

Annex 5

to the Procedure for Conducting Clinical Trials of Medicinal Products and Expert Evaluation of Materials Pertinent to Clinical Trials

COMPLETE DOSSIER OF INVESTIGATIONAL MEDICINAL PRODUCT

Complete dossier of Investigational Medicinal Product shall include information as follows:

1. Active substance (for medicinal products containing more than one active substance, full information shall be provided for each):

General information;

Manufacture;

Characteristics;

Control of active substance;

Standard samples or substances;

Packaging/closure system;

Stability.

2. Medicinal product:

Description and composition of medicinal product;

Pharmaceutical development;

Manufacture;

Control of excipients;

Control of medicinal product;

Standard samples and substances;

Packaging/closure system;

Stability.

3. Supplement:

Technical resources and equipment;
Foreign microorganisms safety assessment;
New excipients;
Solutions for reconstitution and solvents.

4. Pharmacology and toxicology pre-clinical data:

Pharmacodynamics;
Pharmacokinetics;
Toxicology.

5. Clinical trial data (if available):

Clinical pharmacology;
Clinical pharmacokinetics;
Human exposure;
Risk/benefit assessment.

6. If materials lack separate parts of documents, the reason should be stated in an appropriate place with related title.

7. Additional information shall be given for medicinal products of animal origin as follows:

Data about species, age, diet of animals the raw material has been produced from;
Data about nature (category) of tissue, the raw material is obtained from for manufacturing medicinal product in view of the risk of containing prions;
Technological scheme for processing raw material, specifying extragents, temperature regimen;
Methods for feedstock control, including methods for prion detection in the finished product (if necessary).

*{Annex in wording of MoH Order № 523 of
12.07.2012}*