

## REPORT FORM "LACK OF EFFICACY OF MEDICINES"

ALL THE INFORMATION PROVIDED BY YOU IS CONFIDENTIAL AND IS NOT SUBJECT TO DISCLOSURE EXCEPT AS OTHERWISE PERMITTED BY THE LAW

### INFORMATION ABOUT A PATIENT

|   |  |                                   |  |
|---|--|-----------------------------------|--|
| <b>INITIALS</b><br>(first letters of patient's surname, name and patronymic): | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | <b>Hepatic disease</b>            | <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> no information |
| <b>Sex:</b>   | <input type="checkbox"/> male <input type="checkbox"/> female              | <b>Renal disease</b>              | <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> no information |
| <b>Date of birth (age):</b>   |  | <b>Pregnancy</b>                  | <input type="checkbox"/> yes <b>Term</b> _____ weeks   |
| <b>Weight (kg):</b>   |  | <b>Allergy (please, specify):</b> | <input type="checkbox"/> yes <input type="checkbox"/> no   |
| <b>Height (cm):</b>   |  |                                   |  |

### SUSPECTED PHARMACEUTICAL PRODUCT(-S) (SPP)

| Brand name | International non-proprietary name | Pharmaceutical form | Batch No | Dosage, frequency and method of administration | Prescribed for | Start date | End date |
|------------|------------------------------------|---------------------|----------|--|----------------|------------|----------|
|            |                                    |                     |          |  |                |            |          |
|            |                                    |                     |          |  |                |            |          |
|            |                                    |                     |          |  |                |            |          |

### OTHER PHARMACEUTICAL PRODUCTS (administered in the last 3 months)

| Brand name | International non-proprietary name | Pharmaceutical form | Batch No | Dosage, frequency and method of administration | Prescribed for | Start date | End date |
|------------|------------------------------------|---------------------|----------|--|----------------|------------|----------|
|            |                                    |                     |          |  |                |            |          |
|            |                                    |                     |          |  |                |            |          |
|            |                                    |                     |          |  |                |            |          |

### LACK OF EFFICACY (LOE)

|  |                          |                        |
|--|--------------------------|------------------------|
| <b>Description of lack of efficacy signs (including any results of relevant supportive laboratory tests and other investigations)</b>  | <b>Start date of LOE</b> | <b>End date of LOE</b> |
|  |                          |                        |
| <b>Did changing of SPP result in LOE disappearance?</b> <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> SPP was not discontinued   |                          |                        |
| <b>Did rechallenge of SPP cause repeated LOE?</b> <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> no rechallenge of SPP  |                          |                        |
| <b>Measures taken:</b> <input type="checkbox"/> replacement of the SPP to another (name): <input type="checkbox"/> concomitant treatment cancelling<br><input type="checkbox"/> SPP dosage increase <input type="checkbox"/> non-pharmacological therapy (including surgical treatment)<br><input type="checkbox"/> prescription of concomitant treatment <input type="checkbox"/> other (please, specify):                                      |                          |                        |
| <b>Pharmacological therapy of LOE (if any):</b>  |                          |                        |
| <b>Result:</b> <input type="checkbox"/> recovery without consequences <input type="checkbox"/> death caused by LOE<br><input type="checkbox"/> amelioration <input type="checkbox"/> death not caused by LOE<br><input type="checkbox"/> no changes <input type="checkbox"/> recovery with any consequences (please, specify):<br><input type="checkbox"/> no information  |                          |                        |
| <b>Measures of the seriousness:</b> <input type="checkbox"/> death of the patient (date ___/___/_____) <input type="checkbox"/> prolongation of out-patient treatment<br><input type="checkbox"/> danger to life <input type="checkbox"/> disability<br><input type="checkbox"/> hospitalization or its prolongation <input type="checkbox"/> congenital abnormality<br><input type="checkbox"/> clinically significant event (please, specify): |                          |                        |



Address: P.O.Box 22, Kyiv 02092, Ukraine  
Tel.: (044)4958287; (067)4340378  
E-mail: <pv@kusum.ua>

Report № \_\_\_\_\_ / \_\_\_\_\_

initial  final

(to be filled in by Pharmacovigilance Department)

**INFORMATION ABOUT A REPORTER (a person that informs about LOE)**

|   |   |                      |  |
|---|---|----------------------|--|
| <b>Full name:</b>                       |   |                      |  |
| <b>Occupation:</b>                      | <input type="checkbox"/> doctor <input type="checkbox"/> pharmacist <input type="checkbox"/> medical representative <input type="checkbox"/> other (please, specify): |                      |  |
| <b>Health care institution:</b>         |   |                      |  |
| <b>Address:</b>                         |   |                      |  |
| <b>Phone:</b>                           |   | <b>E-mail:</b>       |  |
| <b>Date of LOE information receipt:</b> |   | <b>Filling date:</b> |  |

I give my consent to Gladpharm LLC for processing my personal data (PD).

I am notified of:

- 1) PD owner – Gladpharm LLC;
- 2) the composition and content of PD – they are specified in this message above;
- 3) their rights under Art. 8 of the Law of Ukraine “On Protection of Personal Data”;
- 4) the purpose of PD processing – ensuring pharmacovigilance over drug efficacy;
- 5) persons to whom PD may be transferred – State Enterprise "State Expert Center of the Ministry of Health of Ukraine", the company Kusum Healthcare Pvt Ltd, India and KUSUM PHARM LLC, Ukraine, as well as their legal successors.

YES  NO

SIGNATURE \_\_\_\_\_

SEAL \_\_\_\_\_