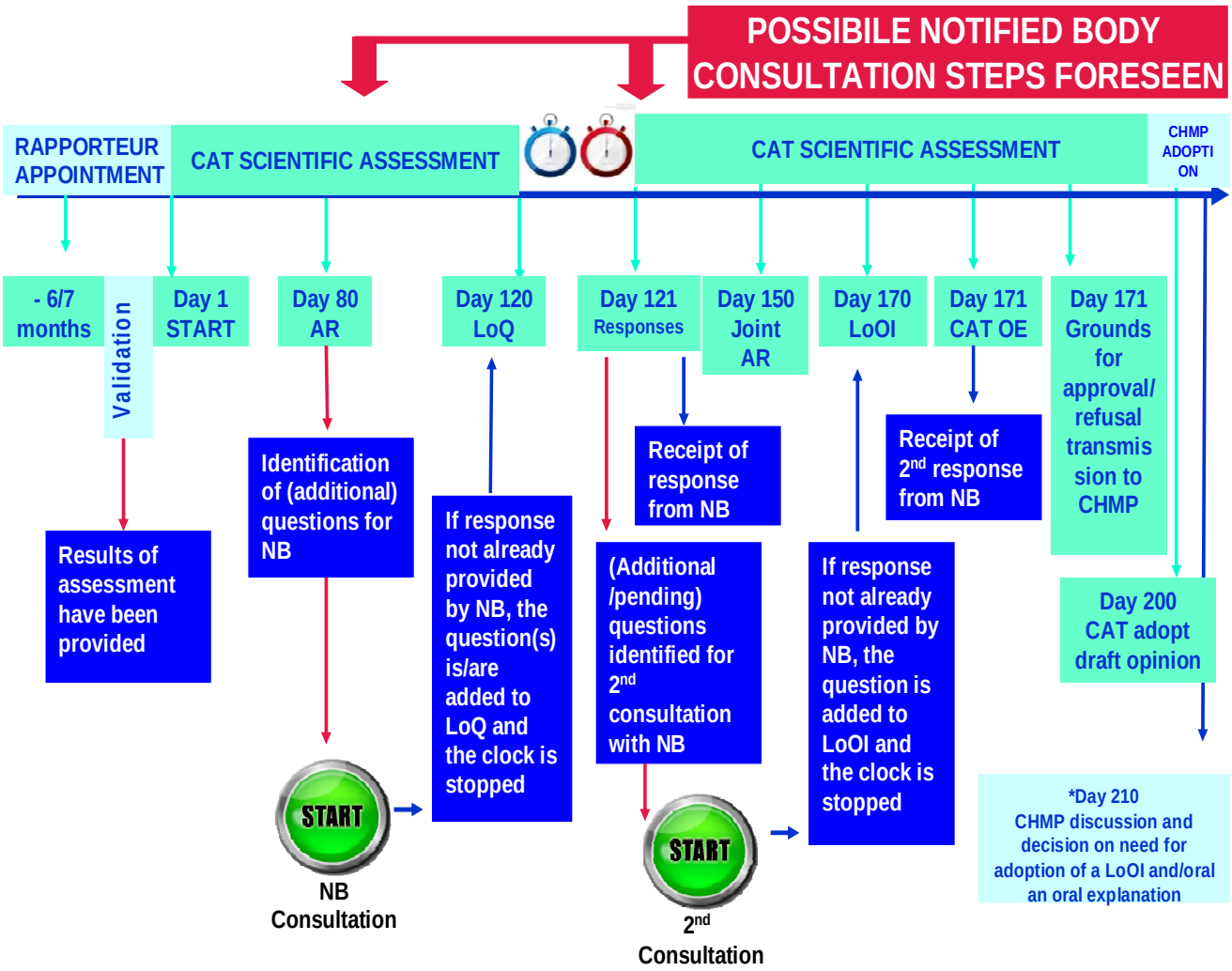
Once the CAT has agreed on the LoQ, the EMA in collaboration with the Applicant sends the LoQ to the NB.

A timetable should be proposed by the CAT and agreed with the NB and the Applicant.

5.2.5. Consultation with the Notified Body at Day 170

If the responses from the NB are not provided by day 170, the request will be added to the LoOI, the clock is stopped and only restarts once an appropriate response to the LoOI is received from the NB..

Scenario 2: Consultation of the Notified Body in order to get the additional information regarding the medical device(s)



ABBREVIATIONS

AIMD: Active Implantable Medical Devices Directive

AR: Assessment Report

ATMP: Advanced Therapy Medicinal Products

CAT: Committee for Advanced Therapies

EMA: European Medicines Agency

EPAR: European Public Assessment Report

LoQ: List of Questions

LoOI: List of Outstanding Issues

MAA: Marketing Authorisation Application

MDD: Medical Devices Directive

NB: Notified Body

OE: Oral Explanation

PTL: Project Team Leader

GHTF: Global Harmonisation Task Force

NANDO: Nando (New Approach Notified and Designated Organisations) Information System

NBOG: Notified Body Operations Group

REFERENCES:

- Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC Regulation (EC) No 726/2004
http://ec.europa.eu/health/files/eudralex/vol-1/reg_2007_1394/reg_2007_1394_en.pdf

- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.
http://ec.europa.eu/health/files/eudralex/vol-1/reg_2004_726_cons/reg_2004_726_cons_en.pdf

- Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (Official Journal L 334, 12/12/2008 p. 7 - 24)
http://ec.europa.eu/health/files/eudralex/vol-1/reg_2008_1234/reg_2008_1234_en.pdf

- Directive 2001/83/EC, as amended of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use *(Consolidated version : 30/12/2008)*.
http://ec.europa.eu/health/files/eudralex/vol-1/dir_2001_83_cons/dir2001_83_cons_20081230_en.pdf

- CAT Rules of Procedure
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004761.pdf

- Procedural Advice on The Evaluation of Advanced Therapy Medicinal Product in accordance with Article 8 of Regulation (EC) No 1394/2007" (EMEA/630043/2008)
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2010/02/WC500070340.pdf

- "Time allowed for applicants to respond to questions and issues raised during the assessment of new marketing authorisation applications in the centralised procedure " (EMEA/75401/2006 Rev. 2)

- MAA Application form published by the European Commission on the EudraLex - Volume 2B - Pharmaceutical Legislation Notice to applicants and regulatory guidelines medicinal products for human use in format or word format.
http://ec.europa.eu/health/documents/eudralex/vol-2/index_en.htm

- EMA Pre-submission meetings:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000157.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac058002251f

- Medical Devices Directive (MDD) 93/42/EEC as amended:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:EN:PDF

- Active Implantable Medical Devices Directive (AIMDD) 90/385/EEC as amended:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1990L0385:20071011:EN:PDF

- Medical Devices Guidance Documents: Borderline products, drug-delivery products and medical devices incorporating, as an integral part, an ancillary medicinal substance or an ancillary human blood derivative /MEDDEV 2.1/3 Rev3
http://www.meddev.info/_documents/2_1_3_rev_3-12_2009_en.pdf

- Medical Devices Guidance Documents: Guidelines for the classification of medical devices MEDDEV 2.4/1 Rev.8: http://www.meddev.info/_documents/2_2_4-1part1_07-2001.pdf

- Medical Devices Guidance Documents: Designation and monitoring of Notified Bodies within the framework of EC Directives on medical devices MEDDEV 2.10-2 Rev 1: http://www.meddev.info/_documents/2_10_2date04_2001.pdf

- Designation Authorities to Define the Notification Scope of a Notified Body Consultation Medical Devices Assessments" http://www.nbog.eu/resources/NBOG_BPG_2009_3.pdf

- NANDO IS: Nando (New Approach Notified and Designated Organisations) Information System: http://ec.europa.eu/enterprise/newapproach/nando/

- NBOG guidance on Design – dossier examination and Report Content http://www.nbog.eu/resources/NBOG_BPG_2009_1.pdf

- Design Dossier following Part 2 of the guideline set up by GHTF for devices classified as high risk devices i.e. : GHTF SG1 N11 : 2008 Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED) : http://www.ghtf.org/documents/sg1/sg1final-n11.pdf

- NBOG: Notified Body Operations Group: www.nbog.eu

- GHTF: Global Harmonisation Task Force: www.ghtf.org