Annex 8
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 Validity Period of Registration Certificate
(item 4 of section IV)

SPECIFIC PROVISIONS
applicable to medicinal products produced according to the approved specifications and to their registration dossier

1. This registration procedure may be applied to specific medicinal products produced according to the approved specifications, which comply with the following:

1) composition of medicinal product, production technology, specification and instructions for medical use shall correspond to those given in the approved specifications;

2) active substances used in medicinal products shall meet the requirements stated in the approved specifications;

3) only changes specified in this Procedure may be introduced in the materials of registration dossier.

2. A set of materials of registration dossier for medicinal products produced according to the approved specifications, which are submitted for state registration, shall contain details stated in Modules 1 and 2 of CTD.

In addition, submitted shall be:

1) methods of quality control and instructions for medical use;

2) data on active substance including manufacturer's name and location, information on manufacture, stability, labelling, type and size of packaging, storage conditions;

3) data on finished medicinal product including information on batch size, stability, labelling, packaging, storage conditions and shelf life;

4) Copy of registration certificate or other licensing document (Marketing Authorization, Certificate of a Pharmaceutical Product, Free Sale Certificate, etc.) issued by the competent authority of country of registration certificate holder (applicant) and/or manufacturer, or other country which regulatory authority follows high quality standards complying with WHO standards at the market where the medicinal product is placed. The list of countries, where the medicinal product has been registered/re-registered shall be provided (if any);

5) Copy of license to manufacture (if according to manufacturer's national legislation the license to manufacture is available in electronic form only (e.g. USA), the printout with reference to appropriate official site certified by applicant's signature/stamp (if any) shall be provided) or other licensing document to manufacture the applied pharmaceutical form in manufacturer's country;

6) Certified copy of document confirming the compliance of manufacture of medicinal product with GMP issued by the State Administration of Ukraine on Medicinal Products according to the MoH Ukraine Order of December 27, 2012 № 1130 “On approval of procedure for confirming compliance of manufacture of medicinal products with GMP” registered with the Ministry of Justice of Ukraine of January 21, 2013 №133/22665 (with amendments) or applicant’s letter of guarantee to submit such document during specialized expert evaluation;

7) 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 8 in wording of MoH Ukraine Order №460 as of 23.07.2015}