



Annex 1

How to request missing or additional terms in eAF drop-down lists

1. Missing "Substances" and "Excipients"

Please email your request to eAF@ema.europa.eu with subject heading "eAF Term request - (H or Vet) Substance" and specify the following in the body of the email:

Mandatory information:

- Human use, veterinary use or both (Human and veterinary use)
- Substance Name
- Substance Class (see published controlled vocabularies from Art.57 [here](#)) - if Human substance
- Bibliographic Source (e.g. EU pharmacopeia)

Optional information:

- CAS number
- Molecular formula
- CBD (chemical/biological description) of the Substance

A provisional term may be added to the list within 5 working days; however, please note that there is a possibility that the term might not be approved in future.

2. Missing or additional terms for other drop-down lists

Please email your request to eAF@ema.europa.eu with the information contained below (*a provisional term may be added to the relevant list within 5 working days but the term might not be approved in future*):

a) Missing "Country"

Email eAF@ema.europa.eu with subject heading "eAF Term request - Country" and specify the following in the body of the email:

- proposed name
- justification: explain why none of the existing terms apply, you should explain clearly what the business requirements are or make reference to any legal grounds.

b) Missing "Pharmaceutical Form"

Email eAF@ema.europa.eu with subject heading "eAF Term request - Pharmaceutical Form" and specify the following in the body of the email:

- addition, deletion or modification of standard term
- Human use, veterinary use or both (Human and veterinary use)
- proposed term name
- proposed term definition
- justification: 1) list other similar existing terms and explain why none of the existing terms apply, 2) provide a short extract of marketing application file that supports why your request is needed
- Attach the proposed SPC for your product.
- Attach a completed EDQM request form which is available [here](#)

c) Missing "Route of Administration"

Email eAF@ema.europa.eu with subject heading "eAF Term request - Route of administration" and specify the following in the body of the email:

- addition, deletion or modification of standard term
- Human use, veterinary use or both (Human and veterinary use)
- proposed term name
- proposed term description
- justification: 1) list other similar existing terms and explain why none of the existing terms apply, 2) provide a short extract of marketing application file that supports why your request is needed
- Attach the proposed SPC for your product.
- Attach a completed EDQM request form which is available [here](#)

d) Missing "Quantity"

Email eAF@ema.europa.eu with subject heading "eAF Term request - Quantity" and specify the following in the body of the email:

- proposed name
- quantity operator symbol
- Justification: explain why none of the existing terms apply, you should explain clearly what the business requirements or scientific grounds are.

e) Missing "Unit"

Email eAF@ema.europa.eu with subject heading "eAF Term request - Unit" and specify the following in the body of the email:

- proposed name
- Unit symbol
- Justification: explain why none of the existing terms apply, you should explain clearly what the business requirements or scientific grounds are.

f) Missing "Container"

Email eAF@ema.europa.eu with subject heading "eAF Term request - Container" and specify the following in the body of the email:

- addition, deletion or modification of standard term
- Human use, veterinary use or both (Human and veterinary use)
- proposed term name
- proposed term definition
- justification: 1) list other similar existing terms and explain why none of the existing terms apply, 2) provide a short extract of marketing application file that supports why your request is needed
- Attach the proposed SPC for your product.
- Attach a completed EDQM request form which is available [here](#)

g) Missing "Species (Vet eAF 2.6.2) / Target Species (Vet eAF 2.1.4)"

Email eAF@ema.europa.eu with subject heading "eAF Term request - Species" and specify the following in the body of the email:

- proposed name
- targetsp:gender - identify the sex of the target animal as to whether male, female or both.
- targetsp:age-range - identify possible ages/stages of the target animal as to whether egg, young, adult, etc.
- targetsp:reproductive-status - identify whether the target animal is intact or neutered.
- targetsp:physiological-status - identify any special physiological condition of the target animal. Examples are pregnant, lactating, etc.
- targetsp:production-type - identify the types of production of the target animals as to whether milk, meat, egg, etc.
- targetsp:size - qualify the sizes of the target animals from very small to very large.
- targetsp:is-VICH-term - identify whether target animal has an VICH associated with it.
- targetsp:is-MRL-term - identify whether target animal has an MRL associated with it.
- targetsp:superior-hierarchy-level - identify the target animal's superior hierarchy level (e.g. BOVINAE).
- targetsp:is-species - identifies the target animal's species (e.g. cattle).
- Justification: explain why none of the existing terms apply, explain clearly what the business requirements or scientific grounds are.

h) Missing "Animal Species"

Email eAF@ema.europa.eu with subject heading "eAF Term request - Animal Species" and specify the following in the body of the email:

- proposed name
- Justification: explain why none of the existing terms apply. There should be a new amendment to Commission Regulation (EC) No 37/2010 prior to any changes to this Controlled Term List. You should explain clearly what the legal grounds are or make reference to the new legislation.
- Attach electronic versions of the applicable legislation or any document that supports the grounds to the Change Request.

i) Missing "Other Provisions"

Email eAF@ema.europa.eu with subject heading "Other provisions request for eAF" and specify the following in the body of the email:

- proposed name
- justification: explain why none of the existing terms apply. There should be a new amendment to Commission Regulation (EC) No 37/2010 prior to any changes to this Controlled Term List. You should explain clearly what the legal grounds are or make reference to the new legislation.
- Attach electronic versions of the applicable legislation or any document that supports the grounds to the Change Request.

j) Missing "Target Tissue"

Email eAF@ema.europa.eu with subject heading "eAF Term request - Target Tissue" and specify the following in the body of the email:

- proposed name
- tissue type - identify whether the tissue is connected with centralised establishment of Maximum Residue Limits (MRL) or for foodstuff of animal origin (edible tissues).
- justification: explain why none of the existing terms apply, you should explain clearly what the business/scientific grounds are or make reference to the new legislation.

k) Missing "Proposed Storage Conditions / Proposed Storage Conditions After First Opening"

Email eAF@ema.europa.eu with subject heading "eAF Term request - Proposed Storage Conditions" and specify the following in the body of the email:

- proposed name
- justification: explain why none of the existing terms apply, you should explain clearly what the scientific grounds are or make reference to any business requirements.