

AMVO-002-3.0	Appendix ./6
Guidance on Potential / Confirmed Incident of Falsification Within the Context of Dispensing or Verifying Medicinal Products in Austria	
Applicable as from: see section 7 - Entry into force	

## Appendix ./6 – Information for Pharmacists “Dispensing in Emergencies Despite Level 5 System Message”

### Background

All the potential scenarios proceed on the same assumptions:

- A patient has been prescribed a certain medicinal product that is subject to prescription.
- At the pharmacy, a check of the safety features of a retail pack of that specific medicinal product has raised a level 5 system message.
- An “emergency situation” as defined in Section 4 (6) of the Austrian Prescription of Medicinal Products Act (*Rezeptpflichtgesetz*, RzeptPG) (“emergency provision”) applies.

The following information is intended to provide guidance to pharmacists on what steps to take in an “emergency situation” situation. Giving due respect to pharmacists’ professional freedom, this is not to be understood as giving them instructions on how to exercise their profession but rather represents the outcome of an evaluation conducted by BASG and AMVO together with the Austrian Chamber of Pharmacists (*Apothekerkammer*) aimed at ensuring the supply of medicinal products to patients in an “emergency situation”. The responsibility for assessing whether or not an “emergency situation” has occurred and what specific steps to take lies entirely with the pharmacist in question, subject to the applicable legal provisions and the specific circumstances. Criteria to assess whether or not an “emergency situation” applies include, without limitation, the availability of medical assistance, the level of urgency to supply the medicinal product and the type of medicinal product (including in respect of long-term medication or potential abuse, etc.).

### Scenarios

#### Scenario (1)

*The pharmacy stocks another retail pack of the same medicinal product.*

Level 5 system message	<input checked="" type="checkbox"/>
Another retail pack of the same medicinal product is in stock	<input checked="" type="checkbox"/>

- Find out whether or not the pharmacy stocks another retail pack of the medicinal product.
- If yes: Verify the safety features of this second retail pack.
- If verification does not raise a level 5 system system message: dispense the second retail package in conformity with the applicable legal framework.

#### Scenario (2)

*The pharmacy does not stock another retail pack of the same medicinal product, but a different medicinal product could be used.*

Level 5 system message	<input checked="" type="checkbox"/>
Another retail pack of the same medicinal product is in stock	x
Dispensing a different medicinal product is admissible.	<input checked="" type="checkbox"/>

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- The pharmacy does not stock another retail pack of the medicinal product.
- Consult with the physician (discuss change before dispensing, if applicable) and document in conformity with applicable legal provisions, in particular the Austrian General Pharmacists – Social Security Agreement (*Apothekergesamtvertrag*) as amended from time to time.
- If consultation with the prescribing physician is not possible: refer to the procedure set out in Section 4 (6) of the Prescription of Medicinal Products Act and, if applicable, dispense in the interest of supplying patients with medicinal products in compliance with the said provision.

### Scenario (3)

*Dispensing a different medicinal product is not an option.*

Level 5 system message	<input checked="" type="checkbox"/>
Another retail pack of the same medicinal product is in stock	x
Dispensing a different medicinal product is admissible.	x

- Dispensing a different medicinal product is not admissible.
- Verify whether or not falsification of the medical product can be ruled out.
- Outcome of the investigation by the pharmacist: if the product packaging has not been tampered with and it can be ruled out beyond doubt that the level 5 system message was triggered by a falsification of the medicinal product, dispense as set out in Article 30 of the Delegated Regulation.

**Note:** Where applicable, the scenarios described above apply analogously to dispensing doctors.