October 2020

CMDh/3017/2013, Rev.3

**EU ASMF number request form**

 ***(< FROM ACTIVE SUBSTANCE MASTER FILE HOLDER ON HEADED PAPER>)***

From:<ASMF Holder name>

 <ASMF Holder address>

 <ASMF Holder <Post code> Town>

 <ASMF Holder Country>

To: <Name and Address of Competent Authority>

<Date>

Subject: Submission of request for **EU/ASMF/XXXXX[[1]](#footnote-1) number**

Dear Sir or Madam:

This Active Substance Master File will be submitted in relation to the following procedure:

|  |  |
| --- | --- |
| Medicinal productAllocated procedure number(Intended) Submission date of the marketing authorisation application (if known) | <Name of the medicinal product><EMEA/H/C/product reference number/procedure reference> <RMS/H/product reference number/procedure reference><DD/MM/YYYY> |

 **Mandatory administrative details for obtaining an EU ASMF number**

This request form should be used for an Active Substance Master File to be assessed as part of a new marketing authorisation through the Centralised or Decentralised procedure only, where a full assessment report will be prepared by a Competent Authority.

In line with the current scope of the ASMF work sharing procedure, a ‘new ASMF’ is defined as an ASMF that has not been previously assessed by a Competent Authority as part of a Centralised, Decentralised or Mutual Recognition new marketing authorisation or variation application - it is accepted that a ‘new ASMF’ may have been assessed as part of a national application.

Where the ASMF holder already holds an ASMF that has been assigned an EU/ASMF reference number and wishes to register another ASMF for the same active substance, e.g. a substantially different route of synthesis (see Annex 1 Assignment of a new ASMF Reference Number), this should also be clearly stated in the Additional information field.

|  |  |
| --- | --- |
| ASMF Holder and address | <ASMF Holder name and address> |
| Active substance name | <INN, common name> (+ salt/water content when applicable) |
| Active Substance Manufacturer´s internal drug substance/API code (if applicable) |  |
| ASMF Holder’s version (as included in the future submission) | Applicants part:Version [version number]/date (dd-mm-yyyy)Restricted part: Version [version number]/date (dd-mm-yyyy) |
| Has this ASMF already been assessed?  | Yes / No **[[2]](#footnote-2)** |
| If yes, please indicate the type of procedure (national or European Procedure (CP, DCP, MRP)) |  |

|  |  |
| --- | --- |
| Additional information (as applicable, e.g. different route of synthesis, particle size distribution) **[[3]](#footnote-3)** |  |

[ ]  I hereby declare that an EU ASMF number under ASMF worksharing procedure has not been requested neither from EMA nor from National Competent Authority for this ASMF dossier[[4]](#footnote-4)

Yours faithfully,

<Signature of authorised contact person>

<Name, address and position in company>

1. EU/ASMF/XXXXX reference number is allocated from the CTS ASMF assessment report repository by the Competent Authority/EMA [↑](#footnote-ref-1)
2. Strike-through which is not applicable. [↑](#footnote-ref-2)
3. May warrant issue of a new EU/ASMF number. [↑](#footnote-ref-3)
4. Condition necessary for the eligibility of the ASMF to receive an EU ASMF number [↑](#footnote-ref-4)