

Annex 25

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 3 of section V)

To _____
General Director,
the State Expert Center MoH Ukraine

LETTER

The applicant (applicant's representative) _____, in the person of _____ (name), guarantees that at the submission of the materials of registration dossier for state registration of the _____ (name and initials) following medicinal product:

(name of medicinal product, pharmaceutical form and strength), the requirements of paragraph fourteen of Article 9, Law of Ukraine "On medicines" are met, namely: the rights of third parties being patent-protected or transferred according to the license are not violated because of the registration of the medicinal product.

I realize that the state registration of the given medicinal product may be rejected in provided such a registration has caused a violation of current intellectual property rights protected by the patent, including those pertinent to manufacturing process, use, sale of medicinal products.

“ _____ ” _____ 20 _____

Seal

(full name)
