**DEFECT!**

**Notice to operators related to a defect in the quality of a medicinal product.**

**<Date>**

**<Name of the medicinal product, name supplement, SÚKL code, and main message>**

(e.g., warning about the appearance of the LP that does not fully correspond to the description in the SPC, or a label that is peeling off ...)

**<Addressing>**

(e.g., Dear Doctor)

**<Name of the marketing authorization holder>** in cooperation with the State Institute for Drug Control (and the European Medicines Agency, if applicable), would like to inform you about ...

**Summary of the issue**

* Brief summary of the quality defect and recommended procedure to minimize risks
* Indication of batch numbers with the described quality defect

**Further information on the MP quality defect and subsequent recommendations**

* Detailed procedure for minimizing risks related to the MP quality defects
* Information on the possible supply of non-defective batches to the Czech market
* Other important information

**Contact details of the marketing authorization holder**

If you have any further questions or require additional information, please contact: Contact person's name, telephone number or email, or company website, company address within the Czech Republic

**<**electronic or handwritten signature, name, and position of the responsible person**>**