

<b>NOTICE TO ASMF HOLDERS FOR ELECTRONIC SUBMISSION OF ASMF TO ANSM VIA CESP.....</b>	<b>2</b>
<b>1. eCTD Format .....</b>	<b>2</b>
a. MR/DC Procedures .....	2
b. National Procedures .....	2
c. ASMF Guidance .....	2
d. Recommendations.....	2
<b>2. How to submit submission via CESP?.....</b>	<b>3</b>
a. CESP Registration .....	3
b. Methods of sending the files .....	4
c. ASMF : Operating procedure.....	4
d. New Delivery File.....	5
<b>3. Be careful .....</b>	<b>5</b>
a. UUID (Universal Unique Identifier) .....	5
b. Submission is not valid .....	6

## NOTICE TO ASMF HOLDERS FOR ELECTRONIC SUBMISSION OF ASMF TO ANSM VIA CESP

### 1. eCTD Format

**In all cases, an electronic filing in eCTD format is mandatory.**

#### a. MR/DC Procedures

From **J**anuary 1<sup>st</sup>, 2018, as part of the transition to eCTD format for all European procedures, the Active Substance Master File (ASMF) used for the Marketing Authorisation Applications (MAA) of these European procedures should also be submitted in eCTD format.

#### b. National Procedures

An ASMF used for a national MMA can also be used for marketing authorisations in centralised or decentralised or mutual recognition procedures. As a result, any submission of an ASMF should be structured in eCTD format.

#### c. ASMF Guidance

All information related to the implementation of the eCTD format for ASMF is available at the following link:

<http://esubmission.ema.europa.eu/eASMF/ASMF%20eCTD%20Guideline%20v2.0.pdf>

#### d. Recommendations

##### i. **ASMF already available in eCTD format**

In order to allow and optimize the management of the ASMF lifecycle, ANSM recommends to applicants to provide all previous eCTD submissions.

For easier processing, ANSM advises to group the historical eCTD submissions with the new submission in single upload to CESP, it is suggested to create two subfolders one for "Historical Submissions" and one for "New Filing"

##### ii. **Paper or NeeS lifecycle**

In order to allow and optimize the management of the ASMF lifecycle, ANSM recommends to applicants to generate a Baseline submission. This Baseline submission must include all the data

approved by ANSM or any other European Member State during the last centralised or decentralised or mutual recognition procedures: this Baseline submission must correspond to a consolidated version of the ASMF.

## **2. How to submit submission via CESP?**

The CESP's registration procedure as well as the procedures for sending the submissions are detailed on the CESP website.

### **a. CESP Registration**

To register please complete the registration form available by selecting the "Register" option on the registration page, once approved your account will be set up and an automated email will be sent to your email account with connection details (<http://cesp.hma.eu>).

Each company must have a least one company administrator which will be setup during the registration process by the CESP support team. Once the company registration has been approved, the nominated company administrator will receive connection details to their registered email address. The company administrator is then responsible for setting up additional companies/users on the system as required. There is no charge to use the system, if you wish to participate please complete the registration process.

#### **Company Use**

To use the Portal: The company must first complete the CESP Portal Registration Form and nominate one or more "Company Administrator/s". Upon receipt of a signed letter, the CESP Group will verify the company administrators and on successful verification grant the company administrator access and administration rights over the designated company.

The company administrator is from that time forward responsible for the setup and administration of standard users on the portal. The CESP group will not setup or administrate users on the system with the exception of Company Administrators.

#### **Non Commercial Use**

To use the Portal: Non Commercial Named Users must first complete the CESP Portal Registration Form. The CESP Group will request a signed letter and upon receipt of this letter will verify the named user. Upon successful verification grant the named user access to the Portal for their own personal use.

The named user from that time forward will act as an individual Non Commercial User on the Portal and will only use the Portal for their own personal user for Non Commercial Submissions, Clinical Trials or Research Cases. The named user will not be allowed to merge or join their account to any Company account. In the case that this become a requirement for a Non Commercial Named User their account will be revoked and a new company user account must be requested from the relevant Company Administrator.

Please be advised that unprocessed registrations will be deleted if not processed within three months, this applies to all registration types within the system. New Non Commercial Named User registrations will only be processed when the requested letter is completed and uploaded in PDF

format to the CESP Portal. New Company registrations will only be processed when the requested information is completed and uploaded on letter headed paper in PDF format to the CESP Portal. The Portal may contain links to other sites, mainly those of other regulatory agencies and other third parties. The CESP Group is not responsible for the privacy practices within any of these other sites. The CESP Group encourages the authorised users to be aware of this when using these links to leave the Portal and to read the privacy statements on other websites which collect personally identifiable information. This privacy statement applies solely to information collected on the Portal.

#### b. Methods of sending the files

To transmit a submission via CESP, registered users must log in with their access code to:

- Complete online and save the XML delivery file;
- Send the submission with the submission form.

#### c. ASMF : Operating procedure

**See below the operating procedure for ANSM's information.**

Submissions must be submitted via CESP in eCTD format with the following information:

- **Company** : Active Substance Master holder
- **Regulatory activity** : Active Substance Master File
- **Procedurenumber** : ANSM's Number of Active Substance Master File (if know)
- **Comment** : European's Number of Active Substance Master File
- **Subactivity** : NA / Initial / Answer to questions
- **Proceduretypeid** : DCP / MRP / National
- **Submissiontype ID** : eCTD
- **NationalagencyID** : NA
- **Nationalcaseno** : NA
- **Productdetailsfilename** : Substance Active
- **Emails** : Contact

**Warning:** For submissions to ANSM, make sure « Human Medicines » is selected.

It's requested to specify in the Cover Letter of Module 1 that the submission sent to ANSM via CESP is submitted only through the above mentioned electronic process.

#### d. New Delivery File

The applicant must:

- Select the transmission mode by which it will transfer the file.
- Complete the login details (« username, password... »)
- Select :
  - First: your Zip file on your local drive
  - Second: the XML File

The transfer progress of these two files is displayed at the bottom of the window.

- Select « log out » to exit.

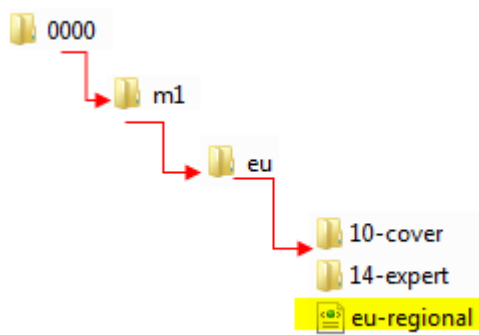
An email confirming that the file is upload to the CESP is automatically forwarded to the sender.

### 3. *Be careful*

#### a. UUID (Universal Unique Identifier)

This unique Key identifies a procedure and should not be modified. This identifier is generated when a first submission of a procedure is created in the dedicated software.

The UUID will be displayed in several documents, including “eu-regional”:



## EU Module 1

DTD version 3.0.1

### Envelope for EMA

Identifier: d714ca40-1890-11e6-8fb8-0002a5d5c51b  
Submission: Type: Active Substance Master File

If you change your eCTD software, make sure you do check the UUID's concordance with the previous submissions.

Should the new software provide new UUIDs, we recommend to contact your software editor to fix this behavior.

**b. Submission is not valid**

There are several types of non compliance:

- ✓ Wrong structure of the electronic submission
- ✓ Invalid report

(cf :[http://www.hma.eu/fileadmin/dateien/Human Medicines/CMD h\\_/procedural\\_guidance/e\\_Submissions/CMDh\\_084\\_2008\\_clean.pdf](http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/e_Submissions/CMDh_084_2008_clean.pdf) )

If the submission isn't valid, an email will be sent by the ANSM: the sequence will have to be modified and sent again with the comment "Cancel and Replace the previous CESP .....xml"