**REPORTING A SUSPECTED QUALITY DEFECT OF A MEDICINAL PRODUCT**

**NAME, SURNAME, AND ADDRESS OF THE PERSON REPORTING, E-MAIL, TELEPHONE, COMPANY:**

**INFORMATION ON THE MEDICINAL PRODUCT SUSPECTED OF HAVING A QUALITY DEFECT:**

**Medicinal product** (name, strength, dosage form, pack size, batch number, expiry date):

**Marketing Authorisation Holder/Manufacturer** (the company named on the packaging of the medicinal product - name and address):

**Description of the fault/problem** (maximum information available to assess the situation):

**A sample is sent to the Institute**

**the claimed medicinal product packaging Yes**  **No**

**an unopened original packaging of the same batch of medicinal product Yes**  **No**

**For more information about the quality defect, the other pages can be used if needed**

Report Date: Signature:

**ALL DATA CAN BE EXPANDED ON THE FOLLOWING PAGES**

**Please send the completed report, preferably to the following e-mail address:** [**zavady@sukl.gov.cz**](mailto:zavady@sukl.gov.cz) **or by post together with the samples to:**

***State Institute for Drug Control***

***Quality Defects Department***

***Šrobárova 49/48***

***100 00 Prague 10***

***Czech Republic***

**tel: 272 185 363, 272 185 258, 272 185 124, 272 185 790, only on working days between 8.00 and 16.30**

**fax: 271 732 377**

**Outside working hours, on Saturdays, Sundays, and public holidays, in serious and urgent cases, please contact the Institute's emergency service electronically at** [**zavady@sukl.gov.cz**](mailto:zavady@sukl.gov.cz) **or by phone at +420 272 185 777**

The State Institute for Drug Control processes the data provided for the purpose of recording and processing reports of suspected defects in the quality of medicines, on the basis of Section 13(2)(c) and (e) of Act No 378/2007 Coll., on Medicinal Products. Further information on the processing of personal data, in particular on your rights such as the right of access and the right to object, can be found on the website https://sukl.gov.cz in the section [Data Protection](https://sukl.gov.cz/ochrana-osobnich-udaju/).