**Change request form for EDQM Standard Terms**

**1. Action requested**

|  |  |  |
| --- | --- | --- |
| [ ]  Add new term | [ ]  Modify existing term | [ ]  Deprecate existing term |

**2. Term class**

|  |  |
| --- | --- |
| [ ]  Pharmaceutical dose form | [ ]  Route/Method of administration |
| [ ]  Combined pharmaceutical dose form | [ ]  Container/Closure/Administration device |
| [ ]  Combined term | [ ]  Unit of presentation |
| [ ]  Combination pack | [ ]  Patient-friendly term |

**3. Term domain**

|  |  |
| --- | --- |
| [ ]  Human and veterinary | [ ]  Veterinary only |

**4. Proposed new term** *(include details of any existing term to be revised/deprecated, if applicable)*

*Click here to enter text*

 **5. Your reference** *(optional identifier for the term/request, if needed to track requests)*

*Click here to enter text*

 **6. Justification for change, including description of the product and a proposed definition**

***- Relevant Summary of Product Characteristics (SmPC) documents must be submitted with all requests***

*Click here to enter text*

 **7. Regulatory status**

Type of application (e.g. national/centralised procedure): *Click here to enter text*

Medicinal product(s) (name(s), active substance(s)): *Click here to enter text*

Crucial date (if applicable): *Click here to enter a date*

 **8. Details of regulatory authority submitting the request**

***- Only authorised national authorities, the EMA or the European Commission can submit change requests***

Name & e-mail address of contact person (telephone and postal address optional):

*Click here to enter text*

Member state (please specify)/EMA/EU Commission: *Click here to enter text*

Date of submission to EDQM: *Click here to enter a date*

Deadline for comments (if applicable): *Click here to enter a date*

**9. Additional information**

*Click here to enter text*