Annex 5
to the Procedure for Conducting Expert Evaluation of Registration Materials Pertinent to Medicinal Products Submitted for the State Registration (Re-registration) and for Expert Evaluation of Materials about Introduction of Changes to Registration Materials during Validity Period of Registration Certificate
(item 4 of section IV)

Structure of Registration Dossier
(Format of Common Technical Document – CTD)

Full registration dossier consists of 5 modules:

Module 1: Administrative information

1.1 Table of contents.

1.2. Registration form (Annex 1 or Annex 2 or Annex 3 of the Procedure).

1.3. Summary of product characteristics, labelling and instructions for medical use:

1.3.1. Copy of summary of product characteristics/instructions for use of medicinal product (instructions for medical use) approved in the manufacturer's/applicant's country or complying with official information for use of medicinal product approved according to legislation of country of the applicant/manufacturer or country which regulatory authority follows high quality standards complying with WHO standards and/or according to results of clinical trials.

1.3.2. Labelling.

1.3.3. Instructions for medical use (hard or electronic copy).

1.3.4. Summary of product characteristics.

1.4. Information about the independent experts:

1.4.1. Information about the quality expert.

1.4.2. Information about the pre-clinical expert.

1.4.3. Information about clinical expert.

1.5 Specific requirements for different types of medicinal products.

1.5.1. Information for medicinal product with well-established medical use.

1.5.2. Information for generic, hybrid medicinal product or biosimilar.

1.6. Environmental risk assessment.

1.7. Information relating to exclusivity of medicinal products of limited use (orphan products).

1.8. Information relating to pharmacovigilance.

1.8.1. Pharmacovigilance system.

1.8.2. Risk management system*.

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* Risk management plan must be submitted in 2 years of implementation of Procedure. Until the specified term, the Risk management plan shall be submitted, if available.

Module 2: Common technical document summaries

2.1. Table of contents of Modules 2 – 5.

2.2. Introduction.

2.3. Quality overall summary.

2.4. Pre-clinical overview.

2.5. Clinical overview.

2.6. Pre-clinical summary.

2.6.1. Pharmacology written summary.

2.6.2. Pharmacology tabulated summary.

2.6.3. Pharmacokinetics written summary.

2.6.4. Pharmacokinetics tabulated summary.

2.6.5. Toxicology written summary.

2.6.6. Toxicology tabulated summary.

2.7. Clinical summary:

2.7.1. Summary of biopharmaceutical studies and associated analytical methods.

2.7.2. Summary of clinical pharmacology studies.

2.7.3. Summary of clinical efficacy.

2.7.4. Summary of clinical safety.

2.7.5. Literature references.

2.7.6 Synopses of individual studies.

Module 3: Quality. Chemical, pharmaceutical and biological information for medicinal products containing chemical and/or biological active substances

3.1. Table of contents.

3.2. Basic data.

3.2.S. Active pharmaceutical ingredient (API)*.

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If there is a master file for API, only the materials related to open part of master file shall be submitted for expert evaluation.

3.2.S.1.General information:

3.2.S.1.1. Nomenclature.

3.2.S.1.2. Structure.

3.2.S.1.3.General properties.

3.2.S.2. Manufacture of API:

3.2.S.2.1. Manufacturer(s).

3.2.S.2.2. Description of manufacturing process and process controls.

3.2.S.2.3. Control of materials.

3.2.S.2.4. Controls of critical steps and intermediates.

3.2.S.2.5. Process validation and/or evaluation.

3.2.S.2.6. Manufacturing process development.

3.2.S.3. Characterization of API.

3.2.S.3.1. Elucidation of structure and other characteristics.

3.2.S.3.2. Impurities.

3.2.S.4. Control of API.

3.2.S.4.1. Specification.

3.2.S.4.2. Analytical procedures.

3.2.S.4.3. Validation of analytical procedures.

3.2.S.4.4. Batch analyses.

3.2.S.4.5. Justification of specification.

3.2.S.5. Reference standards or materials.

3.2.S.6. Container/closure system.

3.2.S.7. Stability:

3.2.S.7.1. Stability summary and conclusions.

3.2.S.7.2. Post-approval stability protocol and stability commitment.

3.2.S.7.3. Stability data.

3.2.P. Finished medicinal product:

3.2.P.1. Description and composition of the medicinal product.

3.2.P.2. Pharmaceutical development:

3.2.P.2.1. Components of the medicinal product.

3.2.P.2.1.1. API.

3.2.P.2.1.2. Excipients.

3.2.P.2.2. Medicinal product.

3.2.P.2.2.1. Formulation development.

3.2.P.2.2.2. Overages.

3.2.P.2.2.3. Physicochemical and biological properties.

3.2.P.2.3. Manufacturing process development.

3.2.P.2.4. Container/closure system.

3.2.P.2.5. Microbiological attributes.

3.2.P.2.6. Compatibility.

3.2.P.3. Manufacture of the medicinal product:

3.2.P.3.1. Manufacturer(s).

3.2.P.3.2. Batch formula.

3.2.P.3.3. Description of manufacturing process and process controls.

3.2.P.3.4. Controls of critical steps and intermediates.

3.2.P.3.5. Process validation and/or evaluation.

3.2.P.4. Control of excipients:

3.2.P.4.1. Specifications.

3.2.P.4.2. Analytical procedures.

3.2.P.4.3. Validation of analytical procedures.

3.2.P.4.4. Justification of specifications.

3.2.P.4.5. Excipients of human or animal origin.

3.2.P.4.6. Novel excipients.

3.2.P.5. Control of medicinal product:

3.2.P.5.1. Specification(s).

3.2.P.5.2. Analytical procedures.

3.2.P.5.3. Validation of analytical procedures.

3.2.P.5.4. Batch analyses.

3.2.P.5.5. Characterisation of impurities.

3.2.P.5.6. Justification of specification(s).

3.2.P.6. Reference standards and materials.

3.2.P.7. Container/closure system.

3.2.P.8. Stability:

3.2.P.8.1. Stability summary and conclusion.

3.2.P.8.2. Post-approval stability protocol and stability commitment.

3.2.P.8.3. Stability data

Appendix:

Facilities and equipment.

Adventitious agents safety evaluation.

Novel excipients.

Additional information.

3.3. Literature references.

Module 4: Preclinical study reports

4.1. Format and presentation.

4.2. Table of contents: main principles and requirements.

4.2.1. Pharmacology:

4.2.2. Pharmacokinetics:

4.2.3. Toxicology:

4.3. Literature references.

Module 5: Clinical study reports

5.1. Format and presentation.

5.2. Table of contents: main principles and requirements.

5.2.1. Reports of biopharmaceutical studies.

5.2.2. Reports of studies pertinent to pharmacokinetics using human biomaterials.

5.2.3. Reports of human pharmacokinetic studies.

5.2.4. Reports of human pharmacodynamic studies

5.2.5. Reports of efficacy and safety studies.

5.2.5.1 Study reports of controlled clinical studies pertinent to the claimed indication.

5.2.5.2 Study reports of uncontrolled clinical studies, reports of analyses of data from more than one study and other clinical study reports.

5.2.6 Reports of post-marketing experience.

5.2.7 Case report forms and individual patient listings.

5.3 Literature References.

{Annex 5 in wording of MoH Ukraine Order №460 as of 23.07.2015}