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Procedural advice on the consultation of Notified Bodies in accordance with Article 9 of Regulation (EC) No. 1394/2007

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Comments should be provided using this template. The completed comments form should be sent to marie-helene.pinheiro@ema.europa.eu

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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

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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 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) prepares a draft 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. In order to ensure an appropriate level of quality and safety, those devices should meet the essential requirements laid down in Annex I to Directive 93/42/EEC and Directive 90/385/EEC, respectively.

As defined in Article 9(3) of Regulation (EC) No 1394/2007, where available, results of the assessment of the medical device by a notified body (NB) for medical devices shall be included in a Marketing Authorisation Application (MAA) for a combined ATMP, and in such circumstances shall be recognised by the EMA. Further consultation of a Notified Body might be found necessary in order to ask any questions relating to the results of the previous assessment of medical device (s) (MDD(s)).

If results of a NB assessment are not available at the time of the submission of the MAA, the EMA/CAT may seek an opinion on the conformity of the device part with the essential requirements of the relevant Medical Device Directives from a suitable designated NB.

It should also be noted that any interaction between the EMA/CAT and the NB(s) will be done in conjunction with the Applicant for marketing authorisation of the combined ATMP.

2. Scope

This document describes the procedure for the interactions between the EMA/CAT and Notified Bodies for medical devices in relation to the assessment 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 with NBs by the EMA/CAT, in conjunction with the Applicant and facilitate the availability of the required assessment of the conformity of the medical device component of the ATMP with the essential requirements provided in the relevant Medical Device Directives (MDDs) during the centralised evaluation of a combined ATMP. Such interaction, when required, should enable the CAT to perform the adequate benefit-risk assessment and to adopt a draft opinion for the combined ATMP, which will be transmitted to the CHMP and recommending (or not) the marketing authorisation of such medicinal product to the European Commission.

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 whether or not a product can be classified as a combined ATMP. The latter is described in the "*procedural advice on the scientific recommendation on classification of ATMPs"* (EMA/CAT/99623/2009).

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. Consultation of a Notified Body

Consultation of a Notified Body on a medical device part of a combined ATMP will be done further to identification of a need by the Agency/CAT within the remit of Article 9 of Regulation (EC) No 1394/2007. When identified, this consultation will be done in conjunction with the combined ATMP Applicant.

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

The scope of such consultation by the Agency/CAT can vary from request for information / clarification on an already submitted NB assessment report on a device component up to an opinion on conformity of the device part with Annex 1 to Directive 93/42/EEC or Annex 1 to Directive 90/385/EEC.

If the results of the assessment of a NB are already provided in the combined ATMP MAA, they shall be recognised by the EMA/CAT insofar as they are relevant for the evaluation of the combined ATMP. Such assessment, when available and submitted as part of the MAA, may facilitate the review of the application and specific consultation with a NB may not be required. If nevertheless required by the Agency/CAT, the consultation would allow the EMA/CAT to request further clarifications on the assessment provided and/or additional new information. In any case, the CAT will clearly identify the question(s), scope and timelines to get the answers from the NB.

An illustration of the above request from the Agency/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. Also in this case, within the remit of Article 9 of Regulation (EC) No 1394/2007, the EMA/CAT may seek an opinion on the effect of the combination on the device part from a NB.

Further details on possible consultation of a NB, are outlined in section 5.1.

4.2. Identification of a Notified Body

When a need for consultation by the EMA/CAT is identified within the scope of Article 9 of Regulation (EC) No 1394/2007, it is the responsibility of the EMA/CAT in conjunction with the Applicant for marketing authorization of the combined ATMP to identify a Notified Body to which the consultation may be addressed.

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

- will be requested to 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 should be provided regardless whether or not the results of the assessment by a NB of the device component of the combined ATMP have been included in the MAA.

  NB scopes of designation can be found in the NANDO Information System http://ec.europa.eu/enterprise/newapproach/nando/index.cfm. 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).

- should make sure it identifies a NB conducting the assessment of the medical device component which is duly designated for assessment of type of device that has been incorporated with an ATMP. In identifying the NB, the Applicant might take into consideration the experience of the NB concerned 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.

4.3. Specific Data Requirements (further details would be provided in a separate document which is under development)

Where a device is incorporated as an integral part of a combined ATMP, the applicant shall include the results of the assessment by a NB of the medical device part or implantable medical device part (in module 3, section 3.2.R of the CTD under the "medical device" section) if available at the time of submission of a MAA to the Agency.

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).

In case results of the assessment of a NB of the device incorporated in the combined ATMP is available, this should be submitted in the MAA by the applicant to the EMA/CAT. It is understood that NBs would be ideally used 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 need for submission of information on the device (whether or not assessed by a NB) once combined with an ATMP may be in the form of the 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), may for example include a description of the interaction and compatibility between genes, cells and/or tissues and the structural components.

Further detailed guidance will be made available as to the format and specific content of what should be submitted.

In any event, a pre-submission meeting at the EMA is strongly recommended before a MAAA 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.

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

Following the submission of a MMA, the EMA/CAT can request at any time – i.e. during the evaluation procedure and/or after the marketing authorisation has been granted -, the combined ATMP Applicant to provide any information related to the device component.

The combined ATMP Applicant will be liable for the content and timely submission of any information requested as well as the provision of any clarifications with regard with such information.

It is the responsibility of the Applicant/MAH to ensure that any necessary agreement 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(s) manufacturer, in case that it is a separate legal entity.

These agreements should include provisions to allow the exchange of information on a timely and on a continuous basis e.g. also following authorisation of the combined ATMP, so that the combined ATMP Applicant is fully aware of any (AI)MD changes which may have an impact on the combined ATMP and file any required variation request in accordance with 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.

Also, it should be recalled 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, it may be that certain information would be published but in all circumstances the combined ATMP applicant will be requested to comment on the proposed EPAR prior to any publication.

All publications made by the Agency on any specific medicinal product are made in line with “Principles to be applied for the deletion of commercially confidential information for the disclosure of EMEA documents” (EMEA/45422/2006) following a consultation prior to any publication with the Applicant/MAH.

4.5. Post-marketing

The combined ATMP MAH, shall inform the CAT/EMA following authorisation of the combined ATMP, of any data relating to the safety of the medical device(s) component(s) that may have an effect on the quality, safety or efficacy of the combined ATMP.

The Agency will also have the responsibility to inform the relevant national competent authorities responsible for implementing Directives 90/385/EEC, 93/42/EEC and 2004/23/EC if any adverse events or reactions occur in relation to the combined ATMP, in accordance with Article 14(5) of Regulation (EC) No 1394/2007.

Further EMA guidance’s will be available in this regard.

5. Procedure to consult a Notify Body

5.1. Reasons for EMA to consult a Notify Body:

There are two scenarios when the EMA may consult a NB:

A/ First, the CAT during evaluation of a combined ATMP, requires further information related to the results of the assessment of the medical device(s) already performed by a NB or any further information on the medical device(s).

In this instance, the results of the assessment of the medical device(s) by a NB are provided with the MAA but the CAT requires additional information or has additional queries regarding the medical device(s). According to the Regulation (EC) No 1394/2007, the NB shall transmit the information within a period of one month.

The CAT may require information with regards to the following (this is not an exhaustive list):

- assessment on the effect of combined the medical device with the ATMP on the technical, clinical and biological characteristics of the device part;
- information and confirmation that the medical device(s) can be used in the intended use as proposed by the marketing authorisation Applicant for the combined ATMP;
- potential interactions between the ATMP(s) and the medical device(s);
- Assessment on the effect in the combination of the medical device with the ATMP on the safety and performance characteristics of the device part.

B/ Secondly, when the Applicant has not provided the results of the assessment of the medical device(s) as part of the MAA, the CAT may decide during evaluation of a combined ATMP to consult a NB to seek an opinion on the conformity of the medical device(s) with the essential requirements of the relevant (AI)MDD(s).

. In this case, 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 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.

The NB will provide the results of the assessment of the medical device(s) within two months.

In both scenarios A and B, the Applicant will pay any fee for the consultation of the NB and any other associated fees directly to the NB.

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

5.2.1. 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, EMA in conjunction with the Applicant may already identify potential Notified Bodies to be consulted in case CAT will find a consultation necessary upon assessment of the application.

5.2.2. 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 Committee to consider the need to consult a NB at ay 1 of the procedure.

The EMA/CAT in conjunction with the combined ATMP Applicant identifies the NB(s).

5.2.3. 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 decide on the need for further consultation of a NB and the need to identify a different NB in conjunction with the Applicant together with the 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 in collaboration with the applicant sends the LoQ to the NB. The Applicant will always be informing of all correspondence exchange with the NB(s). Similarly the NB responses should also be made available to the Applicant and the EMA/CAT Rapporteurs.

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

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 CAT LoQ, the clock is stopped and only restarts once the results are made available by 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 can take place. The CAT should consider the need and adequacy of any request from the combined ATMP Applicant for a further clock stop. 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) should be adhered to, as far as possible.

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

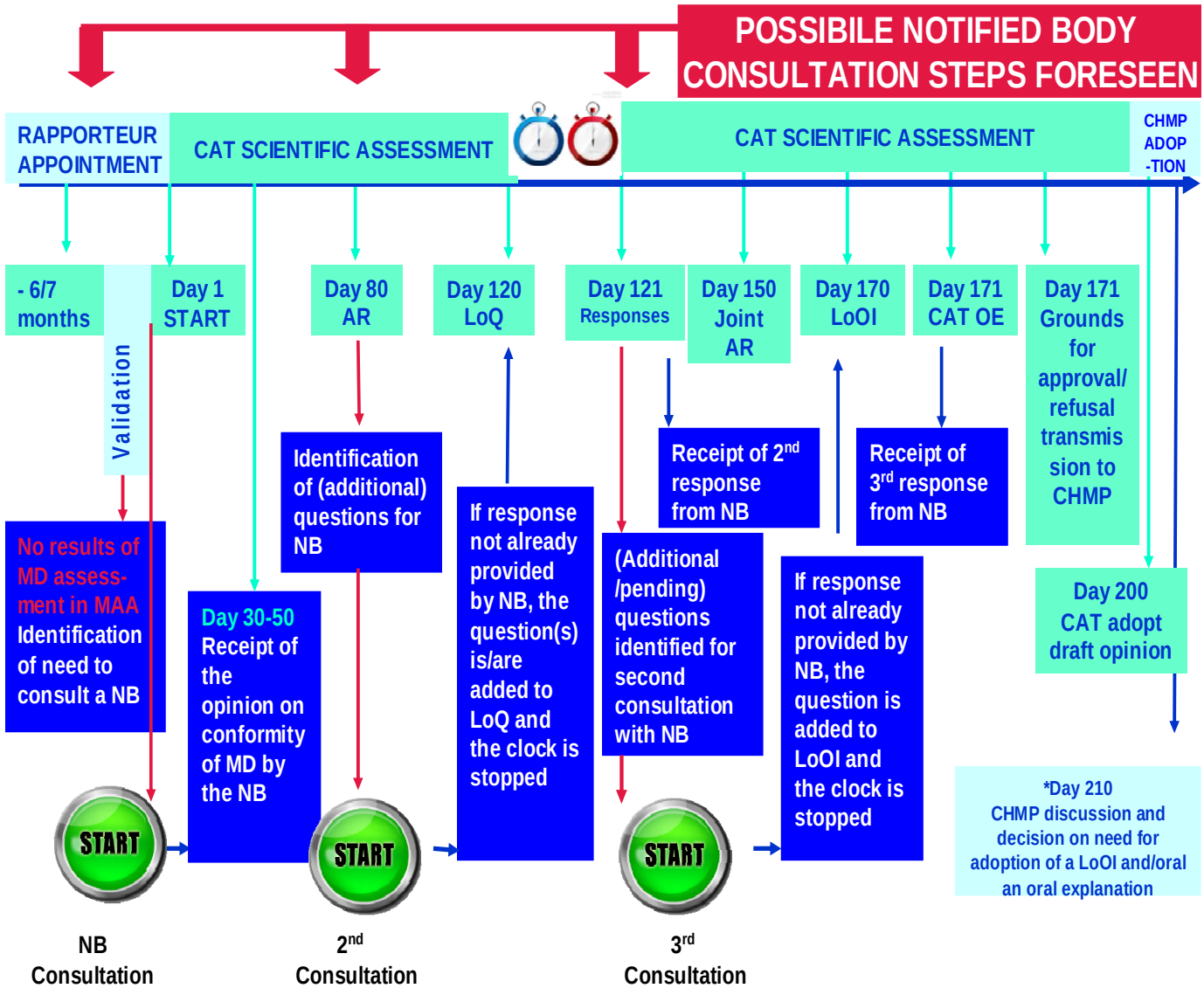
Once the CAT has agreed on the LoQ, the EMA in collaboration with the Applicant sends the LoQ to the NB.

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 List of Outstanding Issues (LoOI), the clock is stopped and only restarts once the results are made available by the NB through the combined ATMP Applicant.

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



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

5.3.1. 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 found necessary to consult a NB to get additional information regarding the medical device.

5.3.2. 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.

5.3.3. 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.

5.3.4. 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 once the responses are made available by the NB through the combined ATMP Applicant.

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.

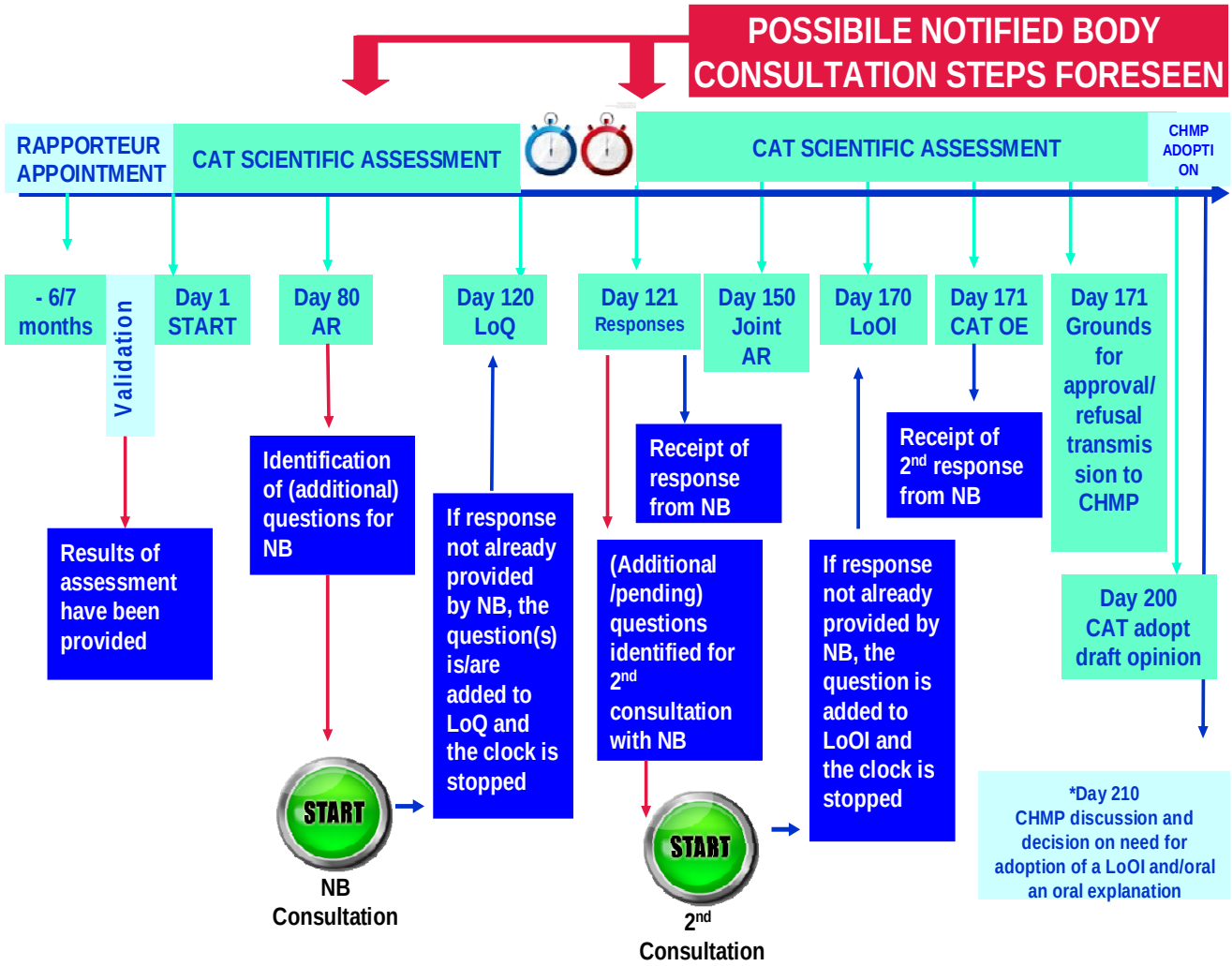
Once the CAT has agreed on the LoQ, the EMA in collaboration with the Applicant sends the LoQ to the NB.

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

5.3.5. 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 the results are made available by the NB through the combined ATMP Applicant.

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

LoQ: List of Questions

LoOI: List of Outstanding Issues

MAA: Marketing Authorisation Application

MDD: Medical Devices Directive

NB: Notified Body

OE: Oral Explanation

GHTF: Global Harmonization Task Force

NANDO IS: 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 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:
  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:EN:PDF

- Active Implantable Medical Devices Directive (AIMDD) 90/385/EEC:
  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 Harmonization Task Force: www.ghtf.org