Annex 24

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) | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

{Annex 25 in wording of MoH Ukraine Order №460 as of 23.07.2015}