



Annex 2  
to item 6.8 of the Procedure for  
Conducting Expert Evaluation of Materials  
Pertinent to Medicinal Products Submitted for  
the State Registration (Re-Registration) and  
for Expert Evaluation of Materials about  
Introduction of Changes to Registration  
Documents during Validity Period of  
Registration Certificate

### Structure of Registration Dossier

Full registration dossier consists of four parts:

Part I. Summary of dossier

I A. Administrative data

Table of contents of registration dossier

Application form

Samples of the medicinal product (sample in final immediate (interior) and secondary (outer) packages. If not available – a sample in final immediate (inside) package without final labeling shall be submitted. In this case a sample in final immediate (inside) and secondary (outer) packages should be given additionally as soon as it is available. Further on, for approval of methods of quality control of the medicinal product the additional samples, reference substances with batch certificate, including date of production, shelf life and storage conditions, could be requested.

Quality certificate for three production batches of the medicinal product or one certificate for one produced batch with obligations to present certificates for two other batches as soon as they are available (any certificate shall be submitted for each declared manufacturing site).

I B. Summary of product characteristics, labeling and package leaflet/insert.

I B1 Summary of product characteristics.

I B2 Proposals for samples/mockups of packaging, labeling, package leaflet/insert.

I B3. Copy of summary of product characteristics already approved in applicant/manufacturer-country.

I C. Reports of independent experts.

I C 1 Expert report on chemical, pharmaceutical and biological documentation.

I C 2 Expert report on pharmaco-toxicological documentation.

I C 3 Expert report on clinical documentation.

Part II. Chemical, pharmaceutical and biological documentation.

Table of contents.

II A. Composition.

II A 1. Formula of the medicinal product.

II A 2. Container (short description).

II A 3 Clinical trial formula

II A 4 Development pharmaceuticals

II B. Method of preparation (flow-chart of technological process or draft of technological regulations)

II B 1 Manufacturing formula

II B 2 Manufacturing process

II B 3 Process validation

II C Control methods of starting materials\*

II C 1. Active substance\*

- II C 1.1. Specifications and standard tests\*
- II C 1.2. Scientific data\*
  - II C 1.2.1. Nomenclature\*
  - II C 1.2.2. Description\*
  - II C 1.2.3. Manufacture\*
  - II C 1.2.4. In-process control of quality\*
  - II C 1.2.5. Development chemistry\*
  - II C 1.2.6 Impurities\*
  - II C 1.2.7. Batch testing\*

\*Minimum of information to be given in Part II C1.

- II C 2. Auxiliary substances (excipients)
  - II C 2.1 Specifications and approved methods of quality control
  - II C 2.2 Scientific information
- II C 3. Packaging material (immediate/outer package)
  - II C 3.1 Specifications and approved methods of quality control
  - II C 3.2 Scientific information
- II D. Methods of quality control of intermediate products (if necessary)
- II E. Methods of quality control of the finished medicinal product
  - II E.1. Specifications and approved methods of quality control
    - II E 1.1. Specifications and approved methods of in-process control, specific standards
    - II E 1.2. Methods of quality control
      - II E 1.2.1. Methods for identification and quantitative expression of active substance (-s)
      - II E 1.2.2. Identification and expression of excipient (-s)
  - II E 2. Scientific information
    - II E 2.1 Validation of analytical methods and comments, standards (working standards)
    - II E 2.2. Batch analysis
- II F. Stability
  - II F 1. Methods of stability testing of active substance (-s)
  - II F 2. Methods of stability testing of finished medicinal product
- II G. Bioavailability/bioequivalence.  
Refer to appropriate sections of Part IV, if necessary

II H. Data related to the environment risk for products containing genetically modified organisms (GMO)

II Q. Other information

Part III. Pharmacological and toxicological documentation

Table of contents

- III A. Single dose toxicity and repeated dose toxicity
  - III A. 1. Single dose toxicity
  - III A 2. Repeated dose toxicity
- III B. Reproductive function (fertility and general performance of reproductive function)
- III C. Data on embryo toxicity and teratogeneity
- III D. Mutagenic potential
- III E. Carcinogenic potential
- III F Pharmacodynamics
  - III F.1. Pharmacodynamic effects with respect to proposed indications
  - III F.2. General pharmacodynamics
  - III F.3. Drug interactions
- III G. Pharmacokinetics
  - III G.1. Pharmacokinetics after a single dose



- III G.2. Pharmacokinetics after repeated administration
- III G.3. Distribution in intact (normal) and pregnant animals
- III G.4 Biotransformation
- III H. Local tolerance
- III Q. Other information (alergenicity data etc.)
- III R. Assessment of the environmental risk potential/ecotoxicity (not resulting from GMO)

Part IV. Clinical documentation

Table of contents

IV A. Clinical pharmacology

IV A.1. Pharmacodynamics

IV A.2. Pharmacokinetics

IV B. Clinical experience

IV B.1. Clinical trials

IV B.2. Post-registration experience (if available)

IV B.3. Published and unpublished experience

IV Q. Other information

If some parts of documentation are not included to the materials, the reason should be indicated in an appropriate place under corresponding (appropriate) heading.

For medicinal products of animal origin in Part II C.1. the following additional information should be presented:

- species, age and diet of animals used as raw stock;
- nature (category) of tissue taken as raw stock for production of medicinal product pertinent to its safety for prions;
- flow-chart of stock processing with indication of extragents, temperature regimen etc.;
- control tests of output raw stock including methods for detection of prions in finished product (if any).

Annex 2 is based on The Rules governing medicinal products in the European Union, v. 2B, Notice to Applicants, 1998.

*(Annex 2 amended by MoH Ukraine Orders  
as of 01.03.2006 № 95, 25.09.2008 № 543)*