EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Standard operating procedure

| Title: Dealing with reports of suspected defective medicinal products | | |
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## 1. Purpose

This SOP defines the actions and responsibilities for the handling of reports of suspected defective centrally authorised medicinal products received by the EMA Secretariat, and which may require immediate action.

This SOP applies to all defective product reports and to all reported product quality problems received by any EMA staff member for medicinal products for human and veterinary use. These reports may concern all or some batches placed on the market for commercial use and/or batches used in clinical trials. The procedure may also be used for reports concerning falsified centrally authorised medicines[1].

The procedure may also be used for co-ordinating follow up action following receipt of reports of confirmed Out of Specification (OOS) or Out of Trend (OOT) results affecting centrally authorised products received from Official Medicines Control Laboratories (OMCL), in the context of the sampling and testing programme or in the context of Official Control and Batch Release (OCABR).

The procedure also applies to dealing with reports or statements of suspected or confirmed GMP non-compliance issued by the competent authorities of member states or from international partners e.g. (FDA Warning Letters, WHO notices of concerns, EDQM), or information received from "whistle-blowers").

It is also a basis for dealing with quality related crises which affect nationally authorised products and where a Member State has requested a central co-ordination of the issue, or where the issue has been referred to the CxMP.

[1] This SOP does not cover reports of infringements of intellectual property rights (IPR), including trademark and patents, or other illegal activities such as diversion of supplies of authorised medicinal products, or theft of authorised medicinal products.

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## 2. Scope

This SOP applies to the Manufacturing and Quality Compliance Section, and should be read in conjunction with the documents listed under section 6.

## 3. Responsibilities

It is the responsibility of each Head of Unit/Sectors/Sections to ensure that this procedure is adhered to within their own Unit/Sector/Section. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of section 9.

The Head of Manufacturing and Quality Compliance Section (P-CI-MQC) is responsible for direct management oversight of the procedure and appoints the P-CI-MQC co-ordinator (MQCC) for a particular issue.

The responsibility of the MQCC is to convene a team, the (reduced) European group for product defects (R)ECG) and to co-ordinate an effective assessment of the reported issue and reach a conclusion on regulatory measures needed. The role of team members may vary and the roles and responsibilities of the different parties involved in dealing with reports of defective medicinal products are summarised in Annex 2.

The (R)ECG consists of representatives from the supervisory authority(ies), the (co)rapporteur, the CxMP members, and the PTL's. Depending on the nature of each case it may be necessary to escalate the procedure to a crisis thereby invoking the involvement of other parties such as the entire CxMP, or the European Commission as appropriate. The purpose of this co-ordinating role is to minimise the hazard to patients and/or animals arising from the distribution of defective medicines.

It achieves this aim by:

- Receiving, compiling and distributing to relevant parties the reports of suspected defective medicinal products. The MQCC acts as a Duty Officer for out of hours reporting.
- Establishing a timetable and co-ordinating the assessment of the reports and facilitating effective communication between all parties involved.
- Mobilising Agency resources.
- Acting as a point of contact and ensuring that all interested parties are rapidly and fully informed.
- Ensuring that concerted action is taken and communicating the details of these actions to relevant parties, as necessary.
- Monitoring agreed actions taken by the MAH and/or manufacturing or import authorisation holder (MIAH).

The P-CI-MQC Section operates a telephone reporting line during normal office hours. Outside core working hours, on Agency holidays and in an emergency situation, a duty officer can be contacted via mobile phone.

## 4. Changes since last revision

Extensive revision to reflect current experience gained regarding quality defects of centrally authorised products (CAPs). Clarify the scope of the procedure, delineate in more detail the responsibilities of the parties involved, clarify some steps in the procedure as well as data requirements and to implement some standard time-frames for parts of the procedure.

The annexes and the reporting forms have been modified. Two new work instructions are referenced for out of officers cover and administrative aspects of dealing with reports of product defects. Templates have been revised. Reflecting changes in EMA organisational structure.

## 5. Documents needed for this SOP

The following documents can be found under X:\Templates\Others\Compliance and Inspection\GMP\Quality Defect:

Annex 1 - Defective product report form template

Annex 2 - Decision checklist template

Annex 3 - EMA Compliance and Inspections Sector contact details

Annex 4 - Summary of the roles of the different parties in the event of a potential quality defect

Annex 5 - Responsibilities of European group for product defects

Annex 6 - Assessment report template

Annex 7 - Follow up actions

## 6. Related documents

- SOP/PDM/1004 Core master files of medicinal products for human and veterinary use following the centralised procedure
- Commission Directive 2003/94/EC (http://ec.europa.eu/health/files/eudralex/vol-1/dir_2003_94/dir_2003_94_en.pdf)
- Directive 91/412 (http://ec.europa.eu/health/files/eudralex/vol-5/dir_1991_412/dir_1991_412_en.pdf)
- Chapter 8 EU GMP Guide (http://ec.europa.eu/health/files/eudralex/vol-4/pdfs-en/2005_12_gmp_part1_chap8_en.pdf)
- Compilation of Community Procedures in inspections and exchange of information: Handling of Reports of Suspected Quality Defects in Medicinal Products (Doc.- Ref: EMA/INS/GMP/313507/2006 Rev 1) (http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004711.pdf)
- Compilation of Community Procedures in inspections and exchange of information: Procedure For Handling Rapid Alerts Arising From Quality Defects (Doc.-Ref: EMA/INS/GMP/313510/2006 Rev 2) (http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004712.pdf)
- Compilation of Community Procedures in inspections and exchange of information: Procedure for dealing with serious GMP non-compliance for voiding/suspension of CEP's thus requiring co-ordinated administrative action (Doc.-Ref.: EMA/INS/GMP/23567/2009) (http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004721.pdf)

- The European Union Regulatory System Incident Management Plan for Medicines for Human Use (Doc.-Ref.: EMEA/579383/2008)
- Regulation 726/2004 Of The European Parliament And Of The Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (http://eur-lex.europa.eu/pri/en/oj/dat/2004/l_136/l_13620040430en00010033.pdf)
- Directive 2001/83/EC of the European Parliament and of the Council (http://ec.europa.eu/health/files/eudralex/vol-1/dir_2001_83_cons2009/2001_83_cons2009_en.pdf)
- Directive 2001/82/EC of the European Parliament and of the Council (http://ec.europa.eu/health/files/eudralex/vol-5/reg_2009-470/reg_470_2009_en.pdf)
- Instructions on Notifying Quality Defects or Product Recalls of Centrally Authorised Products to the EMA (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000238.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580024593)

# 7. Definitions

***Batch recall:*** the action of withdrawing a batch from the distribution chain and users. A batch recall may be partial, in that the batch is only withdrawn from selected distributors or users.

***Crisis due to a quality defect report:*** an event which occurs when new information, which could have a serious impact on public/animal health, is received for a CAP, and which requires immediate and concerted action across the EU Medicines Network.

***Falsified medicine*:** Any medicinal product with a false representation of its identity, source or history.

***Depth of recall:*** level within the distribution channel from which a product is recalled, i.e.: wholesale, retail, user/consumer.

***European Crisis Group:*** European Team responsible for managing a crisis situation and defining the overall strategy to handle the crisis. The composition of the team may vary on a case by case basis: Refer to Annex 2. Most suspected quality defects are handled by a Reduced European Crisis Group (see definition below).

***MAH's person responsible for quality defects (MAH-QD)*:** person nominated by the applicant/MAH for informing the EMA/ Supervisory Authority (SA) and dealing with defective products. The name and contact details can be found in SIAMED.

***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.

***Rapid alert:*** an urgent notification from one supervisory authority to other authorities that a batch recall has been instituted in the country originating the rapid alert. The procedure for issuing rapid alerts is defined in the Compilation of Community Procedures[2].

***Defect classification:*** recalls are classified with regard to the relative health hazard associated with the use of or exposure to the recalled product. There are three possible classifications:

[2] Compilation of Community Procedures on Inspections and Exchange of Information

Class I: defects are potentially life threatening.

Class II: defects could cause illnesses or mistreatment, but are not Class I.

Class III: defects may not pose a significant hazard to health, but withdrawal may be initiated for other reasons.

***Reduced European Crisis Group (RECG):*** It may be appropriate for the crisis to be handled by a reduced European Crisis Group composed of representatives of the Supervisory Authority, Rapporteur, PTL and the MQCC.

***Safety issue:*** pharmacovigilance issues (e.g. an urgent safety hazard).

***Supervisory Authority:*** (defined in Article 18 for human medicinal products and Article 43 for veterinary medicinal products of Regulation 726/2004) In the case of medicinal products manufactured within the Community, the supervisory authorities are the competent authorities of the Member State which have granted the manufacturing authorisation provided for in Article 40(1) [3] of Directive 2001/83/EC in respect of the medicinal product concerned. In the case of medicinal products imported from third countries, the supervisory authority(ies) shall be the competent authority(ies) of the Member State(s) that granted the manufacturing authorisation provided for in Article 40(3) [4] of Directive 2001/83/EC to the importer. This concept is applied to all other medicinal products in the Compilation of Community Procedures.

***Suspected defective medicinal product:*** a medicinal product about which a report has been received suggesting that it is not of the correct quality, as defined above.

## Abbreviations used in the document

| | |
|---|---|
| BWP: | Biologics Working Party |
| CAP: | Centrally authorised product |
| CHMP: | Committee for Medicinal Products for Human Use |
| CVMP: | Committee for Medicinal Products for Veterinary Use |
| CxMP: | CHMP and/or CVMP |
| DHCP: | Dear Healthcare Professional |
| DPR: | Defective product report |
| DREAM: | Document Records Electronic Archive Management |
| EC: | European Commission |
| ECG: | European Crisis Group |
| EDQM: | European Directorate for the Quality of Medicines |
| EMA: | European Medicines Agency |
| MQCC: | EMA Manufacturing and Quality Compliance coordinator for Quality Defects |
| MA: | Marketing authorisation |
| MAH: | Marketing authorisation holder |

[3] Article 44(1) of Directive 2001/82/EC on the Community code relating to veterinary medicinal products
[4] Article 44(3) of Directive 2001/82/EC on the Community code relating to veterinary medicinal products

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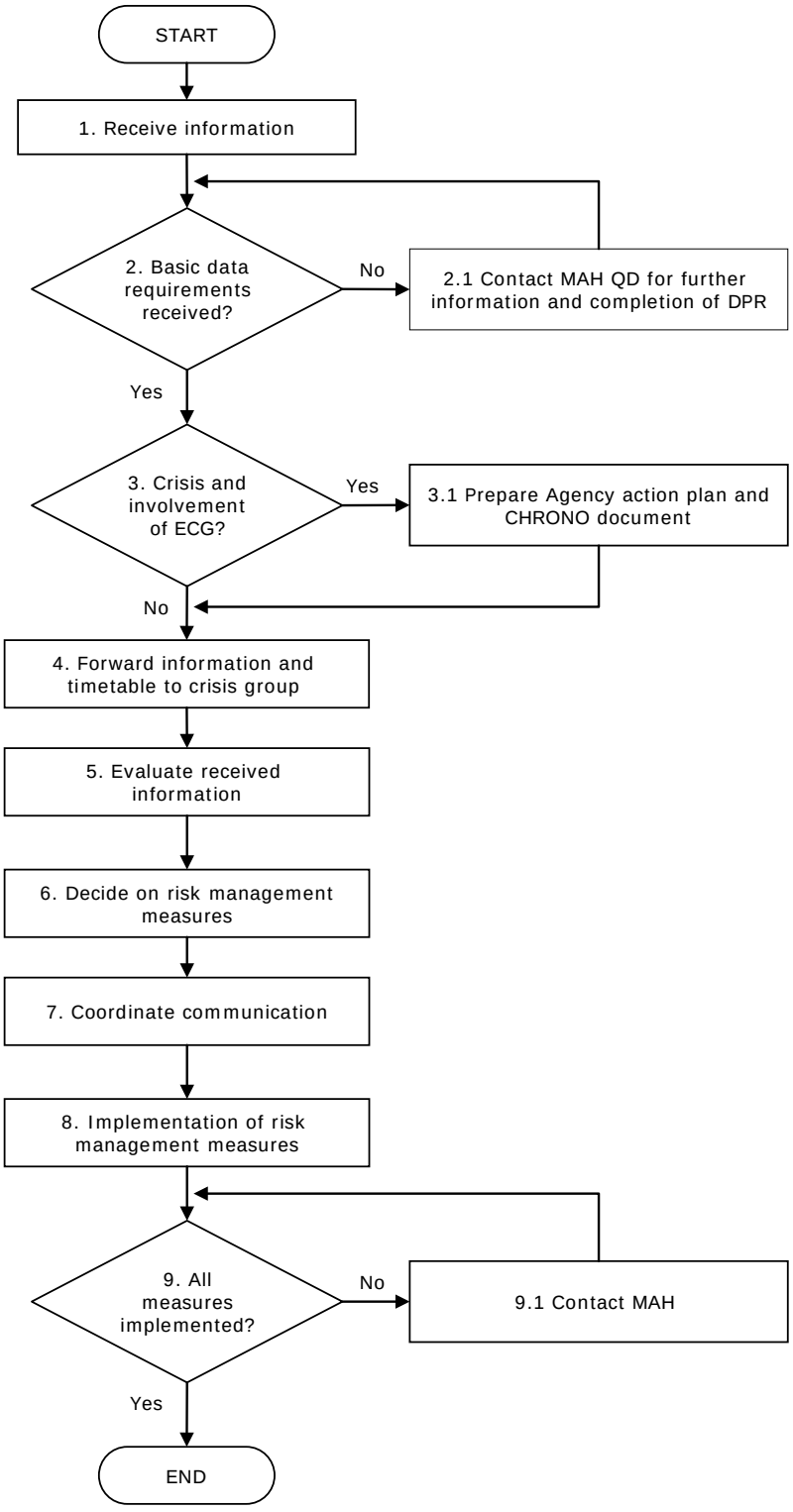
| MAH-QD: | Marketing authorisation holder's person responsible for quality defects |
| MIAH: | Manufacturing or Import Authorisation Holder |
| MRA: | Mutual Recognition Agreement |
| MS: | Member State |
| NCA(s): | National Competent Authority |
| OCABR: | Official Control and Batch Release |
| OMCL: | Official Medicines Control Laboratory |
| OOS: | Out of Specification |
| P-CI-MQC: | Manufacturing and Quality Compliance Section in the Inspection and Compliance Sector in the Patient Health Protection Unit |
| PTL: | Product Team Leader for human products or Project Manager for veterinary medicinal products |
| QDEFECT: | Quality Defect |
| QWP: | Quality Working Party |
| Rapp: | Rapporteur |
| RECG: | Reduced European Crisis Group |
| SA: | Supervisory Authority |
| SIAMED: | Sistema de Información Automatizada sobre Medicamentos, which is a model system for computer assisted drug registration that enables the EMA to track its core processes and retrieve key registration data |

# 8. Process map(s)/ flow chart(s)



# 9. Procedure

| Step | Action | Responsibility |
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| 1 | Receive potential quality defect information through the following channels:<br><br>P-CI-MQC QDEFECT Mail Box: Screen initial report and assign to a MQCC within 4 hours of receipt.<br><br>P-CI-MQC QDEFECT Office Telephone and P-CI-MQC QDEFECT Out of Hours Mobile Phone: Record initial information with reference to Annex 1 of this SOP. Screen callers and if appropriate advise to submit the information in writing through QDEFECT. Agree an appropriate timetable.<br><br>From other EMA staff receiving information suggesting a quality defect: If the initial report is provided to other EMA personnel (e.g. PTL or PM), it should be referred to the QDEFECT inbox with minimum delay. | Any member of P-CI-MQC staff. |
| 2 | Basic data requirements received?<br><br>If no, continue with Step 2.1.<br><br>If yes, continue with Step 3. | MQCC |
| 2.1 | Contact the MAH-QD to obtain all the information necessary to complete an assessment.<br><br>Notifications on product defects can also be received through the pharmacovigilance system. Pharmacovigilance signals such as cases of an adverse reaction, lack of efficacy, or suspicion thereof, which are suspected to be associated with the quality of the medicinal product, may require further follow up with the MAH on the quality and manufacturing of a particular batch.<br><br>It may then be necessary to conduct an initial investigation and assessment following this procedure to establish an underlying problem with the quality of a particular batch. The MQCC should in parallel continue with all steps described in this SOP working together with EMA colleagues responsible for pharmacovigilance procedures. If it has been established that the pharmacovigilance signal was not caused by a quality defect, this procedure finalises and the issue continues to be dealt with according to the pharmacovigilance procedures. Where it is established that the pharmacovigilance signal was caused by a quality defect then the issue will continue to be handled by this procedure.<br><br>Information concerning suspected defective medicinal products or GMP non-compliance may be received from whistleblowers. Allegations from whistleblowers typically originate from within a manufacturing or test facility and may concern centrally authorised | MQCC |

| Step | Action | Responsibility |
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| | or non-centrally authorised medicinal products.<br><br>The level of confidentiality should be agreed with the whistle-blower in advance. The supervisory authority should be asked to investigate the allegations and to report their findings to the EMA.<br><br>Continue with step 2. | |
| 3 | Crisis and involvement of ECG?<br><br>Make a preliminary screening of the report and establish if the ECG or the RECG should be convened. The RECG is normally convened and will recommend whether a full ECG is needed. The ECG can be convened at any later time should the need arise.<br><br>In a crisis situation, continue with Step 3.1.<br><br>If there is no crisis situation, continue with Step 4. | MQCC |
| 3.1 | In a crisis situation, convene the ECG.<br><br>There may be multiple requests for information to be obtained from the MAH from the ECG members covering safety and quality aspects. Ideally, compile a single list of questions and a timetable for transmission to the MAH.<br><br>Prioritise requests for information to ensure that the MAH can focus on the most important questions in order to provide the most relevant information first. It may be necessary to establish and communicate the Agency priorities to the MAH at an early stage in order to focus subsequent actions.<br><br>If necessary, establish a single Agency point of contact between the MAH and the ECG to ensure streamlined and consistent communications and rapid turn around of replies. This policy and the single point of contact should be agreed and regularly reviewed.<br><br>Initiate the preparation of an evolving Agency action plan with tasks, responsibilities and timelines identified. Circulate the action plan to all team members participating in the ECG. Maintain the action plan with all members of the ECG, responsibility for maintenance is agreed depending on the stage of the procedure.<br><br>Initiate the preparation of an evolving CHRONO document to capture the main steps taken by the ECG in a crisis situation. Circulate the CHRONO document to all team members participating in the ECG. Maintain the CHRONO document with all members of the ECG, responsibility for maintenance is agreed depending on the stage of the procedure.<br><br>Initiate a lessons learned exercise. | MQCC |
| 4 | Forward information and timetable to (R)ECG. | MQCC |

| Step | Action | Responsibility |
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| | Ensure that the (R)ECG agrees on a preliminary professional assessment of the nature, extent, urgency of possible public/animal health risk and evaluation of the seriousness of the defect using the recall classification. If more than one SA or Rapporteur is involved, ensure an agreement is reached which SA or Rapporteur takes the leading role.<br><br>It may be necessary to convene a teleconference or meeting with all parties of the ECG or RECG, to agree on the classification and urgency of the issue and propose any concerted action plan needed. | |
| 5 | **Evaluate received information**.<br><br>Ensure that professional assessment of the risk by the (R)ECG involves discussion with the MAH-QD and may include consideration of:<br>• History of the incident.<br>• Any other reports which may be related.<br>• The distribution pattern of the batch (e.g. restricted to known hospitals, widespread through wholesalers, parallel distribution).<br>• Volume of product in the market (e.g. total volume of product distributed with expiry dates, countries involved in the EEA, MRA and third countries) and the consumption rate of the product.<br>• Authentication and/or distinguishing features that may be made known to the public.<br>• Probability that other batches are affected in the same way, and their distribution.<br>• Any remaining stock with the manufacturer.<br>• Effectiveness of the recall (if a voluntary recall has been planned or carried out). This can vary per MS.<br>• Details of the investigation(s) carried into the cause of the defect by the MAH.<br>• Corrective/preventative/follow-up action taken/proposed by the MAH.<br>• Overall conclusions.<br><br>If a recall is being considered other issues to consider include:<br>• Possibility of an out-of stock situation.<br>• Availability of alternative products. | MQCC |

| Step | Action | Responsibility |
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| | • Clinical effect of a disruption in supply.<br><br>When the ECG is convened, ensure that a decision is reached whether the potential hazard to health is such that extraordinary measures must be taken (including the convening of an emergency action group out-of-office hours) or whether further measures may be left for normal office hours.<br><br>Establish if there is a need to develop preliminary "Lines to Take".<br><br>It may also be necessary to contact the MRA or other international partners to communicate on the issue to obtain further information and to agree on concerted actions if possible.<br><br>In the case of a product defect under evaluation by the ECG and/or where the issue is to be discussed at the CxMP or a scientific working party, send to the Rapporteur the template for the Assessment Report (Annex 6). Complete Part I and send the report to the Rapporteur for completion of Part II. The PTL sends the AR to the CxMP or CxMP Working Party for adoption and/or discussion at the next plenary or extraordinary meeting.<br><br>**Falsification**<br><br>Contact also the (R)ECG in the case of suspected falsified CAP to evaluate the extent and implications. There is no need to classify the falsified using the recall classification. In the case of a need to issue a Rapid Alert, the notification is sent to all NCAs (same distribution as a class 1 defect). Alerts for falsified medicines are sent in accordance with the Rapid Alert procedure in the Compilation of Community Procedures.<br><br>Confirmatory testing of a reported suspected falsified product may be necessary to authenticate the suspected falsified product and also to highlight any distinguishing features.<br><br>On a case by case basis, the manufacturer of the authentic product should be able to perform the initial confirmatory testing as validated test methods should normally be already available to perform rapid analysis of the suspect. Valuable work can also be performed by the OMCL which may also examine the samples.<br><br>The manufacturer should always make the analytical results available to the ECG/RECG within the shortest possible timetable.<br><br>The SA or NCA's may already take some preliminary market action to isolate the suspected falsified product pending confirmation of authenticity.<br><br>**GMP non-compliance**<br><br>For GMP non-compliances concerning manufacturers of centrally authorised products, establish if an Article 20 referral procedure is | |

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| | required.<br><br>Initiating and progressing an Article 20 referral as a result of a confirmed GMP non-compliance, or restriction of manufacture or importation by a supervisory authority, is led by P-R-CP and with input from P-CI-MQC. Coordination, organization and reporting of discussions at Agency and CxMP level may be led by the PTL with the input of P-CI-MQC as needed.<br><br>**Whistle-blowers**<br><br>In case of allegations from whistle-blowers, agree with the (R)ECG on the next steps.<br><br>**Completion of the assessment**<br><br>The (R)ECG should agree a timetable for completion of the assessment, the need for a recall, the depth of any recall and issuing a rapid alert.<br><br>The timeframe during which the crisis should be dealt with will depend upon the urgency of the matter.<br><br>The (R)ECG may request at any time to the MAH/manufacturer additional information necessary to complete the assessment. It may be necessary to compile a List Of Questions for transmission to the MAH.<br><br>If time permits, the (R)ECG may decide to seek the advice of a Scientific Working Party or to refer the matter to the CxMP for further discussion and evaluation.<br><br>**Administrative aspects**<br><br>Coordination, organization, and reporting of scientific discussions at BWP/QWP are led by the PTM (Quality), with the input of MQCC as needed.<br><br>The PTL or Head of H-SE-ECV takes the lead on any clinical discussions concerning safety issues and/or product shortages and e.g. the co-ordination of approval of DHCP's.<br><br>Coordination, organization and reporting of discussions on consequential product shortages at Agency and CxMP level are led by the PTL from the Human Medicines Development and Evaluation Unit (H-Unit) with the input of P-CI-MQC as needed.<br><br>MQCC should be part of the team in these discussions for information. | |
| 6 | Ensure that (R)ECG decides on risk management measures. Having considered all the available information, take a decision on appropriate action. If it is considered necessary because of the potential risk to public/animal health this decision may be taken without waiting for full information or participants of the (R)ECG to | MQCC |

| Step | Action | Responsibility |
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| | be available. The actions may be one or more of the following:<br>• Recall of the batches.<br>• Quarantine of remaining stock at manufacturer.<br>• Follow-up GMP inspection.<br>• Further investigation and enforcement action<br>• Distribution of a Dear Health Care Professional (DHCP) to concerned health professionals.<br>• Testing by an official medicines control laboratory.<br>• Communication to the EU Medicines Network and/or international partners.<br>• Public communication.<br>• Filing without follow-up (no further action).<br>If a recall is considered necessary the (R)ECG will agree on who should issue the Rapid Alert in accordance with the procedure described in the Compilation of Community Procedures.<br>The depth of recall (e.g. distributor, pharmacy, patient) should also be agreed depending on the nature of the risk, the potential availability of the batch on the market (e.g. some batches are exhausted by the time of a recall) and the type of product.<br>Class I recalls should normally be to patient level, but other decisions may be made if alternative medicine is not available. In addition, the decision should take into account the clinical effect of a disruption in supply.<br>Patient level is seldom recommended for Class II and III recalls. In these situations, recalls to distributor and sometimes pharmacy level are recommended. | |
| 7 | Coordinate communication. In the case of a serious product defect, evaluate the need to communicate promptly to the following EMA staff:<br>Head of P-CI-CNC: to determine if a defective product has been used in Clinical Trials and proposed actions.<br>P-CI-MQC liaison with HMA WGEO: to inform WGEO of falsified product. In the case of such products discovered only outside of the legitimate EU supply chain this is the only action necessary..<br>Head of P-CI-PDC: to determine and propose actions for those quality defects that may affect the content or validity of an EMA certificate and to verify if the batch/product affected have been parallel distributed, inform Parallel Distributors on serious defects and freeze, if necessary, further PD notifications | MQCC |

| Step | Action | Responsibility |
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| | If a Product Specific Press Release is required then the lead is taken by Medical Information (P-MI) Sector and the PTL from either the Human Medicines Development and Evaluation Unit (H-Unit) or the Community Procedures (P-R-CP) Section, depending on the procedure, with input from P-CI-MQC.<br><br>Where a Q&A is needed, the lead is taken by D-ED and the PTL from either the H-Unit or the P-R-CP Section, and with input from P-CI-MQC.<br><br>Where a reactive "Lines to Take" is needed D-ED and the PTL from either the H-Unit or the P-R-CP Section, take the lead with input from P-CI-MQC.<br><br>If the issuance of a Rapid Alert is recommended by the (R)ECG, the MQCC may assist the issuing authority to follow the procedure described in the Compilation of Community Procedures.<br><br>If time allows it, the exact wording of any rapid alert or notification should be checked by the (R)ECG and agreed with the MAH.<br><br>The alert should be sent to the distribution list according to the Compilation of Community Procedures, MRA agreements and any other EMA arrangements.<br><br>Each Competent Authority has written procedures for the receipt and handling of rapid alerts from other authorities during and outside working hours.<br><br>The Competent Authorities of each EEA Member State, to which a recalled product was distributed, monitors the conduct and effectiveness of any national recall which is instituted as a result of the rapid alert notification.<br><br>Keep any other involved third parties informed in accordance with international agreements (MRA), confidentially arrangements (FDA) or any other internal procedures<br><br>Confer with the International Liaison Officer as appropriate. | |
| 8 | Monitor the implementation of risk management measures. | MQCC |
| 9 | All measures implemented?<br><br>Verify all reasonable efforts have been made by the MAH to remove the defective batches and any necessary corrective action to prevent reoccurrence has been satisfactorily put in place and any follow up actions have been completed (refer to Annex 4 for examples of possible follow up actions).<br><br>If no, continue with Step 9.1.<br><br>If yes, finalise the procedure by informing all involved parties. | MQCC |
| 9.1 | Contact the MAH to follow up on implementation of risk | MQCC |

| Step | Action | Responsibility |
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| | management measures. | |
| 10 | File all documents. | Assistant |

## 10. Records

When completed and approved, the records produced from this SOP are stored electronically in the product folder (‘crisis’ folder), and in accordance with the Table of contents core Master File – Compliance and Inspection – SOP/PDM/1004.