

Annex 28
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 12 of section VI)

LIST
**of documents for expert evaluation of change in applicant (registration
certificate holder)**

1. A letter of guarantee from the new applicant according to annex 25 to the Procedure.

2. Module. Administrative data.

All documents to be submitted from the approved applicant (the Transferor) or from the new applicant (the Transferee) must be formalized on letterhead paper of the approved or the new applicant, as appropriate. Each cover letter should be submitted using a template given below*.

2.1. Name of the registered medicinal product the ownership of which is transferred, number of registration certificate and date of registration (last re-registration).

2.2. Name and location of the approved applicant (holder of registration certificate) who transfers the ownership of the registered medicinal product, and name and location of the new applicant (the transferee) to whom the ownership of the registered medicinal product is transferred (in format of comparative table)

2.3. A document certifying that the up-to-date and complete registration dossier for the registered medicinal product including any data/documents related to the paediatric obligations has been transferred from the approved applicant to the new applicant (in text format).

2.4. A document stating the date on which the approved and new applicants finalise all transfer-related organisational arrangements and the new applicant takes over all responsibilities with regard to the given medicinal product. This date is referred to as the implementation date. The transitional period between the positive conclusion (approval) of the regulatory authority of change in the applicant and the implementation date of change in applicant should be proportionate to the organisational activities that need to be performed by the approved and the new applicant. In any case, the implementation period should not be more than 6 months unless otherwise justified.

2.5. Proof of registration of the new applicant (transferee) in accordance with regulation of a country of origin.

2.6. Documents showing the capacity of the new applicant (the transferee) to perform all the responsibilities required from a registration certificate holder under the country's pharmaceutical legislation:

Information on the new applicant's qualified person responsible for pharmacovigilance (QPPV) with a CV specifying address where he/she carries out his/her tasks, e-mail address, 24-hour telephone and fax numbers, information on qualification and work experience, and registration form for introduction of changes into registration materials in due order;

Information on the contact person in Ukraine – the new applicant’s qualified person responsible for pharmacovigilance (if not the same as above) together with his/her CV specifying address where he/she carries out his/her tasks, e-mail address, 24-hour telephone and fax numbers, information on qualification and work experience, and registration form for introduction of changes into registration materials in due order;

If a short description of the pharmacovigilance system has been given in the registration dossier of the registered medicinal product, and a transfer of ownership of this product has caused a change in qualified person responsible for pharmacovigilance, a statement signed by the new applicant must be submitted that he has at his disposal services of a qualified person and the proper system for collecting and monitoring data on safety of medicinal product at their medical use;

Information on the new applicant’s authorized person, and an authorization to carry on negotiations/ to sign documents on behalf of the new applicant (registration certificate holder);

Contact details of the new applicant’s person responsible for quality defects and batch recall, including full name, address where he carries out his/her tasks, email address, 24-hour telephone and fax numbers.

2.7. If the registered medicinal product has not yet been marketed, this should be specified in a written statement.

2.8. A letter from the new registration certificate holder concerning all remaining guarantees and commitments of the approved applicant (registration certificate holder). If there is no remaining guarantee and commitment the competent authority should also be informed thereof.

2.9. A written statement that no other changes have been made to the summary of product characteristics, instructions for medical use, MQC and labelling text of the registered medicinal products other than those approved according to the established procedure.

2.10. Confirmation from the expert unit that the proposed name of the medicinal product has undergone an expert evaluation, if applicable.

Documents listed in subitems 2.1-2.4 and 2.9. of this item should be signed by the approved applicant (registration certificate holder) and the new applicant (the transferee).

Documents listed in subitem 2.7. of this item should be signed by the approved applicant (registration certificate holder).

Documents listed in subitems 2.5, 2.6 and 2.8 of this item should be signed by the new applicant (the transferee).

3. If applicable, changes made to the appropriate sections of the registration dossier, and revised MQC, summary of product characteristics, instructions for medical use, and propositions related to labelling text on package which pertain to name and address of the new applicant (the transferee).

* This letter shall pertain to (information specified in subitems 2.1 – 2.9 of item 2 of this annex).

(Date)

Dear (full name of head of regulatory authority)

(name of medicinal product (active substance)) + strength + pharmaceutical form).

A statement on transfer of registration certificate (ownership) of this medicinal product from (name of the approved applicant) to (name of the new applicant)

(full text of a letter (statement) as comparative table or in text format as appropriate).

Approved applicant (full name, position) for and on behalf of (company's name)	New applicant (full name, position) for and on behalf of (company's name)
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{ Annex 28 in wording of MoH Ukraine Order №460 as of 23.07.2015 }