Annex 21
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 summary of product characteristics for medicinal product

1. Name of the medicinal product, strength, pharmaceutical form.

2. Qualitative and quantitative composition.

3. Pharmaceutical form.

4. Clinical particulars:

4.1. Therapeutic indications.

4.2. Posology and method of administration.

4.3. Pediatric population.

4.4. Contraindications.

4.5. Special warnings and precautions for use.

4.6. Interaction with other medicinal products and other forms of interaction.

4.7. Pregnancy and lactation.

4.8. Effects on ability to drive and use machines.

4.9. Adverse reactions.

4.10. Overdose

5. Pharmacological properties. Pharmacotherapeutic group. ATC code:

5.1. Pharmacodynamic properties.

5.2. Pharmacokinetic properties.

5.3. Preclinical safety data.

6. Pharmaceutical particulars:

6.1. Excipients.

6.2. Major incompatibilities.

6.3. Shelf life.

6.4. Special precautions for storage.

6.5. Nature and contents of immediate package (container).

6.6. Special precautions for disposal of a (un)used medicinal product or waste materials derived

from the medicinal product (if necessary).

7. Registration certificate holder.

Manufacturer of medicinal product.

8. Registration certificate number.

9. Date of the first registration of a medicinal product

10. Date of revision.

{Annex 21 in wording of MoH Ukraine Order №460 as of 23.07.2015}