Annex 9
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 of limited use (orphan products) and to their registration dossier

1. Medicinal products of limited use (orphan products) shall meet the following criteria:

1) intended for the diagnosis, prevention or treatment of a life-threatening or seriously debilitating rare condition affecting not more than 5 in 10,000 persons when the application is submitted, or they are intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating, or chronic condition and without incentives of the state their marketing would not generate sufficient return to justify the expenses borne by the manufacturer with regard to the medicinal product;

2) there exists no other approved satisfactory method of diagnosis, prevention or treatment of the condition in question or, if such method exists, the medicinal product applied for will be of significant benefit to the patients.

2. The registration form of medicinal product of limited use (orphan product) shall be submitted according to Annex 1 to this Procedure. The following shall be attached to the registration form:

A confirmation of introduction of the medicinal product applied for to the European Community Register of Designated Orphan Medicinal Products, or

A confirmation of the orphan designation issued by the competent authorities of applicant's/manufacturer's country or countries where the medicinal product has this designation, and data on its registration with an orphan designation in other countries;

A commitment in writing to submit annually a confirmation of the orphan designation obtained from the European Community's Committee for Orphan Medicinal Products or competent authorities of the applicant's/manufacturer's country or countries where the medicinal product has this designation.

3. The materials of registration dossier shall be drawn up according to the requirements of Annex 6 of this Procedure (in Common Technical Document format).

Provisions of item 7 of section IV of this Procedure may be applied during the submission of the materials of registration dossier for medicinal products of limited use (orphan products). In this case in the summary of preclinical and clinical data the applicant shall justify the impossibility to provide a comprehensive data and substantiate a benefit/risk balance for the orphan products applied for.

4. The registration form shall cover only those therapeutic indications, which correspond to conditions specified in item 1 of this Annex. This shall not impede the submission of a separate application for new registration of such medicinal product with other indications for use, which do not correspond to the above-specified conditions (according to other registration dossier).

{Annex 9 in wording of MoH Ukraine Order №460 as of 23.07.2015}