Annex 13
to Pharmacovigilance Procedure
(item 6 of chapter 3 of part V)

FORM
for cumulative safety data related to medical use of medicinal product/vaccine/tuberculin in Ukraine during the validity period of the most recent registration certificate to be submitted by applicant (or his representative)

Calendar year	Number of adverse reactions (serious/non-serious)	Volume of sales	Patient exposure to medicinal product, vaccine, tuberculin
1	2	3	4
Total			

CONCLUSION

_____
(specify explicit data, reasoning for introducing changes
_____
to safety information on medicinal product, vaccine, tuberculin
_____
(to instructions for medical use), relevant actions proposed by the applicant (or his representative), etc.)
_____

Notes:

1. Form should be completed by applicant (or his representative) and signed by qualified person for pharmacovigilance/contact person for pharmacovigilance (QPPV/CPPV).

2. Calendar year (calendar years over the validity period of the most recent registration certificate should be specified in chronological order).

3. Number of adverse reactions (serious/non-serious) (the ratio of serious/non-serious adverse reactions information about which was obtained by the applicant (or his representative) at the territory of Ukraine should be specified, except for information obtained from Public Enterprise “The State Expert Center of the Ministry of Health of Ukraine”)

4. Volume of sales (number of unit dosage forms (tablets, ampoules, vials.) should be specified). The header should be completed if requested by the Center.

5. Patient’s exposure to medicinal product (indicator of exposure should be specified in accordance with the indicator mentioned in section "Estimated exposure and used patterns" of Addendum to clinical overview according to sub-item 2.3 of item 2 of Annex 15 to the Procedure for Conducting

Expert Evaluation of Materials Pertinent to Medicinal Products, which are Submitted for State Registration (Re-Registration) and Expert Evaluation of Materials about Introduction of Changes to the Registration Documents during the Validity Period of Registration Certificate, approved by the MoH Ukraine Order of 26 August 2005 N 426, registered at the Ministry of Justice of Ukraine of October 07, 2015 under № 1210/27655 (in wording of MoH Ukraine Order of July 23, 2015 № 460), or in section V "Estimated exposure and use patterns" of the recent periodic safety report for medicinal product according to requirements of Annex 12 to Pharmacovigilance Procedure, approved by the MoH Ukraine Order of September 26, 2016, № 996).