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Management of rapid alerts arising from quality defects risk assessment

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Procedure for managing rapid alerts arising from quality defects risk assessment

1. Scope

This procedure covers the transmission across a "Rapid Alert Network" of a rapid alert notification when urgent action is required to protect public or animal health and covers both human and veterinary medicinal products

The rapid alert may be issued to:

1. recall of one or more batches of a medicinal product suspected of having a quality defect
2. recall of one or more batches of a medicinal product suspected to be falsified
3. embargo or quarantine on the distribution of products following suspension or withdrawal of a manufacturing / wholesale authorisation.
4. transmit information such as cautions-in-use, marketing authorisation withdrawals or suspension for safety reasons which may require recall of one or more batches of product from the market.
5. notify quality defects, fraud or falsification in active pharmaceutical ingredients
6. notify quality defects, fraud or falsification in investigational medicinal products
7. follow-up messages to any of the above listed categories

The rapid alert is exchanged between:

1. Competent Authorities in the European Economic Area (EEA) (the "Member States");
2. EU candidate and acceding countries;
3. Mutual Recognition Agreement (MRA) countries, as this procedure operates within the scope of the relevant "Two Way Alert" programmes established between the EU and MRA partners;
4. Authorities participating in PIC/S;
5. The European Commission;
6. The European Medicines Agency (EMA);
7. International organisations (Council of Europe/EDQM, WHO).

Rapid alert notifications and the information shared with the rapid alert network are considered confidential. The further dissemination of the information, if needed, should only be done with EEA member states, MRA partners, EU candidates, WHO and PIC/S participating authorities. The content of the rapid alert notifications should not be published without the consent of the issuing authority.

Pharmacovigilance or Medical Device alerts are not included within the scope of this procedure.

2. Introduction

2.1. Each holder of an authorisation referred to in Article 40 of Directive 2001/83/EC (for medicinal products for human use), Article 61(1) of Regulation (EU) No 536/2014 (for investigational medicinal products) or Article 88 of Regulation 2019/6 (for veterinary medicinal products) is required by Article 13 of Directive (EU) 2017/1572 (for human medicinal products), Article 14 of Commission Delegated Regulation (EU) 2017/1569 (for investigational medicinal products for human use) or Article 13 of Directive 91/412/EEC (for veterinary medicinal products) to implement an effective procedure for the recall of defective products. The authorisation holder is required to notify the relevant Competent Authority of any defect that could result in a recall and indicate, as far as possible, the countries of destination of the defective product.

2.2. In addition, for centrally authorised products, Council Regulation EC/726/2004, Article. 16(2) (for human products) or Regulation 2019/6, Article 58 (10) (for veterinary products), the marketing

authorisation holder is obliged to inform the European Medicines Agency of any prohibition or restriction of supply imposed by the competent authority of any country in which the medicinal product is marketed and of any new information which may influence the evaluation of the benefits and risks of the medicinal product.

2.3. In order to protect public health and animal health, EU authorities can avail of the "Rapid Alert System" which allows exchange of urgent information including urgent measures such as the recall of one or more defective batch (es) of a medicinal product during its marketing period or of an investigational product during clinical trials.

2.4. Each Competent Authority should have a written procedure for the issue, receipt and managing of notifications of defective products, risk assessment of the quality defect, batch recalls and other rapid alerts during and outside normal working hours.

2.5. The Competent Authority of each Member State should assist the authorisation holder in the recall process, as appropriate, and monitor its effectiveness. The Competent Authority should ensure that information concerning the recall of medicinal products is notified rapidly to other potentially concerned Member States, if the nature of the defect presents a high risk to public health. This information should be transmitted by means of the "Rapid Alert System".

3. Definitions

3.1 **Quality defect report**. A report, usually a standard template in use by the receiving authority, informing about a quality defect issue impacting one of more batch (es) of a certain medicinal product or API for human or veterinary use.

3.2 **Quarantine**. Storage in separate areas, clearly marked and with access restricted to authorised personnel.

3.3 **Rapid Alert for Quality Defects/Recall action**. Notification of urgent information on quality defects from one competent authority to other authorities. The information transmitted can be related to a batch recall action that has been instituted in the country originating the rapid alert and may concern other authorities. A rapid alert may also concern a quality defect or other serious information, regardless of whether a recall action has been initiated in the originating country.

3.4 **Rapid Alert Network (RAN).** Network of competent authorities who exchange urgent information on quality defects and/or recalls related to medicinal products through the Rapid Alert System. RAN is composed by competent Authorities in the EEA, EU candidate and acceding countries, Mutual Recognition Agreement (MRA) countries, authorities participating in PIC/S, the European Commission and international organisations (Council of Europe/EDQM, WHO).

3.5 **Rapid Alert System (RAS)**. System in use amongst Authorities part of the Rapid Alert Network (RAN) to transmit alert on quality defects and/or recalls related to medicinal products whose urgency and seriousness cannot be delayed. The RAS includes also the "two-way alert" system established between the EU and MRA authorities.

3.6 **Recall action**. The action of retrieving one or more batch (es) from the distribution chain and users. A batch recall may be partial, in that the batch is only recalled from selected distributors or users. The extent of the recall of a batch is defined by the level of the quality risk associated and can go from a recall on patients' level (including owners of animals) to a recall limited to community pharmacies, veterinarians or wholesalers. Batch recalls may or may not be accompanied by withdrawal of a marketing authorisation.

3.7 **Supervisory Authority**. Authority of the country where the manufacturing facilities interested by the quality defect are located. These facilities could be the sites where the issue occurred or where the batch takes place.

3.8 **Suspected defective product**. A medicinal product about which a report has been received suggesting that it is not of the correct quality, as defined by its Marketing Authorisation.

3.9 **Suspected falsified medicine**. Any medicine with a false representation of its

1. identity, including its packaging and labelling, and the name, composition and strength of any of its ingredients including excipients;

2. source, including its manufacturer, country of manufacturing, country of origin and its marketing authorisation holder;

3. history, including records and documents on distribution channels used.

3.10 **Withdrawal of marketing authorisation**. Interruption of placing on the market of the medicinal product by the marketing authorisation.

4. Criteria for issuing a rapid alert

4.1 The aim of the "Rapid Alert System" is to transmit urgent and serious alerts without any delay.

4.2 Before any Rapid Alert is issued to communicate a potential recall issue, a risk-based classification should be assigned to the rapid alert and the recall action if relevant. In this regard, the following should be noted:

1. The classification assigned to a recall action and to a rapid alert should reflect case urgency and seriousness.

2. In this context, the term 'urgency' relates to the urgency in taking a recall or other action in order to adequately protect patients, animals and users of medicines from the risks posed by quality defects in those medicines. When considering the 'urgency' of a recall action or a rapid alert, the risk-based classification that has been assigned to the quality defect report (High Risk, Moderate Risk, Low Risk) is taken into account. Refer to the procedure titled "Management and Classification of Reports of Suspected Quality Defects in Medicinal Products and Risk-based Decision Making "for more details in this regard, as well as Appendix 1 to that procedure.

4.3 There are three different risk-based classifications that may be assigned to a rapid alert (with or without a recall action) and to recall actions:

1. Class I

2. Class II

3. Class III

The above risk-based classification is defined in Part III of Appendix 1 of the procedure for management and classification of reports of suspected quality defects in medicinal products and risk-based decision-making.

4.4 The dissemination of the Rapid Alert takes into account the assigned class and also the countries effectively concerned by the batch (es) distribution.

5. Issue of a rapid alert notification

5.1. Responsibility

5.1.1. For a batch manufactured in a Member State, or a batch manufactured in a third country and imported into the EEA, which is the subject of a national (including mutually recognised or decentralised) marketing authorisation, the Competent Authority of the Member State in which the defect was first identified should investigate the defect and issue the rapid alert (the issuing authority).

5.1.2. In the case of a centrally authorised product, and in the exceptional case of a product that has both a centralised and a national authorisation, the Competent Authority of the Member State in which the defect occurred should lead the investigation of the defect and issue the rapid alert. If the defect occurred in a third Country, the Supervisory Authority identified by the EMA should lead the investigation of the defect and issue the rapid alert.

5.1.3. In the event of immediate danger to patients, animals, consumers or environment, the Competent Authority of the Member State where the defect was first identified should lead the investigation and issue the rapid alert.

5.1.4. In both cases the alert should include a recommendation on proposed action(s) for all affected authorities.

5.1.5. In the case of centrally authorised products and when time allows, the content of the proposed action(s) should be agreed between:

1. the Supervisory Authority,
2. the Issuing Authority (if different from the Supervisory Authority),
3. the European Medicines Agency and the CxMP rapporteur.

5.1.6. In some circumstances and especially when the Supervisory Authority has conducted all the required assessment, the Member State in which the defect was first identified may delegate to the Supervisory Authority the issuing of the Rapid Alert.

5.1.7. When, due to the urgency of the defect there is not sufficient time to develop a harmonised proposed action, this section of the Rapid Alert notification should inform all recipients that the European Medicines Agency will co-ordinate further action in co-operation with the relevant Supervisory Authority, in accordance with the Agency's Crisis Management Procedures and that harmonised follow- up actions will be transmitted when ready.

5.1.8. In the case of parallel distribution of a centrally authorised product and where no repackaging is done, the procedure described under 5.1.2 applies. This procedure also applies if the defect resulted from a repackaging operation. Where repackaging is carried out but the defect results from the original manufacturing process, the procedure described under 5.1.2 still applies, but the rapid alert should include descriptions of the different packaging in which the product might appear (for example different language versions and pack sizes) where this information is available from the European Medicines Agency.

5.1.9. In the case of a parallel import, the Competent Authority of the Member State in which the defect was first identified should issue the rapid alert.

5.2. Format of the rapid alert and its transmission

5.2.1. A suitable format for the notification of quality defects by the Rapid Alert System is given in Appendix 1.[1] The form should be completed clearly in English. The notification and relevant documents should be sent to the rapid alert contact list by electronic mail. The contact list and any relevant documents should be attached to the notification.

5.2.2. The electronic mail message should use a unique subject line to identify the rapid alert and any follow-up messages. The subject line should consist of the following:

<table>
<tr><th colspan="2">Type of rapid alert</th><th>Class</th><th>Medicine type</th><th>Product</th><th>Action</th><th>Reference number</th></tr>
<tr><td rowspan="3">RapidAlert</td><td>Qdefect</td><td rowspan="3">I
II</td><td rowspan="3">H or V</td><td rowspan="3">Name + INN</td><td>Recall</td><td rowspan="3">Country/Class/N°/N°</td></tr>
<tr><td>Falsified</td><td>No Recall</td></tr>
<tr><td>Fraud</td><td>Follow-up</td></tr>
</table>

Figure: 1. Example: RapidAlert; Qdefect; I, H; Product X; Follow-up, CH/I/07/01.

[1] The template can be downloaded at the following link: https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/compliance-post-authorisation/quality-defects-recalls

5.2.3. The rapid alert should be given a unique reference number with the following format: Country code (country where the original alert was issued)/Region or Authority code (where applicable)/classification/year/sequential number/correspondence number. (For example, ES/II/2019/05/02 would indicate a class II rapid alert initiated by Spain, being the 5th rapid alert initiated by Spain in 2019 and that it is the second correspondence regarding this rapid alert.) The sequential number should reset every year.

5.2.4. Transmission of a Class I and, whenever feasible of a Class II, rapid alert must be concurrent with the national action and in all cases should be within 24 hours of the national notification.

In the case of a Class I alert, it may be necessary to notify authorities in different time zones in addition by telephone.

5.2.5. When an authority issues an additional rapid alert for a batch, the field 21 in the form in Appendix 1 "Detail of Defect/Reason for recall" should begin with the text: "Rapid Alert following original rapid alert #ref. no.#".

5.3. Rapid alert contact list

5.3.1. The European Medicines Agency maintains the contact list for the rapid alert notifications of the competent authorities covered by Section 1. There is normally one contact per authority nominated by each member state. Changes to contact names or details must be notified to the European Medicines Agency (qdefect@ema.europa.eu) and are circulated immediately to the entire list by electronic mail. Contact details include telephone and fax numbers, electronic mail address, which should be monitored at all times.

6. Fraud and falsified products

6.1. It is acknowledged that the meaning of words such as "falsified" and "fraud" may vary from one country to another. It is also acknowledged that, in the European Union, the meaning of "falsified medicinal product" corresponds to the definition provided by Article 1 (c) of directive 2011/62/EU.

6.2. The Rapid Alert System should be used to notify competent authorities of the possible presence in the legal distribution network of falsified products or those resulting from fraud in manufacture, packaging, distribution or suspicious offer and products containing qualitative and/or quantitative different active substances than those described in the marketing authorisation.

6.3. The Competent Authority of the Member State or MRA partner in which the fraud or falsification was first detected should issue the Rapid Alert. The format for the rapid alert notification in Appendix 1 may be used, but the heading on the document should make clear that the notification relates to fraud or to a falsified product and sufficient information should be provided under "details of defect" to enable it to be identified. Notification should be sent to the entire Rapid Alert contact list.

7. Follow-up action

7.1. The Competent Authority of each Member State and MRA partner to which a recalled product was exported should monitor the conduct and effectiveness of any national recall that it initiates as a result of the rapid alert notification.

7.2. The relevant Supervisory Authority should investigate the circumstances that led to the manufacturing and distribution of the defective product and ensure that any necessary corrective action is taken by the manufacturer, parallel trader, wholesaler, and marketing authorisation holder as appropriate.

7.3. The European Medicines Agency should co-ordinate follow-up action for recalls of centrally authorised products.

7.4. All follow-up actions transmitted through the Rapid Alert System should use the form for Follow-up and non-urgent messages for Quality Defects detailed in Appendix 2 to separate it from Rapid Alerts. It should have a reference number linking it to the original Rapid alert following the same format as described above.

8. Further use of rapid alert contact list

8.1. Although the contact list for rapid alert notifications shall be only used for the transmission of notification related to product quality defects GMP non-compliance procedure, in exceptional cases, if deemed relevant by the competent authority, the list may be used for the communication of other important and urgent information related to pharmaceutical products. These messages should clearly identify the subject and whether they are for information or action. For example, the European Medicines Agency disseminates urgent information from its scientific committees in this way.

9. Appendices

9.1. Appendix 1: Format for rapid alert notification of a quality defect

9.2. Appendix 2: Format for follow-up and non-urgent information for quality defects

Appendix 1

IMPORTANT: DELIVER IMMEDIATLY- Rapid alert notification of a Quality Defect/Recall

"Confidential. For regulatory authority use only. Not intended for publication"

Add letter head of sender

1. Reference Number

2. Recall Number Assigned (if available)

\+ -

Attach file

3. To: (see list attached, if more than one)

4.Files attached?

5. For use in

6. Product recall/class of defect

7. Reason

+ Product - Product

	8. Product	9. Strength	10. INN or Generic name	11. Pack size and Presentation
1				

12. Brand/Trade Name	13. Dosage Form	14. Marketing Authorisation Number

+ Batch - Batch

	15. Batch Number (and bulk, if different)	16. Date manufactured	17. Expiry Date
1.1			

18. Marketing Authorisation Holder

Name

Address

E-mail

Phone

19. Manufacturer

Name

Address

E-mail

Phone

20. Recalling Firm (if different)

Name

Address

E-mail

Phone

21. Site where the defect occurred (where the defect is attributed to a manufacturing site and if different from 19)

Name

Address

E-mail

Phone

22. Details of the Defect/Reason for the Recall

23. Information on Distribution including exports (type of customer, including parallel distribution/importation)

24. Action Taken by the Issuing Authority

25. Proposed Action

26. Issuing Authority

From (Issuing Authority)

Phone

Contact person **E-mail**

Signature **27. Date/Time**

Appendix 2

Follow-up and Non-urgent Information for Quality Defects

"Confidential. For regulatory authority use only. Not intended for publication"

Add letter head of sender	**1. National Reference Number (when applicable)**	
	2. Recall Number Assigned	

+ | -

Attach files

3. To: **(see list attached, if more than one)**

4.Files attached?

+ Product | - Product

1

5. Product | **6. Strength** | **7. INN or Generic name**

8. Brand/Trade Name | **9. Dosage form** | **10. Marketing Authorisation Number**

+ Batch | - Batch

11. Batch number (and bulk, if different)

1.1

12. Marketing Authorisation Holder		**13. Manufacturer**	
Name		**Name**	
Address		**Address**	
E-mail		**E-mail**	
Phone		**Phone**	

14. Subject title

15.Issuing Authority Contact Person

From (Issuing Authority)

Contact Person **E-mail** **16. Date/Time**

Phone **Signature**