Active Substance Master File (ASMF) worksharing procedure

The EU/ASMF repository number

Initial ASMF submissions

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The EU/ASMF Repository Number

- **The EU/ASMF Repository Number** is a **centralised, version specific ASMF identification number**, assigned by the ASMF Assessment Report Repository, that will allow Competent Authorities to track where the same version of the ASMF is used within Europe

EU/ASMF/XXXXX/YYYY

- where
  - EU/ASMF/XXXXX is the **EU/ASMF Reference Number**, which is sequentially assigned to the ASMF in order of request, independently of the ASMF holder and active substance
  - YYYY is the **Assessment Report Number**, which is sequentially assigned to the version of the ASMF. It applies to the entire version of the ASMF submitted in the MAA / MAV application, regardless of whether the AP and/or RP have been updated – also includes subsequent ASMF updates, provided in response to deficiency questions
  - Each version of the ASMF that has been accepted for use in a medicinal product will have a corresponding assessment report

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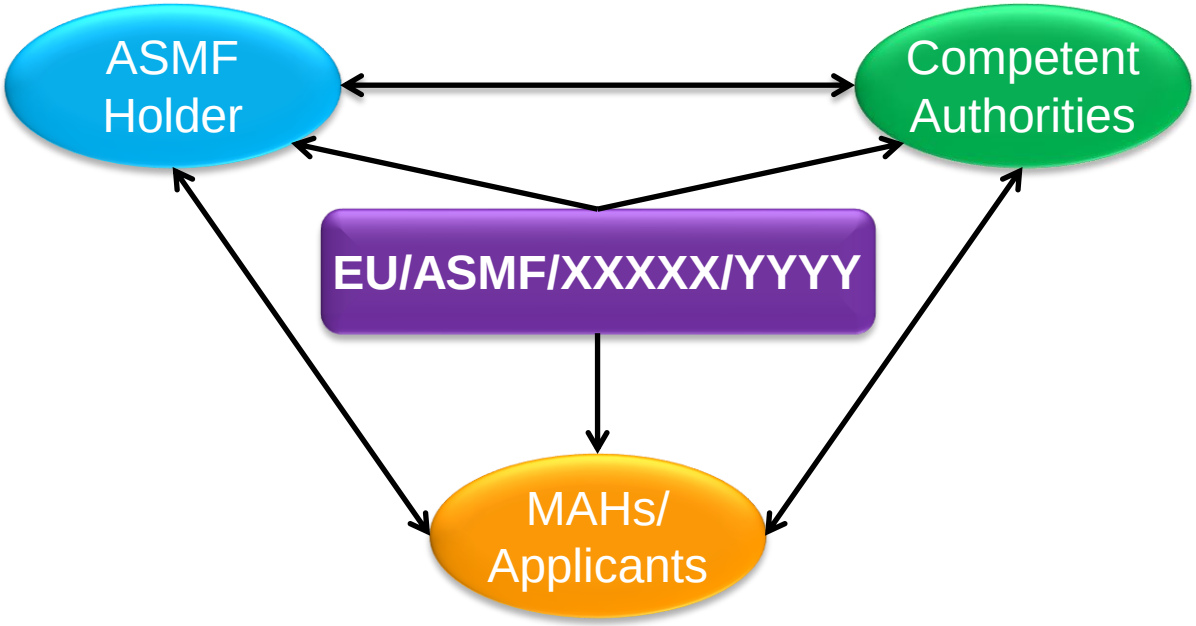
What do I do with the EU/ASMF Repository Number?

The EU/ASMF Repository Number should be used in ALL correspondence relating to the version of the worksharing ASMF, including the ID in eCTD/NeeS sequences



Note:
Competent Authorities may issue additional national ASMF reference numbers for their own national administrative reasons

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How do I get an EU/ASMF Reference Number?

- To obtain a EU/ASMF/XXXXX Reference Number, the ASMF holder should submit a completed **EU/ASMF Reference Number request form** to the RMS/EMA of the associated DCP/CAP procedure

- List of Contact Points for requesting an EU/ASMF/XXXXX Reference Number will be published on the webpage for the CMD Joint Working Group on ASMF procedures

National contact points providing the EU/ASMF Reference Number

COUNTRY	E-MAIL
EUROPEAN MEDICINES AGENCY	PA-BUS@ema.europa.eu
AUSTRIA	rms@ages.at
BELGIUM	asmfnumber@fagg-afmps.be
BULGARIA	ASMF@bda.bg
CROATIA	ASMF@halmed.hr
CYPRUS	gtheophanous@phs.moh.gov.cy
CZECH REPUBLIC - human	ASMF@sukl.cz
CZECH REPUBLIC - veterinary	suchy@uskvbl.cz
DENMARK	licensing@dkma.dk
ESTONIA	mrp@ravmiamet.ee
FINLAND	mrp@fimea.fi
FRANCE - human	DMF-ASMF@ansm.sante.fr Beatrice.blaisot@ansm.sante.fr Maryam.mehmandoust@ansm.sante.fr
FRANCE - veterinary	enreg@anses.fr
GERMANY (BfArM) - human	Petra.Wagner@bfarm.de
GeRMANY (BVL) - veterinary	asmf@bvl.bund.de
GREECE	vviolakis@eof.gr pgalatoula@eof.gr
HUNGARY	mrp-dcp-new-rms@ogyei.gov.hu
ICELAND	Ulrike.Muus@lyfjastofnun.is
IRELAND	submissions@hpra.ie
ITALY	f.cavallaro@aifa.gov.it
LATVIA	ASMF@zva.gov.lv
LIECHTENSTEIN	rms@ages.at
LITHUANIA	IlonaAlisauskiene@vvkt.lt
LUXEMBOURG	Jacqueline.genoux-hames@ms.etat.lu
MALTA	mrp-dcp.adm@gov.mt
THE NETHERLANDS	_Dienstpostbuscmdh@cbg-meb.nl
NORWAY	pk@legemiddelverket.no
POLAND	joanna.bokus@urpl.gov.pl
PORTUGAL	dam@infarmed.pt
ROMANIA	mrp-dcp.info@anm.ro
SLOVAK REPUBLIC	maria.pollakova@sukl.sk
SLOVENIA	asmf@jazmp.si
SPAIN	asmf_aemps@aemps.es
SWEDEN	RIC@mpa.se
UNITED KINGDOM - human	Mr-dcprocedures@mhra.gsi.gov.uk
UNITED KINGDOM - veterinary	i.jenkins@vmd.defra.gsi.gov.uk

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EU/ASMF Reference Number request form - Template

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] **number**

Dear Sir or Madam:

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

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

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

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>
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)

Additional information (as applicable, e.g. different route of synthesis, particle size distribution) [2]	

[2] May warrant issue of a new EU/ASMF number.

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EU/ASMF Reference Number request form - Example

ASMF-Holdings Ltd
100 High Street, London, UK
www.ASMF-holdings-ltd.com

EU ASMF number request form

From: ASMF-Holdings Ltd
100 High Street
London, UK

To: Medicines and Healthcare products Regulatory Agency
151 Buckingham Palace Road.
Victoria,
London,
SW1W 9SZ

1 Oct 2013

Subject: Submission of request for **EU/ASMF/XXXXX[1] number**

Dear Sir or Madam:

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

Medicinal product	Aceopril 2.5mg, 5mg, 7.5mg, 10mg, 15mg and 20mg film-coated tablets
Allocated procedure number	UK/H/99999/01-06/DC
(Intended) Submission date of the marketing authorisation application (if known)	12/October 2013

Yours faithfully,

Dr RA Smith
Head of Regulatory Affairs
ASMF-holdings Ltd

[1] EU/ASMF/XXXXX reference number is allocated from the CTS ASMF assessment report repository by the Competent Authority/EMA

ASMF-Holdings Ltd
100 High Street, London, UK
www.ASMF-holdings-ltd.com

Mandatory administrative details for obtaining an EU ASMF number

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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-Holdings Ltd 100 High Street London, UK
Active substance name	Aceopril
Active Substance Manufacturer's internal drug substance/API code (if applicable)	ACE
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)

Additional information (as applicable, e.g. different route of synthesis, particle size distribution) [2]	N/A

[2] May warrant issue of a new EU/ASMF number.

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EU/ASMF Reference Number request form - Example

ASMF-Holdings Ltd
100 High Street, London, UK
www.ASMF-holdings-ltd.com

ASMF holder's headed paper

EU ASMF number request form

From: ASMF-Holdings Ltd
100 High Street
London, UK

ASMF holder's address

Name & address of Competent Authority

To: Medicines and Healthcare products Regulatory Agency
151 Buckingham Palace Road.
Victoria,
London,
SW1W 9SZ

1 Oct 2013

Date

Subject: Submission of request for **EU/ASMF/XXXXX[1] number**

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EU/ASMF Reference Number request form - Example

Subject: Submission of request for **EU/ASMF/XXXXX[1] number**

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Allocated procedure number	UK/H/99999/01-06/DC
(Intended) Submission date of the marketing authorisation application (if known)	12/October 2013

Yours faithfully,

Dr RA Smith
Head of Regulatory Affairs
ASMF-holdings Ltd

Name of the medicinal product

DCP/CAP procedure number

Intended submission date for the medicinal product, if known

Signature of the authorised contact person

Name, address of position of the authorised contact person for the ASMF holder

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EU/ASMF Reference Number request form - Example

Mandatory administrative details for obtaining an EU ASMF number

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ASMF Holder and address	<ASMF Holder name>
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]
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]	

ASMF holder's name & address

Active substance name & Active Substance Manufacturer's API code

Version numbers of Applicant's and Restricted Parts of the ASMF

Include whether ASMF has been assessed before

Additional information, e.g. synthesis route, grade, etc

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Submitting the EU/ASMF Reference Number request form

- The EU/ASMF Reference Number request form should be submitted **no more than 2 weeks** before the intended ASMF submission date

- The Competent Authorities will issue the EU/ASMF/XXXXX reference number **within 10 days** of the request

- An EU/ASMF reference number **will not be issued without an associated DCP/CAP number** to prevent ASMF holders reserving reference numbers '*en bloc*'
  - ASMF holders should discuss intended MA submission dates with the MA applicants and use the procedure with the earliest submission date in the request form.

The Assessment Report Number & the EU/ASMF Repository Number

- At ASMF submission, the ASMF-AR repository will assign the 0001 Assessment Report Number to the initial version of the ASMF

  e.g.

  EU/ASMF/99999/0001
  Applicant's Part: ACE/AP/01/2010-03-28
  Restricted Part: ACE/RP/01/2010-03-28

- Therefore, the EU/ASMF Repository Number identifies the version of the ASMF

- Once the EU/ASMF repository number has been assigned to the version of the ASMF, it can then be communicated to all Applicants
  - A change to the submission date of the procedure used to obtain the EU/ASMF reference number will not impact other procedures

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Creating an EU/ASMF repository record for the ASMF

- The Competent Authority will use the information in the EU/ASMF reference request form to create a record for the ASMF in the ASMF assessment report repository

- The information provided in the EU/ASMF reference request form is sufficient to identify duplicate records for the same ASMF, therefore, it is important that all fields are completed by the ASMF holder

When can I use the same EU/ASMF reference number?

- The following list of non-exhaustive examples will require a new EU/ASMF/XXXXX reference number*:
  - Different active substance
  - Different set of specification (except when finished product specific):
    - Different salt of an active substance
    - Different complex of an active substance
    - Different solvate or hydrate form of an active substance
    - Different isomer or mixture of isomers of an active substance
    - Opposite enantiomer of an active substance
    - Racemate of an optically pure active substance
  - Introduction of a new substantially different route of synthesis
  - The active substance is used for both human and veterinary medicinal products and is controlled to different quality standards

* As jointly agreed by QWP and CMD

When can I use the same EU/ASMF reference number?

- The same EU/ASMF/XXXXX reference number can be used in the following non-exhaustive examples*:
  - Slightly different routes of synthesis which do not result in changes to important quality characteristics of the active substance, such as the qualitative and/or quantitative impurity profile requiring qualification or physico-chemical properties impacting on bioavailability
  - Different manufacturing sites using the same or similar routes of synthesis
  - Other changes which do not result in a changes to important quality characteristics of the active substance, such as qualitative and/or quantitative impurity profile requiring qualification or physico-chemical properties impacting on bioavailability
  - Transfer of ownership of an existing ASMF from one ASMF holder to another
  - Change in the name and/or address of the existing ASMF holder

- If in doubt, the ASMF holder should consult the appropriate Competent Authority

* As jointly agreed by QWP and CMD

End of Presentation