Agence nationale de sécurité du médicament et des produits de santé

Electronic submission to ANSM through the CESP

Pilot phase

Notice to applicants for marketing authorisation of medicines for human use

June 2015 (version 6.1)

ansm.sante.fr

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1. History of changes

1.1. Changes introduced in version 6.1 of this note to applicants (june 2015)

- Paragraph « 4.2.1. Regulatory activities covered under the pilot phase »
    - Update of this chapter in order to indicate the possibility to submit all regulatory activities entering in the product lifecycle excepted the Centralised Procedure

- Paragraph « 4.3.2. Performance »
    - Update of this chapter in order to integrate a new step (step IV Bis), and in order to indicate the date of the launch of this step IV Bis of the pilot phase.

- Paragraph « 4.5.Some figures on the pilot phase »
    - Delete of this chapter

- Paragraph « 5.4. Criteria for electronic admissibility»
    - Update of this chapter in order to indicate the possibility to submit all regulatory activities entering in the product lifecycle excepted the Centralised Procedure

2. Preamble

The French National Agency for Medicines and Health Products Safety (ANSM) has undertaken a process for standardising the dematerialised exchanges.

With this objective, the ANSM has implemented a pilot phase during which it offers the applicants the option, to voluntarily submit their dossiers using the CESP (Common European Submission Platform) mechanism.

This note to applicants giving details about the features of the CESP and the process for submitting the dossiers under this pilot phase, does not supersede the note to applicants for Marketing Authorisation (MA) of medicines for human use (being updated) available on the ANSM website at the following address: http://ansm.sante.fr/Activites/Autorisations-de-Mise-sur-le-Marche-AMM/Constitution-de-dossier-d-AMM/(offset)/1

3. CESP

3.1. Presentation

CESP is a mechanism for sending data electronically to Health Agencies of the EU Member States.

CESP, the implementation of which falls under the aegis of the Heads of Medicines Agencies (HMA), has been technically developed by the Irish Medicines Board.

This mechanism allows secure transmission of dossiers, without size limit, to several recipients simultaneously (several Health Agencies).

It is a one-directional process: the transmission is made only to the Agencies.

3.2. Technical characteristics

CESP allows submitting dossiers in accordance with three secure Internet protocols:

- either through a secure Website that allows transferring files (web based file transfer system) – Standard web browser with Java (sha1RSA 2048 bits);

- or through a SFTP server (SSH file transfer protocol – ftp under ssh tunnel) accessible through a standard ftp client (such as Filezilla or CuteFTP);

- or through a FTP server (file transfer protocol) encapsulated in a VPN tunnel (Virtual Private Network - 3DES), having the advantage of enabling faster transfers.

3.3. Website

All information about CESP is available on its Website:

> **cesp.hma.eu**

This website:
- lists the Agencies that authorise the transmission of dossiers through the CESP;
- gives details about the registration procedure for applicants who want to use the CESP;
- describes the dossier transmission process;
- provides tutorials on how to use it as well as a FAQ.

Questions specific to the CESP asked by users may be sent by e-mail or telephone to:

E-mail address: **cesp@hma.eu**

Telephone: **+353 16 34 38 01**

3.4. Financing

CESP has been made available free of charge to applicants. It is financed by the Health Agencies of the Member States.

3.5. Nature of dossiers submitted through the CESP

CESP allows the transmission of all types of dossiers pertaining to medicine, medicine for human use or veterinary medicine.

However, **under the pilot phase proposed by the ANSM**, **initially it will be possible to submit only some types of dossiers to it** (ref. paragraph 3.3.2 of this note to applicants).

3.6. CESP in some figures

CESP has been operational since 14 November 2012.

As of 30 November 2013, i.e. one year after its implementation, we had:

- 29 Health Agencies (human and/or veterinary medicine) under production
- 1120 registered pharmaceutical firms
- During October and November 2013 : 16500 requests per month submitted through CESP
  (against 730 requests submitted in June 2013)
  NB : 1 request = 1 Member state
  If 18 Member states are concerned for one given application, 18 requests are counted.
- Mainly variations of marketing authorisations

3.7. How to submit dossiers through the CESP

The procedure for registering for the CESP as well as the methods of sending the dossiers are given in detail on the CESP Website.

3.7.1. *Registration*

The registration step has to be cleared before the CESP can be used.

The registration is done by an "administrator" appointed within the company that wants to use the CESP.

A future applicant may appoint one or more administrators.

The administrator is mainly responsible for making new user accounts, deleting and/or closing the accounts.

Registration is done online at the CESP Website (http://cesp.hma.eu) through a form.

Once the form is filled, the administrator will receive an e-mail informing him that his request has been acknowledged. He shall then have to send a mail (scanned) on the company's letterhead and signed by a director of the company by e-mail to the attention of the CESP manager.

The CESP manager shall then contact the person appointed as the administrator in the form for conducting verifications. Once these verifications are completed, the company shall be registered in the CESP and it will be authorised access. An e-mail shall then be sent by the CESP to the company's administrator giving him his access code and password.

The company's administrator should then go to the CESP homepage and enter his access code and password.

A connection confirmation screen to the CESP will then appear. This screen will have a new menu bar that will give access to new options, such as user management. Using this user management interface, the administrator can create new users or delete them.

Other, non-administrative users, must be registered with CESP before any use. The registration procedure requires filling in some items of an *ad hoc* form after entering the company's access code. These users shall not have access to functions reserved to administrators such as user management.

3.7.2. *Methods of sending the dossiers*

In order to transmit a dossier through the CESP, the registered users (ref. paragraph 2.7.1) must connect with their access code to:
- complete a submission form online and save it in XML format;
- transmit the file that he would like to submit, along with a submission form.

3.7.2.1. Submission form

The applicant should:

- Select the option: "Select New Delivery File";
- Complete the submission form:
  - by providing the name of the company and the type of medicine (human);
  - and by filling in the fields relating to the regulatory activity* under which it is covered (e.g.: variation of type IA), to type of procedure (mutual recognition (MRP), decentralised (DCP), national), procedure number, electronic submission format (eCTD, NeeS), submission security key (checksum), Agency reference number(s) of the submitted dossier, the validation utility used.

* ref. glossary

> Attention
>
> For dossiers submitted to ANSM, the Agency reference number refers to the “NLxxxxx” number.
>
> It is important to mention this ANSM number, in order to enhance the processing of the submitted dossier.

- mention :
  - in case of a dossier falling under a mutual recognition or decentralised procedure, the Agency of the reference Member State as well as the Agency(ies) of recipient Member States (check boxes);
  - in case of a dossier covered under the national procedure, the concerned Agency(ies)

> Attention
>
> In case of submissions to ANSM, please ensure that you select "human medicine".

- download and save the XML file corresponding to the submission form.

3.7.2.2. Transmission of the dossier

The applicant should then:

- Select the transmission mode through which he will transmit the dossier (Web Based File Transfer System or sFTP) ;
- Enter the connection parameters ("login details": user ID, password, etc.).
- Select:
  - the file of the dossier that he would like to transmit by selecting it in the file tree structure of his computer;
  - the XML file of the corresponding submission form (ref. paragraph 3.7.2.1);
- Drag/drop these two files into the send box (to the right of the window) starting with the file of the dossier to be transmitted (Note: the XML file of the submission form must be dropped second).

  The transmission progress of these two files through the CESP now appears in a box at the bottom of the window.
- Select "log out" to exit.

An e-mail confirming that the file has been downloaded in the CESP is then automatically sent to the sender.

4. The pilot phase

4.1. Objectives

This pilot phase has been implemented by ANSM to allow the applicants to voluntary test electronic submission† of dossiers through the CESP, which, it is expected, will result in saving time at each step of the dossiers' directions: *to be more precise*, the authorisations asked by the applicants (new MA requests, variation of the MA, etc.) shall be faster.

Initiation of these new submission methods* require a test step prior to their standardisation. The framework of this test step is defined by this pilot phase.

> Submission of dossiers under the pilot phase **is presently not mandatory**;
>
> However, given:
> - the expected gains from using this mechanism;
> - its standardisation once the pilot phase is completed (extension to other regulatory activities not covered under the pilot phase),
>
> the applicants are strongly encouraged to submit the dossiers in line with this framework.

> **Why does AMSM expect to save time if CESP is used by the applicants?**
>
> ANSM expects to save time on submission of dossiers through CESP mainly due to:
> - removal of the "physical" dossier handling step (paper or CD/DVD);
> - traceability and archiving optimisation of dossiers submitted electronically;
> - faster and easier accessibility to files for the ANSM assessors;
> - faster browsing through documents during the dossier evaluation step;
> - the option of extracting data through "copy/paste" operations, thereby facilitating the preparation of reports.

4.2. Scope of the pilot phase

4.2.1. *Regulatory activities‡ covered under the pilot phase*

The pilot phase covers all regulatory activities entering in the product lifecycle submitted based on the following procedures:

- national;
- or European: mutual recognition, decentralised, **excepted Centralised Procedure**

as well as responses received to questions raised during the assessment of these requests.

† ref. glossary
‡ ref. glossary

4.2.2. *Regulatory activities and health products not covered under the pilot phase*

Following are not covered under the pilot phase:

- Regulatory activities other than MA

  These dossiers are not related to MA, and include:
  - clinical trials;
  - temporary authorisations for use (ATU);
  - advertising.
  - DMF - ASMF

- Health products other than medicine

  These dossiers cover other health products falling under the competency of the ANSM, such as:
  - medical devices;
  - cosmetic products;

4.3. Launch and performance of the pilot phase

4.3.1. *Launch*

The pilot phase has been launched on: **1st October 2013**

(1st October 2013: launch of step I – ref. paragraph 4.3.2 of this note to applicants)

Since this date, applicants may use the CESP to submit their dossiers to the ANSM, in compliance with the instructions given hereunder.

The applicants are not required to pre-inform ANSM about their intention to submit dossiers through the CESP.

4.3.2. *Performance*

The pilot phase shall be conducted in 6 **successive steps** in order to be able to adapt the device, if required, based on feedback from ANSM and the applicants.

During each of these steps, **it will be possible to submit only some types of dossiers**.

Step I:	Generic medicines: MA variations [1] [2] of IB and II type **Start date: 1st October 2013**
Step II:	All medicines: MA variations [2] of IB and II type **Start date: 17th February 2014**
Step III:	All medicines: all types of MA variations [2] (IA or IA_{IN}, IB and II) **Start date: 2nd June 2014**
Step III bis:	All medicines: all types of MA variations (IA or IA_{IN}, IB and II), including centralised applications **Start date: 1st October 2014**
Step IV:	All regulatory activities structured in eCTD or NeeS format **Start date: 12th january 2015**
Step IV bis:	All regulatory activities structured in eCTD or NeeS format excepted Centralised Procedures (**Mandatory use of eSubmission Gateway)** **Start date: 02nd june 2016**

[1] This pertains to MA variations of medicines identified as generic either while granting the MA, or later.
[2] Other than the requests covered under the centralised procedure.

During each of these steps, the responses received to questions raised as part of directives of these requests may also be submitted.

Once step I has been initiated (launch of the pilot phase), the opening dates of the other steps shall be informed on the ANSM Website one month in advance. The chronology of their launch shall be adjusted based on the feedback from users and the ANSM on the current step.

4.4. Wrongly transmitted dossiers

As indicated in the previous paragraph, the type of dossiers that may be transmitted through the CESP shall vary according to the steps of the pilot phase.

It is important to comply with these dossier types.

In fact, a dossier that is not eligible to be sent through the CESP since it is not covered under the ongoing pilot phase step, but is nevertheless transmitted through the CESP, shall be deemed as a wrongly transmitted dossier.

The non-eligibility for transmission through the CESP shall be assessed within reasonable time after the dossier is received by the ANSM.

The receipt filed in the dossier submitted incorrectly through the CESP must be re-filed (same receipt) in the re-submitted dossier.

The ANSM shall inform the applicants of these dossiers by e-mail and within good time:
- about this wrong transmission;
- that they shall have to file their request on another media (electronic filing in CD or DVD format or paper filing);
- **that these dossiers shall not be processed since they are not eligible for submission through the CESP.**

5. Submitting a dossier to the ANSM under the pilot phase

5.1. Attention

For any electronic submission to the ANSM through the CESP, **it is prohibited to alongside file all or part of the modules on paper or CD/DVD media**.

Non-compliance with this instruction may result in slowing down of the processing process of the submitted dossier.

Moreover, the applicants are not required to pre-inform ANSM about their intention to submit dossiers through the CESP.

For any electronic submission to the ANSM through the CESP, **it is no longer requested to send in parallel to the Vendargues'ANSM site a copy of the pharmaceutical module of the dossier.**

Moreover, the applicants are not required to pre-inform ANSM about their intention to submit dossiers through the CESP.

5.2. General information about the CTD

With regard to the submission modalities, the standard format called CTD (Common Technical Document) for presenting the MA request dossier is common for all States of the European Union: both for requests evaluated under European procedures (mutual recognition procedure, decentralised procedure and centralised procedure) and for the national requests.

Description of the format and of the contents of the dossier is available on the website of the European Commission's Directorate-General for Enterprise and Industry at the following address:
http://www.ec.europa.eu/health/files/eudralex/vol-2/b/update_200805/ctd_05-2008_en.pdf

The applicant must refer to the texts published by the European Commission as part of the "Regulations of medicinal products in the European Union, volumes 2A and 2B - Note to MA applicants and regulatory guidelines for medicinal products for human use in the Member States of the European Union", (Eudralex, volume 2, Pharmaceutical Legislation: Note to Applicants).

These documents drafted by the European Commission are available on the website of DG Entreprise and Industrie of the European Commission at the following address:
http://ec.europa.eu/health/documents/eudralex/vol-2/index_en.htm

5.3. Electronic submission formats accepted by the ANSM

There are two types of CTD organisations in electronic format that exist in the European Union and are accepted by the ANSM:
- eCTD;
- EU-NeeS.

These two electronic dossier formats have common features in the entire European Union.

> The ANSM does not accept other electronic dossier formats.

Special case of dossiers filed earlier in paper format

When previous regulatory activities submissions of same specialty (MA request and variations) have been submitted in paper format and now if the applicant would like to file the variation requests through the CESP:

- he should not file a consolidated dossier ("baseline");
- it is not necessary to file complete module(s) referred to in the variation request in the eCTD electronic submission format. Thus, for example, for a pharmaceutical request for variation related to the extension of the storage period (section 3.2.P.8), it is not necessary to submit all other sections of module 3.

5.3.1. *Characteristics of the CTD format*

The format and content of eCTD have been defined by ICH (International Conference on Harmonisation) and are therefore common and harmonised in the United States, in Japan and in the European Union, except for module 1, the contents of which meet specific regional needs (including the "Application form" and production information proposals).

Supplementary information on the eCTD is available on the following websites:
- http://www.emea.europa.eu
- http://esubmission.emea.europa.eu/tiges/tigesdocuments.html

5.3.2. *Features of the EU-NeeS format*

This dossier structure is common to the entire European Union.

Harmonised specifications are available on the website of the European Medicines Agency (EMA) at the following address: http://esubmission.emea.europa.eu/tiges/tigesdocuments.html

With regard to the names of files, the conventions recommended by ICH must be stringently followed for the EU-NeeS.

Ref. ICH, eCTD specification v5.0, naming conventions: http://estri.ich.org/eCTD/index.htm

5.4. Criteria for electronic admissibility

A dossier transmitted to the ANSM through the CESP, in order to be considered as electronically admissible, must comply with the points detailed hereunder.

To note: electronic admissibility is included in the overall admissibility step of the dossier.

- **Submitted regulatory activity**

  Under the pilot phase, the submissions in eCTD and EU-NeeS format are accepted for all regulatory activities entering in the product lifecycle submitted based on the following procedures:

  - national;
  - or European: mutual recognition, decentralised, and **excepted the Centralised Procedure**

  as well as responses received to questions raised during the assessment of these requests.

With regard to the regulatory activities submitted in electronic format

When one of the regulatory activities listed above has been submitted in an electronic format to the ANSM (eCTD or NeeS), the ANSM then waits for any later filing in an electronic submission format, irrespective of the regulatory activity in question:

- eCTD format for future filings if the submission was in eCTD format;

- NeeS or eCTD format for future filings if the submission was in NeeS format (if passage in eCTD format, this format must then be kept later).

- **A submission must:**

  - refer to a single procedure number[§] ;
  - and comprise a single regulatory activity.

- **In case of several identical requests for different specialities representing different dosages and/or different pharmaceutical forms of same product, and if the documentation is common, the applicant can:**

  - ♦ either submit them as part of same common dossier:

    - Module 1 with:
      - o for new MA requests: as many "application form" files as dosages or pharmaceutical forms. With regard to "Product information", this document can be specific to each of the specialties in question or just one and common to all of them;
      - o for variations: either a single "application form", listing all the specialties referred to in the dedicated heading, or as many "application form" files as dosages or pharmaceutical forms,

    - Module 2 to Module 5 common;

  - ♦ or submit complete and separate dossiers for each dosage or each pharmaceutical form (one media for each dosage/pharmaceutical form).

Whichever solution is selected, it must be followed for all later submissions.

The "Parent/Child" structure is not acceptable, either for submissions in eCTD format, or for submissions in NeeS format. Thus, for example, if an applicant files a new MA request in January 2014 targeting three different dosages in a single sequence[**] (10, 20 and 30 mg) (sequence 0000), any later filings for requests for variation must follow the lifecycle as detailed hereunder:

Variation(s)	Sequence
- for the 10 mg dosage - filed in February 2015	0001
- for the 20 mg dosage - filed in March 2015	0002
- for the 10 mg dosage - filed in June 2015	0003
- for the 30 mg dosage - filed in September 2015	0004
- grouped for the 10, 20 and 30 mg dosages - filed in October 2015	0005

[§] In case of dossiers submitted in accordance with the national procedure, the procedure number is not available at the time of submission.

[**] ref. glossary

- **Zipped or compressed files**

It is advisable to transmit the files in a compressed format using only the following compression systems:
- Winzip;
- Microsoft Compressed Folders.

- **Contents of the study submitted file must be complete**

- **Computer validation (eCTD or NeeS)**

Any electronic submission is computer checked by the ANSM based on the criteria defined in the European guidelines (pdf version, structure, naming of file, MD5 for the eCTD), any problem will result in non-acceptance of the submission for reason of its electronic non-compliance.

For this purpose, a validation tool ("validator") has been provided to the applicants. This validator[††] can be freely downloaded from the ANSM site at the following address:
http://ansm.sante.fr/Activites/Autorisations-de-Mise-sur-le-Marche-AMM/Constitution-de-dossier-d-AMM/(offset)/1 .

This validator was developed by the company Extedo in partnership with the European National Agencies and the EMA that use the review software EURS is Yours.

Each submission must be tested with this utility by the applicant before sending its letter through the CESP.

The applicant shall file a submission with the ANSM only if the validation report* is valid (non detection of blocking points). The validation report must be attached with his submission that constitutes an indispensable expected document.

For this, the presence of the validation report does not in any way prejudge the overall acceptability of the submission.

Attention

1. Any submission that does not comply with this pre-requisite shall receive a regularisation request by the ANSM first by mail and then by courrier. The applicant that does not produce the required items within the time granted by the ANSM shall be deemed to have given up its request. The items present in the submission (receipt(s), electronic media, etc.) shall then be considered as used up.

2. This electronic validation does not apply to centralised applications, since this validation is already performed by EMA before the submission to Member states.

5.5. Content of the submission transmitted to the ANSM through the CESP

A single regulatory activity must be submitted for each transmission made through the CESP.

The submissions transmitted to the ANSM through the CESP must comprise 2 dossiers:
- On the one hand, the relevant modules of the CTD,
- On the other hand, the administrative documents ("working documents").

5.5.1. *Relevant modules of the CTD*

These modules are filed in the NeeS or eCTD format.

[††] ref. glossary

To note:

1. Certification of submission through CESP only

In the covering letter put in module 1, it must be specified that this submission transmitted to the ANSM through the CESP is filed only through this mechanism.

2. Payment of taxes

Items pertaining to the payment of taxes must be put in appendix 5.1 of "the application form" of module 1.

Thus, any submission to the ANSM must comprise:

- **the payment receipts** corresponding to the request and delivered by the *"Direction des Créances spéciales du Trésor"* at Châtellerault (Directorate of Special Loans of the Treasury at Chatellerault);
- a summary **deposit slip** of the receipts transmitted as part of the filing, filled in by the applicant (ref. template on the ANSM Website: http://ansm.sante.fr/Activites/Taxes/Transfert-des-taxes-de-l-ANSM-a-l-Etat/%28offset%29/0).
  This slip may have as many pages as required (Attention, this is not the slip to be sent to the "*Direction des Créances spéciales du Trésor at Châtellerault")*.

To remember:

- Any request for a Marketing Authorisation (original request for variation, only regulatory activities covered by the pilot phase) must include the payment of tax in compliance with the regulation in force.

  Tax must be paid for each MA request or for each MA variation request. Consequently, as many taxes must be paid as there are MA requests.

  Payment modalities are identical irrespective of the submission media.

  Taxes must be paid to the *Direction des Créances spéciales du Trésor at Châtellerault* before sending the MA request or MA variation request to the ANSM.
  The tax slabs are fixed by the Decree no. 2012-381 (19/03/2012).

  The slip to be sent to the *Direction des Créances spéciales du Trésor at Châtellerault* is available at the following address:
  http://www.impots.gouv.fr/portal/deploiement/p1/fichedescriptiveformulaire_7452/fichedescriptiveformulaire_7452.pdf

  Explanatory **note** listing the codes to be used for filling this slip are given at the following address:
  http://www.impots.gouv.fr/portal/deploiement/p1/fichedescriptiveformulaire_7450/fichedescriptiveformulaire_7450.pdf

- For centralised applications no fees are required in France.

5.5.2. *Administrative documents*

These documents must be provided in PDF format or scanned.

- **The ANSM form dedicated to electronic submission**

One form for each submission (regulatory activity) duly filled must be attached.

For dossiers submitted through the CESP, the « ANSM form for e-CTD or NeeS submission » (Version 1.1 – January 2014), available on the ANSM Internet website (« Soumission électronique via le CESP – Phase pilote proposée par l'ANSM »), should be used:
http://ansm.sante.fr/Activites/Autorisations-de-Mise-sur-le-Marche-AMM/Constitution-de-dossier-d AMM/(offset)/1

- **The validation report**

This report is meant to validate the compliance of the electronic submission with the criteria defined in the European guidelines in terms of structure, naming of files, format and version of the PDF used. This report is generated by executing the validation utility (validator[‡‡]) (ref. paragraph 5.4 point 5 of this note to applicants).

Click on the following link for downloading the validation utility that is recommended for use by the ANSM: http://ansm.sante.fr/Activites/Autorisations-de-Mise-sur-le-Marche-AMM/Constitution-de-dossier-d-AMM/(offset)/1.

> Electronic submission through the CESP shall not under any circumstances result in a request for additional CD/DVD or paper copies once the submission has been deemed as electronically and administratively admissible.

5.6. Practical recommendations

> 1. All volumes of a dossier must be filed by way of a single transmission through the CESP: **the dossier should not be split.**
>
> 2. Dossier supplements
>
> Any dossier supplement (answers to questions, additional requests, etc.) must be filed on the same media and in the same format as those of the initial filing:
>
> - If eCTD submission: new sequence;
> - If NeeS submission: new NeeS.

6. Questions

Questions about the application methods of the pilot phase are handled by the ANSM, and those about using the CESP (registration modalities, dossier submission modalities) are handled by the Irish Medicines Board.

Thus the recipient of the question shall depend on the issue being raised.

1. Questions about the **pilot phase:**

> E-mail: **e-recevabilite@ansm.sante.fr**

2. Questions about the **CESP**:

> E-mail: **cesp@hma.eu**
>
> Telephone: **+353 16 34 38 01**

[‡‡] ref. glossary

7. Glossary

eCTD (electronic CTD)
Electronic submission wherein the data submitted in support of the request follows an eCTD type structure and file formats.

Electronic submission
Submission in which the CTD data provided in support of the request is filed electronically in accordance with the harmonised EU recommendations for file formats and the tables of content.

EU-NeeS (European Union Non eCTD electronic Submission)
Electronic submission wherein the data submitted in support of the request follows an EU-NeeS type structure and file formats.

Regulatory activity
Purpose of a dossier's submission.
Examples: new request for marketing authorisation (MA), variation of type IA or IA_{IN}, IB or II, Periodic Safety Update Report (PSUR), renewal, monitoring measurement (as part of assessing the medicine's safety after granting the MA).

Request (type of)
Characterising the aim of the submission defined by the regulatory activity, for example new chemical entity or different range/dosage or new pharmaceutical form for a new MA request, extension of indication or variation request of heading 4.6 of the Summary of Product Characteristics (RCP) for a type II variation.

Sequence
Specific to the eCTD format, a sequence corresponds to a submission of which the numbering is defined as follows: 0000 first submission, 0001 second submission, etc.
Generally the 0000 sequence corresponds to an MA request and the following sequences to variation requests, PSUR, renewal, etc.
Nevertheless, it is possible to adopt the eCTD format during the product's lifecycle, for example, at the time of a major variation.

Submission
A submission corresponds to all the (simultaneous) request(s) filed by a firm. The submission can pertain to several specialities, documentation common to all these requests is then submitted as part of a single submission.

Validation (report)
After executing the utility, the validation report is a document to be generated and printed. The report is a document expected with every electronic submission and does not in any way prejudge the overall acceptability of the submission.

Validator
Free utility provided by the company Extedo, which can be downloaded from the ANSM website at the following address:
http://ansm.sante.fr/Activites/Autorisations-de-Mise-sur-le-Marche-AMM/Constitution-de-dossier-d-AMM/(offset)/1 .
This utility is meant to validate the compliance of the electronic submission with the criteria defined in the European guidelines in terms of structure, naming of files, format and version of the PDF used.

8. List of acronyms

ANMV	Agence nationale du médicament vétérinaire (French National Veterinary Medicine Agency)
ANSM	Agence nationale de sécurité du médicament et des produits de santé (French National Agency for Medicines and Health Products Safety)
CTD	Common Technical Document
CESP	Common European Submission Platform
EMA	European Medicines Agency
EU-NeeS	European Union Non eCTD electronic Submission
HMA	Heads of Medicine Agencies
MA	Marketing Authorisation
PP	Pilot Phase
PSUR	Periodic Safety Update Report
VPN	Virtual Private Network