



## List of required documents for renewal

The following documents are submitted together with the application for re-registration:

1. Cover letter.
2. Comprehensive table of contents.
3. The application for the state re-registration with the following annexes:
  - 3.1. Details about authorized persons (qualified person of applicant in Ukraine for pharmacovigilance).
  - 3.2. Statement of GMP compliance (by competent authority for at least three years), if any.
  - 3.3. Copy of license to manufacture.
  - 3.4. List of countries, where the product is on the market and indicating the date of the first registration.
4. Chronological list of claims for the product, received during recent 5 years in Ukraine, with the analysis of details which caused the claims and the measures taken by the applicant to prevent it in future.
5. Chronological list of guarantees and specific obligations, submitted since the registration/re-registration indicating scope, status, date of submission and date when the issue has been solved (recommendations for post-registration investigation, elimination of any defects, specified by control and other agencies, etc.).
6. Revised list of all remaining guarantees and obligations and signed letter of commitment (where applicable).
7. Product information:
  - 7.1. The drafts of the updated SPC, package (labelling) and package leaflet. The current SPC in Ukrainian, Russian or English (with relevant translation) or, if appropriate, the proposed SPC with all changes clearly highlighted in Ukrainian, Russian or English (with relevant translation);
8. Approved at registration and up-dated methods of quality control of the finished product.
9. Approved at registration and up-dated technological regulation or data concerning the manufacturing technique.
10. Periodic safety updated report on medicinal product or bridging summary report.
11. The manufacturer's/Applicant's (or his representative) summary data about safety status of medicinal product in Ukraine during the validity period of the most recent registration certificate in the format approved according to Annex 8 to the Procedure for Surveillance over Adverse Reactions to Medicinal Products Permitted for Medical Use approved by Order of the Ministry of Health of Ukraine dated 27.12.2006 № 898 Note. If changes to registration materials, which have not been approved in established order during the validity period of registration certificate, are declared in submitted applications for state re-registration of medicinal product, the applicant shall submit the application for state re-registration together with an application about introduction of changes to registration materials and documents justifying introduction of such changes.