Annex 19
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 the Validity Period of Registration Certificate
(item 2 of section V)

STRUCTURE
of instructions for medical use of medicinal product

Name of the medicinal product (Ukrainian)

Name of the medicinal product (English - optional for manufacturer)

Composition:

Active substance(s): (INN, if any, or abridged chemical name)

Composition per unit dosage form;

Excipients:

Pharmaceutical form.

Main physicochemical properties:

Pharmacotherapeutic group. ATC code.

Pharmacological properties/Immunological and biological properties

Pharmacodynamics.

Pharmacokinetics.

Clinical particulars.

Indications.

Contraindications.

Special warnings and precautions (if any).

Interaction with other medicinal products and other forms of interaction.

Peculiarities of use.

Pregnancy or lactation.

Effects on ability to drive and use machines.

Method of administration and doses.

Pediatric population.

Overdose.

Adverse reactions.

Shelf life.

Storage conditions.

Incompatibility (if any).

Packaging.

Dispensing category.

Manufacturer/applicant.

Location of manufacturer and address where his activity takes place/location of applicant and/or applicant’s representative.

Date of revision.

{Annex 19 in wording of MoH Ukraine Order №460 as of 23.07.2015}