Annex 16
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 10 of section IV)

LIST OF DOCUMENTS
submitted for re-registration of medicinal products produced according to the approved specifications

1. The registration form according to Annex 14 of the Procedure with its annexes.

2. Instruction for medical use of medicinal product valid in Ukraine and draft instruction for medical use of medicinal product.

3. Letter confirming that composition, manufacture and control of medicinal product comply with specification in the List of medicinal products produced according to the approved specifications (MoH Ukraine Order of November 26, 2012 № 949).

{Annex 16 in wording of MoH Ukraine Order №460 as of 23.07.2015}