|  |
| --- |
| Annex 18 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}