# Instructions for applicants for submitting the conventional dossier for medicinal products

These instructions refer to the submission of documentation in the paper form.

## 1. Marking of the documentation for a medicinal product

On the cover page of every filing folder or binder and on the first page after the cover page please provide a list with the following data:

- procedure number (for MRP, DCP and CP procedures)
- applicant
- type of procedure (i.e. granting of Marketing Authorisation)
- name of medicinal product
- INN or other usual product name (in case the INN does not exist)
- date of the documentation issue (i.e. February 2012/date of ASMF)
- documentation code (the documentation code issued by the applicant or manufacturer/code ASMF and the version number)
- dossier format (CTD)
- type and number of variation (i.e. IA 15) – *if applicable*
- part of documentation contained in the filing folder or binder (i.e. Module 3, ASMF open part, etc.). If a part of the documentation is contained in more folders or both folders and binders, it is necessary to indicate which part of the documentation with associated sections is contained in each single folder or binder.
- Examples:
  Module 3.1 – 3.2.S.7.3.
  Module 3.2.P. if a whole section for a medicinal product is contained in one technical unit
  Module 3.2.P.1 – 3.2.P.4.
  Module 3.2.P.5.1 – 3.2.P.5.2

Data should be written in Croatian or English.

On the folder ridge, the following data should be written in capital letters, as shown in the following example:

- „Documentation for a medicinal product“
- „Agency for Medicinal Products and Medical Devices (HALMED)“
- year of submission
- applicant
- product name
- part of documentation with associated sections contained in each folder or binder

*DOCUMENTATION FOR MEDICINAL PRODUCT*

*HALMED*

*2012*

*APPLICANT*

*PRODUCT NAME*

*MODULE 3.2.P.1 – 3.2.P.7.*

**2. Documentation equipment**

The Agency is committed to the long-term documentation storage and therefore filing folders and binders should be equipped accordingly. To this end, the Agency suggests to avoid the use of metal clamps and other metal fasteners, elastic rubbers and plastic inserting binders.

We also suggest using folders in a box (instead of a self-standing folder) and the use of the mechanism with four arms instead of the mechanism with two arms.

**3. The submission of the documentation in the arranged state**

Filing folders and binders should be submitted in the arranged state, which means that documents are inserted in a filing folder or binder in a way that there are no fly end pages that could fall off, that documents are inserted according to the CTD documentation format, and that filing folders and binders are properly marked.

The adequate number of documents should be inserted into filing folders and the latter should not be overcrowded, so that they can be handled accordingly.

Optical media (CD, DVD) should be submitted in a hard plastic cover alongside the documentation and not inside the documentation folder.

We suggest that the documentation of smaller volume (up to 70 pages) be submitted in card binders instead of the plastic ones, with obligate page binding.

**4. Additional guideline concerning internal digitalisation of submitted documentation on medicinal products**

In order to prepare the submitted documentation for digitalisation more quickly, we ask applicants who submit documentation in paper form, in addition to instructions under points 2 and 3, not to attach documents with clamps, fasteners and staples. Furthermore, please, do not use elastic rubber bands and plastic binders inside filing folders.

**Document submitted on optical media (CD)** should be delivered on separate CDs, as specified underneath. The type of document should be specified on the CD cover.

**First CD:** Working documents:
- Application form (eAF)
- Summary of Product Characteristics
- Package Leaflet
- Labelling
- Mock-up of outer and inner packaging of a medicinal product in Croatian language (if applicable)

**Second CD:** Modules 4 and 5