EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Cover during out of agency office hours for a potentially serious problem with a Centrally Authorised Product		
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1. Purpose

This SOP covers the process of providing cover in case of a potentially serious problem with a Centrally Authorised Product outside the Agency working hours (Monday to Friday 9:00-17:30) and during EMA holidays. This does not include the procedure for handling product quality defects and recalls, which is covered by SOP/Insp/2018.

2. Scope

This SOP applies to the Unit for Patient Health Protection, the Unit for Human Medicines Development and Evaluation and the Unit for Veterinary Medicines and Product Data Management only.

3. Responsibilities

It is the responsibility of each Head of Sector to ensure that this procedure is adhered to within their own sector. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of "9. Procedure".

4. Changes since last revision

Updated to reflect the Agency's new organisation.

5. Documents needed for this SOP

The following documents are needed for this SOP:

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- Template memo to be sent internally regarding the EMA holidays for a particular year
- Template for the email message to all National Competent Authorities and the European Commission
- List of documents to be provided to the Head of Unit Patient Health Protection (see WIN/H/3237).

The templates are saved in documentum\Docbases\EDMS\Projects\24 hours coverage and Permanence\Coverage YYYY.

6. Related documents

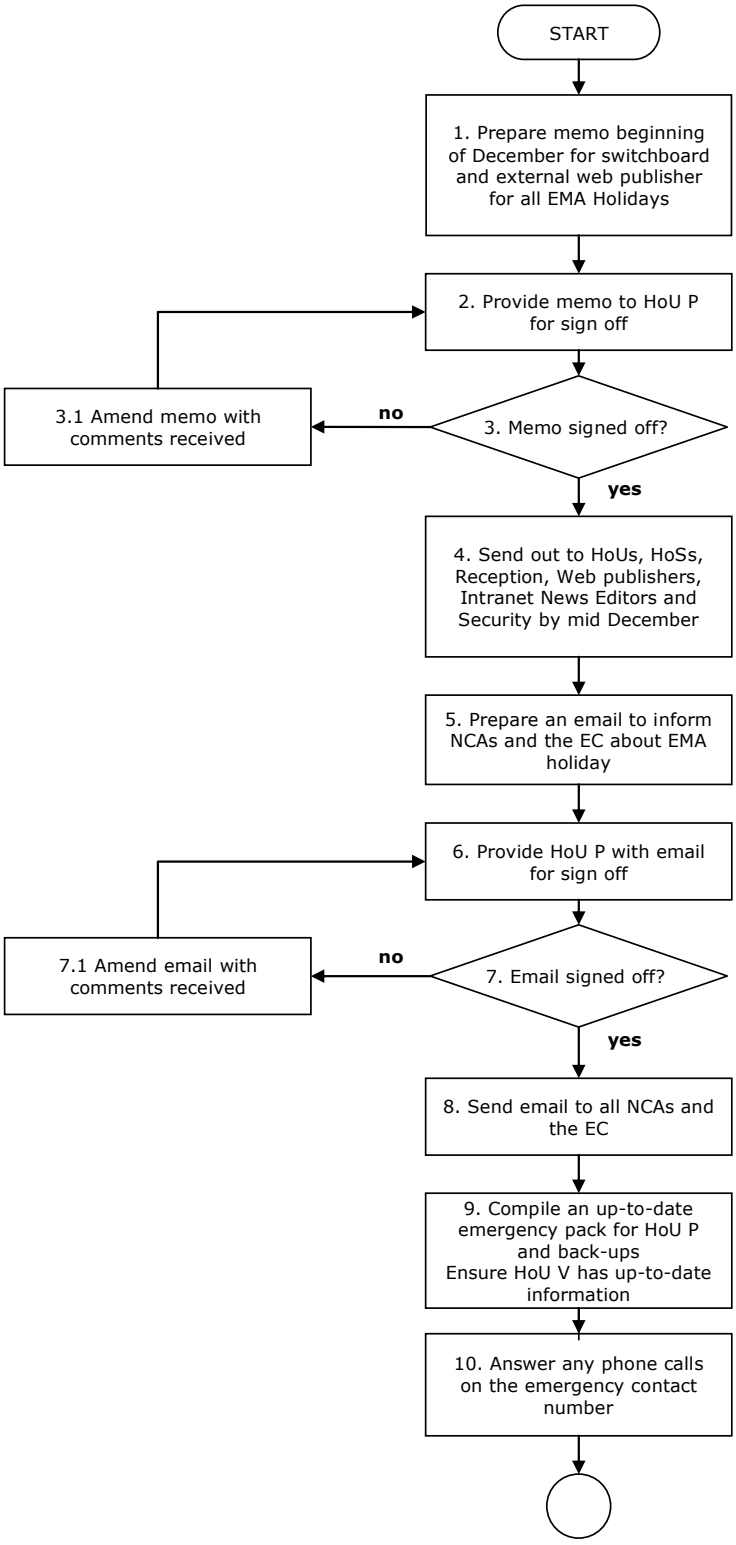
- The European Union Regulatory System Incident Management Plan for Medicines for Human Use (Doc. Ref. EMEA/579383/2008/Final) (pilot phase)
- Eudralex, Volume 9A of the rules governing medicinal products in the European Union (Pharmacovigilance for Medicinal Products for Human Use (March 2007)) http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-9/pdf/vol9_2007-07_upd07.pdf
- Crisis Management Plan regarding Safety Issues for Centrally Authorised Products for Veterinary Use. EMEA February 2004. Doc. Ref. EMEA/CVMP/159/04. http://www.emea.europa.eu/pdfs/vet/phvwp/015904en.pdf
- Inspections – Product defects and recalls. Information on EMA website: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000078.jsp&jsenabled=true
- Article 16(2) and 41(4) of Regulation (EC) No 726/2004.
- WIN/H/3237 – Compilation of Out of Office Cover Packs – Patient Health Protection
- SOP/Insp/2018 - Dealing with Reports of Defective Medicinal Products

7. Definitions

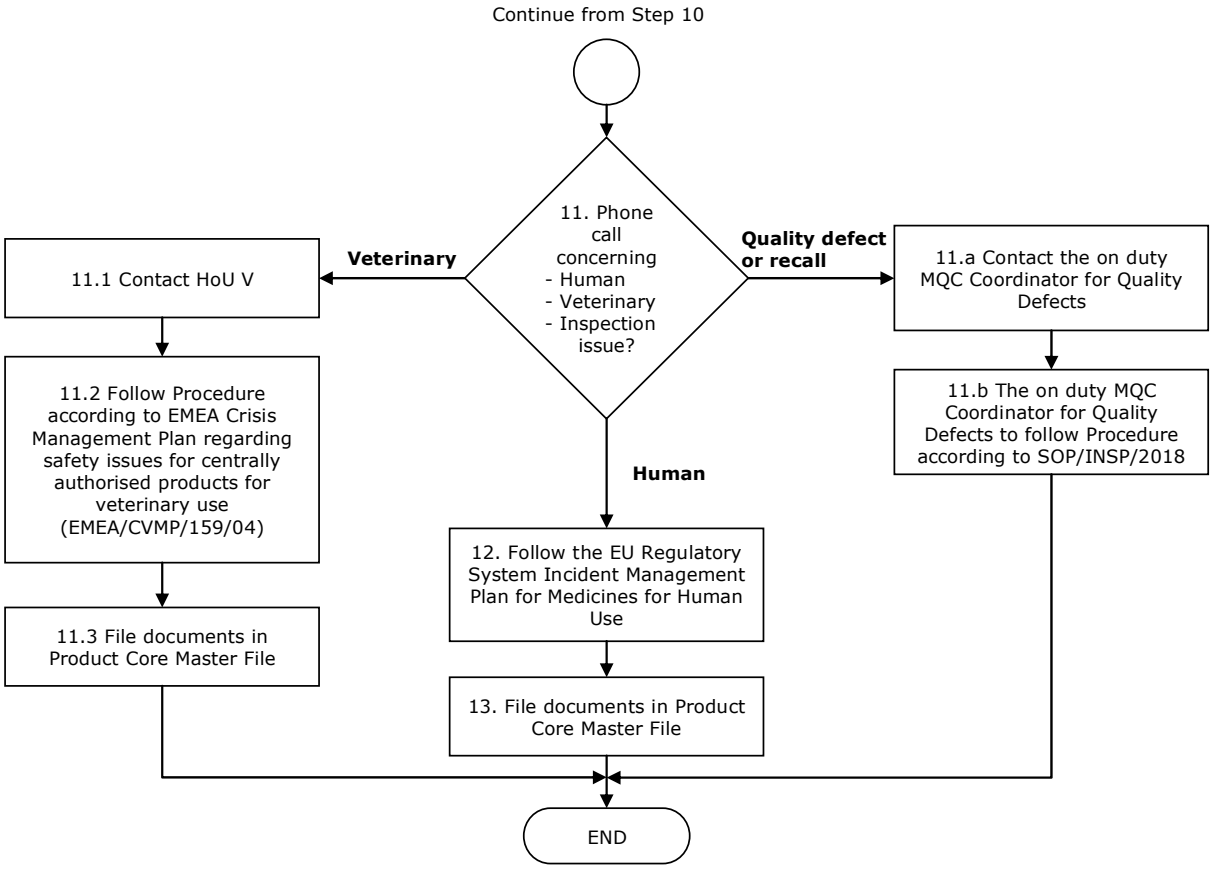
The following definitions and abbreviations are used in this SOP:

EC:	European Commission
HoS:	Heads of Sector
HoU:	Heads of Unit
HoU P:	Head of Unit Patient Health Protection
HoU V:	Head of Unit Veterinary Medicines and Product Data Management
HoU Sec P:	Head of Unit Secretary for the Head of Unit Patient Health Protection
HoU Sec V:	Head of Unit Secretary for the Head of Unit Veterinary Medicines and Produt Data Management
NCAs:	National Competent Authorities
On duty CI coordinator:	On duty Compliance and Inspection Sector's co-ordinator for quality defects

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



Continue with Step 11.


Continue from Step 10
11. Phone call concerning
- Human
- Veterinary
- Inspection issue?
Veterinary
Quality defect or recall
Human
11.1 Contact HoU V
11.2 Follow Procedure according to EMEA Crisis Management Plan regarding safety issues for centrally authorised products for veterinary use (EMEA/CVMP/159/04)
11.3 File documents in Product Core Master File
11.a Contact the on duty MQC Coordinator for Quality Defects
11.b The on duty MQC Coordinator for Quality Defects to follow Procedure according to SOP/INSP/2018
12. Follow the EU Regulatory System Incident Management Plan for Medicines for Human Use
13. File documents in Product Core Master File
END

9. Procedure

Step	Action	Responsibility
1	Prepare by beginning of December each year a draft memo for switchboard and external web publishers. The memo informs them of the message that needs to be given by the answering machine for the switchboard and on the extenal web for out of office hours including any EMA holiday throughout the following year. The message will inform stakeholders about what to do in case of a potentially serious problem with a Centrally Authorised Product.	HoU Sec P
2	Provide the HoU Patient Health Protection (HoU P) with the memo for sign off.	HoU Sec P
3	Memo signed off? If no, go to Step 3.1 If yes, continue with Step 4.	HoU Sec P
3.1	Amend the documents according to comments. Go to Step 2.	HoU Sec P
4	Send out the memo to all HoUs, HoSs, Reception, Web publishers, Intranet News Editors and Security by mid December. File original memo.	HoU Sec P
5	Prepare two weeks before an EMA holiday an email to all NCAs and to the EC reminding them of the provision of cover for outside of business hours and during the holiday in case of a potentially serious problem.	HoU Sec P
6	Provide the HoU P with the email for sign off.	HoU Sec P
7	Email signed off 2 weeks prior to an EMA holiday? If yes, go to Step 8 If no, go to Step 7.1	HoU Sec P
7.1	Amend the email according to comments received. Go to Step 6.	HoU Sec P
8	Send out email to all NCAs (Human and Veterinary) and to the EC one week before every EMA holiday. Where appropriate several EMA holidays in a particular month can be combined in the same message. Print out and file email reminder.	HoU Sec P
9	Compile one week before an EMA holiday an updated emergency pack for HoU P and back ups (see WIN/H/3237) and provide the	HoU Sec P

Step	Action	Responsibility
	updated pack to the HoU P and back ups. Liaise one week before an EMA holiday with the HoU V to ensure that the information needed in case of a potential serious problem is up to date.	HoU Sec V
10	Answer any phone calls on the emergency contact number.	HoU P
11	Does the phone call concern a product quality defect/recall or a potentially serious problem for a human or veterinary centrally authorised product? If related to a product quality defect or recall, go to Step 11a If related to a veterinary product, go to Step 11.1 If related to a human product, go to Step 12	HoU P
11.a	Contact the on duty CI co-ordinator for quality defects.	HoU P
11.b	The on duty MQC co-odinator for quality defects will follow SOP/Insp/2018. End	On duty MQC coordinator
11.1	Contact the HoU V.	HoU P
11.2	In case of a potentially serious problem related to a veterinary product the EMEA Crisis Management Plan regarding safety issues for centrally authorised products for veterinary use (EMEA/CVMP/159/04) will be followed.	HoU V
11.3	File documents related to the safety issues in the Product Core Master File. End	PM
12	In case of a potentially serious problem related issue for a product for human use follow the EU Regulatory System Incident Management Plan for Medicines for Human Use (pilot phase).	HoU P
13	File documents related to the safety issue in the Product Core Master File.	PTL

10. Records

The original of the memos sent out internally are kept in a folder and filed by the HoU Sec P. The email informing all NCAs and the EC about the EMA holidays are printed out and kept in the same folder.

An electronic copy is saved in EDMS (path: documentum\Docbases\EDMS\Products\Crisis Management\Out of office hours coverage XXX (XXX = Year).