



Standard operating procedure

Title: Incident management plan for medicines for veterinary use		
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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 Surveillance and Regulatory Support (V-SR) 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 the third revision of the incident management plan, including a refined definition of incidents, which takes into account lessons learned from the 2016 simulation exercise and management of incidents triggered subsequently.

Further updated in line with Regulation (EU) 2019/6 on veterinary medicinal products and relevant associated secondary legislative acts.



5. Documents needed for this SOP

- IMP Tracking tool (EMA/167154/2012)
- Toolkit - Checklist for IMP procedure (EMA/268703/2017)

6. Related documents

- Incident management plan for medicines for veterinary use (EMA/711053/2010)
- SOP/PDM/1004 on core master files of medicinal products for human and veterinary use following the centralised and referrals procedures

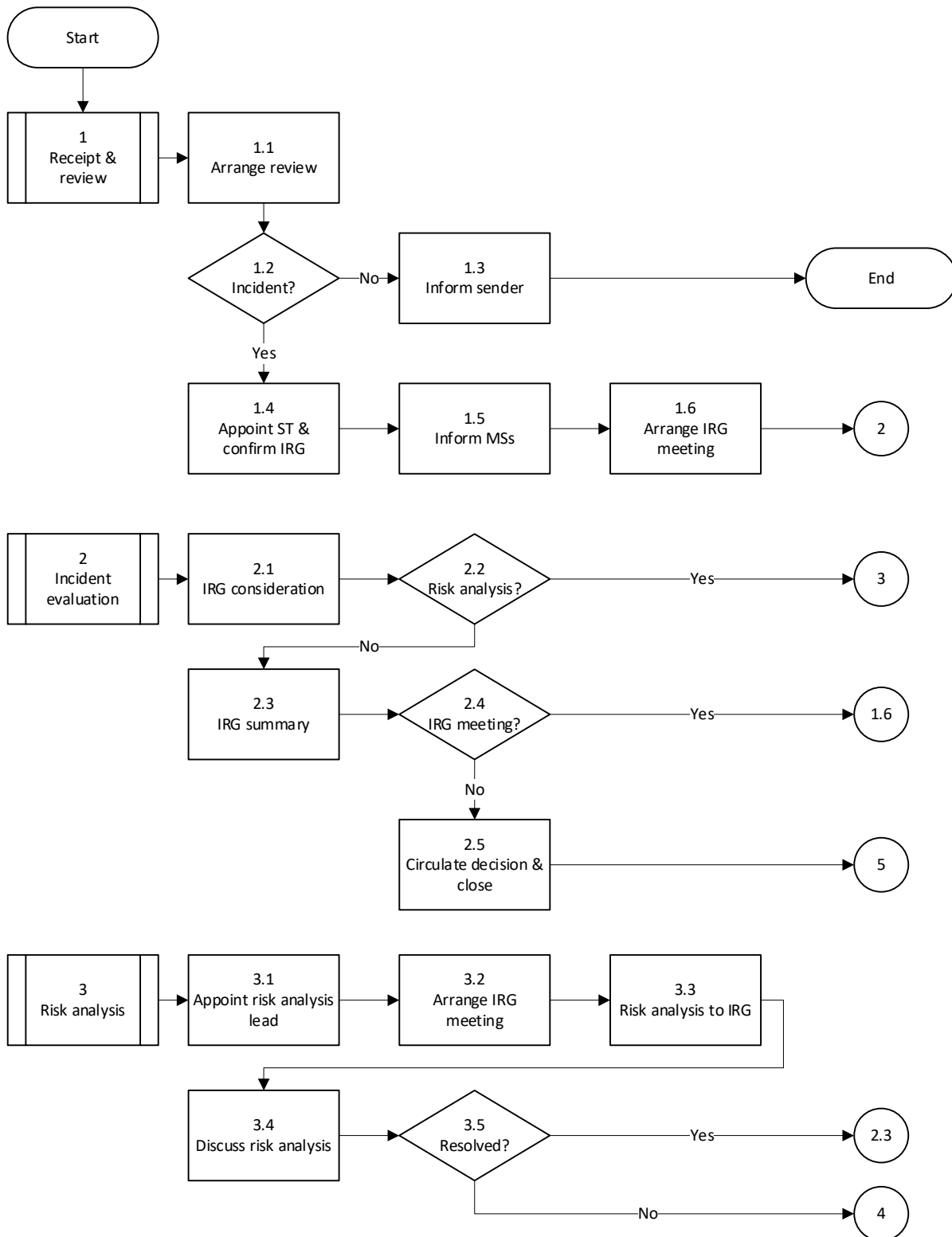
7. Definitions

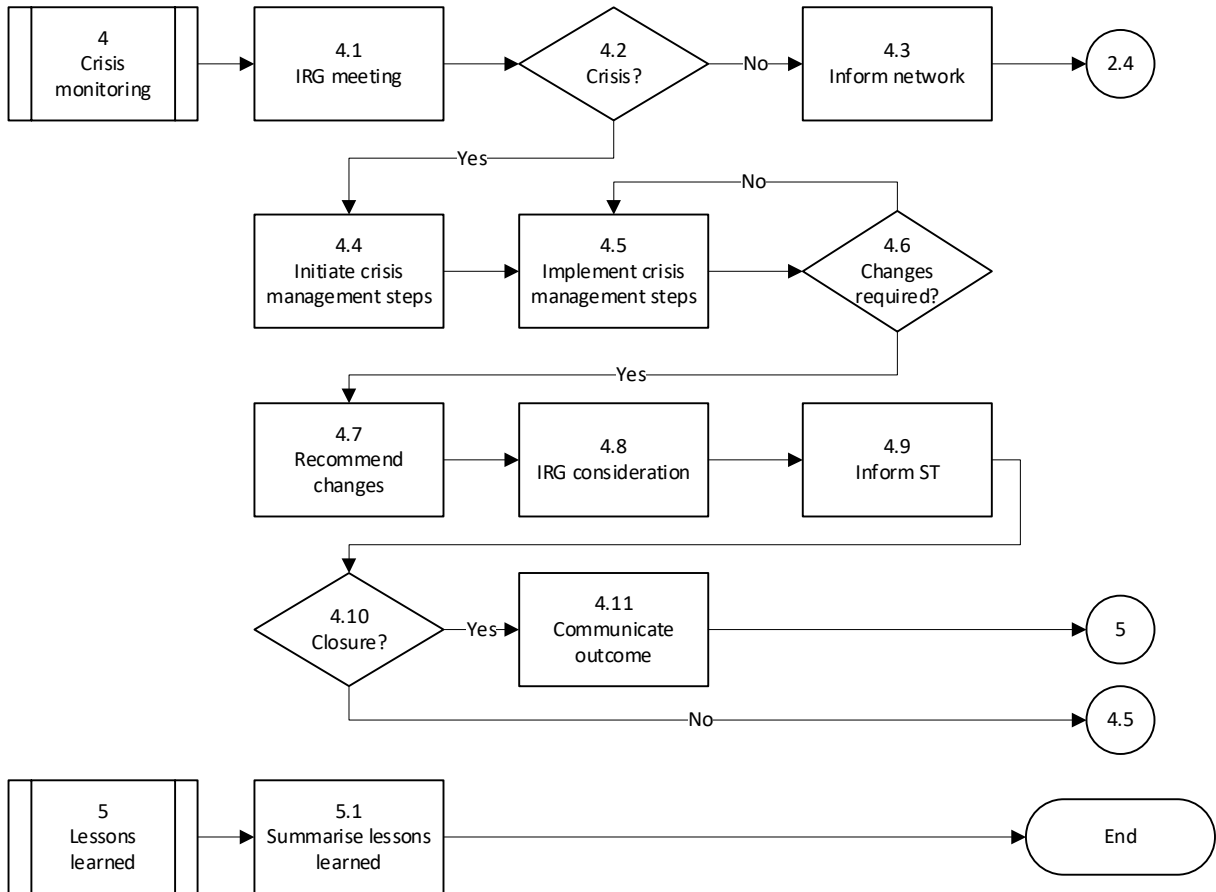
Incident:	An event/finding/new information that arises, irrespective of whether this is in the public domain or not, in relation to one or more veterinary medicinal products authorised in the EU, irrespective of the authorisation route, that could have a serious impact on animal and/or public health or the environment.
Crisis:	A situation where, after assessment of the incident's associated risks, urgent and coordinated action within the EU regulatory network is required to manage and control the situation and where established procedures are not deemed sufficient.
CAP	Centrally authorised [veterinary medicinal] product
CMDv	Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary
CVMP	Committee for Veterinary Medicinal Products
EC	European Commission
EMA	European Medicines Agency
EU	European Union
HDep	Head of Department
HDiv	Head of Division
HSer	Service Head
IRG	Incident review group: a multidisciplinary group comprising staff from the EMA, NCAs and the EC, 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 arising from safety issues involving veterinary medicinal products authorised in the EU
MS	Member State
NCA	National Competent Authority
Non-CAP	Non-centrally authorised [veterinary medicinal] product
PC	Procedure Coordinator (in V-SR-PHV; assigned to procedure)
PhV alert	A potential concern, including emerging safety issues, arising from pharmacovigilance data or other information impacting animal or public health or the environment that may

require urgent consideration by the competent authority responsible for the veterinary medicinal product(s)

PhV SA	Scientific Administrator responsible for veterinary pharmacovigilance (in V-SR-PHV)
PhVWP-V	Pharmacovigilance Working Party
RMS	Reference Member State
SA	Scientific administrator (in V Div)
SL	Scientific Lead (appointed at start of procedure)
ST	Support team (EMA IRG): EMA operational team supporting the IRG
V Div	Veterinary Medicines Division
V-SR	Veterinary Surveillance and Regulatory Support department in the Veterinary Medicines Division
V-SR-PHV	Pharmacovigilance service in the Veterinary Surveillance and Regulatory Support department
V-SR-RAR	Regulatory Affairs and Referrals service in the Veterinary Surveillance and Regulatory Support department

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





9. Procedure

Step	Action	Responsibility
1.0	Receipt and initial screening of incident	
1.1	Upon receipt of potential incident, notify HSer/HDep/HDiv (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. Confirm the need to convene IRG and, where appropriate, appoint the SA responsible for responding to sender.	PhV SA 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, and if necessary, inform sender of the appropriate procedure to be followed. Update IMP tracking tool. Proceed to 6.0	PhV SA PhV SA
1.4	Appoint ST (e.g. SL, PC, 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: <ul style="list-style-type: none"> the EMA HDep of V-SR (Chair); the Head(s) of the triggering party/NCA(s) and/or those identified as immediately affected; the EMA HSers of PhV and RAR; the relevant rapporteur of the CAP or ongoing referral procedure/RMS expert(s)/Lead MS expert(s) for non-CAPs, as applicable; the Chair(s) of the PhVWP-V, CVMP and/or CMDv, Inspectors working groups as applicable; and a representative from the Veterinary Medicines Unit of the EC DG SANTE the relevant EMA SA(s) 	HDep
1.5	Ensure MSs are informed of potential incident via Eudranet, if applicable.	SL
1.6	Arrange IRG meeting (virtual), ideally within one working day of receipt of incident reported, or as soon as possible. Forward background documents to IRG members via Eudranet. Proceed to 2.0	SL

Step	Action	Responsibility
2.0	Incident evaluation	
2.1	<p>At the IRG meeting: review incident, from a managerial perspective, considering the following, including timeframes, where appropriate:</p> <ul style="list-style-type: none"> • 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, if so, the need for a more detailed risk analysis; • whether any additional actions are required to manage the incident; and • whether a further IRG meeting will be required. <p>If the IRG has been convened to follow up on an incident previously considered, agree on necessary actions and/or closure of the incident.</p>	HDep
2.2	<p>Is a more detailed risk analysis required?</p> <p>If yes, go to 3.0 If no, go to 2.3</p>	
2.3	<p>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.</p>	SL
2.4	<p>Is a further IRG meeting required?</p> <p>If yes, go to 1.6 If no, go to 2.5</p>	
2.5	<p>Update IMP tracking tool with ‘final IRG decision’ and lessons learned, as applicable.</p> <p>Circulate the final IRG decision within the network, as required.</p> <p>Inform sender of outcome, and if necessary, inform sender of the appropriate procedure to be followed.</p> <p>Proceed to 5.0</p>	SL SL SL
3.0	Risk analysis	
3.1	<p>Ensure IRG appoints a lead to prepare the risk analysis, specifying deadline for submission of report to IRG.</p> <p>Update IMP tracking tool and monitor receipt of risk analysis.</p>	HDep SL
3.2	<p>Organise IRG meeting for consideration of risk analysis.</p>	SL

Step	Action	Responsibility
3.3	Ensure risk analysis is circulated to IRG by agreed deadline, sending reminders as necessary.	SL
3.4	Ensure IRG discuss risk analysis, including preferred management option and risk analysis lead revises/finalises risk analysis as required. Update IMP tracking tool with IRG decision.	HDep SL
3.5	Can the incident be addressed through the measures proposed in the risk analysis? If yes, go to 2.3 If no, go to 4.0	
4.0	Crisis confirmation & monitoring	
4.1	At IRG: determine whether the crisis management steps of the IMP should be initiated and agree on action(s) required, including communication strategy.	HDep
4.2	Is incident confirmed as crisis? If yes, go to 4.4 If no, go to 4.3	
4.3	Inform network of decision and any necessary recommendations for action. Update IMP tracking table as required. Go to 2.4	SL SL
4.4	Initiate crisis management steps of IMP: <ul style="list-style-type: none"> • Inform EMA Executive Director of confirmation of crisis; • Review and amend ST, as required, in consultation with HDiv; • Inform stakeholders, as required. Ensure IMP tracking tool is updated, as necessary.	HDiv HDep SL SL
4.5	Ensure ST implements crisis management steps as agreed by the IRG according to agreed timelines; and that ST monitors the implementation at agreed time intervals. Ensure IMP tracking tool is updated as required.	HDep SL
4.6	Are changes to the crisis management steps, or closure of the crisis, proposed? If yes, go to 4.7 If no, go to 4.5	
4.7	Ensure ST recommends changes to crisis management steps (or closure) to the IRG. Ensure IMP tracking tool is updated as required.	HDep SL

Step	Action	Responsibility
4.8	IRG consideration of recommendations from ST and agrees either amendment to crisis management steps or closure of the crisis.	HDep
4.9	Ensure IRG informs ST of decision.	HDep
4.10	Can the crisis be closed? If yes, go to 4.11 If no, go to 4.5	
4.11	Ensure ST updates IMP tracking tool with final IRG decision. Communicate closure of crisis to MSs and stakeholders, as required. Proceed to 5.0	HDep SL
5.0	Lessons learned evaluation	
5.1	Ensure lessons learned evaluation is conducted. Prepare summary for approval by HDep/HDiv and disseminate as required. Update IMP tracking tool as required. Proceed to 6.0	HDep SL SL
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).

Documentation is archived electronically in the appropriately labelled folder in DREAM (Cabinets/03. Pharmacovigilance/PhV - Veterinary/Surveillance; linked to the appropriate product folder) and, if appropriate, the core master file.