

1 General Information

Question	Answer
Drug	
1.1 Denomination of the drug product at hand / of the suspected counterfeit	
1.2 Name of manufacturer / market authorisation holder	
1.3 Origin of the drug product	
1.4 Where is the drug product being sold?	
1.5 Name of the original product	
Visual Inspection	
1.6 Place of the inspection	
1.7 Date of the inspection	
1.8 Name of the person inspecting	
1.9 Phone number / e-mail for further inquiries	
1.10 Attachments to this form	

This checklist assists in the evaluation of suspected counterfeits on site. If the suspicion is being confirmed, the checklist can also be used as notification form.

The notification / checklist should be sent to:

Mail address Swissmedic, Swiss Agency for Therapeutic Products
 Division Central Market Surveillance
 Counterfeits
 Hallerstrasse 7
 CH - 3000 Bern 9

or
 E-Mail market.surveillance@swissmedic.ch

or
 Fax +41 31 322 07 22

Hotline Tel +41 31 323 16 63

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2 General items to be checked

Note: an examination of the items to be checked should be done as far as possible. If a question cannot be answered, no box has to be ticked (at best with comment "unknown" or "not applicable").

Comments with explanatory details to the questions are desirable.

Item	YES	NO	comment
Packaging			
2.1 Are the measures of the primary packaging ¹ suitable for the product? (i.e. do the covering and the contents suit to each other?)	<input type="checkbox"/>	<input type="checkbox"/>	
2.2 Are packaging and any closure conditioned to protect the drug against outside influences?	<input type="checkbox"/>	<input type="checkbox"/>	
Labelling			
2.3 Is the product name spelled correctly?	<input type="checkbox"/>	<input type="checkbox"/>	
2.4 Are the labels written in German, French and Italian?	<input type="checkbox"/>	<input type="checkbox"/>	
2.5 Are the labels affixed correctly? (check if they are displaced, not labelled equally on all packs or partially overlapping)	<input type="checkbox"/>	<input type="checkbox"/>	
2.6 Does the information on the primary packaging match with the secondary packaging ² ? (Especially check if lot number or expiry date are identical on all components)	<input type="checkbox"/>	<input type="checkbox"/>	
2.7 Is a barcode printed on the secondary packaging?	<input type="checkbox"/>	<input type="checkbox"/>	
2.8 Is a Swissmedic vignette printed on the secondary packaging?	<input type="checkbox"/>	<input type="checkbox"/>	
2.9 Is the name of the market authorisation holder printed on the packaging? (e.g. „Distributed by ..." or "Distributer ...")	<input type="checkbox"/>	<input type="checkbox"/>	

¹ Primary packaging = container in direct contact with the drug (e.g. glass bottle, blister)

² secondary packaing = container enveloping the primary packaging (z.B. box)

Item	YES	NO	comment
Lot number and expiry date			
2.10 Are lot number and expiry date legibly and inalterably printed on primary and secondary packaging?	<input type="checkbox"/>	<input type="checkbox"/>	
2.11 Has the drug expired?	<input type="checkbox"/>	<input type="checkbox"/>	
Contents of the packaging			
2.12 Is a patient information leaflet enclosed?	<input type="checkbox"/>	<input type="checkbox"/>	
2.13 Is the leaflet written in German, French and Italian?	<input type="checkbox"/>	<input type="checkbox"/>	
2.14 Does the number of contained drugs (tablets, capsules, vials) match with the indication on the packaging?	<input type="checkbox"/>	<input type="checkbox"/>	
Physical Characteristics of Particular Drugs			
Tablets / Capsules			
2.15 Do the tablets / capsules all have the same appearance regarding form, size, surface (e.g. roughness), colour?	<input type="checkbox"/>	<input type="checkbox"/>	
2.16 Do the tablets / capsules look damaged?	<input type="checkbox"/>	<input type="checkbox"/>	
2.17 Is there any mark on the tablet / capsule (e.g. print or embossing)?	<input type="checkbox"/>	<input type="checkbox"/>	
2.18 Is the respective mark mounted on all tablets / capsules in a consistent way?	<input type="checkbox"/>	<input type="checkbox"/>	
Ampoules / Vials			
2.19 Are the ampoules / vials consistently filled?	<input type="checkbox"/>	<input type="checkbox"/>	
2.20 Is there any mark on the ampoules / vials (e.g. colour dot, colour ring, flip-off seal)?	<input type="checkbox"/>	<input type="checkbox"/>	
2.21 Is the respective mark mounted on all ampoules / vials in a consistent way?	<input type="checkbox"/>	<input type="checkbox"/>	

3 Additional items to be checked by experts / inspectors

Item	YES	NO	comment
Labelling			
3.1 Does the label text contain any mistakes (e.g. dimension units, technical terms, active ingredient name)?	<input type="checkbox"/>	<input type="checkbox"/>	
3.2 Is the following information mentioned on the secondary or primary packaging?			
Name of the drug product	<input type="checkbox"/>	<input type="checkbox"/>	
Dosing	<input type="checkbox"/>	<input type="checkbox"/>	
Qualitative & quantitative composition	<input type="checkbox"/>	<input type="checkbox"/>	
Galenical form	<input type="checkbox"/>	<input type="checkbox"/>	
Name and address of the MA holder	<input type="checkbox"/>	<input type="checkbox"/>	
Market authorization number	<input type="checkbox"/>	<input type="checkbox"/>	
Lot number	<input type="checkbox"/>	<input type="checkbox"/>	
Expiry date	<input type="checkbox"/>	<input type="checkbox"/>	
Market Authorisation			
3.3 Is the trade name of the drug registered in Switzerland?	<input type="checkbox"/>	<input type="checkbox"/>	
3.4 Is the name of the market authorisation holder indicated on the packaging identical with the company that obtained the authorisation?	<input type="checkbox"/>	<input type="checkbox"/>	
3.5 If indicated, is the address of the market authorisation holder correct?	<input type="checkbox"/>	<input type="checkbox"/>	
3.6 Is any authorisation number indicated?	<input type="checkbox"/>	<input type="checkbox"/>	
3.7 Is the authorisation number correct?	<input type="checkbox"/>	<input type="checkbox"/>	
3.8 Has the indicated dosing been registered in Switzerland?	<input type="checkbox"/>	<input type="checkbox"/>	
3.9 Is the drug being sold in pharmacies or sites with authorisation to sell drugs (e.g. no illegal channel) ?	<input type="checkbox"/>	<input type="checkbox"/>	
Patient Information leaflet			
3.10 Does the patient information leaflet give all required particulars?	<input type="checkbox"/>	<input type="checkbox"/>	

