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European Medicines Agency

How to use the (Suspected) Falsified Medicinal Product Report template to report a case of (Suspected) Falsified Medicinal Product to European Medicines Agency

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1. The (Suspected) Falsified Medicinal Product Report

1.1 Download the (Suspected) Falsified Medicinal Product Report template (SFMPR) from the European Medicines Agency (EMA) external website.

1.2 It is the responsibility of the reporter to ensure that the information provided is accurate and complete.

1.3 Mandatory fields (**marked in red**) must be completed in order to save and send the SFMPR template.

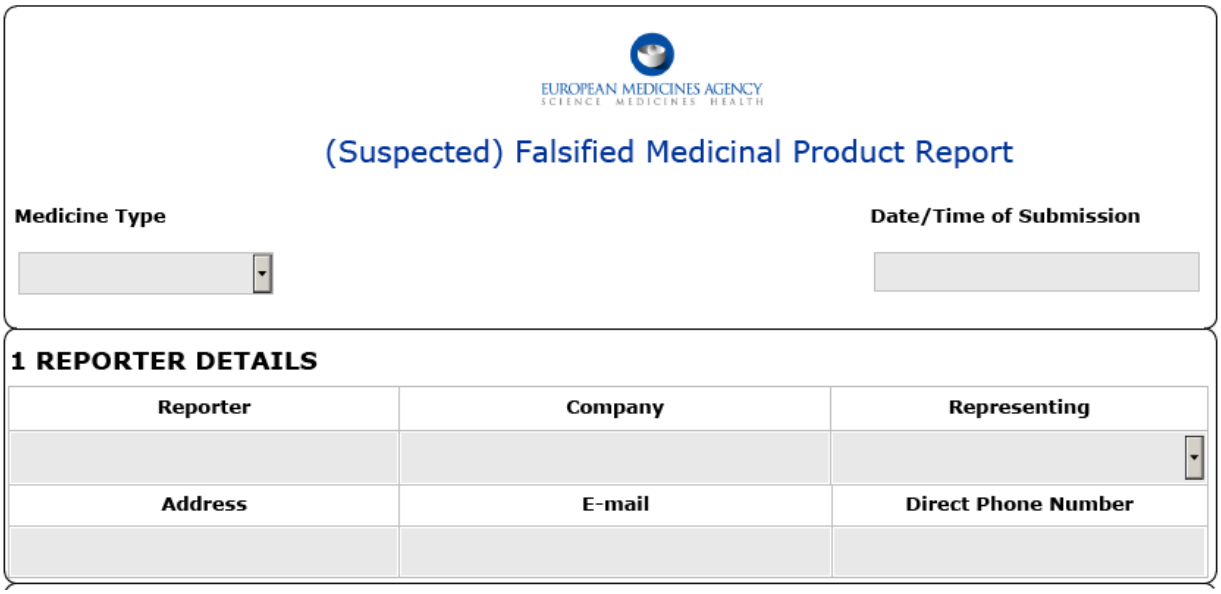
1.4 The SFMPR template is divided into three parts:

- Reporter Details
- Product Details
- Investigation and action details

1.5 What follows is a description of the main features present in the new EMA report. Most of the fields are self-explanatory. If there are any data fields that are not clear please do not hesitate to contact us at: qdefect@ema.europa.eu

2. Reporter Details

This section captures details of the reporter:


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

(Suspected) Falsified Medicinal Product Report

Medicine Type

Date/Time of Submission

1 REPORTER DETAILS

Reporter	Company	Representing
Address	**E-mail**	**Direct Phone Number**

2.1 Reporter name, Company name, email address, postal address and direct phone number are all self-explanatory.

2.2 **Date/Time of Submission**: this field is automatically completed on clicking “Submit Notification”. The e-mail address (qdefects@ema.europa.eu) will be automatically inserted in the address bar of your e-mail.

2.3 **Medicine Type**: choose the correct selection from the drop-down menu (Human/Veterinary/both).

2.4 **Representing**: choose the correct selection from the drop-down menu:

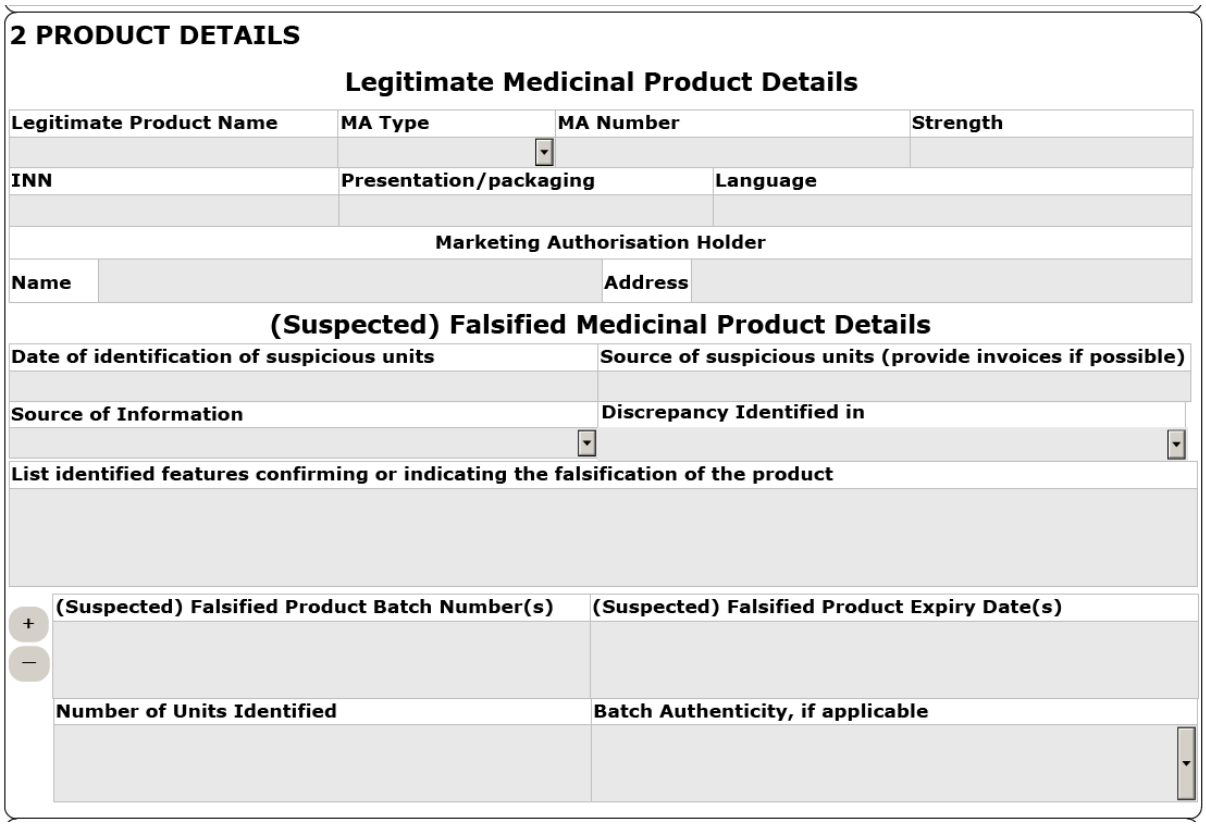
- Manufacturer
- MAH (Marketing Authorisation Holder)
- Parallel Distributor/Parallel Importer
- Other, please specify
- If other, please detail in the related box.

Note that only reports related to Centrally Authorised Products (CAPs) are sent to the EMA. Reports related to Nationally Authorised Products (NAPs) and Mutual Recognition Procedure/Decentralised Procedure (MRP/DCP) should be sent to the relevant National Competed Authority.

3. Product details

This section captures legitimate product and (Suspected) Falsified Medicinal Product/Suspicious Offer details. The data to be provided is divided in “Legitimate Medicinal Product details” and “(Suspected) Falsified Medicinal Product details”.

3.1 **Product details**. Use this part to provide any details related to the legitimate product. The information provided should then be compared with the information related to the (Suspected) Falsified Medicinal Product.



3.1.1 Some fields in this section are mandatory and self-explanatory.

3.1.2 **Marketing Authorisation (MA) Type**: choose the correct selection from the drop-down menu (CAP/NAP/MRP/DCP).

Note that only reports related to CAPs are sent to the EMA. Reports related to Nationally Authorised Products (NAPs) and Mutual Recognition Procedure/Decentralised Procedure (MRP/DCP) should be sent to the relevant National Competed Authority.

3.2 **(Suspected) Falsified Medicinal Product details:** use this part to provide any details related to the (Suspected) Falsified Medicinal Product or to the Suspicious Offer received. From the information provided must be clear why the product is considered to be falsified or why the activity is considered to be illegal.

3.1.1 **Source of Information**: choose the correct selection from the drop-down menu:

- Competent Authority
- Customer complaint
- Healthcare provider

- MAH (Marketing Authorisation Holder)
- Parallel Distributor/Parallel Importer
- Pharmacy
- Safety Features Repository System
- Veterinarian Surgeon
- Wholesaler/Distributor

3.1.2 **Discrepancy identified in**: choose the correct selection from the drop-down menu

- Labelling
- Active pharmaceutical ingredient
- Other, please specify

If other, please add the detail in the related field. Provide more details in the free text field: "List of the features proving the falsification of the product identified (offered)".

3.1.3 **List of identified features confirming or indicating the falsification of the product**: provide a detailed description of all features confirming the falsification. Use this field to also provide information on the distribution of the product (if known).

3.1.4 The two fields (3.1.5 and 3.1.6) can be duplicated by clicking on: "**+**" allowing reporting of additional batch(es) and expiry date(s) identified.

3.1.5 **(Suspected) Falsified Product Batch Number(s):** if known, add the information below:

(Suspected) Falsified Medicinal Product: add any batch number(s) appearing on the outer and inner packaging;

Suspicious offer: add any batch number(s) of the product being offered.

3.1.6 **(Suspected) Falsified Product Expiry Date(s)**: if known, add the information below:

(Suspected) Falsified Medicinal Product: add any expiry date(s) appearing on the outer and inner packaging;

Suspicious Offer: add the expiry date (s) of the batch being offered.

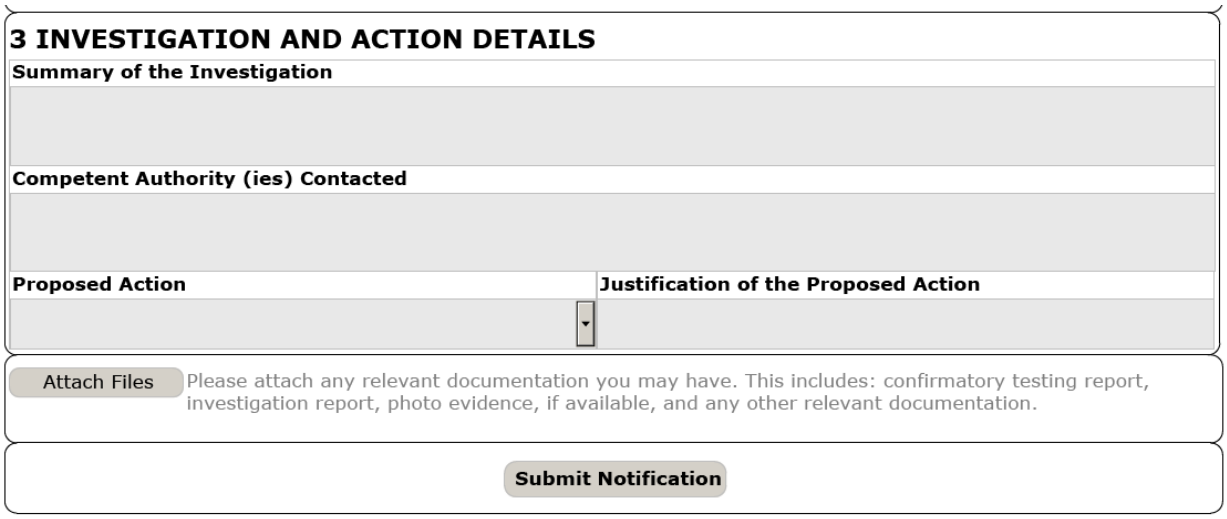
3.1.7 **Number of units identified**: specify how many suspicious units you have identified.

3.1.8 **Batch Authenticity**: specify if the MAH confirmed the authenticity of the batch(es) by choosing the correct selection from the drop-down menu:

- Confirmed
- Not confirmed
- Not determined
- Not applicable

4. Investigation and action details

This final part captures description of the investigation performed and actions proposed:



4.1 Some fields are mandatory. Free text boxes allow the reporter extra flexibility.

4.2 **Summary of the investigation:** describe the investigation performed and the action taken. Provide details of the involved trades, if known.

4.3 **Proposed action**: choose the correct selection from the drop-down menu:

- No recall
- Quarantine
- Recall class I
- Recall class II
- Recall class III
- Other, please specify

If other, please add details. Note that the action will be agreed with the relevant Competent Authority.

4.4 **Attach Files**: attach key documentation such as confirmatory testing report, investigation report, photo evidence of legitimate and falsified suspected/falsified packaging, if available, and any other relevant documentation.

Provide a timeline for your submission if any information is outstanding at the time of reporting.

5. List of abbreviations

CAP: Centrally Authorised Product

INN: International Non-proprietary Name

MA: Marketing Authorisation

MAH: Marketing Authorisation Holder

MRP/DCP: Mutual Recognition Procedure/Decentralised Procedure

NAP: Nationally Authorised Product