UST-15 VERSION 7 Procedure for health professionals and sellers of reserved medicines in case of suspected quality defect or counterfeit of a medicinal product

This instruction supersedes UST-15 version 6, effective February 1, 2025.

The instruction is issued based on and in accordance with the provisions of Section 23(1)(c) and (d) of Act No. 378/2007 Coll., on Medicinal Products and on Amendments to Some Related Acts (the Act on Pharmaceuticals), as amended.
The guideline is advisory.

This guideline is intended for persons dispensing medicinal products, sellers of reserved medicines, and persons providing healthcare, and, in view of some persistent confusion in the field, is intended to help standardise the procedure when a suspected quality defect or counterfeit of a medicinal product from the legal distribution network is detected. A functional system will accelerate the evaluation of a possible quality defect, including the determination of the level of health risk of the suspect medicinal product to the patient and, if necessary, the implementation of measures to minimise the risk associated with the use of the medicinal product, including timely information to the professional and lay public.

The instruction is based on the requirements of Act No. 378/2007 Coll., On Medicinal Products and on Amendments to Some Related Acts, as amended (hereinafter referred to as 'the Act on Pharmaceuticals)), under which, pursuant to the provisions of Section 23(1)(c) and (d), persons dispensing medicinal products or sellers of reserved medicinal products or persons providing healthcare are obliged to immediately notify the State Institute for Drug Control (hereinafter referred to as 'the Institute') of a suspected defect in the quality/defect of a medicinal product or excipient and, if necessary, to provide the Institute with a sample to verify the quality of the medicinal product.

A defective/counterfeit medicinal product can be detected in various situations. Apart from manufacturing or distribution, where manufacturers and distributors have developed systems of measures for these, a defective or counterfeit medicinal product can be the most frequently detected:

- by a physician, nurse or health care professional when administering the medicine or when notified by the patient,
- by the pharmacist or pharmaceutical assistant or the seller of the reserved medicine at the time of receipt or dispensing of the medicinal product or after notification by the patient,
- by the patient when using the medicine.

A sign of reduced quality of a medicinal product is any unusual characteristic that does not correspond to the description of the medicinal product in the summary of product characteristics. This could be, for example:

- **change in the appearance of the medicinal product** (e.g. change in colour or shape of tablets, turbidity or precipitated particles in the case solutions, content of foreign or unusual particles/objects, unusual labelling on the packaging, leaks in the packaging, inconsistency in the labelling of the inner and outer packaging of the product or the package leaflet which may indicate confusion or if it is a counterfeit
- **absence of package leaflet** (except for homeopathic preparations), **measuring cup, application aids**, etc.
- **an atypical characteristic that does not correspond to the summary of product characteristics** (e.g., does not dissolve, cannot be shaken, cannot be divided)

Note: Medicinal products with obviously damaged packaging, stored under other than prescribed conditions or with an expired shelf life are unusable medicinal products and must be disposed of, including their packaging, in such a way as to avoid endangering the life or health of persons

If health care professionals or sellers of reserved medicinal products suspect that a medicinal product is of reduced quality, the dispensing, sale, and use of all packages of the same batch of the medicinal product have to be suspended. Exceptions may be made in cases where failure to administer the medicinal product could endanger the life or cause serious harm to the health of the patient, another package of the product without the defect is not available, and the quality defect is not serious.

Non-serious quality defects are, e.g.:

- Missing or incorrect SÚKL code, or missing batch number or expiry date on secondary packaging, or outdated package leaflet

In such cases, the assessment of the situation depends on the experience of the doctor or pharmacist.

In some cases, it may be useful to ask for help from the Institute's Information Department (tel.: +420 272 185 333, email: infs@sukl.gov.cz) or on working days between 8:00 and 16:30 from the Institute's Quality Defects Department (tel.+420 272 185 363, +420 272 185 258 258, +420 272 185 124, +420 272 185 790, email: zavady@sukl.gov.cz) in the event of a serious quality defect also outside working hours and on free days at the Institute's emergency service (email: zavady@sukl.gov.cz, tel.: +420 272 185 777).

In case of a suspected defect in the quality of a medicinal product, the State Institute for Drug Control shall be informed of the case following the Act on Pharmaceuticals, using the form "Report of a suspected defect in the quality of a medicinal product", which is attached as Annex 1 to this Instruction. The following should be ensured:

1. The claimed packaging* - this packaging has to be provided directly to the Institute and cannot be handed over to another person (e.g., marketing authorisation holder, authorised person, distributor) without the Institute's knowledge.
2. All available information that may facilitate the identification, confirmation, or exclusion of a quality defect (patient or doctor contact),
3. An unopened original package of the same batch* of the medicinal product suspected of having a quality defect, if it is available.

**The prescribed storage conditions must be observed when sending samples.*

and send it immediately by one of the methods listed below:

- **Including photo documentation of the suspicious packaging to the following email address:** zavady@sukl.gov.cz
- **via a web form on the Institute's website:**
  Reporting a suspected defect in the quality of a medicinal product | State Institute for Drug Control
- **by post to**
  State Institute for Drug Control
  Quality Defects Department
  Šrobárova 49/48
  100 00 Prague 10
  Czech Republic

In case of suspicion of a counterfeit medicinal product originating from a legal network, the procedure is similar to the procedure for suspicion of a quality defect, however, the form "Report of suspicion of a counterfeit medicinal product", which is part of this instruction, see Annex 2, or the web form at the address: Report of suspicion of a counterfeit medicinal product in the legal distribution chain | State Institute for Control

Patients can be referred to the public information portal, see links: https://sukl.gov.cz/verejnost/leciva/encyklopedie/encyklopedie-leciva/zavady-v-jakosti-leciv/?%3Ar1%3A-page=1 (in Czech only) or Reporting a suspected quality defect of medicines – SÚKL or Reporting of suspected falsified medicinal product – SÚKL

Annexes:

Annex 1: Form "Reporting a suspected defect in the quality of a medicinal product"

Annex 2: Form "Reporting a suspected counterfeit medicinal product in the legal distribution chain"