EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Procedure to be followed when the incident management plan for medicines for veterinary use is triggered		
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1. Purpose

This standard operating procedure (SOP) describes the process to be followed when the incident management plan for medicines for veterinary use is triggered by the European Medicines Agency (EMA), a national competent authority (NCA) or the European Commission.

2. Scope

This SOP applies to the staff of the Veterinary Medicines Division.

3. Responsibilities

It is the responsibility of the Head of the Veterinary Medicines department to ensure that this procedure is adhered to. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of section “9. Procedure”.

4. Changes since last revision

Update to reflect new Agency structure and contact details and reference to revised incident management plan which now applies to all veterinary medicinal products, regardless of authorisation route.

5. Documents needed for this SOP

- Incident management plan tracking tool (EMA/167154/2012) *(to be replaced by Veterinary Pharmacovigilance Surveillance module, when available)*

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6. Related documents

- Incident management plan for medicines for veterinary use (EMA/711053/2010 - Rev.1)
- SOP/V/4041 on Management of pharmacovigilance rapid alerts (RAs) and non urgent information (NUI) for medicinal products for veterinary use
- SOP/PDM/1004 on core master files of medicinal products for human and veterinary use following the centralised procedure

7. Definitions

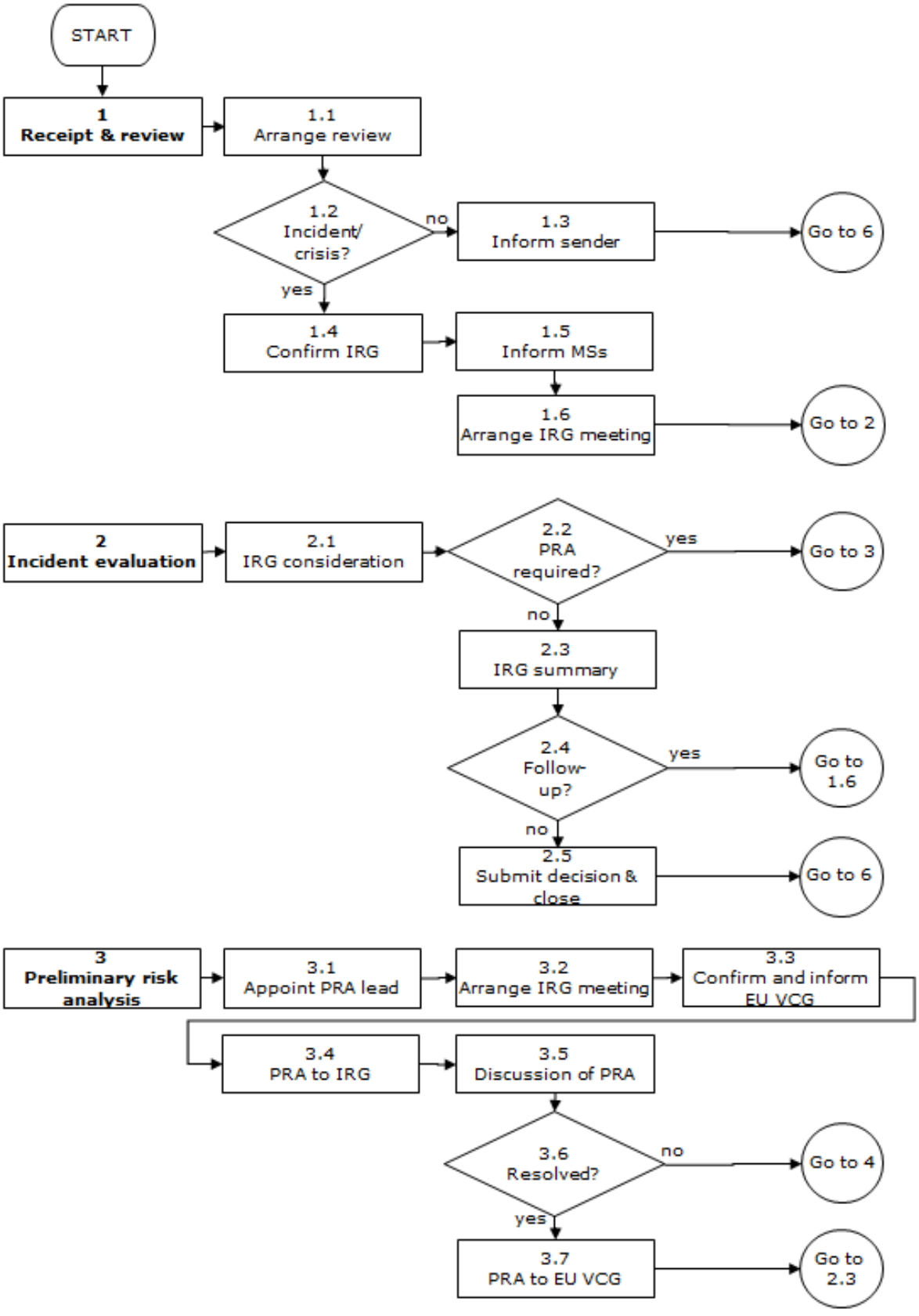
Incident: An event/finding/new information that arises, irrespective of whether this is in the public domain or not, in relation to one or more veterinary medicinal products, irrespective of the authorisation route, that could have a serious impact on animal and/or public health or the environment.

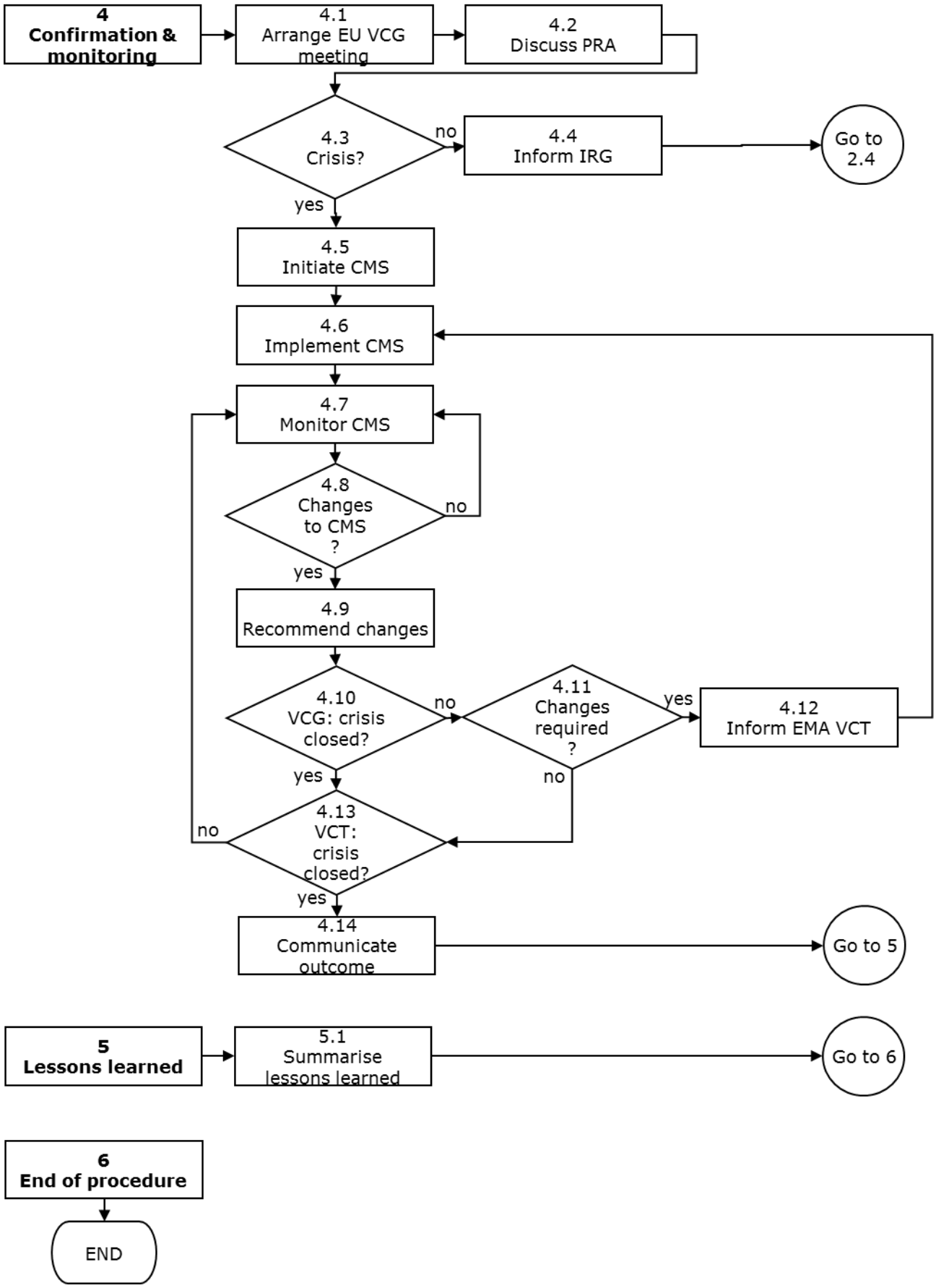
Crisis: a situation where, after assessment of the incidents associated risks, urgent and coordinated action within the EU regulatory network is required to manage and control the situation where routine measures or procedures are not deemed sufficient.

APH	Animal and Public Health (service in V-VM)
AST	Assistant (in V-VM; assigned to procedure)
CAP	Centrally authorised [veterinary medicinal] product
CMDv	Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary
CMS	Crisis management steps
CVMP	Committee for Medicinal Products for Veterinary Use
EC	European Commission
EMA	European Medicines Agency
EMA VCT	Veterinary crisis team: EMA operational team supporting the EU VCG to manage crises
EU	European Union
EU VCG	Veterinary crisis group: strategic multidisciplinary group whose principal role is to confirm crises and initiate the crisis management steps of the IMP
HDiv	Head of Division
HDep	Head of Department
HSer	Service Head
IRG	Incident review group: a multidisciplinary group comprising staff from the EMA and NCAs whose principal role is to review incidents from a managerial perspective
IMP	Incident management plan [for medicines for veterinary use]: plan outlining a strategy for the rapid and efficient handling of incidents involving veterinary medicinal products authorised in the EU
LMS	Lead Member State

MS	Member State
NCA	National Competent Authority
Non-CAP	Non-centrally authorised [veterinary medicinal] product
NUI	Non urgent information
PhV SA	Scientific Administrator responsible for veterinary pharmacovigilance (in APH)
PhVWP-V	CVMP Pharmacovigilance Working Party
PM	Project manager (appointed at start of procedure)
PRA	Preliminary risk analysis
RA	Rapid alert
RMS	Reference Member State
SA	Scientific administrator (in V-VM)
V-VM	Veterinary Medicines Department
VROS	Veterinary Regulatory and Organisational Support

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




4
Confirmation & monitoring
4.1
Arrange EU VCG meeting
4.2
Discuss PRA
4.3
Crisis?
no
4.4
Inform IRG
Go to 2.4
yes
4.5
Initiate CMS
4.6
Implement CMS
4.7
Monitor CMS
4.8
Changes to CMS ?
no
yes
4.9
Recommend changes
4.10
VCG: crisis closed?
no
4.11
Changes required ?
yes
4.12
Inform EMA VCT
yes
no
4.13
VCT: crisis closed?
no
yes
4.14
Communicate outcome
Go to 5
5
Lessons learned
5.1
Summarise lessons learned
Go to 6
6
End of procedure
END

9. Procedure

Step	Action	Responsibility
1.0	**Receipt and initial screening of incident**	
1.1	Upon receipt of potential incident (via a RA, a NUI requesting IRG advice or other source e.g. information concerning action taken by non-EU regulatory authority) notify HDep (if not already informed). Arrange internal screening meeting with HDep and appropriate HSer(s), SA(s) and legal sector representative as necessary and advised by HDep.	SA
	Confirm the need to convene IRG and, where appopriate, appoint the SA responsible for responding to sender.	HDep
1.2	Does the issue fulfil the criteria for an incident or crisis? If yes or unsure, go to 1.4 If no, go to 1.3	
1.3	Inform sender of outcome, if necessary informing of the appropriate procedure to be followed.	SA
	Update IMP tracking tool.	SA
	Proceed to 6.0	
1.4	Appoint project team (e.g. PM, AST, HSer) to support incident management and confirm IRG participants (to be done on a case-by-case basis). The IRG may comprise, but is not limited to, a combination of the following: • the EMA HDep of V-VM (Chair); • the Head of the affected NCA(s); • the EMA HSer APH or VROS; • the relevant rapporteur of the CAP or ongoing referral procedure/RMS expert(s)/LMS expert(s) for non-CAPs, as applicable; • the Chair(s) of the PhVWP-V, CVMP and/or CMDv, Inspectors working groups as applicable; and • the relevant EMA SA(s).	HDep
1.5	Ensure MSs are informed of potential incident via RA/NUIS, if applicable.	PM
1.6	Arrange IRG meeting (via teleconference/virtual meeting system) within one working day of receipt of incident reported, or as soon as possible. Forward background documents (e.g. RA/NUI/other correspondence, other supporting documentation etc.) to IRG	PM

Step	Action	Responsibility
	members. Proceed to 2.0	
2.0	**Incident evaluation**	
2.1	At the IRG meeting: review incident, from a managerial perspective, giving consideration to the following, including timeframes where appropriate: • whether the identified concerns are likely to be addressed through routine measures; • the most appropriate legal/regulatory framework to be used for management of the incident; • the need to prepare for any (media) queries and preparation of "lines to take"; • whether the incident represents a potential crisis and the need for a PRA; and • whether a further IRG meeting will be required. If the IRG has been convened to follow up on an incident previously considered, agree on necessary actions and/or closure of the incident.	HDep
2.2	Is a PRA required? If yes, go to 3.0 If no, go to 2.3	
2.3	Prepare summary of IRG discussion and conclusions (including the need for further IRG follow up i.e. further meetings) in IMP tracking tool for approval by IRG Chair and disseminate as required. Ensure IMP tracking tool is updated as necessary.	PM PM
2.4	Does the IMP require a further IRG meeting? If yes, go to 1.6 If no, go to 2.5	
2.5	Update IMP tracking tool with 'final IRG decision' and lessons learned, as applicable. Circulate the final IRG decision to IRG and within the network, as required. Inform sender of outcome, if necessary informing of the appropriate procedure to be followed. Proceed to 6.0	PM PM PM

Step	Action	Responsibility
3.0	**Preliminary risk analysis**	
3.1	Ensure IRG appoints a lead to prepare PRA, specifying deadline for submission of report to IRG. Update tracking tool to monitor receipt of PRA. *NB. The PRA lead is decided on a case by case basis, taking into account the type(s) of product(s) involved, for example:* • *for CAPs: CVMP (co)-rapporteur(s) and the EMA;* • *for non-CAPs: RMS/LMS.*	HDep PM
3.2	Organise IRG meeting for consideration of PRA.	PM
3.3	Confirm EU VCG composition with IRG chair. The core composition of the EU VCG includes the following: • the Chair of the CVMP and/or the CMD(v); • the Chair of the PhVWP-V or Vice Chair (in case of a pharmacovigilance issue) or Inspectors working group (in case of a purely quality related issue); • the rapporteur of the CAP or referral/Article 78 procedure and/or a representative of the RMS/LMS (for non-CAPs), supported by their scientific assessment team; • HDiv of Veterinary Medicines (Chair); • HDep of V-VM, as well as the other members of the EMA VCT (for further details, see IMP); • a nominated representative from the European Commission; and • the Head of the relevant NCA(s), if they wish, and particularly in cases where they initiate a request for assistance with coordination Inform EU VCG of PRA request.	PM PM
3.4	Ensure PRA is circulated to IRG by agreed deadline, sending reminders as necessary.	PM
3.5	Ensure IRG discuss PRA, including preferred management option and PRA lead revises/finalises PRA as required. Update IMP tracking tool with IRG decision.	HDep/ PM
3.6	Can the incident be addressed through the measures proposed in the PRA? If yes, go to 3.7 If no, go to 4.0	
3.7	Circulate PRA to EU VCG for information. Go to 2.3	PM

Step	Action	Responsibility
4.0	**Crisis confirmation & monitoring**	
4.1	Arrange EU VCG meeting, confirming required participants with IRG Chair.	PM
	Forward PRA, summary of IRG discussion and conclusions (as extracted from IMP tracking tool) and any other relevant documents to EU VCG.	PM
4.2	At EU VCG: Ensure review of PRA, determine whether the crisis management steps of the IMP should be initiated and agree on action(s) required, including communication strategy.	HDiv
4.3	Is incident confirmed as crisis? If yes, go to 4.5 If no, go to 4.4	
4.4	Inform IRG of decision and any necessary recommendations for action.	PM
	Update IMP tracking table as required.	PM
	Go to 2.4	
4.5	Initiate CMS of IMP:	
	• Inform EMA Executive Director of confirmation of crisis;	HDiv
	• Assign EMA VCT members, in consultation with HDep;	HDiv
	• Definition of CMS including communication strategy by EU VCG; and	HDiv
	• Inform EMA VCT and stakeholders, as required.	PM
	Ensure IMP tracking tool is updated, as necessary.	PM
4.6	Ensure EMA VCT implements CMS as agreed by the EU VCG according to agreed timelines.	HDep
	Ensure IMP tracking tool is updated as required.	PM
4.7	Ensure EMA VCT monitors implementation at agreed time intervals.	HDep
4.8	Are changes to the CMS, or its closure, proposed? If yes, go to 4.9 If no, go to 4.7	
4.9	Ensure EMA VCT recommends changes to CMS (or closure) to the EU VCG.	HDep
	Ensure IMP tracking tool is updated as required.	PM

Step	Action	Responsibility
4.10	EU VCG consideration of recommendations from EMA VCT. Can the crisis be closed? If yes, go to 4.13 If no, go to 4.11	HDiv
4.11	Are changes required to the CMS? If yes, go to 4.12 If no, go to 4.13	
4.12	Ensure EU VCG determines necessary changes to CMS. Inform EMA VCT of decision. Go to 4.6	HDiv HDiv
4.13	Ensure EU VCG informs EMA VCT of decision. Has the crisis been closed by the EU VCG? If yes, go to 4.14 If no, go to 4.7	HDiv
4.14	Ensure EMA VCT updates IMP tracking tool with final EU VCG decision. Communicate closure of crisis to MSs and stakeholders, as required. Proceed to 5.0	HDep PM
5.0	**Lessons learned evaluation**	
5.1	Ensure lessons learned evaluation is conducted. Prepare summary for approval by HDiv and disseminate as required. Update IMP tracking tool as required. Proceed to 6.0	HDep PM
6.0	**End of procedure**	

10. Records

All steps of the EU IMPs triggered, corresponding decisions and lessons learned are tracked via the IMP tracking tool (EMA/167154/2012; to be replaced by Veterinary Pharmacovigilance Surveillance module, when available).

Documentation is archived electronically in the appropriately labelled folder in DREAM (Cabinets/06. Corporate governance/06.2 Integrated Management System/2. IMS Manual/2. Corporate controlled documents/4. SOPs and WINs/*4000 - 4999 V (Veterinary)/4003 SOP - Incident management plan procedure/Working area/Incidents triggered; linked to the appropriate product folder) and, if appropriate, the core master file, as necessary.