EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committees and Inspections
Manufacturing and Quality Compliance

How to use the defective product report to notify a quality defect to European Medicines Agency

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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1. The Defective Product Report (DPR)

1.1 Download the DPR template on European Medicines Agency (EMA) external website.

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

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

1.4 The new DPR temple is divided into four parts:

- **Reporter Details**
- **Product Details**
- **Defect Details**
- **Investigation and actions details**

1.5 What follows is the 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 do not hesitate to contact us at qdefect@ema.europa.eu

2. Reporter details

This section captures the details of the reporter.


Annex 1 to SOP EMA: SOP/INSP/2018

EUROPEAN MEDICINES AGENCY
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Defective Product Report

Medicine Type

Date/Time of Submission

1 REPORTER DETAILS

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

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

2.2 **Medicine Type**: choose the correct selection from the dropdown menu (Human/Veterinary/both)

2.3 **Reporter**, **Company**, **Address**, **E-mail** and **Direct Phone Number** are all self-explanatory.

2.4 **Representing**: choose the correct selection from the dropdown menu:

- Manufacturer

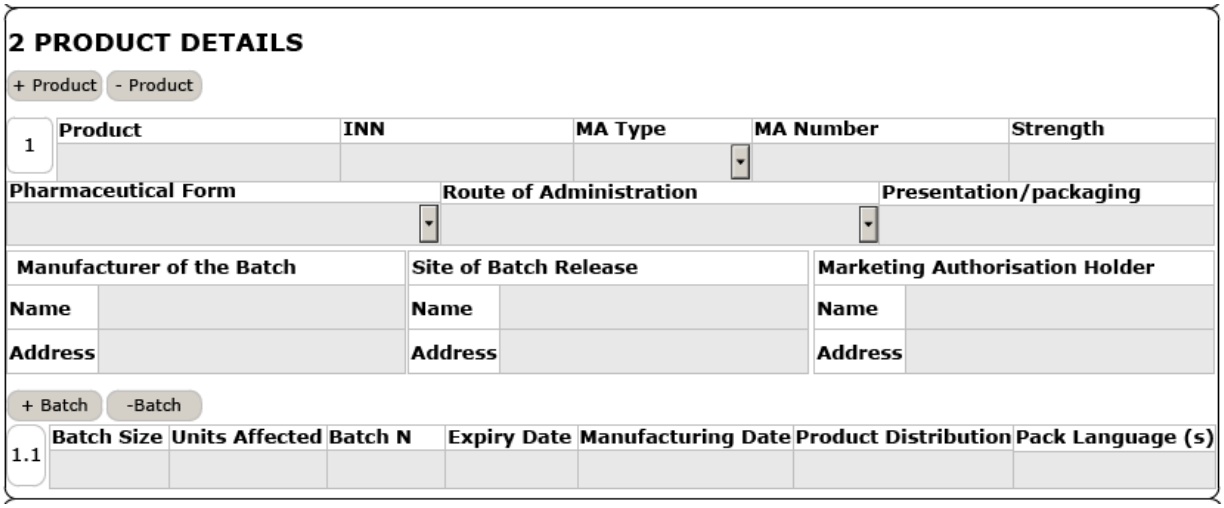
- MAH (Marketing Authorisation Holder)
- Parallel Distributor/ Parallel Importer
- Wholesaler
- Other, please specify

If other, please detail in the related field.

Note that only reports from "Parallel Distributors" and 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) are required to be sent to the relevant National Competed Authority.

3. Product details

This section captures details of product (s) and batch (es) affected by the issue being reported.



3.1. All fields in this section are mandatory and self-explanatory.

3.2 Tables can be duplicated by clicking respectively on:

+ Product: this function duplicates the entire table and allows reporting of additional products impacted by the quality defect (QD). A sequential number (e.g. 1,2,3. Etc.) is assigned to each product/MA number impacted.

+ Batch: this function duplicates the batch table allowing the reporting of all batches of a particular product / MA number impacted by the QD. A sequential sub-number referring to the product reported will be assigned (e.g. for the first product reported (assigned product 1) batch numbers impacted will be linked as 1.1, 1.2 and 1.3; for product 2 impacted batches will be captured as 2.1, 2.2, 2.3 etc.).

3.3 **MA Type**: choose the correct selection from the dropdown menu (CAP/NAP/MRP/DCP).

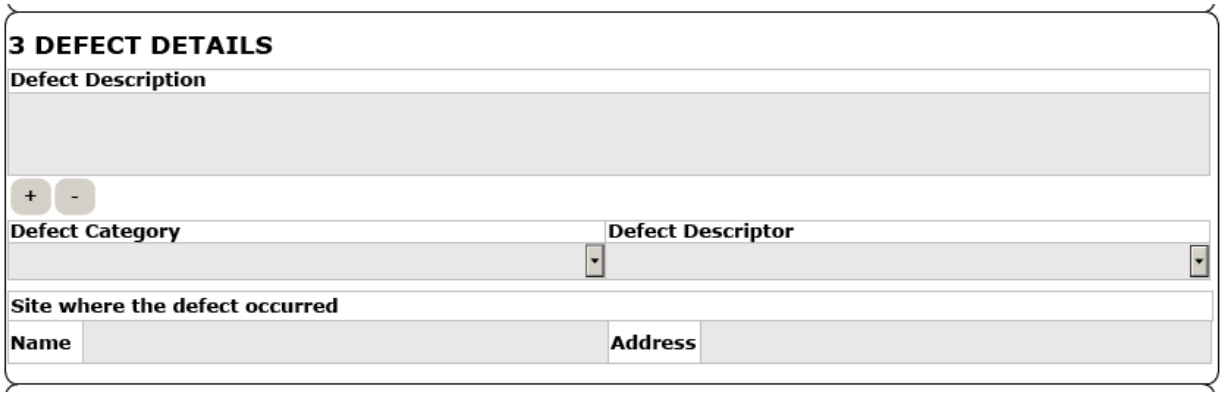
Note that only reports related to CAPs are sent to EMA. Reports related to Nationally Authorised Products (NAPs) and Mutual Recognition Procedure/ Decentralised Procedure (MRP/DCP) are required to be sent to the relevant National Competed Authority.

3.4 **Presentation/packaging**: provide the number of units present in each pack, as per marketing authorisation (e.g. 2 blisters containing 15 tables each)

3.5 **Manufacturer of the Batch** and **Site of Batch Release** are fields to be completed.

4. Defect details

This section captures the description and categorisation of the defect identified.



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

4.2 **Defect Description**: use free text to describe in detail the issue being reported.

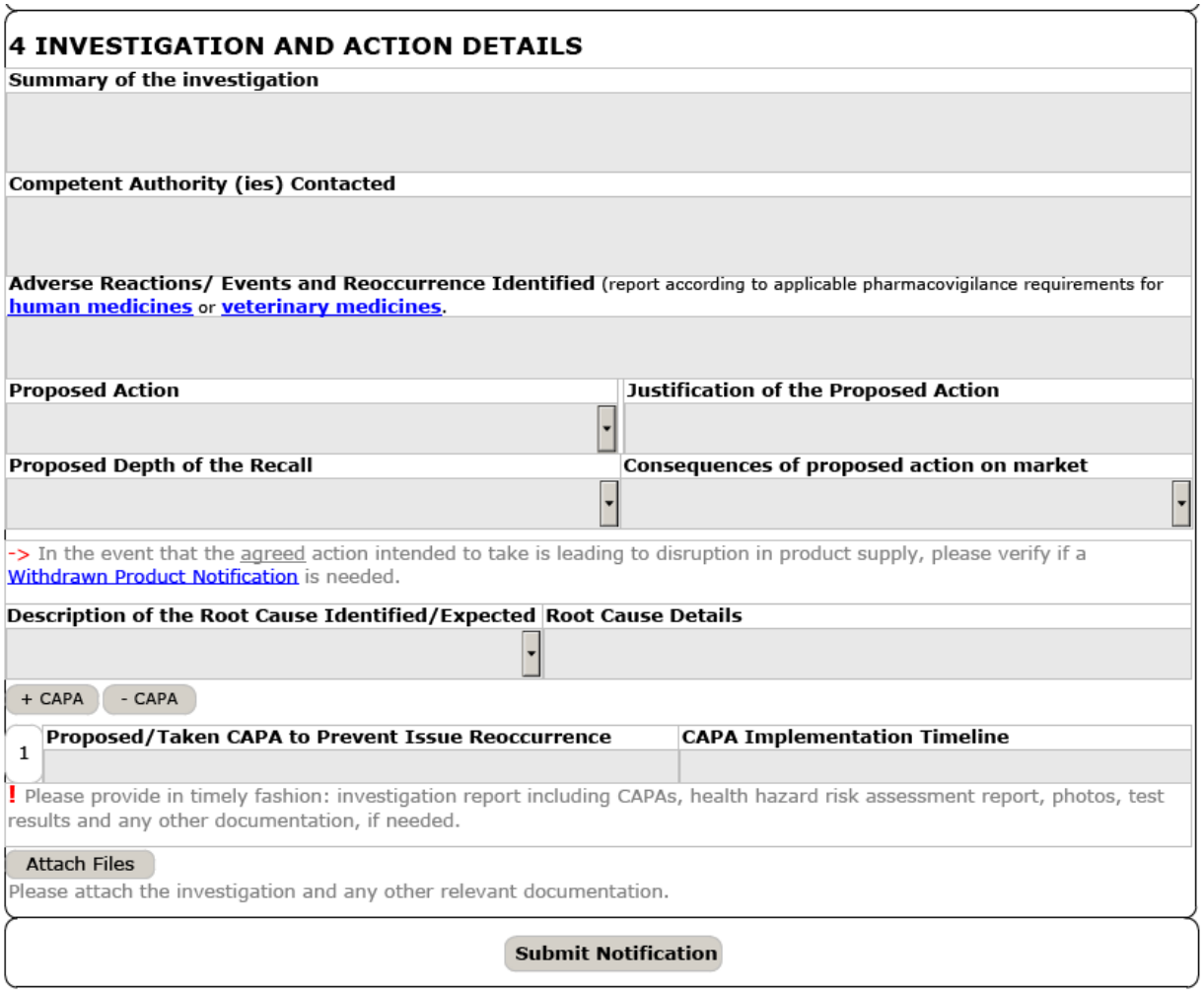
4.3 **Defect Category**: choose the correct selection from the dropdown menu. This contains 5 High Level Terminology (HLTs) enabling the defect to be categorised.

4.4 **Defect Descriptor**: choose the correct selection from the dropdown menu. This contains a set of Preferred Terminology (PTs) linked to the HLT previously selected. Refer to Annex 1 for more details.

4.5 **Site where the defect occurred**: name and address of the facility where the defect originated.

5. Investigation and action details

This final part captures information on the investigation performed and the actions planned/proposed.



5.1 **Summary of the investigation**: summarise the main findings of the investigation. Provide the investigation report.

5.2 **Proposed Action**: choose the correct selection from the dropdown menu (Market Suspension/ No Recall/Quarantine/Recall Class I/Recall Class II/Recall Class III/Other, please specify). If other please detail in the related field. Note any action proposed must be agreed with the local authority.

5.3 **Consequences of proposed action on market**: evaluate the impact of the proposed action on the market. Inform the Agency in case product market disruption is foreseen. Verify if the foreseen consequence is such that a Withdrawn Product Notification is required.

5.4 **Attach Files**: Attach as a minimum investigation report, corrective actions/preventive actions (CAPAs) and health hazard risk assessment report. Add any relevant data to support the regulatory review of the case. If any information is outstanding at the time of the reporting provide a timeline for submission.

6. List of abbreviations

CAP: Centrally authorised product

CAPA: Corrective actions preventive action

DPR: Defective product report

EMA: European Medicines Agency

HLT: High Level Terminology

INN: International non proprietary name

NAP: nationally authorised product

MA: Marketing authorisation

MRP/DCP: mutual recognition procedure/ decentralised procedure

PT: Preferred Terminology

7. Annex – Defect categorisation terminology adopted

SOC System Organ Class	HLGT High Level Group Term	HLT High Level Term	PT Preferred Term	Examples
Product issues	Product quality, supply, distribution, manufacturing and quality issues	*1.0 Manufacturing laboratory controls issue	1.1 Manufacturing laboratory controls issue	Process control issue/ Product quality control issue
			1.2 Out of specification test results	Any type of OOS (stability, release for API and finished product)
				Product formulation issue
				Product impurity
				Product compounding issue
				Product measured potency issue
				Product quality issue (more details required)
		2.0 Product contamination and sterility issues	2.1 Product contamination chemical	Pharmaceutical product contamination
				Preservation media contamination
				Therapeutic product contamination
			2.2 Product contamination microbial	Product biofilm coating
				Product contamination bacterial/ viral/ fungal/ endotoxin/ exotoxin
			2.3 Product contamination physical	Product contamination foreign material/ glass/ hair/ insect/ metal/ plastic/ soil
				Product contamination particulate matter
			2.4 Product contamination with body fluid	Product contamination with blood/ blood derivative
			2.5 Product sterility lacking	Product sterile packaging disrupted
				Product sterile packaging missing
			2.6 Suspected transmission of an infectious agent via product	
		3.0 Product label issues	3.1 Physical product label issue	Physical product label issue
				Product label damaged/ loose/ missing/ missing text
			3.2 Product barcode issue	Product barcode missing
				Product barcode on wrong product

SOC System Organ Class	HLGT High Level Group Term	HLT High Level Term	PT Preferred Term	Examples
				Product barcode readability issue
			3.3 Product expiration date issue	Product expiration date illegible/ incorrect /missing
			3.4 Product identification number issue	Product identification number (excluding batch/lot) illegible/ incorrect /missing
			3.5 Product label issue	Carton label issue
				Product label issue
			3.6 Product label on wrong product	
			3.7 Product lot number issue	Product lot/ batch number illegible/ incorrect/ missing
		4.0 Product packaging issues	4.1 Product blister packaging issue	Product blister packaging separated
				Unit-dose blister pack issue
			4.2 Product closure issue	Product closure deterioration/ missing
				Product stopper coring
			4.3 Product commingling	Wrong and correct product strengths in same container
				Wrong and correct product in same container
			4.4 Product container issue	Product container damaged/ leak/ size or type incorrect
			4.5 Product container seal issue	
			4.6 Product dropper issue	Product dropper calibration unreadable/ improperly calibrated
				Product dropper missing/ tip issue/ tip missing
			4.7 Product outer packaging issue	
			4.8 Product packaging issue	
			4.9 Product packaging quantity issue	Package dosage units missing
				Package empty units
				Package quantity incorrect (overfilling-under filling)
				Unit-dose packaging partial fill

SOC System Organ Class	HLGT High Level Group Term	HLT High Level Term	PT Preferred Term	Examples
		5.0 Product physical issues	5.1 Product coating issue	Product coating cracked/ incomplete
			5.2 Product deposit	Ophthalmic medication precipitation
				Product crystals/deposit/precipitate/sedimentation present
			5.3 Product dosage form issue	Product dosage form imprint incorrect
			5.4 Product gel formation	
			5.5 Product physical issue	Product colour issues
				Product friable
				Product shape issue
				Product size issue
				Product solubility abnormal/decreased/increased
				Product reconstitution issue
				Product taste abnormal
				Product odour abnormal
				Product adhesion issue (e.g. medicinal patch adhesion issue)
				Product difficult to swallow/ Product too hard to chew
				Capsule extra shell/ fill abnormal/ separation issue
				Tablet chipped/ clumping/ cracked/ damaged issue
				Product leakage
				Product physical consistency issue

* Numbers for HLTs and PTs have been added by EMA for defect classification purposes.