

EU and National Specific Controlled Terms

The Controlled Terms in EUTCT can be for use EU wide or limited to one or more Member States. A term that is for use EU wide is referred to as an “EU Controlled Term”, while one that should only be used in a limited number of Member States is referred to as a “National Specific Controlled Term”.

It is envisaged that the EU Controlled Terms meet some or all of the following criteria:

- Approved by an official list owner (e.g. EDQM)
- Applicable to a medicinal product that is marketable in all EEA Member States (Centrally Authorised Medicinal Product).
- Do not have an equivalent National Specific Controlled Term
- Covers Clinical Trials terminology that is not covered by other list owners (EU provisional if not otherwise approved)

It is envisaged that the National Specific Controlled Terms meet some or all of the following criteria:

- Their use can be demonstrated even if for legacy data (“In use” means in active historical records, electronically or otherwise, that are required for either Clinical Trials, Marketing Authorisations or Pharmacovigilance purposes)
- Fall into a domain not covered by the List owner, for example homeopathic products.
- Are terms used in national specific procedures
- Are combinations of EU Controlled Terms to assist NCAs with technical implementation issues in current IT systems.
- Do not have an equivalent EU Controlled Term

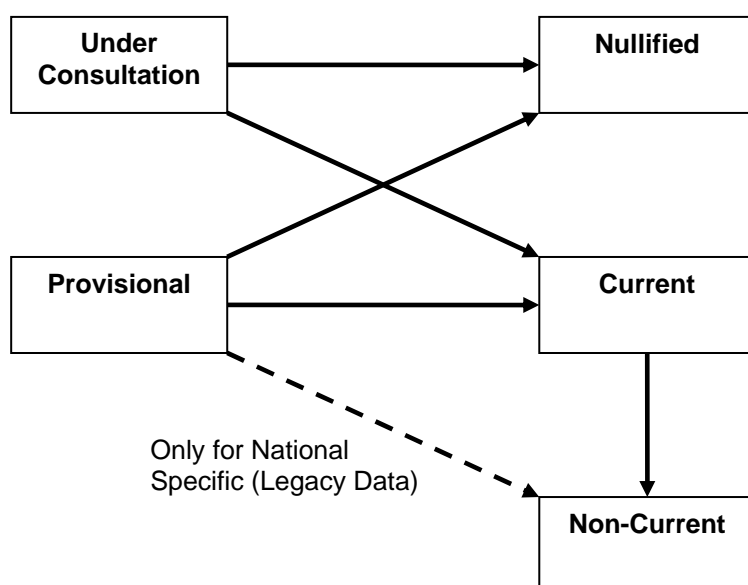
Controlled Term Status

The Controlled Terms in EUTCT have a number of statuses associated with them that identify how the terms should be used.

The following table describes the uses in the scope of an EU and National Specific Controlled Terms.

Status	EU Controlled Term	National Specific Controlled Term
Under Consultation	The Controlled Term is entered into the EUTCT system prior to the initial sign-off of the Controlled Term List and should not be used for anything other than the consultation process.	Not Applicable
Provisional	The Controlled Term is entered into the EUTCT system after the initial sign-off of the Controlled Term List, but prior to its approval.	
Nullified	A Provisional Controlled Term has been published by mistake and needs to be removed.	
Current	The Controlled Term is approved for use in new applications/records.	The Controlled Term is approved for use in new applications/records within the identified Member States (covers Current National data)
Non-Current	The Controlled Term is not approved for use in new applications/records, but is included to cover legacy data.	The Controlled Term is not approved for use in new applications/records, but is included to cover legacy data.

The following diagram shows the valid changes in the status of a Controlled Term.



Controlled Term Viewing

The viewing of the Controlled Terms changes depending on the user's role. The following table identifies which Controlled Terms a user with a given role can see.

Status/Role	Guest	Licensed	Change Requestor	Secretariat
Under Consultation	➡	➡	➡	➡
Provisional	➡	➡	➡	➡
Nullified	➡	➡	➡	➡
Current	➡	➡	➡	➡
Non-Current	➡	➡	➡	➡

Languages

The Controlled Terms are requested and approved in English and optionally in the national language of the Change Requestor.

Once the Controlled Term has been approved in English it will be included in EUTCT with a status of Current and the additional language with a status of Provisional. In the future there will be a process whereby the Controlled Terms will be translated into all EEA languages and be approved so that the status of the translations becomes Current.