EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 November 2022
EMA/711053/2010-Rev.3
Veterinary Medicines Division

Incident management plan for medicines for veterinary use

The incident management plan defines a strategy for the rapid and efficient handling of any events (not only safety related) considered incidents relating to any veterinary medicinal products authorised (either nationally or centrally) in the European Union (EU). It outlines the procedures and management structures put in place to evaluate a potential incident, manage the response with coordination between the national competent authorities (NCAs), communicate with all involved parties within the regulatory network and concerned marketing authorisation holder(s) for veterinary medicinal products and effect closure of the incident. The incident management plan enables a comprehensive approach to be taken at EU level to manage incidents and to avoid them developing into "crisis" situations.

The incident management plan was initially implemented for a two-year pilot phase and was revised in 2015 taking into account the experience gained with the incidents managed until then. In 2016 a simulation exercise was conducted to test out the revised incident management plan and subsequently the plan was also triggered on four occasions. The latest experience gained during the simulation and the incidents managed in 2016 provided an opportunity for further improvements to the incident management plan which are incorporated in the current document and the procedure supporting it. In 2021, the plan was updated to reflect the changes in the management of veterinary pharmacovigilance and organisational changes within the EMA and to update the legal references to Regulation (EU) 2019/6.

The general principle of the incident management plan is to establish an EU-centralised approach for identification and coordination of incidents or potential crises, i.e. events which may potentially have a serious impact on animal or public health or the environment at EU level in relation to veterinary medicinal products which may require urgent remedial action to avoid them developing into a crisis.

This is a two-fold process, i.e.:

a) the continuous monitoring of events and new information to be routinely assessed on their potential to escalate into an incident; and

b) the management of the response through coordination of actions across the Network (EMA and Member States (MSs)) for a confirmed incident.

Implementation of this incident management plan emphasises the established right of the NCAs to take pre-emptive action at national level, in accordance with the provisions of Community legislation but in a transparent and coordinated way with other NCAs. The incident management plan shall not be

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

An agency of the European Union

invoked for purely national issues without a potential European interest, e.g. not in the case of product defects for a purely nationally authorised product in a single Member State.

2.1. Scope

The scope of this incident management plan is defined by the type of event/new information and veterinary medicinal products involved.

Qualifying event or new information

An event or new information may be related to the efficacy and/or safety and/or quality of a veterinary medicinal product. Examples include urgent safety hazards, i.e. pharmacovigilance issues (e.g. emerging safety issues); problems of viral contamination of biological products (quality and safety concerns); or events or information concerning products subject to a referral or related procedure (e.g. Article 82 or Article 70(11) of Regulation (EU) 2019/6) or temporary safety restrictions (e.g. Article 129 of Regulation (EU) 2019/6).

Situations arising purely from quality concerns without a safety component (e.g. product quality reports or defective product reports) should be dealt with in accordance to the Compilation of Union procedures on inspections and exchange of information[1,2] and the incident management plan will be triggered only in cases where there is a major public health impact relating to the safety, efficacy or availability of medicinal products (impact of shortages), or where one or more MSs perceive that the measures currently foreseen in the 'compilations' fail to result in adequate protection of animal health at Community level, thereby requiring escalation of the incident within the network.

Qualifying veterinary medicinal product(s)

This incident management plan applies to individual products or to several products in the same therapeutic class. It applies to all products, regardless of their route of authorisation, i.e. centralised, mutual recognition, decentralised or purely national products authorised in more than one EU Member State.

2.2. Definitions

The following definitions are used in relation to this incident management plan. However, it is acknowledged that some events or new information may not be readily categorised into one of the two definitions proposed below and therefore some incidents may be defined as potential crises or vice versa. Ultimately, however an issue is defined, the most important factor is to ensure the incident management plan is triggered to ensure due consideration is given.

Factors that could trigger an incident or a crisis may include newly published data in scientific journals, coverage in the lay press and/or action taken by a non-EU regulatory authority, in terms of their actual or perceived impact on animal and/or public health or the environment.

2.2.1. Definition of an incident

An incident is defined as '*an event or finding or 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*'.

[1] The SOP "Dealing with Reports of Defective Medicinal Products" (SOP/INSP/2018) applies in this situation.
[2] N.B. The procedure for dealing with serious Good Manufacturing Practice (GMP) non-compliance includes reference to the CMDv Best practice guidance on collaboration between MSs in relation to serious GMP non-compliance issues which is currently under development.

The definition above includes events that at first may not appear to have a serious impact on animal or public health or the environment if they are in the public domain (irrespective of whether they attract media attention or not) and may lead to serious public concerns about one or more products. Likewise, cases where there may be a negative impact on the appropriate use of a product(s) or on their availability (e.g. resulting in discontinued use of the product(s)) also fall within the definition of an incident.

2.2.2. Definition of a crisis

A crisis is defined as *'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'*.

2.3. Identification and triggering of incidents

The incident management plan may be triggered by any stakeholder from the European Commission, the EMA or NCAs. Established systems used within the network will be continuously monitored as part of the routine screening process to identify events that may escalate into potential incidents and therefore necessitate triggering of the incident management plan. Such established systems include the pharmacovigilance rapid alert (RA) system and the quality defect RA system, for example. Taking into account the scope and definition of an incident (or crisis) described above, in general, pharmacovigilance alerts would automatically trigger the incident management plan (please also refer to Section 4.1.1). However, where it is considered that issuing a RA will in itself be an adequate response to the situation then no further action will be required.

Potential incidents may also be identified via other sources, for example, such as a request for advice from the incident review group, communication received from non-EU regulatory authorities or press or scientific publications, for example.

3. Incident and crisis management

The incident review group is established to support management of incidents and, where necessary, crises. The procedure for both incident and crisis management follow the same principles. However, in the event of a crisis, the frequency of incident review group meetings and intensity of activity is foreseen to be much greater compared to that for an incident, until the crisis has been managed or closed.

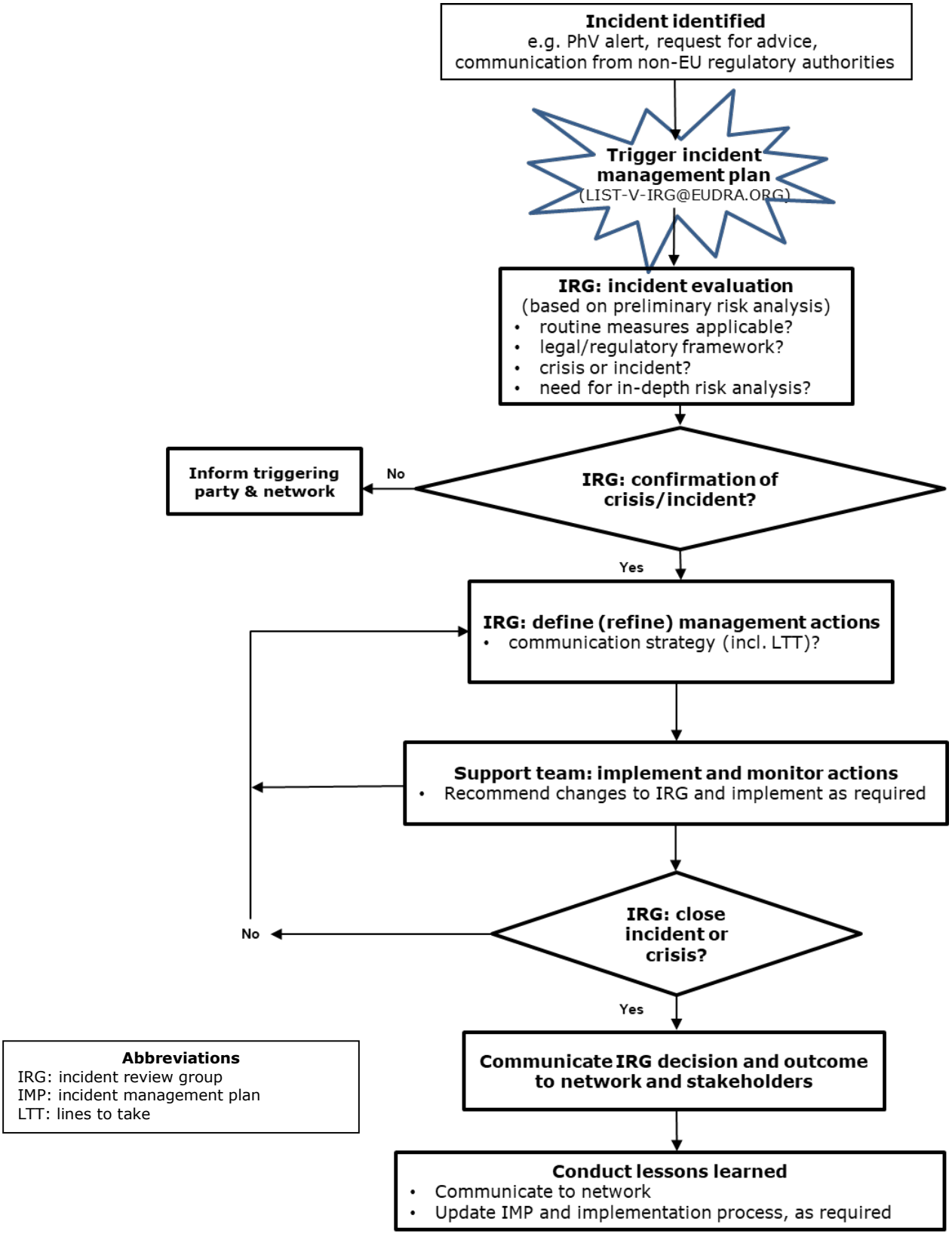
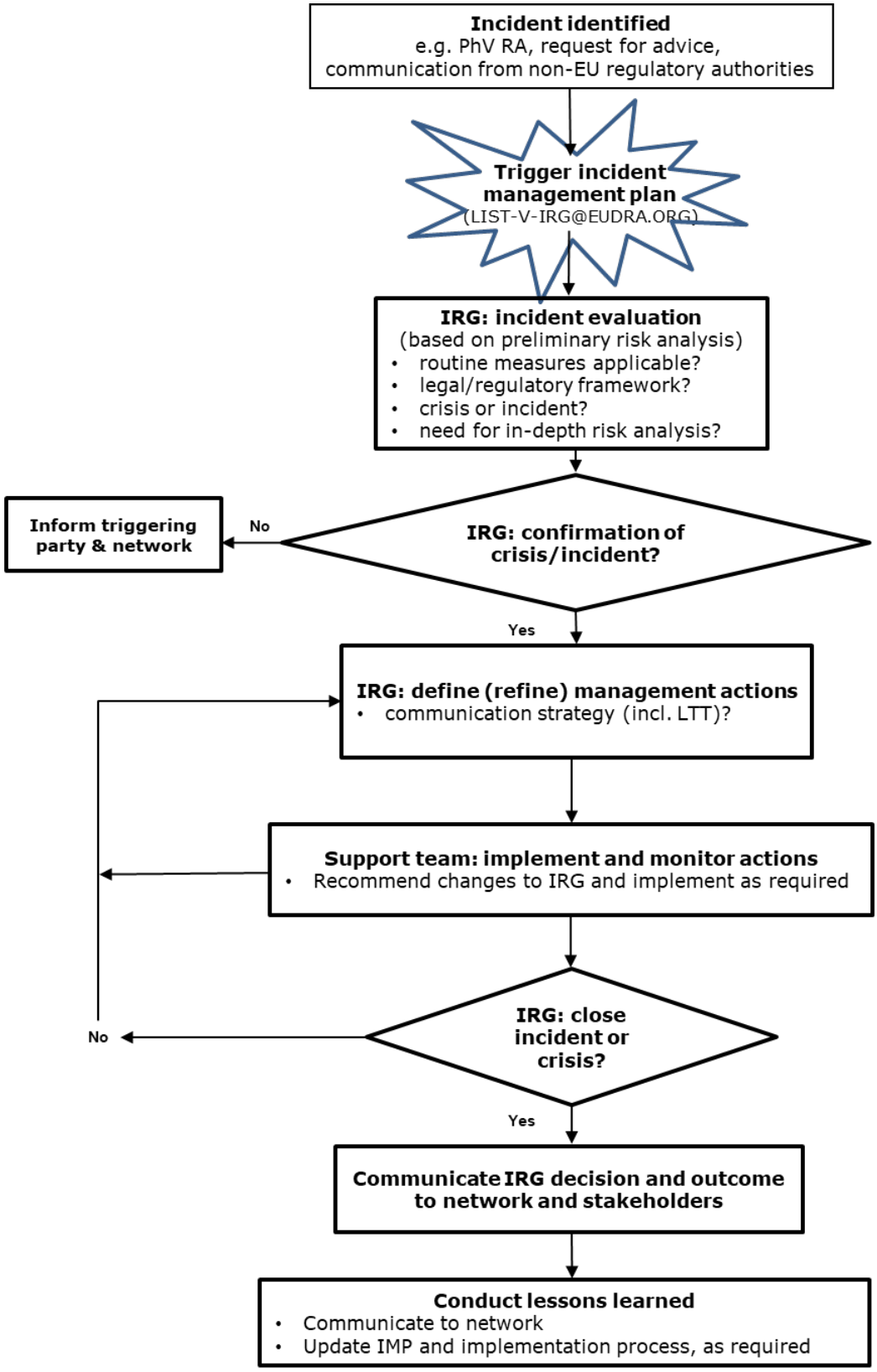


Figure 1: Overview of incident management procedure


Incident identified
e.g. PhV RA, request for advice, communication from non-EU regulatory authorities
Trigger incident management plan
(LIST-V-IRG@EUDRA.ORG)
IRG: incident evaluation
(based on preliminary risk analysis)
• routine measures applicable?
• legal/regulatory framework?
• crisis or incident?
• need for in-depth risk analysis?
IRG: confirmation of crisis/incident?
No
Inform triggering party & network
Yes
IRG: define (refine) management actions
• communication strategy (incl. LTT)?
Support team: implement and monitor actions
• Recommend changes to IRG and implement as required
IRG: close incident or crisis?
No
Yes
Communicate IRG decision and outcome to network and stakeholders
Conduct lessons learned
• Communicate to network
• Update IMP and implementation process, as required

3.1. Incident review group

The incident review group is a dedicated structure for management of incidents and/or crises whose composition may vary depending on the nature of the issue considered. For logistical reasons and rapid and efficient management, the group may need to be convened at short-notice, even if under-represented. Additional members and expertise may be co-opted into the group as the need arises. The incident review group comprises:

- the EMA Head of Surveillance and Regulatory Support Department of the Veterinary Medicines Division, who would act as chair;
- the Head of the NCA(s) triggering the incident or that are immediately identified as affected by the incident, or their nominated delegates;
- the relevant rapporteur of the CAP or ongoing referral procedure, or the reference MS (RMS) expert(s), or the lead MS(s) expert(s) for non-CAPs, supported by their scientific assessment team;
- the chairs of the Pharmacovigilance Working Party (PhVWP-V), CVMP or Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary (CMDv), and Inspectors working group will be invited as appropriate to ensure a link with the relevant scientific committees or working party/group;
- a nominated representative from the relevant unit responsible for veterinary medicinal products in the European Commission; and
- the relevant EMA Head of Veterinary Risk and Surveillance or Veterinary Regulatory and Organisational Support and EMA project manager(s) in addition to representatives from the:
  - Veterinary Medicines Division;
  - Supply and Availability of Medicines and Devices in the Regulatory Science and Innovation Task Force;
  - Communication Department; and
  - Legal Department.

Its role is as follows:

- actively review, from a managerial point of view, incidents reported within one working day of receipt in terms of their animal or public health or environmental impact and ascertain whether the identified concerns are likely to be addressed through established procedures and therefore whether the incident is considered a potential crisis. As part of their review, the incident review group should take into consideration the incident's potential impact when they conduct the preliminary risk analysis;
- address requests for advice from individuals concerning a potential incident or intended referral procedure, in terms of the animal and/or public health or environmental impact and whether remedial action can be undertaken through established procedures;
- review other incidents reported via alternative means (i.e. not pharmacovigilance alerts) brought to the attention of the incident review group through existing EMA stakeholder networks and investigate the possibility of applying established procedures to address these concerns. For example where one or more Head of Agency requests the Agency to assist the network with coordination of an incident or crisis measures; in such cases all [concerned] Members States would be informed of the outcome;

- provide advice on emerging issues with a (potential) major public or animal health or environmental impact (e.g. supply shortages caused by manufacturing or Good Manufacturing Practice (GMP) compliance problems);
- identify the need to prepare key core messages for communication and lines to take for any (media) queries;
- identify the most appropriate legal or regulatory framework to be used to address the situation (see section 4.1.2.);
- on the basis of a preliminary risk analysis, the incident review group should determine whether the incident is a crisis. Where it is determined the issue represents a crisis, the Executive Director of the Agency would be informed. The outcome of the incident review groups consideration would be communicated by the Agency to all involved parties, including, where appropriate the CVMP or CMDv and PhVWP-V. This also includes confirmation of issues which, after review, are not deemed to be incidents;
- where a crisis has been confirmed by the incident review group, the group should define and initiate the actions required to manage the crisis ('crisis management steps') including the communication strategy. When deemed appropriate, the incident review group will agree on the closure of the crisis;
- where appropriate inform third country regulatory authorities of the incident or crisis (e.g. United States Food and Drug Administration (US FDA), US Department of Agriculture – Center for Veterinary Biologics (USDA/CVB), Health Canada, Japanese Ministry of Agriculture, Forestry and Fisheries (JMAFF));
- where appropriate, in the event the incident or crisis involves issues outside of the remit of the veterinary medicines regulatory authorities, for example, with implications for human health, other organisations would be informed; for example the European Food Safety Authority (EFSA), European Centre for Disease Control (ECDC), World Organisation for Animal Health (WOAH), United Nations (UN) Food and Agricultural Organisation (FAO) etc.; and
- consider the lessons learned when closing the incident or crisis.

3.2. European Medicines Agency incident review group support team

The EMA incident review group support team is an internal EMA operational structure supporting the incident review group for incident or crisis management by providing the required administrative and scientific input. Its responsibilities are to:

1) implement the decisions taken by the incident review group in a timely manner for incident or crisis management;
2) operate the crisis management steps defined by the incident review group, including communication aspects, ensuring that all relevant stakeholders are rapidly and fully informed;
3) follow-up implementation and evaluation of the response(s), including communication aspects;
4) propose any necessary remedial actions for changes for implementation to the incident review group; and
5) propose closure of the incident or crisis to the incident review group and prepare an evaluation of the incident management plan implementation ('lessons learned').

The team's core membership comprises EMA staff assigned as required. The specific tasks for the core members of the EMA support team are described as follows:

The ***EMA Head of Surveillance and Regulatory Support Department*** of the Veterinary Medicines Division is responsible for:

- organising and co-ordinating the actions of the EMA support team;
- centralising all updated information related to the crisis;
- reviewing and approving all documents for external communication; and
- informing and coordinating with the Head of Veterinary Medicines Division concerning all developments.

The ***EMA Head of Service (e.g. Veterinary Risk and Surveillance or Veterinary Regulatory and Organisational Support)*** is responsible for:

- coordinating cross-service activities or cross-Agency (if appropriate) to ensure delivery of remedial actions.

The ***EMA Veterinary Medicines Division project manager*** is responsible for:

- managing the delivery of the activities for which the Agency is responsible in the incident management plan with appropriate support from the Supply and Availability of Medicines and Devices in the Regulatory Science and Innovation Task Force, Communication and Legal Departments, as required;
- liaising with the rapporteur/representative of the RMS/lead MS on all scientific aspects and coordinating their input;
- liaising with the qualified person for pharmacovigilance (QPPV) of the MAH(s) and collecting all urgent information required, as necessary;
- providing all updated internal and external information to the Head of Veterinary Medicines Department on an ongoing basis; and
- ensuring that appropriate records are maintained, particularly the major events and key action points, in order to provide input to the evaluation.

The ***EMA Communication Department project manager*** is responsible for:

- preparing answers for any (media) queries or lines to take;
- ensuring good coordination between NCAs for information to be made public, including defining the appropriate timing for publication; and
- informing the concerned MAH(s).

The ***EMA Legal Department project manager*** is responsible for:

- advising on the most appropriate legal/regulatory framework to be used to address the situation.

4. Incident management procedure

4.1. Outline of the steps of the incident management plan

The incident management plan procedure consists of the following key steps:

- continuous monitoring of incidents and triggering the incident management plan;
- evaluation of incidents to define potential actions, including communication (i.e. the need to prepare for any (media) queries) and to identify the most appropriate legal or regulatory framework to be used to address the situation;
- confirmation (or not) of a crisis and initiation of the crisis management steps of the incident management plan, including the communication strategy;
- monitoring implementation and identification of the need for remedial action, where necessary;
- closure of the incident or crisis; and
- conduct of 'lessons learned' and evaluation of incident management plan implementation.

4.1.1. Continuous monitoring of incidents and triggering the incident management plan

A Eudranet distribution list (LIST-V-IRG@EUDRA.ORG) has been established for triggering the incident management plan and subsequent communication on incidents or crises to be considered by the incident review group. Established communication systems should be continuously monitored within the network to identify potential incidents; these include the pharmacovigilance RAs and quality defect RA system. Taking into account the scope and definition of an incident, a pharmacovigilance alert would generally automatically trigger the incident management plan. Efficacy and/or safety issues with or without a link to quality aspects may also fall within the scope of an incident. Purely quality related issues such as GMP compliance problems which may lead to supply shortages may also trigger the incident management plan. The identification of incidents will rely on notification via Eudranet (LIST-V-IRG@EUDRA.ORG) or on the existing communication structures that exist between the Agency and its collaborator, specialist and stakeholder networks.

In the case of referrals, before a formal procedure is initiated, prior discussion with the EMA, as detailed in the Notice to Applicants, or relevant standard operating procedure is recommended and creates an opportunity for discussion with the potential referring MS on whether the situation is considered an incident and if the relevant Head of Agency wishes to request the Agency to play a coordination role.

In addition the incident management plan could be triggered upon receipt of, for example, communication from a non-EU regulatory authority or identification of an issue in the press or scientific publications

Where an individual seeks advice from the incident review group as to whether an issue represents a potential incident or crisis this should be clearly highlighted in the request.

When invoking the incident management plan, the triggering party should include their own preliminary analysis of the issue to share with the network as a basis for discussion at the initial incident review group meeting. Where relevant, preferably, this should include a summary of the relevant background data relating to the issue, description of the facts, and the triggering party's risk analysis (i.e. the reason for triggering the IMP), including their initial judgement of whether the issue is

considered a crisis or otherwise. This will facilitate the incident review group's consideration of the issue, particularly, for example, in the event urgent safety measures are required.

Any party within the EU Regulatory Network (e.g. MSs, EMA or the European Commission) can trigger an incident (via LIST-V-IRG@EUDRA.ORG) when they consider that the situation should be harmonised between MSs with respect to a product, including those foreseen within the Compilation of Community procedures, at national or EU-level either due to the nature of the incident or as a result of Community legislation.

4.1.2. Evaluation of incidents

Involvement of the incident review group

On the basis of the evaluation of the incident the incident review group will determine whether or not the incident is likely to be managed by established procedures, consider the potential impact of the incident and decide on the need to expand the risk analysis to include data or impact assessments from other NCAs, to determine whether the incident has the potential to develop into a crisis. All communication for the attention of the incident review group should be done via the established Eudranet distribution list (LIST-V-IRG@EUDRA.ORG). As highlighted previously, the outcome of the evaluation will be communicated by the Agency on behalf of the incident review group to all involved parties (including the CVMP, CMDv and PhVWP-V, where applicable) leading to the end of the incident review groups involvement. This includes communicating whether any issues were not considered to represent potential incidents, in which case no further action would be required from an incident management perspective.

In addition to reviewing incidents in terms of their impact on animal and/or public health and/or the environment and identifying the most appropriate legal/regulatory framework to be used, the incident review group will have to consider the need to prepare for any (media) queries or for proactive communication. The principles for communication during an incident or crisis are included in the Annex to this document. To allow for replies to such queries the chair of the incident review group will either ask the Agency (for CAPs) or the RMS or lead MS (for non-CAPs) to consider the preparation of key core messages for proactive communication and/or lines to take. In situations where both CAPs and non-CAPs are involved, the Agency will take the lead for preparation of key core messages and lines to take, in close collaboration with the involved MS(s). It shall be defined when and how to communicate. The incident review group may consider the incident a crisis when they consider that the animal and/or public health or environmental concerns are likely **not** to be addressed through established procedures. Such considerations will also take into account the following:

- any new and major scientific findings of general animal or public health or environmental relevance which may affect the European Commission's policy in the medicinal product area and may require Union action (e.g. emerging diseases); and
- any outstanding scientific information related to veterinary medicinal products authorised at national level which may also have an impact at EU level (e.g. on similar products or products of the same class).

Preparation of a preliminary risk analysis

The incident should be carefully assessed by the incident review group on the basis of a preliminary risk analysis prepared by the party triggering the incident, taking into consideration the potential impact of the issue. It is important to emphasise that such a risk analysis will be undertaken in a tight time-frame based on data available (which may be limited at the time) and therefore the term preliminary risk analysis has been used. Where the incident review group determines the need for a

more detailed risk analysis, this should be drafted by the CVMP (co)-rapporteur(s) and the EMA for CAPs, the RMS(s) for products authorised via mutual recognition and decentralised procedures or the lead MS for nationally authorised products. Situations characterised by involvement of both CAPs and non-CAPs require representation of the various structures within the EU regulatory network. The lead for such situations in relation to the preparation of the risk analysis will always be at the level of the CVMP (co)-rapporteurs. There should, however, in all situations be a close collaboration with any MS(s) identifying (a) potential issue(s).

The preliminary risk analysis should follow a structured approach based on the principles of risk analysis as defined by the Codex Alimentarius Commission (risk assessment, risk management and risk communication) but understanding that this may be done on a limited dataset and in a tight time-frame:

- risk assessment (hazard identification, hazard characterisation, exposure assessment and risk characterisation) e.g. collection of the information; identification of the information sources; checking of the accuracy; elaboration of the characteristics of the risk(s) associated with the new findings in as quantitative a way as possible. This risk assessment shall take into account the impact of shortages on other products or in other Member States;
- risk management (identification of preliminary risk management activities, evaluation of risk management options) e.g. preliminary analysis of the wider impact of the risks and of the main options available to address the situation; review of previous/already existing risk assessments on the same issue; and
- risk communication - including preparation of key core messages and lines to take. Assessment of the impact on the public taking into account socio-economical characteristics and potential public perception.

It is important to emphasise that such analysis will be undertaken in a tight timeframe and therefore would not in principle form the basis for regulatory action. This timeframe is set by the incident review group in response to the level of urgency of the issue. In order to allow for efficient decision-making it is important for the preliminary risk analysis to clearly state the various options for managing the incident/crisis which will be discussed between the incident review group and the party responsible for drafting the preliminary risk analysis before its finalisation.

4.1.3. Confirmation (or not) of a crisis and initiation of crisis management steps

Based on the preliminary risk analysis, the incident review group will then decide if the incident constitutes a crisis or not. If so, the incident review group should determine what management steps should be initiated. The incident review group is expected to elaborate on the communication aspects of the incident management plan resulting in the drafting of a communication strategy for use by the relevant regulatory authorities e.g. key core messages, press releases or lines to take. The overall aim is to quickly convey a unified and targeted message to the public (see Annex). The EMA incident review group support team will subsequently implement the decisions taken by the incident review group in accordance with the agreed timelines and will operate the crisis management steps of the incident management plan with respect to CAPs and activities within the remit of the EMA. Likewise for nationally authorised products the actions agreed will be taken by NCAs. Agreements reached at the incident review group have no impact on the rights of the NCAs to take pre-emptive action at national level in accordance with the provisions of Union legislation and ensuring transparency with other NCAs. If it is confirmed that the incident does not represent a crisis, the Head of Surveillance and Regulatory Support Department will communicate the conclusions of the incident review group to the triggering

party and throughout the regulatory network, as appropriate. The key element is to ensure continuous exchange of information throughout the process with all concerned parties.

4.1.4. Monitoring implementation and identifying the need for remedial action

The incident review group and the EMA support team will monitor the implementation of the actions taken including communication aspects. In cases where remedial action is needed, the EMA support team will propose the necessary changes (based on the evaluation of data available at each implementation stage) to the incident review group. It is the incident review group's responsibility to approve any changes for subsequent implementation.

4.1.5. Closure of the incident or crisis

Where the incident review group considers that, following the initiatives taken and considering the results observed, the established procedures are sufficient to address the incident, communication will be sent by the Agency on behalf of the incident review group to all involved parties, leading to the end of the incident review group's involvement, e.g. EMA receipt of a notification letter launching a Union interest referral or the adequate communication has been issued to inform stakeholders as applicable.

Should the crisis management steps have been triggered, the crisis situation will be considered closed once determined by the incident review group, based on advice provided by the EMA support team. The closure of the crisis will be communicated by the Agency to inform all involved parties.

4.1.6. Conduct of 'lessons learned' and evaluation of incident management plan implementation

To continuously monitor the implementation of the incident management plan, 'lessons learned' will be reviewed by the incident review group after closure of each incident and/or crisis to identify any opportunities for improvement of the incident management plan and procedure supporting it.

This may include involvement of external parties (e.g. the pharmaceutical industry) as well as veterinarians and other animal healthcare professionals and their representatives. Recommendations from the lessons learned should be incorporated into future revisions of the incident management plan. As part of the lessons learned, the operational aspects of the incident management plan at EU level should also be reviewed, including experience gained with the preparatory steps leading to the decision to confirm (or not) the crisis to further increase the efficiency of operation.

The Agency will make the lessons learned available to NCAs and all other relevant bodies, normally through the Heads of Medicines Agencies and PhVWP-V, as appropriate, to ensure that best practice can be communicated and incorporated as appropriate into national incident management structures.

5. References

- European Medicines Agency and European Commission (2022): Compilation of Community Procedures on Inspections and Exchange of Information (EMA/572454/2014 Rev 18 Corr.)
- Joint FAO/WHO Codex Alimentarius Commission (2019) Procedural Manual Twenty-seventh edition
- European Medicines Agency (2021): Guideline on veterinary good pharmacovigilance practices (VGVP) Module: Veterinary pharmacovigilance communication (EMA/63454/2021)
- European Medicines Agency (2021) Guideline on veterinary good pharmacovigilance practices (VGVP) Module: Signal Management (EMA/522332/2020)

Annex - Principles for communication during an incident or a crisis

The following principles should be considered when preparing communication activities during an incident or a crisis:

- The overriding principle should be to ensure that the right message is delivered to the right audience at the right time. Consideration should therefore be given to what to communicate (using appropriate terminology and taking into account the different levels of knowledge) in addition to how to communicate, when and to whom, based on an appropriate risk analysis;
- Communication shall be consistent and coordinated between all involved NCAs and the Agency. As part of each incident review group meeting, it should be decided if there is a need to communicate to the public; if so what to communicate and when should be defined;
- A topic-specific communication plan needs to be agreed and the template in Appendix II of Guideline on veterinary good pharmacovigilance practices (VGVP) Module: Veterinary pharmacovigilance communication can be used for this purpose. The key core messages shall be harmonised (i.e. identical) across the network but, where necessary, NCAs may adapt the communication to include additional information to reflect specific national situations. The topic-specific communication plan will define the target audience, level of detail to be included in the communication, timetable to be used and how to disseminate the communication;
- If proactive public communication is not considered appropriate at the time, lines to take may be considered. Although not for publication, lines to take are a type of reactive communication that allows MSs and the Agency to respond to external queries in a consistent manner. They therefore should only contain information that can be released on request (i.e. they should not contain any confidential information);
- Lines to take and key core messages are to be prepared in a very short time-frame (usually a few hours) and are to be circulated to the network promptly;
- In some cases, lines to take may also complement proactive public communication, to cover aspects that are not included in the public communication but that may raise questions;
- Communication between MAHs and NCAs or the Agency is considered essential. As a general principle consultation between the MAH and the NCAs or the Agency (and other partners as appropriate) is advisable regarding a communication; this is considered to be beneficial to all involved parties;
- It is essential that relevant information is communicated to veterinarians, other health-care professionals, concerned partners including professional organisations, learned societies, authorities for food safety and pharmaceutical wholesalers depending on local regulations or conventions and animal owners or consumers;
- In principle, significant new or emerging information should be brought to the attention of veterinarians and other health-care professionals before animal owners, consumers or other users of the veterinary medicinal product, in order to enable them to take action and respond adequately and promptly. The important function of veterinarians and other healthcare professionals in disseminating such information to animal owners or users of the veterinary medicinal product should be recognised and supported;

- It is essential to take into account the different regulations or conventions for diffusing the information. It is the responsibility of each NCA to disseminate and adapt as needed the communication agreed at EU level;
- Considering the impact on animal or public health that the information may have in different MSs, it is important that other NCAs and, where applicable, the Agency are also informed; and
- All messages related to communications should be sent to the network using the Eudranet distribution list (LIST-V-IRG@EUDRA.ORG). It is the responsibility of each Head of Agency to put in place the necessary arrangements to ensure that communication messages received through this list are subsequently processed through their own national procedures for communication within their agency, to animal health professionals and/or to marketing authorisation holders, as appropriate.

The following key points should be considered for communication:

- Communication should describe in a clear and concise way any new important information on an authorised veterinary medicinal product;
- The reason for initiating the communication and the risk analysis should be clearly explained;
- Recommendations to veterinarians and other healthcare professionals on how to deal with the information should be provided if known, for risk minimisation or for action to be taken;
- The information should not be misleading and should be presented objectively by placing the risk in the context of the benefit and should not contain any material or statement which is considered to be promotional or commercial;
- A list of contact points for further information, including websites, telephone numbers and a postal address to write to should be provided at the end of the communication when relevant; and
- A list of literature references should be annexed, when relevant.